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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 585

[Docket No. OTS–2009–0018]

RIN 1550–AC14

Prohibited Service at Savings and Loan Holding Companies; Extension of Expiration Date of Temporary Exemption

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Final rule.

SUMMARY: OTS is revising its rules implementing section 19(e) of the Federal Deposit Insurance Act (FDIA), which prohibits any person who has been convicted of any criminal offense involving dishonesty, breach of trust, or money laundering (or who has agreed to enter into a pretrial diversion or similar program in connection with a prosecution for such an offense) from holding certain positions with respect to a savings and loan holding company (SLHC). Specifically, OTS is extending the expiration date of a temporary exemption granted to persons who held positions with respect to a SLHC as of the date of the enactment of section 19(e). The revised expiration date for the temporary exemption is September 30, 2010.

DATES: *Effective Date:* The final rule is effective on September 29, 2009.

FOR FURTHER INFORMATION CONTACT: Donna Deale, Director, Holding Companies and International Activities, Examinations, Supervision and Consumer Protection, (202) 906–7488, Marvin Shaw, Senior Attorney, Regulations and Legislation Division, (202) 906–6639, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: On May 8, 2007, OTS published an interim final rule adding 12 CFR part 585. This new part implemented section 19(e) of the FDIA, which prohibits any person who has been convicted of any criminal offense involving dishonesty, breach of trust, or money laundering (or who has agreed to enter into a pretrial diversion or similar program in connection with a prosecution for such an offense) from holding certain positions with a SLHC. Section 19(e) also authorizes the Director of OTS to provide exemptions from the prohibitions, by regulation or order, if the exemption is consistent with the purposes of the statute.

The interim final rule described the actions that are prohibited under the statute and prescribed procedures for applying for an OTS order granting a case-by-case exemption from the prohibition. The rule also provided regulatory exemptions to the prohibitions, including a temporary exemption for persons who held positions with respect to a SLHC on October 13, 2006, the date of enactment of section 19(e). This temporary exemption is set to expire on September 30, 2009, unless a case-by-case exemption is filed prior to that expiration date.[1]

OTS is extending the expiration date of the temporary exemption to September 30, 2010. This extension will avoid needless disruptions of SLHC operations while OTS continues to review the public comments and develop a final rule addressing these comments. OTS has concluded that this extension of the exemption is consistent with the purposes of section 19(e) of the FDIA.

Regulatory Findings

Notice and Comment and Effective Date

For the reasons set out in the interim final rule,[2] OTS has concluded that: notice and comment on this extension are unnecessary and contrary to the public interest under section 552(b)(B) of the Administrative Procedure Act; there is good cause for making the extension effective immediately under section 553(d) of the APA; and the delayed effective date requirements of section 302 of the Riegle Community Development and Regulatory Improvement Act of 1994 (CDRIA) do not apply.

Regulatory Flexibility Act

For the reasons stated in the interim final rule,[3] OTS has concluded that this extension does not require an initial regulatory flexibility analysis under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), and that this extension should not have a significant impact on a substantial number of small entities, as defined in the RFA.

Paperwork Reduction Act

OTS has determined that this extension does not involve a change to collections of information previously approved under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*)

Unfunded Mandates Act of 1995

For the reasons stated in the interim final rule,[4] OTS has determined that this extension will not result in expenditures by state, local, and tribal governments, in the aggregate, or by the private sector, of more than $100 million in any one year.

Executive Order 12866

OTS has determined that this extension is not a significant regulatory action under Executive Order 12866.

Plain Language

Section 722 of the Gramm-Leach-Bliley Act (12 U.S.C. 4809) requires the Agencies to use ''plain language'' in all final rules published after January 1, 2000. OTS believes that the final rule containing the extension is presented in a clear and straightforward manner.

List of Subjects in 12 CFR Part 585

Administrative practice and procedure, Holding companies, Reporting and recordkeeping requirements, Savings associations.

Authority and Issuance

■ For the reasons in the preamble, OTS is amending part 585 of chapter V of title 12 of the Code of Federal Regulations as set forth below:

[1] This temporary exemption originally was scheduled to expire on September 5, 2007. OTS has extended the expiration date several times, most recently to September 30, 2009 (74 FR 14457, March 31, 2009).

[2] 72 FR at 25953.

[3] 72 FR at 25953–54.

[4] 72 FR at 25954.

PART 585—PROHIBITED SERVICE AT SAVINGS AND LOAN HOLDING COMPANIES

■ 1. The authority citation for 12 CFR part 585 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, and 1829(e).

■ 2. Amend § 585.100(b)(2) introductory text to read as follows:

§ 585.100 Who is exempt from the prohibition under this part?

* * * * *

(b) * * *

(2) This exemption expires on September 30, 2010, unless the savings and loan holding company or the person files an application seeking a case-by-case exemption for the person under § 585.110 by that date. If the savings and loan holding company or the person files such an application, the temporary exemption expires on:

* * * * *

Dated: September 23, 2009.

By the Office of Thrift Supervision.

John Bowman,

Acting Director.

[FR Doc. E9–23432 Filed 9–28–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–1117; Directorate Identifier 2008–NM–106–AD; Amendment 39–16026; AD 2009–20–03]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 727 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Boeing Model 727 airplanes. This AD requires inspections for cracking of the left- and right-side shear ties and web posts of the kickload beam and the adjacent structure in the vertical stabilizer, and corrective actions if necessary. This AD results from a report of cracking of the left- and right-side web posts and shear ties of the kickload beam. We are issuing this AD to detect and correct cracking of the left- and right-side web posts and shear ties of the kickload beam, which, when coupled with failures in the adjacent structure, could result in structural failure of the vertical stabilizer, and loss of control of the airplane.

DATES: This AD is effective November 3, 2009.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of November 3, 2009.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com*; Internet *https://www.myboeingfleet.com*.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6577; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to all Boeing Model 727 airplanes. That NPRM was published in the **Federal Register** on October 29, 2008 (73 FR 64284). That NPRM proposed to require inspections for cracking of the left- and right-side shear ties and web posts of the kickload beam and the adjacent structure in the vertical stabilizer, and corrective actions if necessary.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comments received from the commenters.

Support for the AD

Boeing concurs with the contents of the NPRM.

Request To Revise Method of Determining Compliance Times

ASTAR Air Cargo (ASTAR) states that the flight hours/flight cycles compliance methods are inconsistent. ASTAR states that it will have 24 airplanes that will need to be initially inspected within 4,000 flight hours or 3,000 flight cycles if it uses the flight-hour compliance method specified in the NPRM. However, ASTAR asserts that it will have only eight airplanes that will need to be initially inspected within 4,000 flight hours or 3,000 flight cycles if it uses the flight-cycles compliance method.

From this comment, we infer that ASTAR requests that we revise the method we used to determine the compliance times proposed in the NPRM. We disagree. We acknowledge that the time each airplane will reach the required compliance time will vary depending on each operator's particular utilization. However, we have confirmed that there is no inconsistency with the method used to determine the compliance time.

We point out that the manufacturer recommended the flight-cycle/flight-hour method for determining the compliance time in Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008. This recommendation was based on the average utilization rate and age of the affected airplanes yet to be inspected, as well as the age of the airplanes on which the subject unsafe condition was identified.

In developing an appropriate compliance time, we considered the safety implications, the manufacturer's recommendation, the time necessary to complete the rulemaking process, and the operators' normal maintenance schedules for timely accomplishment of the required actions. In light of these items, we have determined that the method for determining the initial compliance time is appropriate. However, paragraph (l) of the final rule provides an affected operator the opportunity to apply for an adjustment of the compliance time if the operator also presents data that justify the adjustment. We do not find it necessary to change the final rule in this regard.

Also, from this comment, we infer there is a misunderstanding that an operator has a choice between using the total flight cycles or the total flight hours on an airplane to determine the applicable compliance time. This AD does not provide such an option. To clarify, the ''Condition'' column of Table 1 in paragraph 1.E. of Boeing Special Attention Service Bulletin 727–

55–0093, dated March 12, 2008, specifies, ''All airplanes with more than 52,000 total flight hours or 39,000 total flight cycles.'' This condition means that for a given airplane that has accumulated more than either the specified flight hours or flight cycles, the corresponding compliance time is within 4,000 flight hours or 3,000 flight cycles, whichever occurs first, as specified in Table 1 of paragraph 1.E. of Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008.

Due to the issues discussed previously in this section, we have clarified the compliance time table specified in paragraph 1.E. of Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, by adding new paragraphs (i) and (j) to this AD, described below. We have reidentified the subsequent paragraphs accordingly. We have also revised paragraph (f) of this AD to refer to paragraphs (i) and (j) of this AD.

Paragraph (i) of this AD specifies that the ''Condition'' column of Table 1 of paragraph 1.E. of Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, refers to total flight hours and total flight cycles ''at the date on this service bulletin,'' but that this AD applies to the airplanes with the specified total flight hours and total flight cycles as of the effective date of this AD.

Paragraph (j) of this AD specifies that the ''Condition'' in the first row of Table 1 in paragraph 1.E. of Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, applies to airplanes with less than 52,000 total flight hours ''or'' 39,000 total flight cycles, but that for this AD, the first row of the table is applicable to airplanes with less than 52,000 total flight hours ''and'' less than 39,000 total flight cycles.

Request To Revise Cost Estimate

FedEx Express states that Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, provides two options for accessing the required inspection area specified in the NPRM. FedEx Express explains that the first option is to remove an access panel and proceed down the manholes to the inspection area inside the vertical stabilizer, and the second is to remove the number 2 engine and the aft section of the intake duct. FedEx Express asserts that the second option requires an additional 34 work-hours to the inspection, which will increase the time the airplanes must be out of service for heavy maintenance. The additional time in maintenance concerns FedEx Express for economic reasons.

FedEx Express further points out that the NPRM specifies that 10 work-hours are necessary to do the required inspection; however, FedEx Express reiterates that the number of required work-hours depends on the access method used.

From these comments, we infer that FedEx Express requests that we revise the cost estimate provided in the NPRM to include separate labor costs for inspection based on which option is used. We do not agree to revise the proposed cost estimate. We acknowledge that access option 2 in Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, would take significantly more time and could increase the airplane down-time. However, the cost information below describes only the direct costs of the specific actions required by this AD. Based on the best data available, the manufacturer provided the number of work hours (10) necessary to do the required actions. This number represents the time necessary to perform only the actions actually required by this AD. We recognize that, in doing the actions required by an AD, operators might incur incidental costs in addition to the direct costs. The cost analysis in AD rulemaking actions, however, typically does not include incidental costs such as the time required to gain access and close up, time necessary for planning, or time necessitated by other administrative actions. Those incidental costs, which might vary significantly among operators, are almost impossible to calculate. We have not changed the final rule in this regard.

Request To Verify Adequate Replacement Parts

FedEx Express points out that limited numbers of web post and shear tie kickload beams are available according to the Boeing Parts Page on Boeing's Web site. Further, FedEx Express asserts that the Boeing Parts Page did not provide any information about the timeline for stock replenishment of these parts.

From this comment, we infer that FedEx Express is requesting verification that adequate replacement parts will be available to operators. Since replacement of web post and shear tie kickload beams is required only under certain conditions, the total number of replacement parts needed cannot be determined until inspections required by the AD are done. Therefore, we cannot predict the total number of parts needed prior to issuance of the AD.

We have investigated this issue further and have determined that operators may produce their own parts in accordance with Section 21.303 (''Replacement and Modification Parts'') of the Federal Aviation Regulations (14 CFR 21.303) so that the actions required by this AD can be accomplished within the specified compliance time. We have revised paragraph (f) of this final rule to specify that, as an alternative to using the parts specified in Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, operators may fabricate their own parts in accordance with FAA-approved Boeing data.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We also determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Interim Action

We consider this AD interim action. If final action is later identified, we might consider further rulemaking then.

Costs of Compliance

We estimate that this AD affects 364 airplanes of U.S. registry. The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per product	Number of U.S.-registered airplanes	Fleet cost
Inspection	10	$80	$0	$800, per inspection cycle.	364	$291,200, per inspection cycle.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2009–20–03 Boeing: Amendment 39–16026. Docket No. FAA–2008–1117; Directorate Identifier 2008–NM–106–AD.

Effective Date

(a) This airworthiness directive (AD) is effective November 3, 2009.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Boeing Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from a report of cracking of the left- and right-side web posts and shear ties of the kickload beam. We are issuing this AD to detect and correct cracking of the left- and right-side web posts and shear ties of the kickload beam, which, when coupled with failures in the adjacent structure, could result in structural failure of the vertical stabilizer, and loss of control of the airplane.

Compliance

(e) Comply with this AD within the compliance times specified, unless already done.

Inspections and Corrective Actions

(f) At the times specified in paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008 (''the service bulletin''), except as provided by paragraphs (g), (h), (i), and (j) of this AD: Do the inspections to detect cracking of the left- and right-side web posts and shear ties of the kickload beam, by doing all of the actions specified in Part 2 and the applicable corrective actions specified in Part 3 of the Accomplishment Instructions of the service bulletin, except as provided by paragraph (k) of this AD. Do all applicable corrective actions before further flight. Repeat the inspections thereafter at the intervals specified in paragraph 1.E. of the service bulletin. As an alternative to using the parts specified in Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, operators may fabricate their own parts in accordance with FAA-approved Boeing data.

Clarifications and Exception to the Specified Compliance Times

(g) To determine the compliance times for airplanes having exactly 52,000 total flight hours or 39,000 total flight cycles, for the purposes of this AD, these airplanes are grouped with airplanes having ''less than'' 52,000 total flight hours or 39,000 total flight cycles, as specified in paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008.

(h) Where Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, specifies a compliance time after the date on the service bulletin, this AD requires compliance within the specified compliance time after the effective date of this AD.

(i) Where the ''Condition'' column of Table 1 of paragraph 1.E. of Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, refers to airplanes having accumulated the specified total flight hours and total flight cycles ''at the date on this service bulletin,'' this AD requires compliance for airplanes having accumulated the specified total flight hours and total flight cycles as of the effective date of this AD.

(j) The ''condition'' in the first row of Table 1 of paragraph 1.E. of Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, applies to airplanes ''with less than 52,000 total flight hours or 39,000 total flight cycles.'' For this AD, the first row of Table 1 is applicable to airplanes ''with less than 52,000 total flight hours and less than 39,000 total flight cycles.''

Exception to the Specified Corrective Actions

(k) If any cracking is found during any inspection required by this AD, and Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, specifies contacting Boeing for appropriate action: Before further flight, repair the cracking or damage using a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the Manager's approval letter must specifically refer to this AD.

Alternative Methods of Compliance (AMOCs)

(l)(1) The Manager, Seattle ACO, FAA, ATTN: Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6577; fax (425) 917–6590; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Material Incorporated by Reference

(m) You must use Boeing Special Attention Service Bulletin 727–55–0093, dated March 12, 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of

this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com*; Internet *https://www.myboeingfleet.com*.

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221 or 425–227–1152.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on September 15, 2009.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–22871 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–0390; Directorate Identifier 2007–NM–260–AD; Amendment 39–16028; AD 2009–20–05]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A318, A319, A320, and A321 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

Several cases of cracks on the main landing gear (MLG) door hinge fitting and MLG door actuator fitting on the keel beam were reported.

Such failure could lead to the loss [of] the MLG door and could cause damage to the aircraft and/or hazard to persons or property on the ground.

* * * * *

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective November 3, 2009.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 3, 2009.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2141; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on January 9, 2008 (73 FR 1556). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

Several cases of cracks on the main landing gear (MLG) door hinge fitting and MLG door actuator fitting on the keel beam were reported.

Such failure could lead to the loss [of] the MLG door and could cause damage to the aircraft and/or hazard to persons or property on the ground.

This Airworthiness Directive (AD) mandates a onetime detailed visual inspection (DVI) and special detailed inspection (SDI) of the MLG door hinge fitting and actuator fitting.

The inspections are for cracking, damage, correct installation, and correct adjustment. The corrective actions include correcting incorrect adjustments and installations, and contacting Airbus for instructions to repair damage and cracking. You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comments received.

Request for Partial Credit for Inspections

Air Transport Association (ATA) on behalf of its member Northwest Airlines (NWA) requests that the AD give partial credit for inspections previously accomplished in accordance with Airworthiness Limitation Item (ALI) Task 533154–02–1. NWA specifies that after the ALI task is accomplished, full compliance would then require that certain aircraft maintenance manual (AMM) actions also be performed within the time limits specified in the NPRM. The AMM actions include confirmation that the door actuator and door hinge are correctly installed and adjusted, and that ''A'' and ''H'' dimensions are correct as specified in the service information referred to in the NPRM.

We disagree with the request to change the AD to give partial credit for accomplishing the ALI task. If the actions specified in the ALI task are exactly the same as certain inspection requirements of the AD, then the operator would be in compliance with the corresponding requirements of the AD, as specified in paragraph (f) of the NPRM, which says, ''Unless already done, do the following actions.'' In order to receive credit for accomplishing the actions, an operator would need to provide verification, in accordance with the maintenance recording requirements specified in Section 121.380 of the Federal Aviation Regulations (14 CFR 121.380). However, if the actions specified in the ALI task are not exactly the same then, under the provisions of paragraph (g)(1) of the final rule, we will consider requests for approval of an alternative method of compliance (AMOC) if sufficient data are submitted to substantiate that the alternative method would provide an acceptable level of safety. We have not changed the AD in this regard.

Request To Clarify Root Cause of Cracking

ATA and NWA state that improper rigging might not be the root cause of the cracking identified in the NPRM. NWA states that Airbus identified proper rigging of the main landing gear (MLG) door in accordance with the recently revised AMM as corrective action for preventing cracking. NWA states that it has been rigging the MLG door on its Airbus Model A319 and A320 series airplanes for many years before the AMM was revised and has had no known cracking at this location. Therefore, NWA questions whether or not the root cause of the cracking is due to improper rigging.

We acknowledge that NWA has had no known cracking at this location, but note that, according to Airbus, several cases of cracked structures due to improper rigging have been found elsewhere in the fleet. Improper rigging

of the MLG door has been identified as one possible cause of the cracking and, therefore, re-rigging will help prevent future occurrences of cracking. We have not changed the AD in this regard.

Request To Remove Reporting Requirement

ATA and NWA state that the reporting requirements should be changed so that only positive crack inspection results are provided to Airbus. NWA notes that Airbus Mandatory Service Bulletin A320–53–1195, Revision 02, dated April 5, 2007; and Airbus Mandatory Service Bulletin A320–53–1196, Revision 01, dated November 29, 2006; currently require reporting of all inspection results to Airbus, whether there are findings or not. NWA believes it is an unnecessary burden to report negative findings.

We disagree with removing the requirement to report negative findings. Reporting of both positive and negative findings is necessary to determine the scope of the problem and decide future actions. Reporting all findings will allow the manufacturer to conduct statistical analyses on a continuous basis rather than waiting for the compliance time to expire, which may be several years for certain airplanes. Access to all findings will help the manufacturer to develop final action to address the identified unsafe condition in an expeditious manner. However, we agree that some relief is appropriate regarding negative findings. We have added a new paragraph (f)(4) to this AD to specify that operators have 30 days to report negative findings. We have also revised paragraphs (f)(1) and (f)(2) of this AD to refer to paragraph (f)(4) of this AD. We have also revised applicable paragraphs of this AD to refer to Appendix 01 of Airbus Mandatory Service Bulletin A320–53–1195, Revision 02, dated April 5, 2007; and Airbus Mandatory Service Bulletin A320–53–1196, Revision 01, dated November 29, 2006. Appendix 01 contains instructions for reporting findings.

Additional Clarifications to This AD

We have revised paragraphs (f)(1) and (f)(2) of this AD to clarify the references regarding the service information necessary to do the required action.

Conclusion

We reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD changes described previously. We also determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a NOTE within the AD.

Costs of Compliance

We estimate that this AD will affect 641 products of U.S. registry. We also estimate that it will take 28 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $80 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $1,435,840, or $2,240 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2009–20–05 Airbus: Amendment 39–16028. Docket No. FAA–2007–0390; Directorate Identifier 2007–NM–260–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective November 3, 2009.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A318, A319, A320, and A321 series airplanes, all certified models, certificated in any category, all serial numbers up to manufacturer's serial number (MSN) 2850 inclusive, except MSNs 0115, 0184, 0782, 1151, 1190, 2650, 2675, 2706, 2801, and 2837.

Subject

(d) Air Transport Association (ATA) of America Code 53: Fuselage.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

Several cases of cracks on the main landing gear (MLG) door hinge fitting and MLG door actuator fitting on the keel beam were reported.

Such failure could lead to the loss [of] the MLG door and could cause damage to the aircraft and/or hazard to persons or property on the ground.

This Airworthiness Directive (AD) mandates a onetime detailed visual inspection (DVI) and special detailed inspection (SDI) of the MLG door hinge fitting and actuator fitting.

The inspections are for cracking, damage, correct installation, and correct adjustment. The corrective actions include correcting incorrect adjustments and installations, and contacting Airbus for instructions to repair damage and cracking.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) At the latest of the times specified in paragraphs (f)(1)(i), (f)(1)(ii), and (f)(1)(iii) of this AD, perform detailed visual, high frequency eddy current (HFEC), and ultrasonic inspections (for cracking, damage, correct installation, and correct adjustment, as applicable) of the left hand (LH) and right hand (RH) MLG door actuator fitting on the keel beam, and do all applicable corrective actions before further flight, except as provided by paragraph (f)(4) of this AD. Do all actions required by this paragraph in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–53–1195, Revision 02, including Appendix 01, dated April 5, 2007, except where that service bulletin specifies the applicable corrective action is contacting Airbus, contact Airbus for repair instructions and repair before further flight.

(i) Within 6,000 flight cycles since first flight.

(ii) Within 1,500 flight cycles after the effective date of this AD.

(iii) Within 6,000 flight cycles from the latest MLG door actuator fitting replacement.

(2) At the later of the times specified in paragraphs (f)(2)(i) and (f)(2)(ii) of this AD, perform detailed visual and HFEC inspections (for cracking, damage, correct installation, and correct adjustment, as applicable) of the LH and RH MLG door hinge fitting on the keel beam, and do all applicable corrective actions before further flight, except as provided by paragraph (f)(4) of this AD. Do all actions required by this paragraph in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–53–1196, Revision 01, including Appendix 01, dated November 29, 2006, except where that service bulletin specifies the applicable corrective action is contacting Airbus, contact Airbus for repair instructions and repair before further flight.

(i) Within 4,500 flight cycles since first flight.

(ii) Within 1,500 flight cycles after the effective date of this AD.

(3) Actions done before the effective date of this AD in accordance with the applicable service bulletins listed in paragraphs (f)(3)(i), (f)(3)(ii), and (f)(3)(iii) of this AD are acceptable for compliance with the corresponding actions required by this AD.

(i) Airbus Mandatory Service Bulletin A320–53–1195, dated June 23, 2006.

(ii) Airbus Mandatory Service Bulletin A320–53–1195, Revision 01, dated November 29, 2006.

(iii) Airbus Mandatory Service Bulletin A320–53–1196, dated June 23, 2006.

(4) Where the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–53–1195, Revision 02, including Appendix 01, dated April 5, 2007, or Airbus Mandatory Service Bulletin A320–53–1196, Revision 01, including Appendix 01, dated November 29, 2006, specify to submit a report where no damage or crack is found during of the inspection required by paragraph (f)(1) or (f)(2) of this AD: Send the report to Airbus using the applicable reporting sheet in Appendix 01 of Airbus Mandatory Service Bulletin A320–53–1195, Revision 02, dated April 5, 2007, or Airbus Mandatory Service Bulletin A320–53–1196, Revision 01, dated November 29, 2006. Send the report at the applicable time specified in paragraph (f)(4)(i) or (f)(4)(ii) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2141; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2007–0161, dated June 11, 2007; Airbus Mandatory Service Bulletin A320–53–1195, Revision 02, including Appendix 01, dated April 5, 2007; and Airbus Mandatory Service Bulletin A320–53–1196, Revision 01, including Appendix 01, dated November 29, 2006; for related information.

Material Incorporated by Reference

(i) You must use Airbus Mandatory Service Bulletin A320–53–1195, Revision 02, including Appendix 01, dated April 5, 2007; and Airbus Mandatory Service Bulletin A320–53–1196, Revision 01, including Appendix 01, dated November 29, 2006; as applicable; to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; fax +33 5 61 93 44 51; e-mail: *account.airworth-eas@airbus.com*; Internet *http://www.airbus.com*.

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221 or 425–227–1152.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Issued in Renton, Washington, on September 15, 2009.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–23093 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0682; Directorate Identifier 2001–NM–237–AD; Amendment 39–16025; AD 2009–20–02]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200 and –300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 767–200 and –300 series airplanes, that requires replacing certain door-mounted escape slides and slide-raft assemblies with new slide-raft assemblies. This AD also requires the following actions, as applicable: replacing certain escape system latches with new latches; modifying or replacing certain counterbalance assemblies with new counterbalance assemblies; and adjusting the door counterbalance system. The actions specified by this AD are intended to prevent the escape slides and slide-rafts of the forward and mid-cabin entry and service doors from being too steep for evacuation in the event that the airplane rotates onto the aft fuselage into the extreme tip-back condition. In the extreme tip-back condition, the forward and mid-cabin exits could result in steeper sliding angles, which could cause injury to passengers and crewmembers during an emergency evacuation. This action is intended to address the identified unsafe condition.

DATES: Effective November 3, 2009.

The incorporation by reference of a certain publication listed in the regulations is approved by the Director of the Federal Register as of November 3, 2009.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com*; Internet *https://www.myboeingfleet.com.* This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221 or 425–227–1152.

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Andrew Guion, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6428; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Boeing Model 767–200 and –300 series airplanes was published as a supplemental notice of proposed rulemaking (NPRM) in the **Federal Register** on June 17, 2008 (73 FR 34233). That action proposed to require replacing certain door-mounted escape slides and slide-raft assemblies with new slide-raft assemblies; replacing certain escape system latches with new latches; and modifying or replacing certain counterbalance assemblies with new counterbalance assemblies; as applicable. The supplemental NPRM also proposed to extend the compliance time, add requirements to install a longer firing cable and test the valve of the inflation trigger system of the slide-raft and, for certain airplanes, add procedures to adjust the door counterbalance systems.

Explanation of Revised Service Information

Since we issued the supplemental NPRM, we have reviewed Boeing Service Bulletin 767–25A0266, Revision 3, dated July 3, 2008. We referred to Boeing Service Bulletin 767–25A0266, Revision 2, dated September 27, 2007, in the supplemental NPRM as the appropriate source of service information for replacing the slide-rafts. The procedures in Revision 2 and Revision 3 are essentially the same; however, Revision 3 corrects certain typographical errors, including certain part numbers for the slide-rafts.

We have revised paragraph (a) of this AD to refer to Boeing Service Bulletin 767–25A0266, Revision 3, dated July 3, 2008, as the appropriate source of service information. We have also included Boeing Service Bulletin 767–25A0266, Revision 2, dated September 27, 2007, in Table 1 of this AD to state that actions done before the effective date of this AD in accordance with Revision 2 are acceptable for compliance with the requirements of paragraph (a) of this AD.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Requests To Withdraw Supplemental NPRM or Extend Compliance Time

Air Transport Association (ATA), American Airlines, and Delta Airlines request that we either withdraw the supplemental NPRM or extend the compliance time for replacing the slide-rafts. All Nippon Airways requests a compliance time of 8 years (96 months), and ATA requests a compliance time of 10 years (120 months) rather than the 72 months proposed in the supplemental NPRM.

ATA also cites information to show the improbability of the unsafe condition, and maintains that we should withdraw the NPRM due to its lack of potential to add safety benefit, its significantly disproportional costs, its unjustified compliance period, and the fact that the intent of the proposal is already being accomplished on an attrition basis. ATA also states that if the FAA disagrees with its justifications and proceeds with the final rule, it recommends a 10-year compliance period for better correlation with risk-management methods.

American Airlines and ATA further object to the requirement to replace the slide-rafts. They agree with the manufacturer that the unsafe condition specified in the supplemental NPRM is not a safety issue. American Airlines and ATA state that the likelihood that the scenario described in the supplemental NPRM would result in a time-limited evacuation is extremely improbable.

We partially agree with the commenters. We do not agree with the requests to withdraw the supplemental NPRM. We have determined that an unsafe condition exists. Although the specific conditions addressed in the supplemental NPRM have not been

encountered in service, we have received reports of partial tip-back during accidents/incidents that could have resulted in extreme tip-back given slightly different conditions, making this type of event foreseeable. During at least one of these partial tip-back events, the slides were deployed to facilitate evacuation. We do not agree that the low probability of encountering such a foreseeable event is justification to withdraw the supplemental NPRM. We have also determined that an interval based on the ''useful service life'' of the slides, which is 15 years, would not address the unsafe condition in a timely manner.

However, we do agree that it is appropriate to extend the compliance time. We have determined that a compliance time of 96 months represents an appropriate interval of time in which the required actions can be performed, while still maintaining an adequate level of safety. In developing an appropriate compliance time, we considered the safety implications, parts availability, and normal maintenance schedules for timely accomplishment of the modifications. We also considered the costs to comply with the actions (see updated cost information in the Costs of Compliance section). The revised compliance time will allow operators to offset the costs of complying with this AD with the costs associated with normal slide replacement. Therefore, we have revised paragraph (a) of this AD to extend the compliance time for replacing the slide-rafts from 72 months to 96 months.

Requests To Remove Firing Cable Requirement From the Supplemental NPRM

Continental Airlines, Goodrich, and Boeing ask that we remove paragraph (b), ''Modification of the Firing Cable,'' from the supplemental NPRM. Delta points out that the requirement to modify the firing cable is proposed in Docket FAA–2008–0302 (and is now required by AD 2008–21–05, amendment 39–15689 (73 FR 59486, October 9, 2008)) at a compliance time of 36 months rather than the 72 months proposed in the supplemental NPRM. Boeing states that we should also remove the reference to Boeing Alert Service Bulletin 767–25A0395, dated August 31, 2006, from Table 1 ''Previous Revisions of Service Bulletins,'' because that service bulletin relates to the modification specified in paragraph (b) of the supplemental NPRM.

We agree with the commenters' requests to remove paragraph (b) of the supplemental NPRM and the reference to Boeing Alert Service Bulletin 767–25A0395, dated August 31, 2006. The requirement to modify the firing cable is already included in AD 2008–21–05. Therefore, we have revised this AD as requested. The requirement to modify the firing cable will remain part of AD 2008–21–05, which also includes other tasks related to the firing cable.

Requests To Revise Cost Impact

Goodrich, and ATA, on behalf of its member American Airlines, request that we revise the ''Cost Impact'' paragraph. American Airlines states that we did not include the cost of the slide-rafts in the original NPRM; as the slide-rafts are the dominant cost of the modification, ATA and American Airlines state that the cost estimate is both incomplete and inaccurate. Goodrich points out that the costs in the supplemental NPRM reflect prices for 2004 and requests that we revise the cost of the slide-rafts to 2008 prices.

We agree with Goodrich to revise the cost of the slide-rafts to reflect 2008 prices. The ''Cost Impact'' paragraph below includes the current price of the slide-rafts. We acknowledge American Airlines' request, but point out that although the original NPRM did not include the cost of the slide-rafts, the supplemental NPRM did include those costs.

Request To Change Applicability

Boeing requests that we change the applicability of the supplemental NPRM to refer to airplanes identified in Boeing Service Bulletin 767–25A0266, Revision 3, dated July 3, 2008, rather than referring only to those Model 767–200 and –300 series airplanes that have line numbers 1 through 793 inclusive, equipped with door-mounted escape slide systems. Boeing states that the applicability, as written in the supplemental NPRM, might make an alternative method of compliance (AMOC) request necessary for Model 767 door-mounted escape system part numbers that are not addressed by the proposed AD.

We agree with Boeing for the reasons stated, and have revised the applicability statement of this AD to include a reference to Boeing Service Bulletin 767–25A0266, Revision 3, dated July 3, 2008, which includes specific details about which airplanes are affected by this AD.

Requests To Extend Comment Period

Delta Airlines and ATA request additional time to review the supplemental NPRM. Delta requests that we extend the comment period for an additional 60 days because of the complex nature of the supplemental NPRM, the inclusion of multiple service bulletins, the extensive background and significant number of comments in response to the original NPRM, the hugely significant costs, and the fact that the original NPRM was thought to have been withdrawn. ATA also requests an extension of 60 days to the comment period, citing costs and the need to assess the complex requirements.

We disagree with the requests to provide additional time to comment on the supplemental NPRM. As Delta points out in their comment, there was a period of 4.5 years between the release of the original NPRM and the supplemental NPRM, which gave operators sufficient time to consider the requirements. We have not changed the AD in this regard.

Request for Industry-Wide Response

Delta Airlines requests that ATA coordinate an industry-wide response to the supplemental NPRM with the goal of gathering enough technical information to support its cancellation. Delta states that, given previous discussions with Boeing regarding risk and probability, the supplemental NPRM does not appear to have adequate merit. Also, given the significant cost impact, the industry would be well-served by opening the time to conduct a coordinated effort to ensure that the action proposed in the supplemental NPRM is not mandated.

We neither agree nor disagree with the request for ATA to coordinate an industry-wide response. This comment is directed to ATA and is beyond the scope of the AD action. We disagree that the supplemental NPRM does not have adequate merit. We consider the proposed actions to be an adequate response to an unsafe condition. As stated previously, although the specific conditions addressed in the supplemental NPRM have not been encountered, there have been accidents/incidents that make this type of event foreseeable. We do not agree that the low probability of encountering such a foreseeable event is justification for withdrawing the supplemental NPRM. Therefore, we have not changed the AD in this regard.

As explained previously, we also considered the costs to comply with the actions proposed in the supplemental NPRM. While we determined that a compliance time based on the ''useful service life'' of the slides would not address the unsafe condition in a timely manner, we did agree to extend the compliance time for replacing the slide-rafts from 72 months to 96 months. The revised compliance time will allow

operators to offset the costs of complying with this AD with the costs associated with normal slide replacement. We have revised paragraph (a) of this AD to extend the compliance time for replacing the slide-rafts from 72 months to 96 months.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 745 airplanes of the affected design in the worldwide fleet. The FAA estimates that 261 airplanes of U.S. registry are affected by this AD. The work hours and required parts per airplane vary according to the configuration group to which the affected airplane belongs. The average labor rate is $80 per work hour. The ''Cost Impact per Airplane Configuration Group'' table shows the estimated costs.

COST IMPACT PER AIRPLANE CONFIGURATION GROUP

Airplane configuration group	U.S.-registered airplanes	Work hours	Kit cost	Slide cost	Cost per airplane	Fleet cost, by configuration group
1	208	6	$1,236	$222,002	$223,718	$46,533,334
2	12	12	2,472	448,502	451,934	5,423,208
3	41	11	98,858	222,002	321,740	13,191,340
4	0	11	34,012	222,002	256,894	0
5	0	17	35,248	448,502	485,110	0

Based on the figures in the ''Cost Impact per Airplane Configuration Group'' table, the cost impact of this AD on U.S. operators is estimated to be $65,147,882.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding the following new airworthiness directive:

2009–20–02 Boeing: Amendment 39–16025. Docket No. FAA–2008–0682; Directorate Identifier 2001–NM–237–AD.

Applicability: Model 767–200 and –300 series airplanes, line numbers 1 through 793 inclusive; certificated in any category; equipped with door-mounted escape slide systems; as identified in Boeing Service Bulletin 767–25A0266, Revision 3, dated July 3, 2008.

Compliance: Required as indicated, unless accomplished previously.

To prevent the escape slides and slide-rafts of the forward and mid-cabin entry and service doors from being too steep for evacuation in the event that the airplane rotates onto the aft fuselage into the extreme tip-back condition, accomplish the following:

Replacement of Slide-Rafts

(a) Within 96 months after the effective date of this AD, replace the applicable slide-rafts at the applicable door or doors, and do all other applicable actions including, but not limited to, changing the latches, and replacing or modifying the counterbalance assemblies, by accomplishing all applicable actions specified in the Accomplishment Instructions in Boeing Service Bulletin 767–25A0266, Revision 3, dated July 3, 2008.

Credit for Actions Accomplished Previously

(b) Actions done before the effective date of this AD in accordance with the service bulletins listed in Table 1 of this AD are

acceptable for compliance with the corresponding requirements of this AD.

Boeing Service Bulletin	Revision level	Date
Alert Service Bulletin 767–25A0266	1	December 4, 2006.
Alert Service Bulletin 767–25A0266	2	September 27, 2007.

Alternative Methods of Compliance

(c)(1) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Andrew Guion, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6428; fax (425) 917–6590. Or, e-mail information to *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

Incorporation by Reference

(d) You must use Boeing Service Bulletin 767–25A0266, Revision 3, dated July 3, 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com*; Internet *https://www.myboeingfleet.com.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221 or 425–227–1152.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Effective Date

(e) This amendment becomes effective on November 3, 2009.

Issued in Renton, Washington, on September 11, 2009.

Stephen P. Boyd,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–22668 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–0574; Directorate Identifier 2009–CE–028–AD; Amendment 39–16030; AD 2009–20–07]

RIN 2120–AA64

Airworthiness Directives; DORNIER LUFTAHRT GmbH Models Dornier 228–100, Dornier 228–101, Dornier 228–200, Dornier 228–201, and Dornier 228–202 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

A stub axle failure of the main landing gear on a Dornier 228–200 aeroplane was reported to RUAG Aerospace. Investigations revealed that the fracture of the axle—manufacturer Part Number (P/N) A–511000B28B was due to fatigue. Already in the year 1993 two failures of P/N A–511000B28B axles occurred. Those events led in 1994 the Luftfahrt-Bundesamt—Germany's National Aviation Authority—to publish Airworthiness Directive (AD) D–1994–042 to mandate the replacement of A–511000B28B axles by improved-design axle with P/N A–511000C28B (Dornier Luftfahrt GmbH Service bulletin 228–214).

It is believed that a misinterpretation of the Dornier 228 repair/maintenance documentation caused inadvertent installation of A–511000B28B axle on the accident aeroplane's main landing gear with P/N A–511000C00F. This configuration was not approved for installation and was therefore not addressed by LBA AD D–1994–042 or Dornier SB–228–214.

The actions specified in this Airworthiness Directive are intended to prevent main landing gear failure, which could result in loss of control of the aeroplane during landing operations.

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective November 3, 2009.

On November 3, 2009, the Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Greg Davison, Glider Program Manager, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4130; fax: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on June 25, 2009 (74 FR 30247). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

A stub axle failure of the main landing gear on a Dornier 228–200 aeroplane was reported to RUAG Aerospace. Investigations revealed that the fracture of the axle—manufacturer Part Number (P/N) A–511000B28B was due to fatigue. Already in the year 1993 two failures of P/N A–511000B28B axles occurred. Those events led in 1994 the Luftfahrt-Bundesamt—Germany's National Aviation Authority—to publish Airworthiness Directive (AD) D–1994–042 to mandate the replacement of A–511000B28B axles by improved-design axle with P/N A–511000C28B (Dornier Luftfahrt GmbH Service bulletin 228–214).

It is believed that a misinterpretation of the Dornier 228 repair/maintenance documentation caused inadvertent

installation of A–511000B28B axle on the accident aeroplane's main landing gear with P/N A–511000C00F. This configuration was not approved for installation and was therefore not addressed by LBA AD D–1994–042 or Dornier SB–228–214.

The actions specified in this Airworthiness Directive are intended to prevent main landing gear failure, which could result in loss of control of the aeroplane during landing operations.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a Note within the AD.

Costs of Compliance

We estimate that this AD will affect 15 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this AD. The average labor rate is $80 per work-hour.

Based on these figures, we estimate the cost of this AD on U.S. operators to be $1,200 or $80 per product.

In addition, we estimate that any necessary follow-on actions would take about 16 work-hours and require parts costing $23,734, for a cost of $25,014 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD Docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2009–20–07 Dornier Luftfahrt GmbH: Amendment 39–16030; Docket No. FAA–2009–0574; Directorate Identifier 2009–CE–028–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective November 3, 2009.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Models Dornier 228–100, Dornier 228–101, Dornier 228–200, Dornier 228–201, and Dornier 228–202 airplanes, all serial numbers, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 32: Landing Gear.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

A stub axle failure of the main landing gear on a Dornier 228–200 aeroplane was reported to RUAG Aerospace. Investigations revealed that the fracture of the axle—manufacturer Part Number (P/N) A–511000B28B was due to fatigue. Already in the year 1993 two failures of P/N A–511000B28B axles occurred. Those events led in 1994 the Luftfahrt-Bundesamt—Germany's National Aviation Authority—to publish Airworthiness Directive (AD) D–1994–042 to mandate the replacement of A–511000B28B axles by improved-design axle with P/N A–511000C28B (Dornier Luftfahrt GmbH Service bulletin 228–214).

It is believed that a misinterpretation of the Dornier 228 repair/maintenance documentation caused inadvertent installation of A–511000B28B axle on the accident aeroplane's main landing gear with P/N A–511000C00F. This configuration was not approved for installation and was therefore not addressed by LBA AD D–1994–042 or Dornier SB–228–214.

The actions specified in this Airworthiness Directive are intended to prevent main landing gear failure, which could result in loss of control of the aeroplane during landing operations.

The MCAI requires inspection of the main landing gear (MLG) and, if applicable, replacement of the MLG stub axle.

Actions and Compliance

(f) Unless already done, do the following actions following RUAG Aerospace Defence Technology Dornier 228 Service Bulletin SB–228–276, dated October 16, 2008:

(1) Within the next 14 days after November 3, 2009 (the effective date of this AD), inspect the main landing gear (MLG) stub axle.

(2) If any P/N A–511000B28B stub axle is found, before accumulation of 9,500 total landings on the axle, or before further flight if total landings on the axle exceed 9,500 total landings on November 3, 2009 (the effective date of this AD), replace the axle or the housing assembly with a new axle P/N A–511000C28B. If the total number of landings accumulated by the stub axle cannot be positively determined, the stub axle must be considered to have accumulated more than 9,500 total landings.

(3) Operators that do not have landing (or cycle) records may determine the number of landings (or cycles) by dividing the number of hours time-in-service of each airplane by the time of the average flight for the aircraft of that type in the operator's fleet.

Note 1: P/N A–511000C28B axle together with the housings P/N A–511000C27B and P/N A–521000C27B form the Axle Assemblies P/N AD511010A00C and P/N AD521010A00C, which are life limited to 48,000 landings per the Dornier 228 Time Limits/Maintenance Checks Manual (TLMCM) Chapter 05–10–10.

(4) As of November 3, 2009 (the effective date of this AD), do not install MLG assemblies P/N A–511000C00F and P/N A–521000C00F fitted with a P/N A–511000B28B stub axle on any airplane.

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Greg Davison, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4130; fax: (816) 329–4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to EASA AD No.: 2009–0062, dated March 13, 2009; and RUAG Aerospace Defence Technology Dornier 228 Service Bulletin SB–228–276, dated October 16, 2008, for related information.

Material Incorporated by Reference

(i) You must use RUAG Aerospace Defence Technology Dornier 228 Service Bulletin SB–228–276, dated October 16, 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact RUAG Aerospace Services GmbH, Dornier 228 Customer Support, P.O. Box 1253, 82231 Wessling, Federal Republic of Germany, telephone: +49 (0)8153–30–2280; fax: +49 (0) 8153–30–3030; E-mail: *custsupport.dorner228@ruag.com*; Internet: *http://www.ruag.com/*.

(3) You may review copies of the service information incorporated by reference for this AD at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the Central Region, call (816) 329–3768.

(4) You may also review copies of the service information incorporated by reference for this AD at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Kansas City, Missouri, on September 21, 2009.

Scott A. Horn,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–23211 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–0881; Directorate Identifier 2009–CE–050–AD; Amendment 39–16027; AD 2009–20–04]

RIN 2120–AA64

Airworthiness Directives; Glaser-Dirks Flugzeugbau GmbH Model DG–100 Gliders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

The Elevator control bearing stand RU19 was required to be inspected for correct production in 1978 in accordance with Technical Note (TN) No.301/6. In 2009, an accident occurred with a DG–100. The suspension bolt was found torn out of the bearing stand making the elevator uncontrollable. The investigation confirmed that the bearing stand had not been produced correctly. It is therefore assumed that the inspections per TN 301/6 did not produce reliable results.

This AD requires actions that are intended to address the unsafe condition described in the MCAI.

DATES: This AD becomes effective October 19, 2009.

On October 19, 2009 the Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD.

We must receive comments on this AD by November 13, 2009.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Greg Davison, Glider Program Manager, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4130; fax: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued Emergency AD No.: 2009–0163–E, dated July 29, 2009 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> The Elevator control bearing stand RU19 was required to be inspected for correct production in 1978 in accordance with Technical Note (TN) No.301/6. In 2009, an accident occurred with a DG–100. The suspension bolt was found torn out of the bearing stand making the elevator uncontrollable. The investigation confirmed that the bearing stand had not been produced correctly. It is therefore assumed that the inspections per TN 301/6 did not produce reliable results.
>
> As a consequence, this new Airworthiness Directive (AD) mandates replacement of the bearing stand with a reinforced version.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

DG Flugzeugbau GmbH has issued Technical note No. 301/26 Rev. 1, dated August 4, 2009. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all information provided by the State of Design Authority and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might have also required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are described in a separate paragraph of the AD. These requirements take precedence over those copied from the MCAI.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because a recent accident occurred with a Glaser-Dirks Flugzeugbau GmbH Model DG–100 Glider where the suspension bolt was found torn out of the bearing stand. The investigation confirmed that the bearing stand had not been produced correctly. On December 18, 1997, the FAA issued Special Airworthiness Information Bulletin (SAIB) No. ACE–98–19 that recommended an inspection of the elevator control bearing stand RU19 following DG Flugzeugbau Technical note No. 301/6. We have determined that the SAIB recommended inspection was either not done or did not produce reliable results. As a consequence, this AD requires an immediate inspection of the bearing stand. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2009–0881; Directorate Identifier 2009–CE–050–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2009–20–04 Glaser-Dirks Flugzeugbau Gmbh: Amendment 39–16027; Docket No. FAA–2009–0881; Directorate Identifier 2009–CE–050–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective October 19, 2009.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Model DG–100 gliders, serial numbers 5 and 21 through 103, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 27: Flight Controls.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

The Elevator control bearing stand RU19 was required to be inspected for correct production in 1978 in accordance with Technical Note (TN) No. 301/6. In 2009, an accident occurred with a DG–100. The suspension bolt was found torn out of the bearing stand making the elevator uncontrollable. The investigation confirmed that the bearing stand had not been produced correctly. It is therefore assumed that the inspections per TN 301/6 did not produce reliable results.

As a consequence, this new Airworthiness Directive (AD) mandates replacement of the bearing stand with a reinforced version.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) Before further flight after October 19, 2009 (the effective date of this AD), inspect the bearing stand RU19 following paragraph 1 of the Instructions section of DG Flugzeugbau Technical note No. 301/26, Rev. 1, dated August 4, 2009. You may take credit for this paragraph if the bearing stand was inspected before October 19, 2009 (the effective date of this AD) following DG Flugzeugbau Technical note No. 301/26, dated July 16, 2009.

(2) If any discrepancy is found (crack, delamination, etc.), before further flight replace the bearing stand RU19 following paragraph 3 of the Instructions section of DG Flugzeugbau Technical note No. 301/26, Rev. 1, dated August 4, 2009.

(3) Within 3 months after October 19, 2009 (the effective date of this AD) replace the bearing stand RU19 following paragraph 3 of the Instructions section of DG Flugzeugbau Technical note No. 301/26, Rev. 1, dated August 4, 2009. You may take credit for this paragraph if the bearing stand RU19 has been replaced before October 19, 2009 (the effective date of this AD) following DG Flugzeugbau Technical note No. 301/6, dated May 29, 1978, or following paragraph 3 of the Instructions section of DG Flugzeugbau Technical note No. 301/26, dated July 16, 2009.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows:

(1) DG Flugzeugbau GmbH Technical Note No. 301/26, Rev. 1, dated August 4, 2009, states that instruction 1 may be executed by the pilot/owner. By FAA regulations, this AD requires all affected gliders to have the required actions done by an appropriately rated mechanic.

(2) The MCAI states to do the actions following DG Flugzeugbau GmbH Technical Note No. 301/26, dated July 16, 2009. DG Flugzeugbau GmbH updated the technical note after the MCAI was issued. We are requiring you use the updated technical note (DG Flugzeugbau GmbH Technical Note No. 301/26, Rev. 1, dated August 4, 2009) to do the actions of this AD, unless the AD specifies otherwise.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Greg Davison, Glider Program Manager, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4130; fax: (816) 329–4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et.seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) Emergency AD No.: 2009–0163–E, dated July 29, 2009, DG Flugzeugbau GmbH Technical Note No. 301/26, dated July 16, 2009; DG Flugzeugbau GmbH Technical Note No. 301/26, Rev. 1, dated August 4, 2009; and DG Flugzeugbau Technical note No. 301/6, dated May 29, 1978, for related information.

Material Incorporated by Reference

(i) You must use DG Flugzeugbau GmbH Technical Note No. 301/26, Rev. 1, dated August 4, 2009, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact DG Flugzeugbau GmbH, Otto-Lilienthal-Weg 2, 76646 Bruchsal, Federal Republic of Germany; telephone: + 49 (0) 7251 3020140; Fax: +49 (0) 7251 3020149; Internet: *http://www.dg-flugzeugbau.de/index-e.html;* E-Mail: *dirks@dg-flugzeugbau.de.*

(3) You may review copies of the service information incorporated by reference for this AD at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the Central Region, call (816) 329–3768.

(4) You may also review copies of the service information incorporated by reference for this AD at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Kansas City, Missouri, on September 17, 2009.

Kim Smith,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–23047 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–0431; Directorate Identifier 2007–NM–174–AD; Amendment 39–16029; AD 2009–20–06]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A310–203 and –222 Airplanes and Model A300 B4–620 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are superseding an existing airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

DGAC [Direction Générale de l'Aviation Civile] France AD 86–102–74(B) [which corresponds to FAA AD 88–06–03, amendment 39–5871] was issued to prevent development of damage, which was discovered during [a] fatigue test in the attachment angles of the rear pressure bulkhead (fuselage frame 80/82).

Following the life extension activities linked to the A310 program, the interval of inspection for A310–200 aircraft series was reduced from 12000 flight cycles (FC) to 9000 FC * * *.

Some stress analysis conducted in the frame of the life extension activities of the A300–600 program leads the manufacturer to reduce as well the interval of inspection applicable to A300B4–620 and A300C4–620 aircraft models.

* * * * *

The unsafe condition is cracking in the attachment angles of the rear pressure bulkhead, which could result in failure of the rear pressure bulkhead. We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective November 3, 2009.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 3, 2009.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Stafford, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1622; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on May 7, 2009 (74 FR 21274), and proposed to supersede AD 88–06–03, Amendment 39–5871 (53 FR 7730, March 10, 1988). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

DGAC [Direction Générale de l'Aviation Civile] France AD 86–102–74(B) [which corresponds to FAA AD 88–06–03] was issued to prevent development of damage, which was discovered during [a] fatigue test in the attachment angles of the rear pressure bulkhead (fuselage frame 80/82).

Following the life extension activities linked to the A310 program, the interval of inspection for A310–200 aircraft series was reduced from 12000 flight cycles (FC) to 9000 FC, which prompted the issuance of EASA AD 2007–0157, superseding DGAC France AD 86–102–74(B).

Some stress analysis conducted in the frame of the life extension activities of the A300–600 program leads the manufacturer to reduce as well the interval of inspection applicable to A300B4–620 and A300C4–620 aircraft models.

EASA AD 2007–0297 superseded EASA AD 2007–0157, retaining for A310 aircraft the requirements of EASA AD 2007–0157 and requiring the application of Airbus Service Bulletin (SB) A300–53–6005 Revision 4 on Airbus A300–600 aircraft, reducing the inspection interval from 12000 FC to 9000 FC.

[EASA] AD [2007–0297] has been revised to remove an inappropriate reference regarding the normal inspection program from the Compliance section, Note 3.

The unsafe condition is cracking in the attachment angles of the rear pressure bulkhead, which could result in failure of the rear pressure bulkhead. The required actions include a modification of the rear pressure bulkhead to improve the fatigue life of the attachment angles at frame (FR) 80/82, and, for certain airplanes, repetitive inspections for cracks in the rear pressure bulkhead and repair if necessary.

The modification includes installing additional attachment angles on the circumference of FR 80/82; installing a filler; installing additional supports between the aft pressure bulkhead and FR 80/82; installing an additional frame stiffener and support between the aft pressure bulkhead and FR 79 at stringer (STGR) 13; modifying the aft lavatories; applying surface protection to the modified area of the aft pressure bulkhead; modifying, reidentifying, and installing the heat and sound insulation in the area of STGR 9 and STGR 13 and between FR 79 and FR 80/82, left and right; and for certain airplanes, doing related investigative and corrective actions if necessary.

The related investigative action is doing a visual inspection around the entire circumference between FR 80/82 and the aft pressure bulkhead for damaged filler. The corrective action is removing any damaged filler and the adjacent area around the damage.

You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comment received.

Request To Revise Paragraph (f)(4) of the NPRM

Airbus requests that we revise paragraph (f)(4) of the NPRM. Airbus states that for the airplanes identified in paragraph (f)(4) of the NPRM, it is not necessary to do the actions in accordance with the service bulletins specified in paragraph (f)(4) of the NPRM. Airbus further states that those airplanes are affected by Airworthiness Limitation Item (ALI) Task 531919–01–1A, as specified in the service bulletins identified in paragraph (f)(4) of this AD and the MCAI.

We agree with the commenter. The actions specified in paragraph (f)(4) of the NPRM are not required for the airplanes identified in that paragraph because those airplanes are already inspected in accordance with ALI Task 531919–01–1A, and no additional actions are necessary. We have confirmed with EASA that this is the intent of the MCAI. We have removed paragraph (f)(4) of the NPRM as it is unnecessary, and added a new Note 1 to this AD to clarify that no action is required by this AD for the airplanes discussed in this paragraph. We have re-identified the subsequent paragraphs accordingly.

Conclusion

We reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a NOTE within the AD.

Costs of Compliance

We estimate that this AD will affect about 32 products of U.S. registry. We also estimate that it will take about 668 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $80 per work-hour. Required parts will cost about $15,322 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs

higher than estimated here. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $2,200,384, or $68,762 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Amendment 39–5871 (53 FR 7730, March 10, 1988) and adding the following new AD:

2009–20–06 Airbus: Amendment 39–16029. Docket No. FAA–2009–0431; Directorate Identifier 2007–NM–174–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective November 3, 2009.

Affected ADs

(b) This AD supersedes AD 88–06–03, Amendment 39–5871.

Applicability

(c) This AD applies to Airbus Model A310–203 and –222 airplanes, and Model A300 B4–620 airplanes; certificated in any category; all serial numbers except airplanes on which Airbus Modification 05526 has been incorporated in production.

Subject

(d) Air Transport Association (ATA) of America Code 53: Fuselage.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

DGAC (Direction Générale de l'Aviation Civile) France AD 86–102–74(B) [which corresponds to FAA AD 88–06–03, amendment 39–5871] was issued to prevent development of damage, which was discovered during [a] fatigue test in the attachment angles of the rear pressure bulkhead (fuselage frame 80/82).

Following the life extension activities linked to the A310 program, the interval of inspection for A310–200 aircraft series was reduced from 12000 flight cycles (FC) to 9000 FC, which prompted the issuance of EASA AD 2007–0157, superseding DGAC France AD 86–102–74(B).

Some stress analysis conducted in the frame of the life extension activities of the A300–600 program leads the manufacturer to reduce as well the interval of inspection applicable to A300B4–620 and A300C4–620 aircraft models.

EASA AD 2007–0297 superseded EASA AD 2007–0157, retaining for A310 aircraft the requirements of EASA AD 2007–0157 and requiring the application of Airbus Service Bulletin (SB) A300–53–6005 Revision 4 on Airbus A300–600 aircraft, reducing the inspection interval from 12000 FC to 9000 FC.

[EASA] AD [2007–0297] has been revised to remove an inappropriate reference regarding the normal inspection program from the Compliance section, Note 3.

The unsafe condition is cracking in the attachment angles of the rear pressure bulkhead, which could result in failure of the rear pressure bulkhead. The required actions include a modification of the rear pressure bulkhead to improve the fatigue life of the attachment angles at frame (FR) 80/82; applicable related investigative and corrective actions; and, for certain airplanes, repetitive inspections for cracks in the rear pressure bulkhead and repair if necessary.

Requirements of This AD: Actions and Compliance

(f) Unless already done, do the following actions.

Modification

(1) Except as required by paragraph (f)(2) of this AD: Before the accumulation of 12,000 total flight cycles since first flight, or within 1,500 flight cycles after the effective date of this AD, whichever occurs later, modify the aft pressure bulkhead to improve the fatigue life of the attachment angles at frame 80/82 and do all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–53–6006, Revision 3, dated March 24, 1989; or Airbus Mandatory Service Bulletin A310–53–2025, Revision 06, dated August 3, 2006; as applicable. Do all applicable related investigative and corrective actions before further flight.

(2) For airplanes identified in paragraph (c) of AD 2006–22–03, amendment 39–14800: At the earlier of the compliance times specified in paragraphs (f)(2)(i) and (f)(2)(ii) of this AD, do the actions specified in paragraph (f)(1) of this AD.

(i) Before the accumulation of 12,000 total flight cycles since first flight, or within 1,500 flight cycles after the effective date of this AD, whichever occurs later.

(ii) At the compliance time specified in paragraph (h) of AD 2006–22–03.

Inspections and Corrective Action

(3) For airplanes on which the modification required by paragraph (f)(1) or (f)(2) of this AD is done after the accumulation of 6,000 total flight cycles since first flight: At the times specified in paragraphs (f)(3)(i) and (f)(3)(ii) of this AD, do an eddy current inspection for any cracking in the critical area of the rear pressure bulkhead between stringers 8 and 18, and repair all cracking before further flight, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–53–6005, Revision 04, dated July 18, 2007; or Airbus Mandatory Service Bulletin A310–53–2024, Revision 05, dated October 13, 2006; as applicable.

(i) Before or concurrently with the modification required by paragraph (f)(1) or (f)(2) of this AD, as applicable; and

(ii) Before the accumulation of 18,000 total flight cycles since first flight, or within 1,500 flight cycles after the effective date of this AD, whichever occurs later; and thereafter at intervals not to exceed 9,000 flight cycles.

Note 1: For airplanes on which the modification required by paragraph (f)(1) or (f)(2) of this AD is done at or before the accumulation of 6,000 total flight cycles since first flight: No action is required by this AD. For these airplanes, refer to Airbus A300–600 ALI Task 531919–01–1A or Airbus A310 ALI Task 531919–01–1A, as applicable, for guidance on the normal inspection program.

(4) Modifications done before the effective date of this AD in accordance with the service bulletins identified in Table 1 of this AD are acceptable for compliance with the requirements of paragraph (f)(1) and (f)(2) of this AD.

TABLE 1—MODIFICATIONS DONE USING PREVIOUS SERVICE BULLETINS

Model—	Airbus Service Bulletin—	Revision—	Dated—
A300 B4–620 airplanes	A300–53–6006	Original	May 6, 1986.
	A300–53–6006	1	September 19, 1986.
	A300–53–6006	2	August 11, 1988.
A310–203 and –222 airplanes	A310–53–2025	Original	April 21, 1986.
	A310–53–2025	1	September 19, 1986.
	A310–53–2025	2	February 16, 1987.
	A310–53–2025	3	April 7, 1987.
	A310–53–2025	4	October 20, 1987.
	A310–53–2025	5	March 24, 1989.

(5) Inspections done before the effective date of this AD in accordance with the service bulletins identified in Table 2 of this AD are acceptable for compliance with the requirements of paragraph (f)(3) of this AD.

TABLE 2—INSPECTIONS DONE WITH PREVIOUS SERVICE BULLETINS

Model—	Airbus Service Bulletin—	Revision—	Dated—
A300 B4–620 airplanes	A300–53–6005	Original	May 6, 1986.
	A300–53–6005	1	June 20, 1986.
	A300–53–6005	2	September 22, 1986.
	A300–53–6005	3	April 22, 1987.
A310–203 and –222 airplanes	A310–53–2024	Original	April 21, 1986.
	A310–53–2024	1	June 20, 1986.
	A310–53–2024	2	October 2, 1986.
	A310–53–2024	3	February 17, 1987.
	A310–53–2024	4	February 2, 1988.

(6) Modification of the aft pressure bulkhead to improve the fatigue life of the attachment angles at frame (FR) 80/82 in accordance with paragraph (h) of AD 2006–22–03 is acceptable for compliance with the corresponding requirement of paragraphs (f)(1) and (f)(2) of this AD.

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows. This AD includes a compliance time specified in paragraph (f)(2) of this AD for airplanes that are also affected by AD 2006–22–03. We realize that the requirements of this AD will necessitate that some operators do the modification required by paragraph (h) of AD 2006–22–03 early. However, accomplishing the modification within the compliance time specified in this AD is required to address cracking in the attachment angles of the rear pressure bulkhead, which could result in failure of the rear pressure bulkhead.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Tom Stafford, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1622; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI EASA Airworthiness Directive 2007–0297R1, dated September 17, 2008, and the service bulletins listed in Table 3 of this AD, for related information.

TABLE 3—RELATED SERVICE BULLETINS

Airbus Service Bulletin	Revision	Date
Airbus Mandatory Service Bulletin A300–53–6005	04	July 18, 2007.
Airbus Mandatory Service Bulletin A310–53–2024	05	October 13, 2006.
Airbus Mandatory Service Bulletin A310–53–2025	06	August 3, 2006.

TABLE 3—RELATED SERVICE BULLETINS—Continued

Airbus Service Bulletin	Revision	Date
Airbus Service Bulletin A300–53–6006	3	March 24, 1989.

Material Incorporated by Reference

(i) You must use the service information contained in Table 4 of this AD to do the actions required by this AD, unless the AD specifies otherwise.

TABLE 4—MATERIAL INCORPORATED BY REFERENCE

Airbus Service Bulletin	Revision	Date
Airbus Mandatory Service Bulletin A300–53–6005	04	July 18, 2007.
Airbus Mandatory Service Bulletin A310–53–2024	05	October 13, 2006.
Airbus Mandatory Service Bulletin A310–53–2025	06	August 3, 2006.
Airbus Service Bulletin A300–53–6006	3	March 24, 1989.

Airbus Service Bulletin A300–53–6006, Revision 3, dated March 24, 1989, contains the following effective pages:

Page Nos.	Revision level shown on page	Date shown on page
1, 29, 47, 48	3	March 24, 1989.
2–28, 30–46, 49–52	2	August 11, 1988.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Airbus SAS—EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; e-mail: *account.airworth-eas@airbus.com*; Internet *http://www.airbus.com*.

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221 or 425–227–1152.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on September 16, 2009.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–23094 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–13–P

SUSQUEHANNA RIVER BASIN COMMISSION

18 CFR Parts 806 and 808

Review and Approval of Projects

AGENCY: Susquehanna River Basin Commission.

ACTION: Final rule.

SUMMARY: This document contains amendments to the project review regulations of the Susquehanna River Basin Commission (Commission) including provisions restricting the use of docket reopening petitions to avoid abuses of process; amending the ''Approval by Rule'' (ABR) process to allow for project sponsors to utilize approved water sources at approved drilling pad sites without the need for modification of the ABR; clarifying that the public hearing requirement for rulemaking shall be applicable to the proposed rulemaking stage of that process; and further providing for the time period within which administrative appeals must be filed. These amendments were first proposed in a Notice of Proposed Rulemaking (NOPR) that appeared at 74 FR 31647 on July 2, 2009.

DATES: These rules are effective on November 1, 2009.

ADDRESSES: Susquehanna River Basin Commission, 1721 N. Front Street, Harrisburg, PA 17102–2391.

FOR FURTHER INFORMATION CONTACT: Richard A. Cairo, General Counsel, *telephone:* 717–238–0423, ext. 306; *fax:* 717–238–2436; *e-mail: rcairo@srbc.net.* Also, for further information on the final rulemaking, visit the Commission's Web site at *http://www.srbc.net.*

SUPPLEMENTARY INFORMATION:

Background and Purpose of Amendments

The Commission convened public hearings on August 4, 2009, in Harrisburg, Pennsylvania and on August 5, 2009, in Elmira, New York. A written comment period was held open until August 15, 2009. Comments were received at both the hearings and during the comment period. A summary of the comments and the Commission's responses thereto follows.

Comments by Section, Part 806

Section 806.4 Projects Requiring Review and Approval

Comment: The Commission's proposal to require review and approval for any hydroelectric project regulated by the Federal Energy Regulatory Commission (FERC) and initiating a licensing or licensing amendment is defective and should not be adopted because: (1) As currently worded, the

proposed amendment to 18 CFR 806.4 (a) would exceed the Commission's project review powers under Section 3.10 of the Susquehanna River Basin Compact (Compact); (2) The proposed amendment to 18 CFR 806.4 (a) would produce duplicative and redundant licensing proceedings for review of hydroelectric projects and run afoul of the intent of Congress under the Federal Power Act and paragraph (w) of the Federal Reservations to the Compact to retain sole, unimpeded licensing authority in FERC; and (3) the Commission already has sufficient powers under its existing regulations and its compact authority to review aspects of hydroelectric and nuclear projects that affect water resources, and there is no need to single out these facilities for review in the proposed amendment to 18 CFR 806.4 (a). Despite the Commission's claim in the Notice of Proposed Rulemaking (NOPR) that it is merely codifying its current practice, the proposal represents a break with past Commission practice regarding both hydroelectric facility and nuclear power plant review without any explanation or justification for the change, and is therefore arbitrary and capricious.

The NOPR seeks to infringe on the exclusive authority of FERC granted to it under the Federal Power Act and reserved by Congress when it consented to the Compact. Nothing in the Compact provides, or even suggests, that the United States and the other parties to the Compact intended to grant the Commission review and approval authority of licensing or license amendment proceedings before FERC. There is no need for the additional language proposed in the NOPR in that the Commission has ample authority to review and approve ''projects'' that are separately undertaken and that affect the water resources of the basin under its existing regulatory program. With regard to projects regulated by the Nuclear Regulatory Commission (NRC), the Compact, the Commission's existing regulatory program and current practices are clear enough, well-established, and fully recognized by NRC, thus questioning the need for the suggested modification.

The Commission appears to be proposing that before an application can even be submitted to FERC or the NRC, application and approval must first be obtained from the Commission, which directly and materially interferes with FERC and NRC's procedures and processes.

Response: The Commission exercises concurrent jurisdiction with FERC and the NRC and believes that its exercise of same is both appropriate and authorized under the Compact. Furthermore, it has no intention of exercising that authority in a manner that conflicts or interferes with that exercised by these two federal agencies. Nor was it the intention of the proposed change to require Commission approval prior to the submission of licensing applications to the federal agencies. Rather, the intention was to have the initiation of federal licensing likewise initiate project review by the Commission. As was the case in a recent hydroelectric facility licensing process, the Commission undertakes a single, coordinated review with all federal and state resource agencies that serves both regulatory schemes.

However, it is apparent from the comments received and the Commission's own reconsideration that the proposed changes, as drafted, do not provide the clarification originally sought. Therefore, the Commission believes it is appropriate to suspend final action on this element of the NOPR so that it can be re-drafted, particularly to ensure that it does not interfere with FERC and NRC procedures. (This is especially the case with respect to the comment that the proposal could be interpreted as requiring both review and approval prior to initiating licensing actions.) The Commission will move forward with publication of a new NOPR at such time as it completes development of a revised set of proposed changes for projects involved in licensing procedures.

Licensing and licensing amendment actions are projects that often have significant effects upon the water resources of the basin and the SRBC Comprehensive Plan. Federal Reservations, Section 2, paragraph w of the Compact, while preserving the authority of federal licensing authorities, also makes clear that use of the waters of the basin shall be subject to approval in accordance with the terms of the Compact.

Both the Compact and the Commission's current regulations require review and approval for, but not limited to: (1) Projects on or crossing the boundary between signatory states; (2) projects in one signatory state having a significant effect on the water resources within another signatory state; and (3) projects included in the Commission's Comprehensive Plan or which would have a significant effect upon the plan. All hydroelectric and nuclear facilities in the basin meet one or more of these requirements. The Commission will therefore continue, as appropriate and as it has done in the past, to exercise concurrent authority with federal licensing authorities to review and approve such projects.

Comment: The deletion of the existing § 806.4(a)(8) language, which requires Commission review and approval of any natural gas well development project targeting the Marcellus or Utica shale formations and involving a withdrawal, diversion or consumptive use of water, regardless of quantity, was alarming. The Commission's acknowledgement that the deletion of § 806.4(a)(8) was a drafting error, the public recognition of the error it posted on its Web site upon discovery of the error, and its willingness to correct the error at the final rulemaking stage is appreciated.

Response: The Commission regrets the inadvertent proposed deletion of the provision and any confusion resulting from the error. Given that the Commission is not moving forward with any revisions to § 806.4(a)(8) as a part of this final rulemaking action, the error is of no effect and the provision in question remains effective. At such time as the Commission moves forward with revisions to § 806.4 as part of a new NOPR, it will be certain not to repeat the error.

Section 806.22 Standards for Consumptive Use of Water

Comment: Deletion of the contiguous landowner notification requirement in exchange for a display ad newspaper notice would leave such landowners without direct or effective notice, nor any guarantee that newspaper notification would provide adequate time for meaningful participation in the Approval by Rule (ABR) process. Any participation in the process would be markedly diminished, even though they remain the citizens most immediately affected. Moreover, some contiguous landowners do not reside on the affected land and thus may not be reached by the general newspaper notice. And as more newspapers fold as a result of declining readership and advertisement revenue, such notice will become increasingly inadequate.

Do not eliminate the requirement that project sponsors notify contiguous landowners as part of the ABR process; it is only fair that notice be given to the persons who are directly affected by such projects, and adjacent landowners are well placed to inform the Commission about potential adverse impacts of the approval.

Contiguous landowners need to have notice concerning water withdrawals since the presence of streams, pond or wetlands, and groundwater, contributes significantly to the value of the property. They should be entitled to notice and allowed a sufficient amount

of time to comment on the impact of proposed withdrawals.

If the Commission wants to enhance public transparency, it should make information concerning applications submitted to it available on the Commission's Web site. In addition to providing information on the name of applicants, amount of water requested, location of withdrawals, date, and details of final action taken by the Commission, it should also plot withdrawals on a map display so that it is easy to see how much water is being withdrawn in a given area.

Response: The Commission acknowledges the concerns raised in the comments, but notes that there is some confusion about the scope of the ABR process. First, the process does not involve approvals for withdrawals from surface or groundwater sources. A number of the comments received spoke to the legitimate right of contiguous landowners to receive notice of proposed withdrawals because of the potential impact of their use and enjoyment and potentially diminished value to their land. Withdrawals are regulated separately by the Commission, they require separate docket approval, and contiguous landowner notification is required in advance of any Commission action. The proposed revisions do not modify those notification provisions in any way.

The ABR process involves an administrative approval for consumptive use at the natural gas well drilling pad site and enables the Commission to track all sources of water transported to the site, the quantities used in development of the well, and the fate of flowback and produced fluids. These data are important to assess the cumulative impact of this industry's activity on the water resources of the basin. A number of the comments received, however, spoke to the appropriateness of landowner notification if well drilling and hydrofracing activity was occurring adjacent to their property. The ABR process does not involve approval to drill or hydrofrac; it is limited to regulating the consumptive use of water involved in either of those activities. Approval to drill (and to undertake the related hydrofracture development activity) is a separate governmental action undertaken by the Commission's member states in the form of gas well permitting.

The impetus behind the Commission's proposal to modify contiguous landowner notice provisions in the ABR process stem from the fact that they have been problematic, administratively burdensome, and often lead to confusion at the landowner level. And while those shortcomings are pronounced with the ABR process, given the recent level of natural gas development activity, the Commission acknowledges that a number of those shortcomings are likewise present with its contiguous landowner notification requirements for docket applications as well. Therefore, after review and consideration of the comments received, as well as its own reconsideration of the appropriate scope of amendments to its existing notification procedures, the Commission believes it is appropriate to suspend action on this element of the NOPR as part of this final rulemaking action. Accordingly, it will move forward with publication of a new NOPR at such time as it completes development of a revised set of proposed changes to its general application notification requirements.

With respect to public transparency, please note that the Commission continues to increase the amount of information contained on its Web site, *www.srbc.net*, for the benefit of the public. Further improvements are underway and are anticipated to be completed by the end of 2009 that will afford greater access to approvals, requests for approval, lists of approved water sources by project sponsor, location information about approved withdrawal and consumptive use sites, and mapping features to display information to better inform the public.

Comment: The flexible use of approved water withdrawal sources by gas well developers at various drill pad sites without modification of their pad site ABR under proposed regulation § 806.22 (f) (11 & 12) will mean that such withdrawals, and the ABR approved well pad sites they serve, will receive less regulatory scrutiny.

Response: All such withdrawals will have already been fully reviewed and approved by the Commission prior to any use and will have met all public notice requirements at the time of their initial approval. This means that the impacts of withdrawals will have been fully evaluated and appropriate conditions such as passby requirements included. All users of these approved sources will be subject to the same limitations and conditions contained in the approved docket.

In approving a withdrawal, the Commission exercises continuing regulatory oversight and can, at any time, reopen the docket approval and add new conditions or make further orders to meet any changed conditions and otherwise protect the public welfare and the environment. In addition, the main purpose of the proposed change is to simplify administrative procedures without compromising regulatory oversight.

Again, as noted above, the ABR process involves an administrative approval for consumptive use at the natural gas well drilling pad site and enables the Commission to track all sources of water transported to the site, the quantities used in development of the well, and the fate of flowback and produced fluids. The substantive evaluation of withdrawals and the conditions under which they may be undertaken without impact to the environment or other users occurs under the Commission's withdrawal regulations, and not the ABR process for which changes are proposed under this NOPR.

Comment: The proposed changes to § 806.22(f)(11) and (f)(12) would eliminate core safeguards for the water-related values that the Commission is committed to protect by allowing project sponsors to shift water from one project to another without even registering the transfer with the Commission.

Response: This is a misreading of the NOPR and implies that project sponsors will be shifting water sources from one drilling pad site to another without oversight by the Commission. To the contrary, what the Commission is proposing is a system whereby each project sponsor engaged in natural gas development will have an approved list of water sources for which it has received docket approvals, with accompanying conditions to properly limit and monitor its withdrawals from each of those sources. The sources are added to the list at the time of docket approval, which effectively registers them for use at the project sponsor's approved drilling pad sites. The Commission sees no need to require a separate registration action by the project sponsor when it can be done administratively at the time of docket approval. All other sources that the project sponsor may use at its approved drilling pad sites must first be registered or otherwise approved by the Commission.

Comment: The proposed changes to § 806.22(f)(12) would permit project sponsors to share and trade water sources without obtaining new or modified ABRs, and without certifying to the Commission their intention to comply with all terms and conditions of each other's ABRs, and would authorize new sources of water without modifying the existing ABRs.

Response: The terms and conditions incorporated into every water source approval, and every ABR issued by the

Commission, must be adhered to by project sponsors. The purposes of the proposed modifications are to facilitate efficient water use and water sharing by the natural gas industry, and to streamline administrative processes so that the Commission's resources are better focused on substantive review and management of water resources, not inefficient bureaucracy. Issuing a single approval for a given water source and allowing its use at any of the project sponsor's approved drilling pad sites, with appropriate conditions and monitoring requirements, is far preferable than requiring the project sponsor, and the Commission, to modify each and every ABR issued to the project sponsor, which could number in the hundreds over time. From a water resources management standpoint, the issue is whether the source is approvable for use without adverse effect, regardless of whether the project sponsor intends to utilize the source at one site, or multiple sites. Allowing water sharing limits the number of withdrawals across the basin and limits tanker truck traffic by allowing project sponsors to use the closest approved water source site, even if the withdrawal approval was first issued to another operator. Adherence to all docket conditions, and ABR recordkeeping and reporting conditions, will continued to be required of all project sponsors, resulting in a full daily accounting of all water withdrawn across the basin (by source, by date, by project sponsor), where it was delivered to, and quantities used on site.

Comment: The new proposed subsections § 806.22(f)(11) and (f)(12)(ii) contain language requiring the project sponsor to obtain all necessary approvals required for the project from the state agency. However, such reference to the need for state agency approval is absent from new proposed § 806.22(f)(12)(i). For the regulation to be internally consistent and for member state agency coordination purposes, a sentence should be added at the end of § 806.22(f)(12)(i) that is similar to the one contained in § 806.22(f)(12)(ii), indicating that registrations ''shall be subject to any approval or authorization required by the member State to utilize such source(s).'' The proposed language would put the project sponsor on notice that it would also need state-level authorization to use such source at the time it is registered with the Commission and before its use for natural gas well development.

Response: The Commission agrees with the commenter and the final rulemaking incorporates the proffered language.

Section 806.32 Reopening/ Modification

Comment: This procedural change will allow interested parties' to fully participate in Commission processes, while avoiding unnecessary or duplicative proceedings.

Response: The Commission agrees.

Comment: Due process requires that the Commission narrowly construe its proposal to prevent persons whose administrative appeals are denied from petitioning for reopening of the approval seeking the same or similar relief absent new facts not known or readily discernable at the time of the appeal. Concern is raised about the use of the term ''similar'' being applied in such a way as to frustrate legitimate new claims, and the term ''functionally equivalent'' is recommended to be inserted in its place.

Response: The Commission agrees and the final rulemaking incorporates the proffered language.

Comment: We oppose the proposed restrictions to petitioning and reopening a docket.

Response: The Commission believes that any interested party should have the right to petition for a reopening of a project approval, but believes that parties attempting to use this provision to obtain administrative review of matters for which administrative appeals were denied constitutes an abuse of process and should be restricted.

Comments by Section, Part 808

Section 808.1 Public Hearings

Comment: We agree that the Commission should hold at least one public hearing within a reasonable period after rules revisions are initially proposed. The rule leaves open the option of convening additional hearings if, for example, the Commission recommends substantial changes in response to comments on the initial proposed rulemaking.

Response: The Commission agrees with the interpretation of the commenter. As structured, the rule would require the Commission to convene at least one additional hearing in the event changes to an NOPR are substantial and result in re-publication.

Section 808.2 Administrative Appeals

Comment: The proposed constructive notice rule allowing the appeal period for persons other than project sponsors to run 30 days from the date of publication of the action in the **Federal Register** is respectful of due process rights and is commendable.

Response: The Commission agrees that this modification advances the due process rights of interested parties and has retained it in this final rulemaking action.

Comment: This procedural change will maximize interested parties' ability to fully participate in Commission processes.

Response: The Commission agrees.

List of Subjects in 18 CFR Parts 806 and 808

Administrative practice and procedure, Water resources.

■ Accordingly, for the reasons set forth in the preamble, the Susquehanna River Basin Commission amends 18 CFR Parts 806 and 808 as follows:

PART 806—REVIEW AND APPROVAL OF PROJECTS

■ 1. The authority citation for Part 806 continues to read as follows:

Authority: Secs. 3.4, 3.5(5), 3.8, 3.10 and 15.2, Public Law 91–575, 84 Stat. 1509 *et seq.*

Subpart C—Standards for Review and Approval

■ 2. In § 806.22, revise paragraph (f)(11) and add paragraph (f)(12) to read as follows:

§ 806.22 Standards for consumptive use of water.

* * * * *

(f) * * *

(11) A project sponsor issued an approval by rule pursuant to paragraph (f)(9) of this section may utilize any water source approved for use by the project sponsor for natural gas well development pursuant to § 806.4 or this section, at the applicable drilling pad site subject to any approval or authorization required by the member state to utilize such source(s).

(12) The following additional sources of water may be utilized by a project sponsor in conjunction with an approval by rule issued pursuant to paragraph (f)(9) of this section:

(i) Water withdrawals or diversions approved by the Commission pursuant to § 806.4(a) and issued to persons other than the project sponsor, provided any such source is approved for use in natural gas well development, the project sponsor has an agreement for its use, and at least 10 days prior to use, the project sponsor registers such source with the Commission on a form and in a manner as prescribed by the Commission, and provides a copy of same to the appropriate agency of the member state. Any approval issued hereunder shall be further subject to any

approval or authorization required by the member state to utilize such source(s).

(ii) Sources of water other than those subject to paragraph (f)(12)(i) of this section, including, but not limited to, public water supply, wastewater discharge or other reclaimed waters, provided such sources are first approved by the Executive Director pursuant to this section. Any request to utilize such source(s) shall be submitted on a form and in a manner as prescribed by the Commission, and shall be subject to review pursuant to the standards set forth in subpart C of this part. Any approval issued hereunder shall be further subject to any approval or authorization required by the member state to utilize such source(s). The notice requirements related to agencies of member states, municipalities and counties contained in paragraph (f)(2) of this section, and the notice requirements contained in paragraph (f)(3) of this section, shall likewise be applicable to any request submitted hereunder.

Subpart D—Terms and Conditions of Approval

■ 3. In § 806.32, revise paragraph (a) to read as follows:

§ 806.32 Reopening/modification.

(a) Once a project is approved, the Commission, upon its own motion, or upon petition of the project sponsor or any interested party, may at any time reopen any project approval and make additional orders or otherwise modify or impose such additional conditions that may be necessary to mitigate or avoid adverse impacts or to otherwise protect the public health, safety, and welfare or water resources. Whenever a petition for reopening is filed by an interested party, the burden shall be upon that interested party to show, by a preponderance of the evidence, that a significant adverse impact or a threat to the public health, safety and welfare or water resources exists that warrants reopening of the docket. Notwithstanding the foregoing, any petition filed by a party who previously sought the same or functionally equivalent relief identified in the petition pursuant to the administrative appeals process under § 808.2 will not be eligible for consideration by the Commission absent new facts not known or readily discernable at the time of consideration of the petitioner's previous request for administrative appeal filed pursuant to § 808.2.

* * * * *

PART 808—HEARINGS AND ENFORCEMENT ACTIONS

■ 4. The authority citation for Part 808 continues to read as follows:

Authority: Secs. 3.4, 3.5(5), 3.8, 3.10 and 15.2, Public Law 91–575, 84 Stat. 1509 *et seq.*

Subpart A—Conduct of Hearings

■ 5. In § 808.1, revise paragraphs (a)(2) and (c) to read as follows:

§ 808.1 Public hearings.

(a) * * *

(2) Proposed rulemaking.

* * * * *

(c) Notice of public hearing. At least 20 days before any public hearing required by the compact, notices stating the date, time, place and purpose of the hearing including issues of interest to the Commission shall be published at least once in a newspaper of general circulation in the area affected. Occasions when public hearings are required by the compact include, but are not limited to, amendments to the comprehensive plan, drought emergency declarations, and review and approval of diversions. In all other cases, at least 10 days prior to the hearing, notice shall be posted at the office of the Commission (or on the Commission Web site), mailed by first class mail to the parties who, to the Commission's knowledge, will participate in the hearing, and mailed by first class mail to persons, organizations and news media who have made requests to the Commission for notices of hearings or of a particular hearing. With regard to rulemaking, the Commission shall convene at least one public hearing on any proposed rulemaking it approves for public review and comment. For any such hearing(s), notices need only be forwarded to the directors of the New York Register, the Pennsylvania bulletin, the Maryland Register and the **Federal Register**, and it is sufficient that this notice appear only in the **Federal Register** at least 20 days prior to the hearing and in each individual state publication at least 10 days prior to any hearing scheduled in that state.

■ 6. In § 808.2, revise paragraph (a) to read as follows:

§ 808.2 Administrative appeals.

(a) A project sponsor or other person aggrieved by any action or decision of the Commission or Executive Director may file a written appeal requesting a hearing. Except with respect to project approvals or denials, such appeal shall be filed with the Commission within 30 days of the action or decision. In the case of a project approval or denial, such appeal shall be filed by a project sponsor within 30 days of receipt of actual notice, and by all others within 30 days of publication of notice of the action taken on the project in the **Federal Register**.

* * * * *

Dated: September 16, 2009.

Thomas W. Beauduy,

Deputy Director.

[FR Doc. E9–23281 Filed 9–28–09; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket No. USCG–2009–0854]

RIN 1625–AA01

Special Anchorage Areas; Henderson Harbor, NY

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: In this final rule, the Coast Guard removes a note which states from whom one must obtain permission to moor or anchor in the special anchorage areas of Henderson Harbor, NY.

DATES: This rule is effective on September 29, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2009–0854 and are available online by going to *http://www.regulations.gov,* inserting USCG–2009–0854 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Lieutenant Michael C. Petta, Ninth District Legal Office, Coast Guard, telephone 216–902–6010, e-mail *michael.c.petta@uscg.mil.* If you have questions on obtaining permission to moor or anchor in the special anchorage areas of Henderson Harbor, NY, call the Town Board, telephone 315–938–5542. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because this amendment is minor and merely technical in nature in that it simply removes the note which states one must obtain permission from the Town of Henderson Harbormaster to moor or anchor in the special anchorage areas of Henderson Harbor, NY. Notice and comment is unnecessary because, as discussed below, the local ordinance has changed such that the Harbormaster no longer receives requests to moor or anchor.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Good cause exists because the local ordinance has changed such that the Harbormaster no longer receives requests to moor or anchor, and leaving the note in place would provide inaccurate information.

Background and Purpose

On June 11, 2009, the Town of Henderson Harbor revised its boating ordinance. One result of that revision is that the town's harbormaster is no longer the party from whom one obtains permission to moor or anchor in the Henderson Harbor special anchorage areas. This rule responds to the town's request to remove from 33 CFR 110.87 the note which states that the town's harbormaster is the party from whom one must obtain permission.

Discussion of Rule

This rule contains no new provisions. Neither does it amend or remove any substantive provisions. Instead, this rule merely removes from 33 CFR 110.87 the note which states that the town's harbormaster is the party from whom one must obtain permission to moor or anchor in the Henderson Harbor, NY special anchorage areas. This change is necessary because the town of Henderson Harbor recently revised its boating laws to include removing its harbormaster as the permit granting party.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. This rule is not considered a significant regulatory action because the removal of the town's harbormaster as the party from whom one must obtain permission to moor or anchor in the Henderson Harbor special anchorage areas is a minor, non-substantive, and administrative change.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to moor or anchor in either of the special anchorage areas in Henderson Harbor, NY.

The removal of the town's harbormaster as the party from whom one must obtain permission to moor or anchor in the Henderson Harbor special anchorage areas will not have a significant economic impact on a substantial number of small entities because this rule is a minor, technical change to the regulation. It does not alter the size or character of the special anchorage areas.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

The Coast Guard recognizes the treaty rights of Native American Tribes. Moreover, the Coast Guard is committed to working with Tribal Governments to implement local policies and to mitigate tribal concerns. We have determined

that this rule and fishing rights protection need not be incompatible. We have also determined that this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Nevertheless, Indian Tribes that have questions concerning the provisions of this proposed rule or options for compliance are encouraged to contact the point of contact listed under **FOR FURTHER INFORMATION CONTACT**.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(a), of the Instruction. This rule involves the promulgation of a procedural regulation, in that it merely removes the Henderson Harbor's harbormaster as the party from whom one must obtain permission to moor or anchor in the harbor's special anchorage areas. This rule does not alter the size or character of the special anchorage areas. Under figure 2–1, paragraph (34)(a), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 110 as follows:

PART 110—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 1221 through 1236, 2030, 2035, 2071; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

§ 110.87 [Amended]

■ 2. In § 110.87, remove the Note.

Dated: September 17, 2009.

D.R. Callahan,

Captain, U.S. Coast Guard, Commander, Ninth Coast Guard District, Acting.

[FR Doc. E9–23390 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–0884]

RIN 1625–AA11

Safety Zone and Regulated Navigation Area, Chicago Sanitary and Ship Canal, Romeoville, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone and regulated navigation area on the Chicago Sanitary and Ship Canal near Romeoville, IL. This temporary final rule places navigational and operational restrictions on all vessels transiting the navigable waters located adjacent to and over the U.S. Army Corps of Engineers' (USACE) electrical dispersal fish barrier system.

DATES: This temporary final rule is effective from 5 p.m. on September 29, 2009, until 5 p.m. on October 16, 2009. This temporary final rule is enforceable with actual notice by Coast Guard personnel beginning September 18, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2009–0884 and are available online by going to *http://www.regulations.gov*, inserting USCG–2009–0884 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary final rule, call CDR Tim Cummins, Deputy Prevention Division, Ninth Coast Guard District, telephone 216–902–6045. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the U.S. Army Corps of Engineers (USACE) made the decision, without time for a proper notice period, to permanently increase the voltage of the fish barrier to two-volts per inch in response to data which indicates that Asian carp are closer to the Great Lakes waterway system than originally thought. The electric current in the water created by the electrical dispersal barriers coupled

with the uncertainty of the effects of the increased voltage poses a safety risk to commercial vessels and recreational boaters who transit the area. Therefore, it would be against the public interest to delay the issuing of this rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** because of the safety risk to commercial vessels and recreational boaters who transit the area. The following discussion and the Background and Purpose section below provide additional support of the Coast Guard's determination that good cause exists for not publishing a NPRM and for making this rule effective less than 30 days after publication.

In 2002, the USACE energized a demonstration electrical dispersal barrier located in the Chicago Sanitary and Ship Canal. The demonstration barrier, commonly referred to as ''Barrier I,'' generates a low-voltage electric field (one-volt per inch) across the canal, which connects the Illinois River to Lake Michigan. Barrier I was built to block the passage of aquatic nuisance species, such as Asian carp, and prevent them from moving between the Mississippi River basin and Great Lakes via the canal. In 2006, the USACE completed construction of a new barrier, ''Barrier IIA.'' Because of its design, Barrier IIA can generate a more powerful electric field (up to four-volts per inch), over a larger area within the Chicago Sanitary and Ship Canal, than Barrier I. Testing was conducted by the USACE which indicated that two-volts per inch is the optimal voltage to deter aquatic nuisance species. The USACE's original plan was to perform testing on the effects of the increased voltage on vessels passing through the fish barrier prior to permanently increasing the voltage. However, after receiving data that the Asian carp were closer to the Great Lakes than expected, the decision was made to immediately energize the barrier to two-volts per inch without prior testing.

A comprehensive, independent analysis of Barrier IIA, conducted in 2008 by the USACE at the one-volt per inch level, found a serious risk of injury or death to persons immersed in the water located adjacent to and over the barrier. Additionally, sparking between barges transiting the barrier (a risk to flammable cargoes) occurred at the one-volt per inch level. The Coast Guard and USACE developed regulations and safety guidelines, with stakeholder input, which addressed the risks and hazards associated with operating the barriers at the one-volt per inch level. These regulations were published in 33 CFR 165.923, 70 FR 76692 (Dec 28, 2005) and in a series of temporary final rules: 71 FR 4488 (Jan 27, 2006); 71 FR 19648 (Apr 17, 2006); 73 FR 33337 (Jun 12, 2008); 73 FR 37810 (Jul 2, 2008); 73 FR 45875 (Aug 7, 2008); and 73 FR 63633 (Oct 27, 2008). A temporary interim rule was issued on February 9, 2009 (74 FR 6352). Finally, an NPRM was issued on May 26, 2009 (74 FR 24722).

In early August, 2008, the USACE notified the Coast Guard that it planned to immediately increase the voltage of Barrier IIA to two-volts per inch on a full-time basis starting August 17, 2009. Both Barrier IIA and Barrier I will operate at the same time; hence, Barrier I will provide a redundant back up to Barrier IIA.

In the past, the Coast Guard has advised the USACE that it has no objection to the activation of Barrier IIA and Barrier I at a maximum strength of one-volt per inch. Testing on commercial vessels transiting the canal over the fish barrier was conducted at one volt per inch indicating that although the barriers create risks to people and vessels, those risks could be mitigated by following certain procedures. These mitigation procedures for the barrier operating at one volt per inch were implemented in a temporary interim rule establishing a regulated navigation area and safety zone that was published in the **Federal Register** on February 9, 2009 (74 FR 6352), as well as an NPRM published in the **Federal Register** on May 26, 2009 (74 FR 24722).

However, both of these rulemakings reflected the prior operating parameters of the dispersal barriers and contemplated further testing of the effects of higher voltages on commercial and recreational vessels as well as people. The USACE began safety testing in consultation with the U.S. Coast Guard on August 17, 2009, to test various configurations of commercial tugs and barges as well as recreational vessels with non-conductive hulls passing through the Barriers at increased voltage and operating parameters. Because the USACE decided that the voltage and operating parameters had to be immediately increased prior to the completion of safety testing, the USCG determined that temporary closure of the canal to all vessels through a safety zone was necessary until the risks were better understood. This resulted in successive temporary final rules that suspended the prior temporary interim rule. These temporary final rules enacting safety zones were published in the **Federal Register** on August 26, 2009 (74 FR 43055) and September 02, 2009 (74 FR 45318).

Because testing and analysis of the risks to persons and vessels are ongoing and immediate action is needed to prevent injury to people and vessels, it was not possible to provide a full notice and comment period. The Captain of the Port Lake Michigan retains the authority to permit vessels to enter the safety zone. As safety testing results become available, the Captain of the Port Lake Michigan will make every effort to permit vessels to pass for which there is a decreased or known risk of injury or property damage. If vessels wish to enter the safety zone they must receive permission from the Captain of the Port Lake Michigan to do so and must follow all orders from the Captain of the Port Lake Michigan or her designated on-scene representative while in the zone.

If, for any reasons, the safety zone is at any time suspended, the terms of the regulated navigation area will apply to all vessels. The Captain of the Port Lake Michigan will cause notice of the enforcement of the regulated navigation area to be made by all appropriate means to effect the widest publicity among the affected segments of the public.

Background and Purpose

The Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990, as amended by the National Invasive Species Act of 1996, authorized the USACE to conduct a demonstration project to identify an environmentally sound method for preventing and reducing the dispersal of non-indigenous aquatic nuisance species through the Chicago Sanitary and Ship Canal. The USACE selected an electric barrier because it is a non-lethal deterrent with a proven history, which does not overtly interfere with navigation in the canal.

A demonstration dispersal barrier (Barrier I) was constructed and has been in operation since April 2002. It is located approximately 30 miles from Lake Michigan and creates an electric field in the water by pulsing low voltage DC current through steel cables secured to the bottom of the canal. A second barrier, Barrier IIA, was constructed 800 to 1,300 feet downstream of the Barrier I. The potential field strength for Barrier IIA will be up to four times that of the Barrier I. Barrier IIA was successfully operated for the first time for approximately seven weeks in September and October 2008, while Barrier I was taken down for maintenance. Construction on a third barrier (Barrier IIB) is planned; Barrier

IIB would augment the capabilities of Barriers I and IIA.

In the spring of 2004, a commercial towboat operator reported an electrical arc between a wire rope and timberhead while making up a tow in the vicinity of the Barrier I. During subsequent USACE safety testing in January 2005, sparking was observed at points where metal-to-metal contact occurred between two barges in the barrier field.

The electric current in the water also poses a safety risk to commercial and recreational boaters transiting the area. The Navy Experimental Diving Unit (NEDU) was tasked with researching how the electric current from the barriers would affect a human body if immersed in the water. The NEDU final report concluded that the possible effects to a human body if immersed in the water include paralysis of body muscles, inability to breathe, and ventricular fibrillation.

A Safety Work Group facilitated by the Coast Guard and in partnership with the USACE and industry initially met in February 2008 and focused on three goals: (1) Education and public outreach, (2) keeping people out of the water, and (3) egress/rescue efforts. The Safety Work Group has regularly been attended by eleven stakeholders. Key partners include the American Waterways Operators, Illinois River Carriers Association, Army Corps of Engineers Chicago District, Coast Guard Marine Safety Unit Chicago, Coast Guard Sector Lake Michigan/Captain of the Port Lake Michigan, and the Ninth Coast Guard District.

Based on the safety hazards associated with electric current flowing through navigable waterways and the uncertainty of the effects of higher voltage on people and vessels that pass over and adjacent to the barriers, the Coast Guard is closing the waterway until proper testing and analysis of such testing can be completed by the USACE. The Coast Guard appreciates the commercial significance of this waterway and will work closely with the USACE to re-open the waterway as soon as possible; however, it is imperative that this safety zone be immediately enacted to avoid loss of life.

As soon as safety testing and analysis are completed, the Coast Guard plans on publishing a new temporary interim rule (TIR) with requests for comments. Although the Coast Guard anticipates being able to permit some vessels to transit through the fish barrier after testing is complete, it is currently anticipated any subsequent TIR will continue to place restrictions on vessels including prohibiting some vessels from transiting through the fish barrier entirely. The Coast Guard will then likely follow with a supplemental notice of proposed rulemaking (SNPRM) in order to provide a complete notice and comment period for interested parties. We encourage the public to participate in the rulemaking process by submitting and reviewing comments and related materials at *http://www.regulations.gov* to the dockets associated with the anticipated TIR and any subsequent NPRM/SNPRM.

Affected parties are reminded that the USACE may again raise the operating parameters of the fish barrier in response to ongoing tests regarding the effectiveness of the barrier on the Asian Carp. If this occurs, it is possible that fewer vessels will be given permission to enter the safety zone until further safety testing and analysis can be completed and current timelines for a final rule will be extended.

Discussion of Rule

This temporary final rule removes 33 CFR 165.T09–1247. This rule suspends 33 CFR 165.923 until 5 p.m. on October 16, 2009. This rule places a safety zone on all waters located adjacent to and over the electrical dispersal barriers on the Chicago Sanitary and Ship Canal. The safety zone will be enforced at all times the USACE operates the electrical dispersal barrier higher than one volt per inch until safety testing is conducted that indicates vessels may safely pass. The Coast Guard has deemed this safety zone necessary from September 18, 2009, until October 16, 2009, because safety testing is still being conducted on vessels to determine whether and under what conditions vessels can safely pass adjacent to and over the electrical dispersal barriers. Although every effort will be made to permit vessels to pass as information becomes available; current estimates indicate that testing and analysis will not be completed by the USACE until at least October 16, 2009. Therefore, this safety zone is necessary until that time in order to prevent loss of life and damage to property.

This safety zone, which encompasses all the waters of the Chicago Sanitary and Ship Canal located between mile marker 296.0 (approximately 958 feet south of the Romeo Road Bridge) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge), will be enforced by the Captain of the Port Lake Michigan, for such times before, during, and after barrier testing as he or she deems necessary to protect mariners and vessels from damage or injury. The Captain of the Port Lake Michigan will cause notice of enforcement or suspension of enforcement of this safety zone to be made by all appropriate means to affect the widest publicity among the affected segments of the public. Such means of notification will include, but is not limited to, Broadcast Notice to Mariners and Local Notice to Mariners. The Captain of the Port Lake Michigan will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone is suspended. In addition, Captain of the Port Lake Michigan maintains a telephone line that is manned 24-hours a day, seven days a week. The public can obtain information concerning enforcement of the safety zone by contacting the Captain of the Port Lake Michigan via the Coast Guard Sector Lake Michigan Command Center at 414–747–7182.

In the event that the enforcement of the safety zone is temporarily suspended, this rule implements a regulated navigation area to control the movements of all vessels passing over and adjacent to the barriers. The Captain of the Pork Lake Michigan will cause notice of the enforcement of the regulated navigation area to be made by all appropriate means to effect the widest publicity among the affected segments of the public. This regulated navigation area closely mirrors those previously implemented in this area. The regulated navigation area encompasses all waters of the Chicago Sanitary and Ship Canal located between mile marker 295.0 (approximately 1.1 miles south of the Romeo Road Bridge) and mile marker 297.5 (approximately 1.3 miles northeast of the Romeo Road Bridge). The requirements placed on commercial vessels include: (1) Vessels engaged in commercial service, as defined in 46 U.S.C. 2101(5), may not pass (meet or overtake) in the regulated navigation area and must make a SECURITE call when approaching the regulated navigation area to announce intentions and work out passing arrangements on either side; (2) commercial tows transiting the regulated navigation area must be made up with wire rope to ensure electrical connectivity between all segments of the tow; and (3) all up-bound and down-bound barge tows that contain one or more red flag barges must be assisted by a bow boat until the entire tow is clear of the regulated navigation area. Red flag barges are barges certificated to carry, in bulk, any hazardous material as defined in 46 CFR 150.115. Currently, 46 CFR 150.115 defines hazardous material as:

(a) A flammable liquid as defined in 46 CFR 30.10–22 or a combustible liquid as defined in 46 CFR 30.10–15;

(b) A material listed in Table 151.05, Table 1 of part 153, or Table 4 of part 154 of Title 46, CFR; or

(c) A liquid, liquefied gas, or compressed gas listed in 49 CFR 172.101.

In the past, the USACE contracted for bow boat assistance for barge tows containing one or more red flag barges. According to the USACE, operators of tows containing one or more red flag barges should notify the bow boat contractor at least two hours prior to the need for assistance. The tow operator should then remain in contact with the contractor after the initial call for bow boat assistance and advise the contractor of any delays. Information on how to arrange for bow boat assistance may be obtained by contacting the Army Corps of Engineers at 312–846–5333, during normal working hours. All mariners are reminded that the Coast Guard does not provide bow boat assistance. During testing of the barrier, the USACE has contracted for bow boat assistance for commercial vessels. However, there is no guarantee that the USACE will continue to fund bow boat assistance. In the event such funding stops, mariners should be ready to arrange for their own bow boat assistance.

This temporary final rule places additional restrictions and operating requirements on all vessels within a smaller portion of the regulated navigation area, specifically, the waters between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge). Within this smaller area, this temporary final rule prohibits all vessels from loitering, mooring or laying up on the right or left descending banks, or making or breaking tows on the waters between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge). In addition, vessels may only enter the waters between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge) for the sole purpose of transiting to the other side and must maintain headway throughout the transit. All vessels and persons are prohibited from dredging, laying cable, dragging, fishing, conducting salvage operations, or any other activity, which could disturb the bottom of the canal in the area located between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge). The temporary final rule also requires all personnel on open decks to wear a Coast Guard approved Type I personal flotation device while on the waters between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge).

These restrictions are necessary for safe navigation of the regulated navigation area and to ensure the safety of vessels and their personnel as well as the public's safety due to the electrical discharges noted during safety tests conducted by the USACE. Deviation from this temporary final rule is prohibited unless specifically authorized by the Commander, Ninth Coast Guard District or his designated representatives. The Commander, Ninth Coast Guard District designates Captain of the Port Lake Michigan and Commanding Officer, Marine Safety Unit Chicago, as his designated representatives for the purposes of the regulated navigation area.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

We expect the economic impact of this rule to be minimal. This determination is based the following: (1) Initial test results at the current operating parameters of two volts per inch indicate that the majority of commercial and recreational vessels that regularly transit the Chicago Sanitary and Ship Canal will be permitted to enter the safety zone under certain conditions; (2) those vessels that will not be permitted to pass through the barrier may be permitted, on a case by case basis, to pass via a dead ship tow by a commercial vessel that is able to transit; and, (3) in exigent circumstances, it may be possible to temporarily drop the voltage of the fish barrier back to one volt per inch.

Because this safety zone must be implemented immediately without a full notice and comment period, the full economic impact of this rule is difficult to determine at this time. The Coast Guard urges interested parties to submit comments that specifically address the economic impacts of permanent or temporary closures of the Chicago Sanitary and Ship Canal. Comments can be made online by going to *http://www.regulations.gov*, inserting USCG–2009–0884 in the ''Keyword'' box, and then clicking ''Search.''

Small Entities

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider whether regulatory actions would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. An RFA analysis is not required when a rule is exempt from notice and comment rulemaking under 5 U.S.C. 553(b). The Coast Guard determined that this rule is exempt from notice and comment rulemaking pursuant to 5 U.S.C. 553(b)(B). Therefore, an RFA analysis is not required for this rule. The Coast Guard, nonetheless, expects that this temporary final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

The Coast Guard recognizes the treaty rights of Native American Tribes. Moreover, the Coast Guard is committed to working with Tribal Governments to implement local policies and to mitigate tribal concerns. We have determined that these regulations and fishing rights protection need not be incompatible. We have also determined that this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Nevertheless, Indian Tribes that have questions concerning the provisions of this rule or options for compliance are encouraged to contact the point of contact listed under **FOR FURTHER INFORMATION CONTACT**.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that this action is one of the category of actions which do not individually or cumulatively have significant effect on the human environment. Therefore, this rule is categorically excluded, under section 2.B.2 Figure 2–1, paragraph (34)(g), of the Instruction and neither an environmental assessment nor an environmental impact statement is required. This rule involves the establishing, disestablishing, or changing of regulated navigation areas and security or safety zones. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

§ 165.T09–1247 [Removed]

■ 2. Remove § 165.T09–1247.

§ 165.923 [Suspended]

■ 3. Section 165.923 is suspended until October 16, 2009.

■ 4. A new temporary section 165.T09–0884 is added as follows:

§ 165.T09–0884 Safety Zone and Regulated Navigation Area, Chicago Sanitary and Ship Canal, Romeoville, IL.

(a) *Safety Zone.*

(1) The following area is a temporary safety zone: All waters of the Chicago Sanitary and Ship Canal located between mile marker 296.0 (approximately 958 feet south of the Romeo Road Bridge) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge).

(2) *Enforcement Period.* The safety zone will be enforced from 5 p.m. on September 18, 2009, until 5 p.m. on October 16, 2009. This safety zone is enforceable with actual notice by Coast Guard personnel beginning September 18, 2009.

(3) *Notice of suspension of enforcement.* The Captain of the Port

Lake Michigan will enforce the safety zone established by this section at all times. However, the Captain of the Port Lake Michigan may temporarily suspend enforcement of the safety zone. If enforcement of the zone is temporarily suspended, the Captain of the Port Lake Michigan will cause a notice of the suspension of enforcement of this safety zone to be made by all appropriate means to effect the widest publicity among the affected segments of the public including publication in the **Federal Register** as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may also include but are not limited to, Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port Lake Michigan will also issue a Broadcast Notice to Mariners and Local Notice to Mariners notifying the public when the temporary suspension of enforcement is over and the zone is once again in operation.

(4) *Regulations.*

(i) In accordance with the general regulations in section 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan, or her on-scene representative.

(ii) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Lake Michigan or her on-scene representative.

(iii) The ''on-scene representative'' of the Captain of the Port is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Lake Michigan to act on her behalf. The on-scene representative of the Captain of the Port Lake Michigan will be aboard a Coast Guard, Coast Guard Auxiliary, or other designated vessel or will be on shore and will communicate with vessels via VHF–FM radio or loudhailer. The Captain of the Port Lake Michigan or her on-scene representative may be contacted via VHF–FM radio Channel 16.

(iv) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Lake Michigan or her on-scene representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Lake Michigan or her on-scene representative.

(v) If a vessel is permitted by the Captain of the Port Lake Michigan or her on-scene representative to transit the safety zone, all personnel on open decks must wear a Coast Guard approved Type I personal flotation device while in the safety zone.

(5) Persons on board any vessel transiting this safety zone in accordance with the rule or otherwise are advised they do so at their own risk.

(b) *Regulated Navigation Area.* The following is a Regulated Navigation Area: All waters of the Chicago Sanitary and Ship Canal, Romeoville, IL located between mile marker 295.0 (approximately 1.1 miles south of the Romeo Road Bridge) and mile marker 297.5 (approximately 1.3 miles northeast of the Romeo Road Bridge).

(1) *Definitions.* The following definitions apply to this section:

Designated representatives means the Captain of the Port Lake Michigan and Commanding Officer, Marine Safety Unit Chicago.

Red flag barge means any barge certificated to carry any hazardous material in bulk.

Hazardous material means any material as defined in 46 CFR 150.115.

Bow boat means a towing vessel capable of providing positive control of the bow of a tow containing one or more barges, while transiting the regulated navigation area. The bow boat must be capable of preventing a tow containing one or more barges from coming into contact with the shore and other moored vessels.

(2) *Notice of enforcement or suspension of enforcement.* The Captain of the Port Lake Michigan will enforce the regulated navigation area established by this section only upon notice. Captain of the Port Lake Michigan will cause notice of the enforcement of this regulated navigation area to be made by all appropriate means to effect the widest publicity among the affected segments of the public including publication in the **Federal Register** as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may also include but are not limited to, Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port Lake Michigan will issue a Broadcast Notice to Mariners and Local Notice to Mariners notifying the public when enforcement of this regulated navigation area is suspended.

(3) *Regulations.*

(i) The general regulations contained in 33 CFR 165.13 apply.

(ii) All up-bound and down-bound barge tows that contain one or more red flag barges transiting through the regulated navigation area must be assisted by a bow boat until the entire tow is clear of the regulated navigation area.

(iii) Vessels engaged in commercial service, as defined in 46 U.S.C 2101(5), may not pass (meet or overtake) in the regulated navigation area and must make a SECURITE call when approaching the regulated navigation area to announce intentions and work out passing arrangements on either side.

(iv) Commercial tows transiting the regulated navigation area must be made up with wire rope to ensure electrical connectivity between all segments of the tow.

(v) All vessels are prohibited from loitering between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge).

(vi) Vessels may enter the waters between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge) for the sole purpose of transiting to the other side and must maintain headway throughout the transit. All vessels and persons are prohibited from dredging, laying cable, dragging, fishing, conducting salvage operations, or any other activity, which could disturb the bottom of the canal in the area located between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge).

(vii) All personnel on open decks must wear a Coast Guard approved Type I personal flotation device while in the waters between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge).

(viii) Vessels may not moor or lay up on the right or left descending banks of the waters between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge).

(ix) Towboats may not make or break tows if any portion of the towboat or tow is located in the waters between the Romeo Road Bridge (approximate mile marker 296.18) and mile marker 296.7 (aerial pipeline located approximately 0.51 miles north east of Romeo Road Bridge).

(4) *Compliance.* All persons and vessels must comply with this section and any additional instructions or orders of the Ninth Coast Guard District Commander, or his designated representatives. Any person on board any vessel transiting this regulated navigation area in accordance with this

rule or otherwise does so at their own risk.

(5) *Waiver.* For any vessel, the Ninth Coast Guard District Commander, or his designated representatives, may waive any of the requirements of this section, upon finding that operational conditions or other circumstances are such that application of this section is unnecessary or impractical for the purposes of vessel and mariner safety.

Dated: September 18, 2009.

D.R. Callahan,

Captain, U.S. Coast Guard, Commander, Ninth Coast Guard District, Acting.

[FR Doc. E9–23443 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–0474]

RIN 1625–AA00

Safety Zone; Parker US Open Nationals; Parker, AZ

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone upon the navigable waters of Lake Moovalya reigon on the lower Colorado River in support of the Parker US Open Nationals. This safety zone is necessary to provide for the safety of the participants, crew, spectators, participating vessels, and other users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

DATES: This rule is effective from 8 a.m. on October 9, 2009 through 6 p.m. on October 11, 2009.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2009–0474 and are available online by going to *http://www.regulations.gov,* inserting USCG–2009–0474 the ''Keyword'' box, and then clicking ''Search.'' This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Petty Officer Shane Jackson, USCG, Waterways Management, U.S. Coast Guard Sector San Diego at telephone 619–278–7262, e-mail *Shane.E.Jackson@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On July 6, 2009 we published a notice of proposed rulemaking (NPRM) entitled Safety zone; Parker US Open Nationals; Parker, AZ in the **Federal Register** (74 FR 31900). We received no comments on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

This temporary safety zone is established in support of the Parker US Open Nationals, a marine event that includes participating vessels along an established and marked course upon the Colorado River in Parker, AZ. This temporary safety zone is necessary to provide for the safety of the crews, spectators, and participants of the race and is also necessary to protect other vessels and users of the waterway.

Discussion of Comments and Changes

There were no comments submitted and no changes were made to the regulation.

Discussion of Rule

The Coast Guard is establishing a safety zone that will be enforced from 8 a.m. to 6 p.m. on October 9, 2009 through October 11, 2009. The limits of this temporary safety zone are as follows: Starting at the Bluewater Marina in Parker, AZ, extending approximately 6 miles to La Paz County Park. This safety zone is necessary to provide for the safety of the crews, spectators, and participants of the Parker US Open Nationals and to protect other vessels and users of the waterway. Persons and vessels will be prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS). We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. The safety zone is of a limited duration, ten hours per day for a period of three days, and is limited to a relatively small geographic area.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. The safety zone will affect the following entities some of which may be small entities: the owners and operators of pleasure craft engaged in recreational activities and sightseeing. This safety zone will not have a significant economic impact on a substantial number of small entities because the safety zone is limited in scope and duration as it is in effect for ten hours per day for a period of three days.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The

Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g) of the Instruction. This rule involves establishment of a safety zone. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**. This rule involves establishment of a safety zone.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a new temporary zone § 165.T11–205 to read as follows:

§ 165.T11–205 Safety zone; Parker US Open Nationals; Parker, AZ

(a) *Location.* The limits of this temporary safety zone are as follows: Bluewater Marina in Parker, AZ, extending approximately 6 miles to La Paz County Park.

(b) *Enforcement Period.* This section will be enforced from 8 a.m. to 6 p.m. on October 9, 2009 through October 11, 2009. If the event concludes prior to the scheduled termination time, the Captain of the Port will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Definitions.* The following definition applies to this section: *designated representative,* means any commissioned, warrant, and petty officers of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, and local, state, and federal law enforcement vessels who have been authorized to act on the behalf of the Captain of the Port.

(d) *Regulations.* (1) Entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port of San Diego or his designated on-scene representative.

(2) Mariners requesting permission to transit through the safety zone may request authorization to do so from the Patrol Commander (PATCOM). The PATCOM may be contacted on VHF–FM Channel 16.

(3) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated representative.

(4) Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

(5) The Coast Guard may be assisted by other federal, state, or local agencies.

Dated: June 16, 2009.

T.H. Farris,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. E9–23441 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–15–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3020

[Docket No. CP2009–50; Order No. 290]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is adding Global Expedited Package Services 1 (CP2008–4) to the Competitive Product List. In addition, Global Expedited Package Services 2 will also be included as a new category. This action is consistent with changes in a recent law governing postal operations. Republication of the lists of market dominant and competitive products is also consistent with new requirements in the law.

DATES: Effective September 29, 2009 and is applicable beginning August 28, 2009.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, 202–789–6820 or *stephen.sharfman@prc.gov.*

SUPPLEMENTARY INFORMATION: *Regulatory History,* 74 FR 36538 (July 23, 2009).

I. Introduction
II. Discussion
III. Ordering Paragraphs

I. Introduction

In Order No. 262, the Commission authorized the inclusion of an additional Global Expedited Package Service (GEPS) contract within the Global Expedited Package Services 1 (GEPS 1) product.[1] The Postal Service seeks clarification of that order.[2] In its initial filing in this docket, the Postal Service sought to have the instant contract designated as the new baseline agreement for purposes of determining the functional equivalence of future GEPS contracts.[3] The issue was not addressed substantively in Order No. 262. Noting that the GEPS 1 contract currently serving as the baseline will terminate and be removed from the Competitive Product List, the Postal Service requests clarification ''concerning the contract and docket number that it should use for future filings of additional contracts to be added to the GEPS 1 product.'' Request at 2. By this order, the Commission grants clarification.

II. Discussion

In its initial Notice, the Postal Service asserts the new GEPS 1 contract is functionally equivalent to previous GEPS contracts, that it should be included within the GEPS 1 product, ''and it should become the new baseline agreement for determining whether future contracts are functionally equivalent.'' Notice at 2. In support of its contention that the instant contract is functionally equivalent, the Postal Service states that it shares similar cost and market characteristics with previously filed GEPS 1 contracts. *Id.* at 4. It also contends that the contract meets the criteria established in Governors' Decision 08–7. Furthermore, the Postal Service identifies various similarities with other GEPS 1 contracts, *e.g.*, mailers are small and medium-sized businesses, the contract is for one year, and payment by permit imprint, as well as various differences, *e.g.*, volume or postage commitments. *Id.* at 4–5. In addition, the Postal Service identifies various provisions, which it characterizes as minor or incidental, which differ from those contained in the initial GEPS 1 contract. These include, for example, clarifying the availability of other postal products, simplifying notice of mailing requirements, and changes not related to either party's obligation under the agreement. *Id.* at 5–7.

In its Notice, the Postal Service does not expand on its request that the instant contract ''be considered the baseline agreement for determining functional equivalence for additional agreements.'' *Id.* at 7.[4] Apparently, because the initial GEPS 1 contract is terminating and provisions have been added to subsequent GEPS 1 contracts, the Postal Service suggests that the instant GEPS 1 contract be designated as the baseline for purposes of determining the functional equivalence of future GEPS contracts.

The Commission's expectation in labeling the initial GEPS contract (in Docket No. CP2008–5) as GEPS 1 was that it would be followed sequentially by additional GEPS contracts, *e.g.*, GEPS 2, GEPS 3, etc., that exhibited sufficient variation from the initial contract to warrant being classified as a new product. Given that the initial GEPS 1 contract is expiring and that the instant contract contains additional provisions, the Commission will label the latter as GEPS 2.[5] Following the current practice, the Postal Service shall identify all significant differences between any new GEPS contract and the GEPS 2 product. Such differences would include terms and conditions that impose new obligations or new requirements on any party to the contract. The docket referenced in the caption should be Docket No. CP2009–50, in lieu of Docket No. CP2008–4. Following the current practice, a redacted copy of Governors' Decision 08–7 should be included in the new filing along with an electronic link to it.[6]

Future requests to implement a new baseline agreement should be filed as an MC docket since it will result in adding a new product to the product list and may result in removing a product from the product list.[7]

III. Ordering Paragraphs

It is ordered:

1. The GEPS contract filed in Docket No. CP2009–50 is added to the Competitive Product List as a new product, Global Expedited Package

[1] *See* PRC Order No. 262, Order Concerning Filing of Additional Global Expedited Package Services 1 Negotiated Services Agreement, July 29, 2009 (Order No. 262).

[2] United States Postal Service Response to Order No. 262 Concerning Termination Date of Additional Global Expedited Package Services 1 Negotiated Service Agreement and Request for Clarification, July 30, 2009, at 2 (Request). No party filed a response to the Request.

[3] Notice of United States Postal Service Filing of Functionally Equivalent Global Expedited Package Services 1 Negotiated Service Agreement, July 16, 2009, at 2, 7 (Notice).

[4] The Postal Service references PRC Order No. 227 issued in Docket No. CP2009–35 and states that ''[t]he only additional difference between the agreement currently presented in this instant docket and the one presented in Docket No. CP2009–35 is the tender provision, which is described further below. *Id.* at 4, n.6.

[5] This designation would also apply to GEPS contracts filed subsequent to the one in Docket No. CP2009–50, namely Docket Nos. CP2009–51, CP2009–52, CP2009–53, CP2009–58, and CP2009–59.

[6] The Postal Service requests that the Inbound Direct Entry (IDE) contract filed in Docket No. CP2009–62 be considered the new baseline agreement for future IDE contracts. Absent a showing otherwise, the Commission intends to act on this request in a similar manner.

[7] *See e.g.*, Docket Nos. MC2009–34 and CP2009–24, Request of the United States Postal Service to Add Express Mail Contract 4 to Competitive Product List and Notice of Establishment of Rates and Class Not of General Applicability, July 6, 2009.

Services 2 (Docket No. CP2009–50) under Negotiated Service Agreements, International.

2. The additional GEPS contracts filed in Docket Nos. CP2009–51, CP2009–52, CP2009–53, CP2009–58, and CP2009–59 will be classified as GEPS 2 contracts and be included within the Global Expedited Package Services 2 product (Docket No. CP2009–50).

3. The Secretary shall arrange for publication of this order in the **Federal Register**.

List of Subjects in 39 CFR Part 3020

Administrative practice and procedure; Postal Service.

By the Commission.

Shoshana M. Grove,

Secretary.

■ For the reasons stated in the preamble, under the authority at 39 U.S.C. 503, the Postal Regulatory Commission amends 39 CFR part 3020 as follows:

PART 3020—PRODUCT LISTS

■ 1. The authority citation for part 3020 continues to read as follows:

Authority: 39 U.S.C. 503; 3622; 3631; 3642; 3682.

■ 2. Revise Appendix A to Subpart A of Part 3020—Mail Classification Schedule to read as follows:

Appendix A to Subpart A of Part 3020—Mail Classification Schedule

Part A—Market Dominant Products

1000 Market Dominant Product List

First-Class Mail
- Single-Piece Letters/Postcards
- Bulk Letters/Postcards
- Flats
- Parcels
- Outbound Single-Piece First-Class Mail International
- Inbound Single-Piece First-Class Mail International

Standard Mail (Regular and Nonprofit)
- High Density and Saturation Letters
- High Density and Saturation Flats/Parcels
- Carrier Route
- Letters
- Flats
- Not Flat-Machinables (NFMs)/Parcels

Periodicals
- Within County Periodicals
- Outside County Periodicals

Package Services
- Single-Piece Parcel Post
- Inbound Surface Parcel Post (at UPU rates)
- Bound Printed Matter Flats
- Bound Printed Matter Parcels
- Media Mail/Library Mail

Special Services
- Ancillary Services
- International Ancillary Services
- Address List Services
- Caller Service
- Change-of-Address Credit Card Authentication
- Confirm
- International Reply Coupon Service
- International Business Reply Mail Service
- Money Orders
- Post Office Box Service

Negotiated Service Agreements
- HSBC North America Holdings Inc. Negotiated Service Agreement
- Bookspan Negotiated Service Agreement
- Bank of America Corporation Negotiated Service Agreement
- The Bradford Group Negotiated Service Agreement
- Inbound International
- Canada Post—United States Postal Service Contractual Bilateral Agreement for Inbound Market Dominant Services

Market Dominant Product Descriptions

First-Class Mail
[Reserved for Class Description]
- Single-Piece Letters/Postcards
  - [Reserved for Product Description]
- Bulk Letters/Postcards
  - [Reserved for Product Description] Flats
  - [Reserved for Product Description] Parcels
  - [Reserved for Product Description]
- Outbound Single-Piece First-Class Mail International
  - [Reserved for Product Description]
- Inbound Single-Piece First-Class Mail International
  - [Reserved for Product Description]

Standard Mail (Regular and Nonprofit)
[Reserved for Class Description]
- High Density and Saturation Letters
  - [Reserved for Product Description]
- High Density and Saturation Flats/Parcels
  - [Reserved for Product Description]
- Carrier Route
  - [Reserved for Product Description] Letters
  - [Reserved for Product Description] Flats
  - [Reserved for Product Description]
- Not Flat-Machinables (NFMs)/Parcels
  - [Reserved for Product Description]

Periodicals
[Reserved for Class Description]
- Within County Periodicals
  - [Reserved for Product Description]
- Outside County Periodicals
  - [Reserved for Product Description]

Package Services
[Reserved for Class Description]
- Single-Piece Parcel Post
  - [Reserved for Product Description]
- Inbound Surface Parcel Post (at UPU rates)
  - [Reserved for Product Description]
- Bound Printed Matter Flats
  - [Reserved for Product Description]
- Bound Printed Matter Parcels
  - [Reserved for Product Description]
- Media Mail/Library Mail
  - [Reserved for Product Description]

Special Services
[Reserved for Class Description]
- Ancillary Services
  - [Reserved for Product Description]
- Address Correction Service
  - [Reserved for Product Description]
- Applications and Mailing Permits
  - [Reserved for Product Description]
- Business Reply Mail
  - [Reserved for Product Description]
- Bulk Parcel Return Service
  - [Reserved for Product Description]
- Certified Mail
  - [Reserved for Product Description]
- Certificate of Mailing
  - [Reserved for Product Description]
- Collect on Delivery
  - [Reserved for Product Description]
- Delivery Confirmation
  - [Reserved for Product Description]
- Insurance
  - [Reserved for Product Description]
- Merchandise Return Service
  - [Reserved for Product Description]
- Parcel Airlift (PAL)
  - [Reserved for Product Description]
- Registered Mail
  - [Reserved for Product Description]
- Return Receipt
  - [Reserved for Product Description]
- Return Receipt for Merchandise
  - [Reserved for Product Description]
- Restricted Delivery
  - [Reserved for Product Description]
- Shipper-Paid Forwarding
  - [Reserved for Product Description]
- Signature Confirmation
  - [Reserved for Product Description]
- Special Handling
  - [Reserved for Product Description]
- Stamped Envelopes
  - [Reserved for Product Description]
- Stamped Cards
  - [Reserved for Product Description]
- Premium Stamped Stationery
  - [Reserved for Product Description]
- Premium Stamped Cards
  - [Reserved for Product Description]
- International Ancillary Services
  - [Reserved for Product Description]
- International Certificate of Mailing
  - [Reserved for Product Description]
- International Registered Mail
  - [Reserved for Product Description]
- International Return Receipt
  - [Reserved for Product Description]
- International Restricted Delivery
  - [Reserved for Product Description]
- Address List Services
  - [Reserved for Product Description]
- Caller Service
  - [Reserved for Product Description]
- Change-of-Address Credit Card Authentication
  - [Reserved for Product Description]
- Confirm
  - [Reserved for Product Description]
- International Reply Coupon Service
  - [Reserved for Product Description]
- International Business Reply Mail Service
  - [Reserved for Product Description]
- Money Orders
  - [Reserved for Product Description]
- Post Office Box Service
  - [Reserved for Product Description]

Negotiated Service Agreements
[Reserved for Class Description]
- HSBC North America Holdings Inc. Negotiated Service Agreement
  - [Reserved for Product Description]
- Bookspan Negotiated Service Agreement
  - [Reserved for Product Description]
- Bank of America Corporation Negotiated Service Agreement
- The Bradford Group Negotiated Service Agreement

Part B—Competitive Products

2000 Competitive Product List

Express Mail

Express Mail
Outbound International Expedited Services
Inbound International Expedited Services
Inbound International Expedited Services 1 (CP2008–7)
Inbound International Expedited Services 2 (MC2009–10 and CP2009–12)
Priority Mail
Priority Mail
Outbound Priority Mail International
Inbound Air Parcel Post
Royal Mail Group Inbound Air Parcel Post Agreement
Parcel Select
Parcel Return Service
International
International Priority Airlift (IPA)
International Surface Airlift (ISAL)
International Direct Sacks—M-Bags
Global Customized Shipping Services
Inbound Surface Parcel Post (at non-UPU rates)
Canada Post—United States Postal Service Contractual Bilateral Agreement for Inbound Competitive Services (MC2009–8 and CP2009–9)
International Money Transfer Service
International Ancillary Services
Special Services
Premium Forwarding Service
Negotiated Service Agreements
Domestic
Express Mail Contract 1 (MC2008–5)
Express Mail Contract 2 (MC2009–3 and CP2009–4)
Express Mail Contract 3 (MC2009–15 and CP2009–21)
Express Mail Contract 4 (MC2009–34 and CP2009–45)
Express Mail & Priority Mail Contract 1 (MC2009–6 and CP2009–7)
Express Mail & Priority Mail Contract 2 (MC2009–12 and CP2009–14)
Express Mail & Priority Mail Contract 3 (MC2009–13 and CP2009–17)
Express Mail & Priority Mail Contract 4 (MC2009–17 and CP2009–24)
Express Mail & Priority Mail Contract 5 (MC2009–18 and CP2009–25)
Express Mail & Priority Mail Contract 6 (MC2009–31 and CP2009–42)
Express Mail & Priority Mail Contract 7 (MC2009–32 and CP2009–43)
Express Mail & Priority Mail Contract 8 (MC2009–33 and CP2009–44)
Parcel Return Service Contract 1 (MC2009–1 and CP2009–2)
Priority Mail Contract 1 (MC2008–8 and CP2008–26)
Priority Mail Contract 2 (MC2009–2 and CP2009–3)
Priority Mail Contract 3 (MC2009–4 and CP2009–5)
Priority Mail Contract 4 (MC2009–5 and CP2009–6)
Priority Mail Contract 5 (MC2009–21 and CP2009–26)
Priority Mail Contract 6 (MC2009–25 and CP2009–30)
Priority Mail Contract 7 (MC2009–25 and CP2009–31)
Priority Mail Contract 8 (MC2009–25 and CP2009–32)
Priority Mail Contract 9 (MC2009–25 and CP2009–33)
Priority Mail Contract 10 (MC2009–25 and CP2009–34)
Priority Mail Contract 11 (MC2009–27 and CP2009–37)
Priority Mail Contract 12 (MC2009–28 and CP2009–38)
Priority Mail Contract 13 (MC2009–29 and CP2009–39)
Priority Mail Contract 14 (MC2009–30 and CP2009–40)
Priority Mail Contract 15 (MC2009–35 and CP2009–54)
Priority Mail Contract 16 (MC2009–36 and CP2009–55)
Priority Mail Contract 17 (MC2009–37 and CP2009–56)
Outbound International
Direct Entry Parcels Contracts
Direct Entry Parcels 1 (MC2009–26 and CP2009–36)
Global Direct Contracts (MC2009–9, CP2009–10, and CP2009–11)
Global Expedited Package Services (GEPS) Contracts
GEPS 1 (CP2008–5, CP2008–11, CP2008–12, and CP2008–13, CP2008–18, CP2008–19, CP2008–20, CP2008–21, CP2008–22, CP2008–23, and CP2008–24)
Global Expedited Package Services 2 (CP2009–50)
Global Plus Contracts
Global Plus 1 (CP2008–8, CP2008–46 and CP2009–47)
Global Plus 2 (MC2008–7, CP2008–48 and CP2008–49)
Inbound International
Inbound Direct Entry Contracts with Foreign Postal Administrations (MC2008–6, CP2008–14 and CP2008–15)
International Business Reply Service Competitive Contract 1 (MC2009–14 and CP2009–20)
Competitive Product Descriptions
Express Mail
[Reserved for Group Description]
Express Mail
[Reserved for Product Description]
Outbound International Expedited Services
[Reserved for Product Description]
Inbound International Expedited Services
[Reserved for Product Description]
Priority
[Reserved for Product Description]
Priority Mail
[Reserved for Product Description]
Outbound Priority Mail International
[Reserved for Product Description]
Inbound Air Parcel Post
[Reserved for Product Description]
Parcel Select
[Reserved for Group Description]
Parcel Return Service
[Reserved for Group Description]
International
[Reserved for Group Description]
International Priority Airlift (IPA)
[Reserved for Product Description]
International Surface Airlift (ISAL)
[Reserved for Product Description]
International Direct Sacks—M-Bags
[Reserved for Product Description]
Global Customized Shipping Services
[Reserved for Product Description]
International Money Transfer Service
[Reserved for Product Description]
Inbound Surface Parcel Post (at non-UPU rates)
[Reserved for Product Description]
International Ancillary Services
[Reserved for Product Description]
International Certificate of Mailing
[Reserved for Product Description]
International Registered Mail
[Reserved for Product Description]
International Return Receipt
[Reserved for Product Description]
International Restricted Delivery
[Reserved for Product Description]
International Insurance
[Reserved for Product Description]
Negotiated Service Agreements
[Reserved for Group Description]
Domestic
[Reserved for Product Description]
Outbound International
[Reserved for Group Description]
Part C—Glossary of Terms and Conditions
[Reserved]
Part D—Country Price Lists for International Mail [Reserved]

[FR Doc. E9–23488 Filed 9–28–09; 8:45 am]

BILLING CODE 7710–FW–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 0

Commission Organization

CFR Correction

In Title 47 of the Code of Federal Regulations, Parts 0 to 19, revised as of October 1, 2008, on page 93, in § 0.607, reinstate paragraph (d) to read as follows:

§ 0.607 Transcript, recording or minutes; availability to the public.

* * * * *

(d) The Commissioner presiding at the meeting will prepare a statement setting out the time and place of the meeting, the names of persons other than Commission personnel who were present at the meeting, and the names of Commission personnel who participated in the discussion. These statements will be retained in a public file in the Minute and Rules Branch, Office of the Secretary.

[FR Doc. E9–23479 Filed 9–28–09; 8:45 am]

BILLING CODE 1505–01–D

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 11

Emergency Alert System (EAS)

CFR Correction

In Title 47 of the Code of Federal Regulations, Parts 0 to 19, revised as of October 1, 2008, on page 719, in § 11.31, in paragraph (b), before the last sentence, reinstate the following sentence:

§ 11.31 EAS protocol.

* * * * *

(b) * * * Unused characters must be ASCII space characters. * * *

* * * * *

[FR Doc. E9–23478 Filed 9–28–09; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 52

Federal Acquisition Regulation; Conforming Late Offer Treatment

CFR Correction

In Title 48 of the Code of Federal Regulations, Chapter 1 (Parts 52 to 99), revised as of October 1, 2008, on pages 79 and 80, remove and reserve sections 52.214–32 and 52.214–33.

[FR Doc. E9–23475 Filed 9–28–09; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

48 CFR Part 201

Defense Federal Acquisition Regulation Supplement; Electronic Publication of DFARS

CFR Correction

In Title 48 of the Code of Federal Regulations, Chapter 2 (Parts 201 to 299), revised as of October 1, 2008, on page 10, in section 201.304, reinstate paragraph (6) to read as follows:

201.304 Agency control and compliance procedures.

* * * * *

(6) The Director of Defense Procurement publishes changes to the DFARS in the **Federal Register** and electronically via the World Wide Web. Each change includes an effective date. Unless guidance accompanying a change states otherwise, contracting officers must include any new or revised clauses, provisions, or forms in solicitations issued on or after the effective date of the change.

[FR Doc. E9–23476 Filed 9–28–09; 8:45 am]

BILLING CODE 1505–01–D

Proposed Rules

Federal Register
Vol. 74, No. 187
Tuesday, September 29, 2009

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–0795; Directorate Identifier 2009–NM–083–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 757 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Boeing Model 757 airplanes. This proposed AD would require inspecting to verify the part number of the low-pressure flex-hoses of the flightcrew and supernumerary oxygen system installed under the oxygen mask stowage box at a flightcrew and supernumerary oxygen mask location, and replacing with a new non-conductive low-pressure flex-hose of the oxygen system if necessary. This proposed AD results from reports of a low-pressure flex-hose of a flightcrew oxygen system that burned through due to inadvertent electrical current from a short circuit in an adjacent audio select panel. We are proposing this AD to prevent inadvertent electrical current which can cause the low-pressure flex-hose of a flightcrew or supernumerary oxygen system to melt or burn, resulting in oxygen system leakage and smoke or fire.

DATES: We must receive comments on this proposed AD by November 13, 2009.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to http://www.*regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com;* Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221 or 425–227–1152.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Robert Hettman, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6457; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2009–0795; Directorate Identifier 2009–NM–083–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received reports of a low-pressure flex-hose of a flightcrew oxygen system that burned through due to inadvertent electrical current from a short circuit in an adjacent audio select panel. An electrical current went through the support structure to a flightcrew mask stowage box. This caused the spring inside the low-pressure oxygen hose to act as an electrical conductor and heat up, causing the hose to burn through. This condition, if not corrected, could cause the low-pressure flex-hose of the flightcrew or supernumerary oxygen system to melt or burn, resulting in oxygen system leakage and smoke or fire.

Relevant Service Information

We have reviewed Boeing Service Bulletins 757–35A0015, Revision 2; and 757–35A0016, Revision 1; both dated June 15, 2000. The service bulletins describe procedures for replacing the existing low-pressure flex-hoses of the flightcrew and supernumerary oxygen system installed under the oxygen mask stowage box at the flightcrew and supernumerary oxygen mask location with new non-conductive low-pressure flex-hoses of the oxygen system.

FAA's Determination and Requirements of This Proposed AD

We are proposing this AD because we evaluated all relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs. This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between the Proposed AD and the Service Bulletins.''

Differences Between the Proposed AD and the Service Bulletins

Although Boeing Service Bulletins 757–35A0015, Revision 2; and 757–35A0016, Revision 1; both dated June 15, 2000; recommend accomplishing the replacement ''at the earliest opportunity when manpower, material and facilities are available,'' we have determined that this imprecise compliance time would not address the identified unsafe condition in a timely manner. In developing an appropriate compliance time for this proposed AD, we considered not only the manufacturer's recommendation, but the degree of urgency associated with addressing the subject unsafe condition, the average utilization of the affected fleet, and the time necessary to perform the modifications. In light of all of these factors, we find a compliance time of 36 months for completing the required actions to be warranted, in that it represents an appropriate interval of time for affected airplanes to continue to operate without compromising safety. This difference has been coordinated with Boeing.

Boeing Service Bulletin 757–35A0015, Revision 2, dated June 15, 2000, lists Boeing Model 757–200C in the Effectivity paragraph; however, we have confirmed with Boeing that its intent was to list Boeing Model 757–200CB. We have included Model 757–200CB in the Applicability paragraph of this proposed AD.

Other Rulemaking

The oxygen mask installations on certain Boeing Model 737, 747, and 767 airplanes are almost identical to those on the affected 757 airplanes. Therefore, all of these airplanes may be subject to the identified unsafe condition. We are considering similar rulemaking related to the identified unsafe condition for certain Boeing Model 737, 747, and 767 airplanes.

Costs of Compliance

We estimate that this proposed AD would affect 485 airplanes of U.S. registry. We also estimate that it would take 1 work-hour per product to comply with this proposed AD. The average labor rate is $80 per work-hour. Based on these figures, we estimate the cost of this proposed AD to the U.S. operators to be $38,800, or $80 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866,

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Boeing: Docket No. FAA–2009–0795; Directorate Identifier 2009–NM–083–AD.

Comments Due Date

(a) We must receive comments by November 13, 2009.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 757–200, –200CB, –200PF, and –300 series airplanes, certificated in any category; as identified in the service bulletins listed in Table 1 of this AD.

TABLE 1—APPLICABILITY

Boeing service bulletin—	Revision—	Dated—	Applicable model/series—
757–35A0015	2	June 15, 2000	757–200, 757–200CB, 757–200PF
757–35A0016	1	June 15, 2000	757–300

Subject

(d) Air Transport Association (ATA) of America Code 35: Oxygen.

Unsafe Condition

(e) This AD results from reports of a low-pressure flex-hose of a flightcrew oxygen system that burned through due to inadvertent electrical current from a short circuit in an adjacent audio select panel. We are issuing this AD to prevent inadvertent electrical current which can cause the low-pressure flex-hoses used in the flightcrew and supernumerary oxygen system to melt or burn, resulting in oxygen system leakage and smoke or fire.

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection

(g) Within 36 months after the effective date of this AD, do an inspection to determine whether any low-pressure flex-hose of the flightcrew and supernumerary oxygen systems installed under the oxygen mask stowage location has a part number identified in Table 2 of this AD. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number of

the low-pressure flex-hoses of the flightcrew and supernumerary oxygen system can be conclusively determined from that review.

(1) For any hose having a part number identified in Table 2 of this AD, before further flight, replace the hose with a new or serviceable part, in accordance with the Accomplishment Instructions of the applicable service bulletin identified in Table 1 of this AD.

(2) For any hose not having a part number identified in Table 2 of this AD, no further action is required by this paragraph.

Parts Installation

(h) As of the effective date of this AD, no person may install a flightcrew or supernumerary oxygen hose with a part number identified in Table 2 of this AD on any airplane.

TABLE 2—APPLICABLE PART NUMBERS

Boeing specification part No.—	Equivalent Boeing supplier part Nos.—				
	Sierra Engineering	Spencer Fluid	Puritan Bennett	Hydraflow	AVOX (formerly Sierra Engineering)
60B50059–70	835–01–70	9513–20S5–18.0	ZH784–20	38001–70	9513–835–01–70
60B50059–81	835–01–81	9513–20S5–24.0	ZH784–81	38001–81	9513–835–01–81

Actions Accomplished According to Previous Issue of Service Bulletin

(i) Actions accomplished before the effective date of this AD in accordance with Boeing Alert Service Bulletin 757–35A0015, dated September 2, 1999, or Revision 1, dated November 11, 1999; or Boeing Alert Service Bulletin 757–35A0016, dated November 11, 1999; are considered acceptable for compliance with the corresponding actions specified in this AD.

Alternative Methods of Compliance (AMOCs)

(j)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Robert Hettman, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle ACO, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6457; fax (425) 917–6590. Or, e-mail information to *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

Issued in Renton, Washington, on September 18, 2009.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–23421 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–135005–07]

RIN 1545–BG94

Clarification of Controlled Group Qualification Rules

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains a proposed regulation to clarify which corporations are included in a controlled group of corporations. The regulation clarifies that a corporation that satisfies the controlled group rules for stock ownership and qualification is a member of such group, without regard to its status as a component member.

DATES: Written or electronic comments and request for a public hearing must be received by December 28, 2009.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–135005–07), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–135005–07), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–135005–07).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Grid Glyer (202) 622–7930; concerning submissions of comments, Oluwafunmilayo Taylor (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Section 1563(a) defines four types of controlled groups of corporations. This definition is relevant for purposes of allocating certain tax benefits under section 1561, as well as other provisions of the Internal Revenue Code that incorporate the concept of a controlled group of corporations. In order for a corporation to be included in one of these controlled groups under section 1563(a), it must satisfy the stock ownership test for that type of group. In addition, other rules in section 1563 may also apply in order to determine whether a corporation satisfies the applicable stock ownership test. For example, section 1563(c) excludes certain stock of a corporation (for example, nonvoting stock that is limited and preferred as to dividends) from the definition of stock, section 1563(d) determines when to take into account the stock owned by a corporation, and section 1563(e) determines when stock of a corporation is constructively owned.

Section 1563(b) describes which corporations are ''component members'' of a section 1563(a) controlled group of corporations for purposes of section 1561 and section 1563, in part by excluding certain corporations under section 1563(b)(2). For example, certain special purpose corporations, such as tax-exempt corporations, are treated as excluded members and not as component members. *See* sections 1563(b)(2)(B) through 1563(b)(2)(E). Notwithstanding that a corporation is not a ''component member,'' however, the IRS has consistently taken the position that the determination of whether a corporation is included in a controlled group under section 1563(a) is determined without applying section 1563(b).

Explanation of Provisions

The Treasury Department and the IRS propose to amend § 1.1563–1 to clarify

that an excluded member of a controlled group, such as a corporation described in sections 1563(b)(2)(B) through 1563(b)(2)(E), is nevertheless a member of the group. Specifically, the proposal will add paragraph (a)(1)(ii) to § 1.1563–1 and an *Example* to § 1.1563–1(b)(4).

Section 1563 was originally promulgated to limit the use of the tax benefit items described in section 1561 by the component members of a controlled group as defined in section 1563. S. Rep. No. 88–830 at 150 (1964), 1964–1 (Part 2) CB 502, 654. However, since then, certain other statutory and regulatory provisions have referenced the controlled group rules of section 1563 for other purposes. Some of these provisions adjust the definition of a controlled group to state that certain provisions of section 1563 do not apply.

For example, section 41(f)(1)(A)(i) provides that, in determining the amount of the credit for increasing research activities under section 41, all members of the same controlled group shall be treated as a single taxpayer. Section 41(f)(5)(B) provides that the term ''controlled group of corporations'' has the same meaning given to such term by section 1563(a), except that the determination shall be made without regard to subsections (a)(4) and (e)(3)(C) of section 1563. The effect of not applying section 1563(a)(4) is to treat two or more life insurance companies, which would otherwise be treated as members of a separate life insurance controlled group, each as a member of a controlled group described in section 1563(a)(1)-(3) (Section 1563(e)(3)(B) deals with an application of the constructive ownership rules; however, because that application is not relevant to the issue being addressed in this preamble, it will not be further discussed.). However, section 41(f)(5) and similar provisions make no reference to subsection (b) of section 1563. Section 1563(b), among other things, defines which corporations are ''component members'' and ''excluded members'' for purposes of section 1561 and section 1563. Nevertheless, some taxpayers have argued that a corporation that is an ''excluded member'' within the meaning of section 1563(b)(2) cannot, as a consequence, be a ''member'' of a section 1563(a) controlled group generally. This line of argument tends to equate a corporation's membership generally with such corporation's status as a component member.

The Treasury Department and the IRS disagree with such arguments and believe that an excluded member under section 1563(b)(2), while not a component member of a controlled group under section 1563(b)(1), is nevertheless a member of a controlled group under section 1563(a). *See also* § 1.414(b)-1(a).

This position is supported by the clear language of the statute. Section 1563(b)(2) provides, in the introductory text, that a ''corporation which is a *member* of a controlled group of corporations * * * shall be treated as an excluded member of such group * * *''. Moreover, this position is also supported by the legislative history for sections 1561 and 1563, which states that ''the determination of the corporations included within a parent-subsidiary controlled group, or a brother-sister controlled group, is made without regard to the type of corporation involved.'' S. Rep. No. 88–830 at 152 (1964), 1964–1 (Part 2) CB 505, 656; *see also* H.R. Rep. 88–749 at A201–202 (1963), 1964–1 (Part 2) CB 248, 449–450 (providing examples where an ''excluded member'' is treated as a member of a controlled group of corporations). Compare section 1504(a)(1)(A) (affiliated group comprised of includible corporations only). Therefore, this proposed regulation clarifies that a corporation identified in section 1563(b)(2) as an excluded member of a controlled group is nevertheless a member of such group for purposes of section 1563(a). Accordingly, a corporation whose stock is held by such an excluded member may be treated as a component member of the controlled group of corporations.

Finally, this proposed regulation further illustrates that an excluded member of a controlled group is treated as a member of such group by adding an example demonstrating that a controlled group can consist solely of excluded members.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation and because this regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before this proposed regulation is adopted as a final regulation, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and the Treasury Department request comments on the clarity of the proposed regulation and how it can be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person that timely submits written or electronic comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of this regulation is Grid Glyer of the Office of Associate Chief Counsel (Corporate). However, other personnel from the IRS and the Treasury Department participated in its development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.1563–1 is amended by:

1. Redesignating paragraph (a)(1)(ii) as paragraph (a)(1)(iii) and adding paragraph (a)(1)(ii).

2. Adding *Example 4* to paragraph (b)(4).

3. Adding a sentence at the end of paragraph (e).

The additions to read as follows:

§ 1.1563–1 Definition of controlled group of corporations and component members and related concepts.

(a) * * *

(1) * * *

(ii) *Special rules.* In determining whether a corporation is included in a controlled group of corporations, section 1563(b) shall not be taken into account. For rules defining a component member of a controlled group of corporations, including rules defining an excluded member and an additional

member, *see* section 1563(b) and paragraph (b) of this section.

* * * * *

(b) * * *

(4) * * *

Example 4. Individual A owns all of the stock of corporations X, Y and Z. Each of these corporations is an S corporation. X, Y, and Z are each members of a brother-sister controlled group, even though each such corporation is treated as an excluded member of such group. *See* § 1.1563–1(b)(2)(ii)(C).

* * * * *

(e) * * * Paragraph (a)(1)(ii) of this section applies to taxable years beginning on or after the date of publication in the **Federal Register** of the Treasury decision adopting these rules as final regulations.

Linda E. Stiff,

Deputy Commissioner for Services and Enforcement.

[FR Doc. E9–23396 Filed 9–28–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–0484]

RIN 1625–AA00

Safety Zone; San Diego Parade of Lights Fireworks; San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes a safety zone upon the navigable waters of San Diego Bay in San Diego, CA in support of the San Diego Parade of Lights Fireworks. This safety zone is necessary to provide for the safety of the participants, crew, spectators, participating vessels, and other users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

DATES: Comments and related material must be received by the Coast Guard on or before October 29, 2009.

ADDRESSES: You may submit comments identified by docket number USCG–2009–0484 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov*.

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Petty Officer Shane Jackson, USCG, Waterways Management, U.S. Coast Guard Sector San Diego at telephone 619–278–7262, e-mail *Shane.E.Jackson@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2009–0484), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov*, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov*, click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2009–0484'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2009–0484'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Fireworks & Stage FX Inc is sponsoring the San Diego Parade of Lights Fireworks, which will include a fireworks presentation from a barge in San Diego Bay. The safety zone will be a 400 foot radius around the barge in approximate position 32°43′23″ N, 117°11′57″ W. This temporary safety zone is necessary to provide for the safety of the crew, spectators, participants, and other vessels and users of the waterway.

Discussion of Proposed Rule

The Coast Guard is establishing a safety zone that will be enforced from 5:30 p.m. to 10 p.m. on December 13, 2009 and December 20, 2009. The limits of the safety zone will be a 400 foot radius around the barge in approximate position 32°43′23″ N, 117°11′57″ W. The safety zone is necessary to provide for the safety of the crew, spectators, participants, and other vessels and users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS). We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. The safety zone is of a limited duration, four and a half hours per day for a period of two days, and is limited to a relatively small geographic area.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. The safety zone will affect the following entities some of which may be small entities: the owners and operators of pleasure craft engaged in recreational activities. This safety zone will not have a significant economic impact on a substantial number of small entities this reason: the safety zone is limited in scope and duration as it is in effect for four and a half hours per day for a period of two days.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, call or e-mail call Petty Officer Shane Jackson, USCG, Waterways Management, U.S. Coast Guard Sector San Diego at telephone 619–278–7262, e-mail *Shane.E.Jackson@uscg.mil*. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office

of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. This proposed rule involves establishing a safety zone and is categorically excluded under figure 2–1, paragraph (34)(g), of the Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add new temporary zone § 165.T11–222 to read as follows:

§ 165.T11–222 Safety zone; San Diego Parade of Lights Fireworks; San Diego, California.

(a) *Location*. The limits of the safety zone will include a 400 foot radius around the barge in approximate position 32°43′23″ N, 117°11′57″ W.

(b) *Enforcement Period*. This section will be enforced from 5:30 p.m. to 10 p.m. on December 13, 2009 and December 20, 2009. If the event concludes prior to the scheduled termination time, the Captain of the Port will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Definitions*. The following definition applies to this section: *designated representative*, means any commissioned, warrant, and petty officers of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, and local, state, and federal law enforcement vessels who have been authorized to act on the behalf of the Captain of the Port.

(d) *Regulations*. (1) Entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port of San Diego or his designated on-scene representative.

(2) Mariners requesting permission to transit through the safety zone may request authorization to do so from the Sector San Diego Command Center. The Command Center may be contacted on VHF–FM Channel 16.

(3) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated representative.

(4) Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

(5) The Coast Guard may be assisted by other federal, state, or local agencies.

Dated: July 28, 2009.

T.H. Farris,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. E9–23442 Filed 9–28–09; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2009–0547; FRL–8963–8]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Determination of Clean Data for the 1997 Fine Particulate Matter Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: EPA is reopening the comment period for a notice of proposed rulemaking (NPR) published on July 31, 2009 (74 FR 38154) and corrected on August 27, 2009 (74 FR 43653). In the NPR, EPA proposed to determine that Berkeley County, part of the Hagerstown-Martinsburg MD–WV nonattainment area; Wood County and the Grant Tax District in Pleasants County, part of the Parkersburg-Marietta WV–OH nonattainment area; and Marshall County and Ohio County, part of the Wheeling WV–OH nonattainment area for the 1997 National Ambient Air Quality Standard (NAAQS) for fine particulate (PM_{25}) have clean data for the 1997 PM_{25} NAAQS. EPA received comments from EarthJustice pertaining to the design value calculations for the Hagerston-Martinsburg nonattainment area. EarthJustice also requested that the 2009 monitored data referred to in the proposed rule be made available as part of the record and that the proposed rule either be revised or the comment period reopened to allow the public to consider the data. EPA is therefore reopening the comment period and including the data that was relied upon for the clean data determination as well as the 2009 monitored data. The data relied upon by EPA is now provided in a Technical Support Document which is included in the record for this rulemaking. EPA is reopening the comment period through October 29, 2009. All comments received on or before October 29, 2009 will be entered into the public record and considered by EPA before taking final action on the proposed rule.

DATES: Written comments must be received on or before October 29, 2009.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2009–0547 by one of the following methods:

http://www.regulations.gov. Follow the on-line instructions for submitting comments.

B. *E-mail: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2009–0547, Cristina Fernandez, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2009–0547. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov.* or e-mail. The *http://www.regulations.gov.* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov.,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov.* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov.* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

FOR FURTHER INFORMATION CONTACT: Marilyn Powers, (215) 814–2308, or by e-mail at *powers.marilyn@epa.gov.*

Dated: September 18, 2009.

William C. Early,

Acting Regional Administrator, Region III.

[FR Doc. E9–23500 Filed 9–28–09; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2009–0199; FRL–8963–7]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Determination of Clean Data for the 1997 Fine Particulate Matter Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: EPA is reopening the comment period for a notice of proposed rulemaking (NPR) published on July 31, 2009 (74 FR 38161). In the NPR, EPA proposed to determine that the Baltimore, Maryland portion of the Hagerstown-Martinsburg nonattainment areas for the 1997 National Ambient Air Quality Standard (NAAQS) fine particulate ($PM_{2.5}$) have clean data for the 1997 $PM_{2.5}$ NAAQS. EPA received comments from EarthJustice requesting that the 2009 monitored data referred to in the proposed rule be made available as part of the record and that the proposed rule either be revised or the comment period reopened to allow the public to consider the data. EPA is, therefore, reopening the comment period and including the data that was relied upon for the proposed clean data determination as well as the 2009 monitored data. The data relied upon by EPA is now provided in a Technical Support Document which is included in the record for this rulemaking. EPA is reopening the comment period through October 29, 2009. All comments received on or before October 29, 2009 will be entered into the public record and considered by EPA before taking final action on the proposed rule.

DATES: Written comments must be received on or before October 29, 2009.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2009–0199 by one of the following methods:

A. *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *E-mail: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2009–0199, Cristina Fernandez, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2009–0199. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on

the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

FOR FURTHER INFORMATION CONTACT: Jacqueline Lewis, (215) 814–2037, or by e-mail at *lewis.jacqueline@epa.gov.*

Dated: September 18, 2009.

William C. Early,

Acting Regional Administrator, Region III.

[FR Doc. E9–23502 Filed 9–28–09; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R6-ES-2009-0037]
[92210-1117-0000-B4]

Endangered and Threatened Wildlife and Plants; 12–month Finding on a Petition To Revise Critical Habitat for *Eriogonum pelinophilum* (Clay-Loving Wild Buckwheat)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12–month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce our 12–month finding on a petition to revise critical habitat for *Eriogonum pelinophilum* (clay-loving wild buckwheat) under the Endangered Species Act of 1973, as amended (Act). After a thorough review of all available scientific and commercial information, we find that revisions to critical habitat for *E. pelinophilum* are warranted but precluded by other priorities. Given this finding, we intend to initiate rulemaking when we complete the higher priorities and we have the necessary resources to do so.

DATES: The finding announced in this document was made on September 29, 2009.

ADDRESSES: This finding is available on the Internet at *http://www.regulations.gov*. Supporting documentation we used to prepare this finding is available for public inspection, by appointment during normal business hours at the U.S. Fish and Wildlife Service, Western Colorado Ecological Services Office, 764 Horizon Drive, Building B, Grand Junction, CO 81506-3946, by telephone at 970-243-2778; or by facsimile at 970-245-6933.

FOR FURTHER INFORMATION CONTACT: Patty Gelatt, Acting Western Colorado Supervisor, Fish and Wildlife Service, Western Colorado Ecological Services Office, 764 Horizon Drive, Building B, Grand Junction, CO 81506-3946, by telephone at 970-243-2778; or by facsimile at 970-245-6933. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800-877-8339. Please include ''*Eriogonum pelinophilum* scientific information'' in the subject line for faxes and emails.

SUPPLEMENTARY INFORMATION: Section 4(b)(3)(D)(ii) of the Act (16 U.S.C. 1531 *et seq.*) requires that, for any petition containing substantial scientific and commercial information that indicates revisions to critical habitat may be warranted, we make a finding within 12 months of the date of receipt of the petition and publish a notice in the **Federal Register** indicating how we intend to proceed with the requested revision.

Background

Previous Federal Actions

We proposed to list *Eriogonum pelinophilum* as an endangered species in 1983, and we proposed critical habitat at the same time (48 FR 28504; June 22, 1983). We published the final rule designating the species as endangered in 1984, along with a final critical habitat designation (49 FR 28562; July 13, 1984). Critical habitat, as designated in 1984, encompassed 119.8 acres (ac) (48.5 hectares (ha)), which was then the entire known range of the species (49 FR 28562; July 13, 1984).

On July 24, 2006, we received a petition dated July 17, 2006, from the Center for Native Ecosystems, the Colorado Native Plant Society, and the Uncompahgre Valley Association (collectively referred to here as the petitioners) requesting that we amend the critical habitat designation for *Eriogonum pelinophilum* (Center for Native Ecosystems *et al.* 2006, p. 1). The petition clearly identified itself as a petition and included the requisite identification information that 50 CFR 424.14(a) requires. The petition contained a species and habitat description for *E. pelinophilum*, a description of previous Federal actions, a section addressing statutory requirements for *E. pelinophilum*, a description of the various populations and their status, a section addressing threats to *E. pelinophilum*, and recommendations regarding critical habitat for the species. Potential threats discussed in the petition include destruction and modification of habitat, herbivory, and inadequate regulatory mechanisms.

On September 29, 2006, we acknowledged the receipt of the petition but stated that given staff and budget limitations we could not work on the administrative finding at that time (Service 2006, *in litt.*). On November 13, 2006, we received a letter dated November 9, 2006, from the petitioners notifying us of their 60–day intent to sue for our failure to make a 90–day finding for *Eriogonum pelinophilum* (Center for Native Ecosystems 2006, *in litt.*). On March 3, 2008, the petitioners filed suit with the United States District Court for the District of Colorado for our failure to make a 90–day finding for the species (Center for Native Ecosystems 2008). On September 25, 2008, a settlement agreement was reached whereby the Service agreed to submit a 90–day finding to the **Federal Register** by June 15, 2009, and, if the petition was considered substantial, submit a 12–month finding to the **Federal Register** by September 21, 2009 (U.S. Department of Justice 2008). This 12–month finding evaluates the status of existing critical habitat as stipulated in the settlement.

We published our 90–day finding regarding the petition to revise critical habitat for *Eriogonum pelinophilum* on June 22, 2009 (74 FR 29456). We determined the petition presented substantial information indicating that revising critical habitat for *E. pelinophilum* under the Act may be warranted, thus initiating this 12–month finding (74 FR 29456; June 22, 2009). We have fully considered all information received in response to information requested in our 90–day finding.

This 12–month finding discusses only those topics directly relevant to the revisions of existing critical habitat for *Eriogonum pelinophilum*. We also are in the process of preparing a 5–year review for *E. pelinophilum* where we are conducting a more thorough review of the species' status (73 FR 58261; October 6, 2008).

Species Information

Eriogonum pelinophilum was first collected near Hotchkiss, Colorado, in Delta County in 1958 (Reveal 2006, p. 1). The species was first recognized as its own taxon in 1969, and officially described in 1973 (Reveal 1969, pp. 75-76; 1973, pp. 120-122). No other locations were identified until 1984 (Colorado Natural Areas Program (CNAP) 1986, p. 1).

Eriogonum pelinophilum is a low growing, rounded, densely branched subshrub in the buckwheat family (Polygonaceae). It has dark green inrolled leaves that appear needlelike, and clusters of white to cream colored flowers with greenish-red to brownish-red bases and veins at the end of the branches.

The life history of *Eriogonum pelinophilum* has been examined in two short-term demography studies that track a plant population's change in size and structure through time. The first study was conducted on Bureau of Land Management (BLM) lands at the Fairview Research Natural Area in 1987 and 1988 (CNAP 1986; 1987). The second study was conducted at the Wacker Ranch where life history information was gathered in 1990, 1992, 1993, and 1994 (Carpenter and Schulz 1994), and again in 2008 (Lyon 2008). Neither of these studies occurred over sufficient time periods nor were they conducted frequently enough to calculate critical life history stages for *E. pelinophilum*'s success. In addition, neither study has enough demographic detail to assist in the development of a population viability model. However, both studies do add to our understanding of the species' longevity, habitat, and site differences, as described in the following two paragraphs.

The CNAP life history study for *Eriogonum pelinophilum* established four permanent monitoring plots, two plots at Fairview North and two plots 4 miles (mi) (6 kilometers (km)) south at Fairview South, and tagged 220 plants (CNAP 1987, p. 1). Significant differences in aerial cover, flowering rate, and vigor of *E. pelinophilum* between plots (CNAP 1987, p. 3) suggest site characteristics may influence plant characteristics such as abundance and size. *Artemisia nova* (black sagebrush) was the dominant species by basal area in most plots, but *E. pelinophilum* had the greatest density and frequency (CNAP 1987, p. 8). *E. pelinophilum* occurred in the highest densities away from other shrubs (CNAP 1987, p. 8).

Mortality from 1990 to 1994 averaged 6.0 percent at six permanent *Eriogonum pelinophilum* transects at the Wacker Ranch site but varied from 1.2 to 26.1 percent and was spread across age classes (Carpenter and Schultz 1994, p. 3). Observed growth rates and the number of seedlings observed varied considerably by transect (Carpenter and Schultz 1994, p. 3). This information supports the conclusion that *E. pelinophilum* is very long-lived and that environmental conditions vary considerably over relatively short distances (Carpenter and Schultz 1994, pp. 3-4). When five of the six transects were revisited in 2008, 67 percent remained alive after 18 years, further supporting the idea that the plant is long-lived (Lyon 2008, p. 2). In addition to the 181 tagged plants, at least 321 new plants were located along the 5 relocated transects (Lyon 2008, p. 2). Results were not statistically adequate to detect a change in species abundance (Lyon 2008, p. 3), but do suggest that the species may be stable or increasing at the Wacker Ranch site.

Eriogonum pelinophilum requires a pollinator, and for much of the flowering season is the most abundant species in bloom in its habitat (Bowlin *et al.* 1992, p. 300). Flowering typically occurs from late May to early September with individual flowers lasting fewer than 3 days (Bowlin *et al.* 1992, p. 298). Over 50 species of insects visit *E. pelinophilum* flowers (Bowlin *et al.* 1992, pp. 299-300). Roughly half of these 50 species are native bees and 18 species are native ants (Bowlin *et al.* 1992, pp. 299-300). Seed set is similar between plants that were pollinated by ants versus flying pollinators, suggesting the importance of ants to pollination of the species (Bowlin *et al.* 1992, p. 299). Harvester ants remove some fruits (Bowlin *et al.* 1992, p. 299); however, no information is available for the species on seed dispersal mechanisms.

Eriogonum pelinophilum plants have been found to be smaller at disturbed sites but the number, richness, diversity, or equitability of pollinators was not significantly different between disturbed and undisturbed sites (Tepedino 2009, p. 38). Of all *Eriogonum* species studied to date, none has as many pollinators as *E. pelinophilum* (Tepedino 2009, p. 39). These pollinators cover a wide array of taxonomic and functional types of insects that visit the flowers for nectar and pollen (Tepedino 2009, pp. 38-39). No single pollinator or group of pollinators appears particularly important for *E. pelinophilum* pollination (Tepedino 2009, pp. 38-39, Appendix A). Therefore, preservation of specific pollinators is not a significant concern in conservation of the species (Tepedino 2009, p. 38). Conservation of *E. pelinophilum* should focus primarily on the conservation of undisturbed habitat and associated plant species in as many separate areas as possible to manage for the wide array of pollinators (Tepedino 2009, p. 40).

Eriogonum pelinophilum is considered a close relative or synonymous with *E. clavellatum* and a close relative of *E. contortum* (Reveal 2006, p. 3). All three species are currently recognized as distinct (Reveal 2005b, p. 1; J. Kartesz, Biota of North America Project 2009, *in litt.*, p. 1). The most recent assessment indicates that preliminary genetic analyses show that *E. pelinophilum* is allied to, but distinct from *E. clavellatum*, and both are distinct from *E. contortum* (Reveal 2006, p. 3). Morphological and distributional differences also occur between *E. pelinophilum, E. contortum*, and *E. clavellatum*. *E. pelinophilum* has white flowers and occurs in Delta and Montrose Counties, Colorado, whereas *E. contortum* has yellow flowers and occurs farther north in Mesa and Garfield Counties, Colorado, and Grand County, Utah (Spackman *et al.* 1997, *E. pelinophilum* page). *E. pelinophilum* is shorter, measuring 2 to 4 inches (in.) (0.5 to 1 decimeters (dm)), has smaller involucres (bracts below the flowers - 0.12 to 0.14 in. [3 to 3.5 millimeters (mm)] long), with petals all the same length. *E. clavellatum* is taller measuring 4 to 8 in. (1 to 2 dm), has larger involucres (0.16 to 0.18 in. [4 to 4.5 mm] long), with two different sized petals, and is only known from Montezuma County, Colorado and adjacent San Juan Counties in Utah and New Mexico (Spackman *et al.* 1997, *E. pelinophilum* page; Reveal 2005c, p. 1).

Habitat Information

Eriogonum pelinophilum is endemic to the rolling clay (adobe) hills and flats immediately adjacent to the communities of Delta and Montrose, Colorado. The plants extend from near Lazear, east of Delta on the northern end of the species' range, to the southeastern edge of Montrose in Delta and Montrose Counties, Colorado, and occur from 5,180 to 6,350 feet (1,579 to 1,965 meters) in elevation (Colorado Natural Heritage Program (CNHP) 2006, p. 3; Nature Serve 2008, pp. 4-5; CNHP 2009, spatial data; Service 2009a, Table 1). *E. pelinophilum* is known from an area measuring roughly 11.5 mi (18.5 km) from east to west and 28.5 mi (45.6 km) from north to south (CNHP 2009, spatial data). The Delta/Montrose area is dry, receiving an average of 8 to 9 in. (20 to 23 centimeters (cm)) of precipitation a year (Western Regional Climate Center 2009a, p. 1; 2009b, p. 1). Winters are cold, with January being the coldest month, averaging 12 to 39 degrees Fahrenheit (-11 to 4 degrees Celsius). Summers are hot, with July being the hottest month, averaging 55 to 93 degrees Fahrenheit (13 to 34 degrees Celsius) (Western Regional Climate Center 2009a, p. 1; 2009b, p. 1).

The soils where *Eriogonum pelinophilum* are found are whitish, alkaline (with a pH over 7), clay soils of

the Mancos shale formation, a Cretaceous marine sediment formation. Mancos shale outcrops are relatively barren of vegetation in comparison to surrounding areas (Potter *et al.* 1985, p. 137). Several components of the clay soils of the Mancos shale limit plant growth: soils are fine-textured and lose moisture more readily; clay soils are compactable which limits gas exchange and thus root growth; and clay soils hold more water which is unavailable for plant use because water infiltration is slower than other soil types, and the extreme swelling and shrinking of the soils limits water availability and oxygen exchange for plant roots (Potter *et al.* 1985, p. 139). In addition, the soils are calcareous (containing calcium carbonate).

The U. S. Geological Survey is researching the Mancos shale soils occupied by *Eriogonum pelinophilum* at the Gunnison Gorge National Conservation Area (GGNCA). Preliminary results suggest that *E. pelinophilum* is associated with silty clay and silty clay loam soils that can be classified as normal or saline-sodic in relation to pH, electrical conductivity, and sodium adsorption ratio (SAR) of saturated soil paste extracts (Grauch 2009, *in litt.*, p. 1). The principal difference between occupied and unoccupied soils is that the occupied soils have fairly constant SAR values with depth while unoccupied soils have more variable SAR values. Electrical conductivity values of the saturated soil paste extracts have a similar pattern of variation with depth (R. Grauch, *in litt.* 2009, p. 1). A subsequent study comparing the soil samples collected in the study above to soil samples across the Mancos shale terrain of the GGNCA is underway and expected to be available within the next 3 years.

Soils appear to play a large role in the distribution of *Eriogonum pelinophilum*. Therefore, we conducted a geospatial analysis using Natural Resources Conservation Service (NRCS) soil layers (Paonia and Ridgeway soil surveys - NRCS 2006a, metadata; 2008, metadata) to better understand the distribution of *E. pelinophilum*. The analysis overlaid soil types with the distribution of *E. pelinophilum* in an effort to determine which soil types were most common where the plants occur. For this analysis, we buffered all known locations by 33 feet (10 meters). We employed this buffer so that *E. pelinophilum* sites represented by a point would more accurately represent the plant habitat where those points are located (Service 2009b, p. 1). For this reason, acreage figures differ significantly from those listed in the ''Population Status'' section below.

The Paonia and Ridgeway soil surveys differ in their naming and definitions of the various soil units, making the data analysis inconsistent between the two surveys. Data was not available for 9 percent (96 ac (39 ha)) of habitat occupied by *E. pelinophilum*. Given these shortcomings, we found the following five soils were most common within the 1,129 ac (457 ha) of occupied habitat of *E. pelinophilum*: 1) typic torriorthents (both 10- to 25-percent slopes, and –Badland complex with 25- to 75-percent slopes) comprised roughly 35 percent (390 ac (158 ha)); 2) ellaybee-persayo silty clay loams (5- to 12-percent slopes) comprised roughly 26 percent (294 ac (119 ha)); 3) killpack silty clay loam (3- to 12-percent slopes) comprised roughly 7 percent (84 ac (34 ha)); 4) chipeta silty clay (3- to 30-percent slopes) comprised 7 percent (77 ac (31 ha)); and 5) Montrose-Delta complex (0- to 2-percent slopes) comprised 6 percent (64 ac (26 ha)). Soil types are described as erosion remnants weathered from calcareous shale and are highly erodible by water (Soil Conservation Service 1981, pp. 24 and 39; NRCS 2006b, map unit descriptions). Several other soil types occurred within occupied habitat, but none comprised over 3 percent or 30 ac (12 ha).

Eriogonum pelinophilum plants are generally found within swales or drainages where there is more moisture than surrounding areas. These swales are generally located in low-lying areas with rolling topography. Steeper, more barren slopes within the Mancos shale habitats, but with more toxic soils for plant life, exist upslope of where the plants occur, generally within 1 mi (1.6 km). *E. pelinophilum* plants at lower elevation sites near Delta were associated with small areas where snow lingers longer than surrounding areas because of their north- and east-facing aspects (Ewing and Glenne 2009, p. 2).

Plant communities associated with *Eriogonum pelinophilum* are characterized by low species diversity, low productivity, and minimal canopy cover (NatureServe 2008, p. 4). The associated vegetation is sparse, with *E. pelinophilum* generally one of the dominant species (CNAP 1987, Table 2). In lower elevations near Delta, the dominant plant species is *Atriplex corrugata* (mat saltbrush) but at higher elevations near Montrose the dominant plant species is *Artemesia nova* (black sagebrush), although *A. corrugata* is still abundant (Southwest Regional Gap Analysis Project 2004, spatial data). Other associated species include *Atriplex confertifolia* (shadscale), *Atriplex gardneri* (Gardner's saltbush), *Picrothamnus desertorum* (formerly *Artemisia spinescens*) (bud sagebrush), *Xylorhiza venusta* (charming woodyaster), and another local endemic *Penstemon retrorsus* (Adobe Hills beardtongue) (CNAP 1987, Table 2; Coles 2006, p. 1; NatureServe 2008, p. 4).

Population Status

Based on information provided by the CNHP in January 2009, 20 *Eriogonum pelinophilum* Element Occurrences (EOs) are currently known (CNHP 2009, pp. 1-81; Service 2009a, Table 1). The EOs are utilized by Natural Heritage Programs to track rare species and are defined as an area where a species is or was present. For *E. pelinophilum,* EOs are comprised of one to many polygons (sites) based on a standardized maximum separation distance, in this case 1.2 mi (2 km) across suitable habitat and 0.6 mi (1 km) across unsuitable habitat (CNHP 2007, p. 1). However, upon closer examination, we found that several EOs, as designated by CNHP, were within 0.6 mi (1 km) of one another. For the purpose of this discussion, we have left the EOs as designated by CNHP. Of these 20 EOs, 7 have not been relocated in over 20 years and are considered historical. A survey was conducted at an additional EO where no plants were relocated (CNHP 2009, pp. 1-81; Service 2009a, Table 1). Table 1 is provided below to portray the EOs and their land management or ownership status. Figure 1 shows the distribution of *E. pelinophilum* habitat in Colorado with EO Numbers and percent occupancy.

TABLE 1. THE COLORADO NATURAL HERITAGE PROGRAM *Eriogonum pelinophilum* EOS.

The EO ranks A, B, C, and D represent the quality of the EO (from best to worst quality, respectively), H indicates an EO has not been visited in over 20 years, and F indicates an EO that could not be relocated upon subsequent visit.

EO Number	EO Rank[1]	Acreage[2]	Population Name	Land Management with Rough Estimates of Ownership Percentage
001			Lawhead Gulch	private
003	B	67	North Selig Canal	33% BLM- 66% private
004	B	17	Olathe South	private
006	B	15	North Mesa	private
007	H, C		Peach Valley	private
011	C	110	North Fairview	50% BLM - 50% private
012	B	25	Sunshine Road	5% BLM – 95% private
013	H, C	(4)	Cedar Creek	private
014	A	7	Candy Lane/Peach Valley	BLM
015	F	(70)	Selig Canal 3	private
016	C	13	Dry Cedar Creek	BLM
017	H, C	(20)	Oak Grove Road	private
018	A	212	Wacker Ranch/Fairview South	70% BLM – 20% Colorado State (CNAP) – 10% private
019	H	(2)	Star Nelson Airport	private
021	H, C	(26)	Montrose East	private
022	H, C	(19)	Montrose East	private
023	H		Hotchkiss	unknown
024	D	8	Montrose Northeast	private
025	B	18	Selig Canal	90% BLM – 10% private
041	B	6	Garret Ditch	66% BLM – 33% private
none	none	3	Peach Valley North	33% BLM – 66% private
none	none	2	Loutsenhizer Canal	BLM

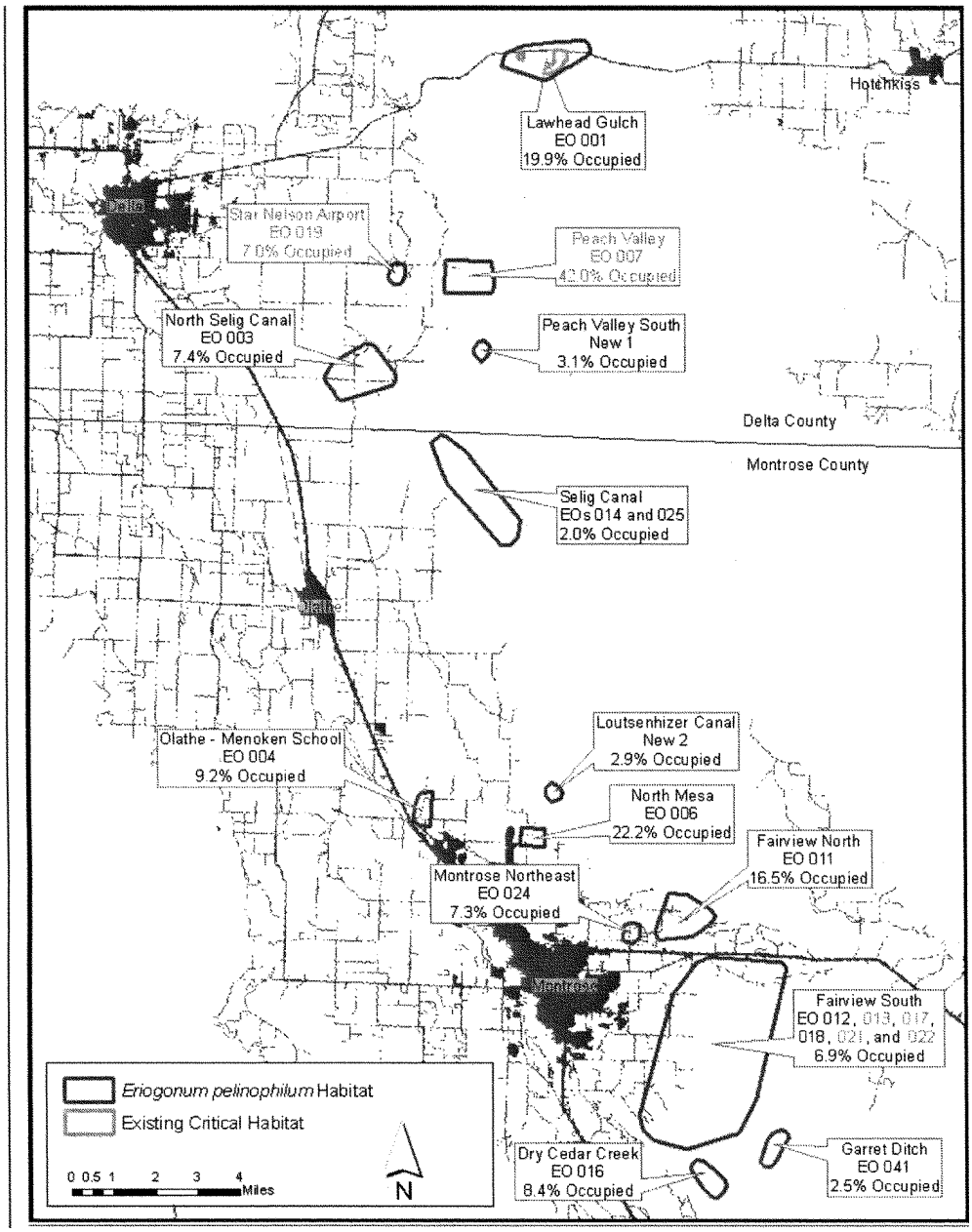
[1] EOs with both historical (H) rank and C (fair) quality ranks were ranked as C prior to becoming H.

[2] Acreages are approximate, are based on a geospatial layer when available, and on surveyor estimates when a geospatial estimate is not available (CNHP 2009, pp. 1-81). Methods for estimating acreage vary between surveys. Acres listed in parentheses are not included in the total based on their historical (H) or failed to find (F) ranks.

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Distribution of Eriogonum pelinophilum habitat in Colorado with Element Occurrence (EO) Numbers and percent occupancy.

FIGURE 1. Distribution of *Eriogonum pelinophilum* habitat in Colorado with Element Occurrence (EO) Numbers and percent occupancy.



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The most recent rangewide *E. pelinophilum* population estimate for all 14 current sites is roughly 277,000 individuals across 582 occupied ac (233 ha). Roughly 46 percent of the acres are in private ownership (14 percent of the total acres have conservation easements), and 54 percent of the acres are managed by either the BLM or the CNAP (CNHP 2009, pp. 1-81; Service 2009a, Table 1). The difference between rangewide population estimates from the 2006 petition and those in 2009 are largely attributable to surveys that occurred in 2007 near Fairview South (EO 018), where increased survey efforts greatly expanded the known locations of *E. pelinophilum* as well as the number of individuals (an increase from roughly 30,000 to 250,000 individuals) (CNHP 2009, EO 18; Ferguson 2007, pp. 2 and 4). Survey intensity has not been consistent in the different EOs.

We are aware of two additional populations of *Eriogonum pelinophilum* that are not incorporated into the CNHP database and, based on appropriate separation distances, would comprise two new EOs (Table 1). Although not yet numbered or named by CNHP, we now refer to these sites as Peach Valley North and Loutsenhizer Canal (Table 1). Peach Valley North has fewer than 100 plants and the Loutsenhizer Canal site has an estimated 500 plants (BIO-Logic Environmental 2004, Site 219 p. 7 and spatial data; BIO-Logic Inc. 2008, Figure 2 and spatial data; Boyle 2009, *in litt.*, p. 1). We have a short report in our files (Reveal 2006, p. 2) with a map portraying seven extirpated *E. pelinophilum* locations. These locations are not included in the CNAP's database. We do not have any information on how these extirpations

were determined, their exact locations, if they were portions of other EOs, or how many plants were lost; therefore, they are not included in our assessment of populations (Table 1).

Of the 14 occupied *Eriogonum pelinophilum* sites, 4 occur wholly on private land; 6 occur on a combination of BLM and private land; 1 occurs on a combination of BLM, Colorado State (CNAP), and private land; and 3 occur wholly on BLM land (Table 1). Sites on Federal lands are afforded the protections of section 7 of the Act. In addition, four EOs have special land designations that provide some additional level of protection: (1) The majority of Lawhead Gulch is protected through a conservation easement held by the Black Canyon Land Trust, as well as being within the existing critical habitat designation; (2) a portion of the North Selig Canal is protected through a conservation easement held by the Black Canyon Land Trust; (3) roughly half of North Fairview is protected as a BLM Area of Critical Environmental Concern (ACEC), and as a Colorado Natural Area, which was fenced in 2008; and (4) Wacker Ranch/Fairview South is partially protected through a BLM designated ACEC, the CNAP (both at the Fairview South ACEC and Wacker Ranch), and The Nature Conservancy at Wacker Ranch.

Each of these special designations protects *Eriogonum pelinophilum* differently. Easements held by the Black Canyon Land Trust provide permanent protection for *Eriogonum pelinophilum*, are not actively managed, and have not yet been surveyed for *E. pelinophilum*, although the presence of the plant has been confirmed on all easements (B. Hawke, Executive Director, Black Canyon Land Trust, *in litt.* 2008, pp. 1-2). The BLM's Fairview ACECs, both north and south, were designated to manage and protect *E. pelinophilum* (Ferguson 2006, *in litt.* pp. 1-6). The Fairview North ACEC has been fenced and livestock use has been halted, whereas the Fairview South ACEC is not fenced and receives livestock use. Both Fairview ACECs also are designated as Colorado Natural Areas. The CNAP has provided qualitative monitoring, quantitative monitoring, and management recommendations at both ACECs (Kurzel 2008, *in litt.* pp. 1-4). Wacker Ranch was acquired through a U.S. Fish and Wildlife Recovery Land Acquisition Grant in 2007 to protect *E. pelinophilum* (McGillivary 2007, *in litt.* p. 1). The property is owned by the Colorado Division of Parks and Outdoor Recreation (CNAP), is a Colorado Natural Area, and is managed by The Nature Conservancy (Colorado Division of Parks and Outdoor Recreation and The Nature Conservancy 2007, pp. 1-5). A formal management plan has been completed and nonnative weed control, qualitative and quantitative monitoring, as well as public outreach are ongoing for this property (Kurzel 2008*, in litt.* pp. 1-4).

Critical Habitat

Current Critical Habitat Designation

At the time we designated critical habitat, the designation represented the entire known range of the species. The rule designating critical habitat included as the primary constituent elements those factors associated with the whitish alkaline clay soils within the sparsely vegetated badlands of Mancos shale. The existing critical habitat for *E. pelinophilum,* as designated in 1984, encompasses 119.8 ac (48.5 ha) and one population (Lawhead Gulch, EO 001,50 CFR 17.96(a)). Within that designation, approximately 65 ac (26 ha) of habitat remains occupied containing approximately 2,000 individual plants. The current critical habitat designation for *E. pelinophilum* includes approximately 65 of 582 ac (26 of 233 ha) of currently occupied habitat (11 percent), and 2,000 of 276,000 individuals (0.7 percent) (Service 2009, Table 1). *E. pelinophilum* has special protections in portions of 4 of 20 extant EOs.

Background

Critical habitat is defined in section 3(5)(A) of the Act as:

(i) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(I) essential to the conservation of the species and

(II) which may require special management considerations or protection; and

(ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means the use of all methods and procedures that are necessary to bring any endangered or threatened species to the point at which the measures provided under the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, or transplantation.

Critical habitat receives protection under section 7 of the Act through the prohibition against Federal agencies carrying out, funding, or authorizing the destruction or adverse modification of critical habitat. Section 7(a)(2) of the Act requires consultation on Federal actions that may affect critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by private landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) would apply, but even in the event of a destruction or adverse modification finding, the landowner's obligation is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

For inclusion in a critical habitat designation, habitat within the geographical area occupied by the species must contain the physical and biological features essential to the conservation of the species, and be included only if those features may require special management considerations or protection. Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas containing the essential physical and biological features essential to the conservation of the species. The essential features consist of the primary constituent elements (PCEs) in the appropriate quantity and spatial arrangement that provide for requisite life cycle needs of the species. Under the Act and regulations at 50 CFR 424.12, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed only when we determine that those areas are essential for the conservation of the species and that designation limited to those areas occupied at the time of listing would be inadequate to ensure the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific and commercial data available. Further, our Policy on Information Standards Under the Act

(published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106-554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

12-Month Finding

Section 4(b)(3)(D)(ii) of the Act requires that if we find that a revision to critical habitate should be made, then we are to indicate how we intend to proceed with such revision and promptly publish a notice of our intention. We have reviewed the best available scientific and commercial information available, and we find that revisions to critical habitat for *E. pelinophilum* under the Act should be made. However, we have determined that the development of a revised critical habitat designation for the species is currently precluded by higher priority listing and critical habitat determinations. The resources available for listing actions, including critical habitat designations and revisions, are determined through the annual Congressional appropriations process. We cannot spend more than is appropriated for the Listing Program without violating the Anti-Deficiency Act (see 31 U.S.C. 1341(a)(1)(A)). Recognizing that designation of critical habitat for species already listed would consume most of the overall Listing Program appropriation, Congress also put a critical habitat subcap in place in FY 2002 and has retained it each subsequent year. In FY 2002 and each year until FY 2006, the Service has had to use virtually the entire critical habitat subcap to address court-mandated designations of critical habitat, and consequently none of the critical habitat subcap funds have been available for other listing activities. In FY 2007, we were able to use some of the critical habitat subcap funds to fund proposed listing determinations for high-priority candidate species. While we were unable to use any of the critical habitat subcap funds to fund proposed listing determinations in FY 2008, we did use a portion of this money to fund the critical habitat portion of some proposed listing determinations. In those cases, this allowed combining the proposed listing determination and proposed critical habitat designation into one rule, thereby increasing efficiency. In FY 2009, we have been able to continue this practise. However, our current projection for FY 2010 is that all of the funding anticipated for the critical habitat portion of the listing allocation will be used to address court-ordered critical habitat designations. As such, we do not anticipate having funding available to work on non-court-ordered actions in FY 2010.

Thus, through the critical habitat subcap, and the amount of funds needed to address court-mandated critical habitat designations, Congress and the courts have in effect determined the amount of money available for critical habitat revisions. Therefore, the funds in the critical habitat subcap, other than those needed to address court-mandated critical habitat for already listed species, set the limits on revisions to critical habitat.

We have endeavored to make our critical habitat designation and revision actions as efficient and timely as possible, given the requirements of the relevant law and regulations, and constraints relating to workload and personnel. We are continually considering ways to streamline processes or achieve economies of scale, such as by batching related actions together.

While we are not proposing to revise critical habitat at this time, we have considered whether the physical and biological features essential to the conservation of the species identified in the previous designation are still appropriate for this species. The original critical habitat designation included only the alkaline clay soils as a primary constituent element, and therefore the feature essential to the conservation of the species. Appropriate native vegetation and features that allow for dispersal were not included. Based on the biology of the species, we intend to revise the PCEs, and therefore the essential features, in order to address the following needs of the species: appropriate native vegetation, appropriate soils, and features that allow for dispersal within units. Such features may include suitable habitat for pollinators, appropriate slopes, depressions, rivulets, and sites where snow banks linger. We find that incorporating these concepts into the revised critical habitat designation for *Eriogonum pelinophilum* is important for identifying the specific areas essential to the conservation of the species. We are soliciting any additional information or input on these potential PCEs and essential features.

How the Service Intends To Proceed

We intend to undertake rulemaking to revise critical habitat for *Eriogonum pelinophilum* when funding and staff resources become available. Based on the best available science, including the status review, we will take the following steps to propose the revision of designated critical habitat for *Eriogonum pelinophilum*: (1) Determine the geographical area occupied by the species at the time of listing; (2) identify the physical or biological features essential to the conservation of the species; (3) delineate areas within the geographical area occupied by the species that contain these features, and which may require special management considerations or protections; (4) delineate any areas outside of the geographical area occupied by the species that are essential for the conservation of the species; (5) conduct appropriate analyses under section 4(b)(2) of the Act; and (6) invite the public to review and provide comments on the proposed revision through a public comment period.

We intend that any revisions to critical habitat for *E. pelinophilum* be as accurate as possible. Therefore, we will continue to accept additional information and comments from all concerned governmental agencies, the scientific community, industry, or any other interested party concerning this finding.

Current Designation and Protections

Until we are able to revise the critical habitat designation for *Eriogonum pelinophilum*, areas that support populations but are outside the critical habitat designation will continue to be subject to conservation actions implemented under section 7(a)(1) of the Act. Federal agency actions are subject to the regulatory protections afforded by section 7(a)(2), as determined on the basis of the best available scientific information at the time of the action. Approximately a third of the areas currently known to be occupied by the species are on private land outside of the current designation. We expect occasional projects on private land to involve a Federal nexus, in which case protections under section 7(a)(2) would also apply. Where a landowner requests Federal agency funding or authorization (i.e., Federal nexus) for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) would apply.

Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome. Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, or carry out are not likely to destroy or adversely modify critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. As a result of this consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species or destroy or adversely modify critical habitat, we also provide reasonable and prudent alternatives to the project, if any are identifiable. We define ''Reasonable and prudent alternatives'' at 50 CFR 402.02 as alternative actions identified during consultation that:

• Can be implemented in a manner consistent with the intended purpose of the action,

• Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

• Are economically and technologically feasible, and

• Would, in the Director's opinion, avoid jeopardizing the continued existence of the listed species or destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies may sometimes need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

References Cited

A complete list of all references cited in this document is available, upon request, from the Western Colorado Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Author

The primary authors of this notice are the staff members of the Western Colorado Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 16, 2009.

Thomas L. Strickland

Assistant Secretary for Fish and Wildlife and Parks

[FR Doc. E9–23155 Filed 9–28– 09; 8:45 am]

BILLING CODE 4310–55–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R4-ES-2009-0066]
[92210-1117-0000-B4]

Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition to Revise Critical Habitat for the Florida Manatee (*Trichechus manatus latirostris*)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 90–day petition finding and initiation of critical habitat review.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce a 90–day finding on a petition to revise the critical habitat designation for the Florida subspecies (*Trichechus manatus latirostris*) of the endangered West Indian manatee (*Trichechus manatus*) under the Endangered Species Act of 1973, as amended. Based on our review, we find that the petition, in conjunction with information readily available in our files, presents substantial scientific or commercial information indicating that a revision of the critical habitat designation for the Florida manatee may be warranted. Therefore, with the publication of this notice, we are initiating a review of the current critical habitat designation for the subspecies to determine how we intend to proceed with the revision. To ensure a comprehensive review, we seek information pertaining to the Florida manatee's essential habitat needs from any interested party.

DATES: To allow us adequate time to conduct this review, we request that you send us information on or before October 29, 2009.

ADDRESSES: You may submit information by one of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Search for docket FWS-R4-ES-2009-0066 and then follow the instructions for submitting comments.

• *U.S. mail or hand-delivery*: Public Comments Processing, Attn: FWS-R4-ES-2009-0066; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will post all information received on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see the **Information Solicited** section below for more details).

FOR FURTHER INFORMATION CONTACT: Dave Hankla, Field Supervisor, Jacksonville, Florida Ecological Services Office, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256, by telephone (904-731-3336), or by facsimile (904-731-3045). If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800-877-8339.

SUPPLEMENTARY INFORMATION:

Information Solicited

When we make a finding that a petition presents substantial information indicating that a revision of a critical habitat designation may be warranted, we initiate a review of that critical habitat to determine how we intend to proceed with the requested revision of the designation. To ensure that the review is complete and incorporates the best available scientific and commercial information, we seek information regarding the revision of critical habitat for the Florida manatee.

We request information from governmental agencies, Native American Tribes, the scientific community, industry, and any other interested parties. We are seeking information regarding:

(1) The historical and current status and distribution of Florida manatee, its biology and ecology, and ongoing conservation measures for the species and its habitat;

(2) Physical and biological features essential to the conservation of the species;

(3) Information on threats to the species and its habitat; and

(4) Data on the increase in growth of Florida's human population since we designated manatee critical habitat in 1976, and examples of related increased threats to the species and subsequent changes to manatee habitat.

In 2007, the Service conducted an extensive review of all available information on the Florida manatee while preparing a 5–year status review of the species (Service 2007). We are particularly seeking information about manatee habitat or manatee use of habitat that has been made available since publication of the review.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination. Section 4(b)(2) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*) directs that ''the Secretary shall designate critical habitat, and make revisions thereto, ...on the basis of the best scientific data available.'' Based on our critical habitat review, we will publish a 12–month notice of our intentions concerning the petition, as provided in section 4(b)(3)(D)(ii) of the Act.

You may submit your information concerning this review by one of the methods listed in the **ADDRESSES** section. If you submit information via *http://www.regulations.gov*, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this personal identifying information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov*. Please include sufficient information with your submission (such as full references) to allow us to verify any scientific or commercial information you include.

Information and materials we receive, as well as supporting documentation we used in preparing this finding, will be available for public inspection on *http://www.regulations.gov*, or by appointment during normal business hours, at the U.S. Fish and Wildlife Service, Jacksonville, Florida Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

Section 4(b)(3)(D) of the Act requires that we make a finding as to whether a petition to revise critical habitat presents substantial scientific information indicating that the revision may be warranted. The standard for substantial scientific or commercial information set forth in our implementing regulations with regard to a 90–day petition finding is ''that amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted'' (50 CFR 424.14(b)). In determining whether substantial information exists, we take into account several factors, including information submitted with, and referenced in, the petition and all other information readily available in our files. To the maximum extent practicable, we are to make this finding within 90 days of the receipt of the petition, and we are to publish the finding promptly in the **Federal Register**.

Our standard for substantial scientific or commercial information within the Code of Federal Regulations (CFR) with regard to a 90–day petition finding is ''that amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted'' (50 CFR 424.14(b)). If we find that a petition presents substantial information indicating that the revision may be warranted, we are required to determine how we intend to proceed with the requested revision within 12 months after receiving the petition and promptly publish notice of such intention in the **Federal Register**.

Critical habitat is defined under section 3(5)(A) of the Act as:

(i) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(I) essential to the conservation of the species and

(II) which may require special management considerations or protection; and

(ii) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our implementing regulations at 50 CFR 424.12 describe our criteria for designating critical habitat. We are to consider essential physical and biological features essential to the conservation of the species. Those features include, but are not limited to: (1) space for individual and population growth, and normal behavior; (2) food, water, air, light, minerals, or other nutritional or physiological requirements; (3) cover or shelter; (4) sites for breeding, reproduction, or rearing of offspring; and (5) habitats that are protected from disturbance or are representative of the historic geographical and ecological distribution of a species. Essential physical and biological features may include, but are not limited to: ''nesting grounds, feeding sites, water quality, tide, and geological formations.'' Our implementing regulations at 50 CFR 424.02 define ''special management considerations or protection'' as any methods or procedures useful in protecting physical and biological features of the environment for the conservation of the species.

Section 4(b)(2) of the Act requires us to designate and make revisions to critical habitat for listed species on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impact, of specifying any particular area as critical habitat. The Secretary may exclude any particular area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines that the failure to designate such area as critical habitat will result in the extinction of the species concerned.

Petition History

On December 19, 2008, we received a petition from Wildlife Advocacy Project, Save the Manatee Club, Center for Biological Diversity, and Defenders of Wildlife, requesting that we revise critical habitat for the Florida manatee (*Trichechus manatus latirostris*) pursuant to the Act and the Administrative Procedure Act (5 U.S.C. Subchapter II). The petition clearly identified itself and included the requisite identification information for the petitioners, as required in 50 CFR 424.14(a). In a January 17, 2009, letter to the petitioners, we responded that we received the petition and would make a finding, to the maximum extent practicable within 90 days, as to

whether or not the petition presents substantial information. We also stated that if the initial finding concludes that the petition presents substantial information indicating that a revision may be warranted, then we have one year from the date we received the petition to determine how we intend to proceed with the requested revision and we will promptly publish in the **Federal Register** a notice of our intentions at the end of this period.

Previous Federal Actions

We originally listed the Florida manatee (*Trichechus manatus latirostris),* a subspecies of the West Indian manatee (*Trichechus manatus*), as endangered in 1967 (32 FR 4001, March 11, 1967) under the Endangered Species Preservation Act of 1966 (Pub. L. 89-669; 80 Stat. 926). In 1970, we amended Appendix A to 50 CFR part 17 to include additional names to the list of foreign endangered species (35 FR 18319, December 2, 1970). This listing incorporated West Indian manatees into the list under the Endangered Species Conservation Act of 1969 (Pub. L. 91-135; 83 Stat. 275) and encompassed the species' range in the Caribbean and northern South America, thus including both Antillean (*T. m. manatus*) and Florida manatees in the listing. The West Indian manatee is currently listed as an endangered species under the Act, and the population is further protected as a depleted stock under the Marine Mammal Protection Act (16 U.S.C. 1361 *et seq.*). We designated critical habitat for the Florida manatee (listed in that regulation as *Trichechus manatus)* on September 24, 1976 (41 FR 41914) in Citrus, Hillsborough, Manatee, Sarasota, Charlotte, De Soto, Lee, Collier, Monroe, Dade, Palm Beach, Martin, West Palm Beach, Volusia, Brevard, Nassau and Duval Counties, Florida. That critical habitat designation appears in our regulations at 50 CFR 17.95(a).

Species Information

For current information on the biology, status, and habitat needs of the Florida manatee, refer to the Service's 5-Year Review of the West Indian Manatee (Service 2007) and the Service's Florida Manatee Recovery Plan (Service 2001), available on the Internet at *http://www.regulations.gov* and at *http://www.fws.gov/northflorida/Manatee/manatees.htm*.

Evaluation of the Petition

In making this 90–day finding, we evaluated whether information regarding the revision of the critical habitat for Florida manatee, as presented in the petition and other information available in our files is substantial, thereby indicating that the petitioned action may be warranted. Our evaluation of this information is presented below.

The petitioners seek to revise the critical habitat designation through proposed revisions of each geographic area or management unit and the inclusion of ''notable constituent elements.'' The petitioners claim that although the currently designated critical habitat is large, because of flaws in the listing, it provides inadequate protection of manatees. The petitioners include the four topics listed below as ''major deficiencies'' in the currently designated critical habitat for the Florida manatee.

(1) Petitioners Claim that Constituent Elements Required by Law are Absent.

The petitioners state that we designated manatee critical habitat in 1976, 2 years before the requirement for constituent elements was included in the 1978 amendments to the ESA in which the term ''critical habitat'' was clearly defined, and included the physical and biological factors (p. 15). The petitioners also state that, because extensive information concerning the manatee's current and projected habitat needs and utilization is now available, it is possible to describe the constituent elements, and we should remedy the lack of such elements in the critical habitat designation (p. 15).

We agree that we did not address constituent elements, or more appropriately, the physical and biological features essential to the conservation of the manatee, in the original 1976 designation of critical habitat, and more information is now available on the habitat needs of the manatee. Therefore, we find that the petitioners have presented substantial information that a revision to the critical habitat for the manatee may be warranted to more adequately address the features essential to the species' conservation.

(2) Petitioners Claim that Changes in Use by the Species Necessitate Revision.

The petitioners include statistics on the increase in growth of Florida's human population since we designated manatee critical habitat and include examples of related increased threats to the species and subsequent changes to habitats now available to manatees (pp. 15-16). They state that a 171 percent increase in the human population of Florida since critical habitat was designated in 1976, through 2005, has increased recreational use of coastal areas and has diminished water quality and the availability of natural warm water for manatees.

We agree that the increase in urban development, particularly on Florida's coasts, has changed the landscape since we designated critical habitat for the manatee. In response to the increase in human growth, and consequent increase in the number of recreational vessels on Florida's waterways, we have published a number of rules to establish manatee protection areas in the State (50 CFR 17.100 through 17.108). This information can be found on the Internet at *http://www.fws.gov/northflorida/Manatee/manatees.htm*. We find that the information provided by the petitioners, along with information in our files, is substantial, indicating that a revision to critical habitat may be warranted to address changes in habitat use by manatees in Florida since the original designation of critical habitat.

(3) Petitioners Claim that Advancements in Science Provide New Information About the Needs of the Species.

The petitioners claim that aerial surveys, radio and satellite telemetry studies, a carcass retrieval database, and the U.S. Geological Survey-Sirenia Project photo-identification database, which were developed after the initial designation of manatee critical habitat, have revolutionized our knowledge of manatee distribution and use of habitat. The petitioners also cite the Florida Manatee Recovery Plan's actions regarding manatee habitat, stating that we are compiling information and sponsoring research to identify and protect important manatee habitats with a longer term goal to conserve a network of manatee migratory corridors, and feeding, calving, and nursing areas (p. 16).

We agree that scientific information regarding manatee conservation has dramatically increased since the original critical habitat designation. On the basis of this information, it is apparent that there has been a change in habitat use by the manatee due to an increasing manatee population and changing habitats. However, the most substantial information otherwise readily available to the Service is not that of the petitioners, but the analysis of threats for the Florida manatee in the Service's 5–year review (Service 2007), which incorporates updates in manatee science and includes both biological information and habitat use. The Service must designate and make revisions to critical habitat on the basis of the best scientific information available. The Service's 5–year review is the most recent analysis of threats to the

species based on those updates in scientific information. Therefore, based on information submitted by the petitioners and information in Service files, we find the information concerning advancements in science and new information concerning the needs of the species to be substantial information. We now know more specifically where habitat exists for manatees that is critical to their survival and recovery. As a consequence, we have determined that a revision to critical habitat for the manatee may be warranted to address new information concerning habitat usage and needs.

(4) Petitioners Claim that The U.S. Fish and Wildlife Service Recognizes the Need for Revision.

The petitioners cite passages from Service consultation documents and the current Florida Manatee Recovery Plan (Recovery Plan) as evidence that we have stated the need to assess and revise critical habitat for the Florida manatee (p. 17). Specifically, the petitioners cite a biological opinion regarding U.S. Army Corps of Engineers Application (No. 4-1-97-F-602): ''The action area is within designated critical habitat for the manatee; however, no specific primary or secondary constituent elements were included in the critical habitat designation, making it difficult to determine when an action adversely modifies critical habitat.'' The petitioners state that the Service's Recovery Plan acknowledges the need to revise critical habitat and cite Recovery Action 3.5 from the Recovery Plan: ''Much has been learned about manatee distribution in the decades since manatee critical habitat was originally defined. The FWS should assess the need to revise critical habitat for the Florida manatee.''

The Service disagrees with the petitioner's statement that the Recovery Plan acknowledges the need to revise critical habitat; however, we do acknowledge that the 2001 Florida Manatee Recovery Plan contains a recovery action, including the recommendation as stated above, to assess the need to revise critical habitat. Although the Service believes ''assessing the need'' is not the same as ''recognizing the need'' for revision, we find that the information submitted by the petitioner in this category to be substantial information indicating that a revision to critical habitat for the manatee may be warranted.

Petitioners' Proposed Revisions to Critical Habitat

In addition to identifying the deficiencies noted above with the current Florida manatee critical habitat designation, the petitioners dedicate an entire section of the petition to specific proposed revisions to manatee critical habitat in Florida. These proposed revisions include a description of geographic boundaries within each regional management unit that would alter the currently designated critical habitat, as well as recommended physical and biological features essential to the conservation of the manatee that would require protection and special attention either throughout all or portions of the petition's proposed geographical boundary revisions.

Within each geographic management unit (Northwest Region, Southwest Region, Atlantic Region, and Upper St. Johns River Region), the petitioners provide a list of the currently designated critical habitat areas followed by their proposed revisions to those areas. In most cases, the petitioners list additional areas that they believe should be included in a revision to the currently designated critical habitat boundaries. They cite available scientific data to support their proposal.

The list of essential features recommended by the petitioners for each of these geographic areas includes warm water (natural springs, passive thermal basins, and power plant thermal discharges); various food sources (seagrasses and freshwater vegetation); travel corridors; shelter (for calving and from disturbances); fresh water; and other habitat features (water depth, water quality and salinity).

The Service recognizes the importance of warm water habitat to manatees; however, we have not evaluated potential physical and biological features essential to the conservation of the manatee. The Service makes no statement at this time on the specific proposals by the petitioners for the constituent elements or for the areas presented as revised critical habitat geographic boundaries. We do believe that any revision to critical habitat should reflect the current understanding of the conservation needs of the species.

Finding

Our process for making this 90–day finding under section 4(b)(3)(D) of the Act is limited to a determination of whether the information in the petition presents ''substantial scientific information,'' which is interpreted in our regulations as ''that amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted'' (50 CFR 424.14(b)).

Based on this review and evaluation, in addition to the information readily available in our files, we find that the petition has presented substantial scientific information indicating that revision of the critical habitat designation for the Florida manatee may be warranted. Therefore, we are initiating a review to determine how we intend to proceed with the request to revise the critical habitat designation under the Act for the Florida manatee.

References Cited

A complete list of all references cited in this rule is available on the Internet at *http://www.regulations.govor* upon request from the Field Supervisor, Jacksonville, Florida Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Author(s)

The primary authors of this notice are the staff members of the Jacksonville, Florida Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 16, 2009.

Thomas L. Strickland

Assistant Secretary for Fish and Wildlife and Parks

[FR Doc. E9–23245 Filed 9–28– 09; 8:45 am]

BILLING CODE 4310–55–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 0909111273–91274–01]

RIN 0648–XR09

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule.

SUMMARY: NMFS proposes a regulation to implement the annual harvest guideline (HG) for Pacific mackerel in the U.S. exclusive economic zone (EEZ) off the Pacific coast. This HG is proposed according to the regulations implementing the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP) and establishes allowable harvest

levels for Pacific mackerel off the Pacific coast. The proposed total HG for the 2009–2010 fishing year is 10,000 metric tons (mt) and is proposed to be divided into a directed fishery HG of 8,000 mt and an incidental fishery of 2,000 mt.

DATES: Comments must be received by October 29, 2009.

ADDRESSES: You may submit comments on this proposed rule identified by 0648–XR09 by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov*
- Mail: Rodney R. McInnis, Regional Administrator, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802.
- Fax: (562)980–4047, Att: Joshua Lindsay

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the report *Pacific Mackerel (Scomber japonicus) Stock Assessment for U.S. Management in the 2009–2010 Fishing Year* may be obtained from the Southwest Regional Office (see **ADDRESSES**).

FOR FURTHER INFORMATION CONTACT: Joshua Lindsay, Southwest Region, NMFS, (562) 980–4034.

SUPPLEMENTARY INFORMATION: The CPS FMP, which is implemented by regulation at 50 CFR part 660, subpart I, divides management unit species into two categories: actively managed and monitored. The HGs for actively managed species (Pacific sardine and Pacific mackerel) are based on formulas applied to current biomass estimates.

During public meetings each year, the biomass for each actively managed species within the CPS FMP is presented to the Pacific Fishery Management Council's (Pacific Council) Coastal Pelagic Species Management Team (Team), the Council's Coastal Pelagic Species Advisory Subpanel (Subpanel) and the CPS Subcommitee of the Scientific and Statistical Committee (SSC). At that time, the biomass, the acceptable biological catch (ABC) and the status of the fisheries are reviewed and discussed. This information is then presented to the Council along with HG recommendations and comments from the Team and Subpanel. Following review by the Council and after hearing public comments, the Council makes its HG recommendation to NOAA's National Marine Fisheries Service (NMFS). The annual HG is published in the **Federal Register** as close as practicable to the start of the fishing season.

For the 2009–2010 Pacific mackerel management season a full assessment for Pacific mackerel was conducted and then reviewed by a Stock Assessment Review (STAR) Panel in May 2009. This most recent full assessment for Pacific mackerel estimates the current biomass to be 282,049 mt. Based on this estimated biomass, the harvest control rule in the CPS FMP produces an ABC of 55,408 mt.

At the June 2009 Pacific Council Meeting, the Council reviewed the current Pacific mackerel stock assessment, biomass numbers, ABC and STAR Panel Report, as well as heard statements/reports from the SSC, Team and Subpanel. Although the assessment for Pacific mackerel was reviewed by a STAR Panel and was approved by the SSC as the best available science for use in management, concerns were expressed by all the advisory groups regarding the data sources that informed the assessment and the uncertainty in the assessment results. Taking into consideration these reports and statements, the Council adopted the most recent assessment for Pacific mackerel along with the calculated ABC, but recommended setting an overall HG for the July 1, 2009 through June 30, 2010 fishing season at 10,000 mt. The Council also recommended that 8,000 mt of this total HG be allocated for a directed fishery and 2,000 mt be set-aside for incidental Pacific mackerel landings in other fisheries should the 8,000 mt directed fishery HG be attained. Should the directed Pacific mackerel fishery attain landings of 8,000 mt, the Council recommends that NMFS close the directed fishery and establish a 45 percent incidental catch allowance when Pacific mackerel are landed with other CPS (no more than 45% by weight of the CPS landed per trip may be Pacific mackerel), except that up to 1 mt of Pacific mackerel can be landed without landing any other CPS.

Information on the fishery and the stock assessment can be found in the report *Pacific mackerel (Scomber japonicus) Stock Assessment for U.S. Management in the 2009–10 Fishing Season* (see **ADDRESSES**).

The harvest control rule formula in the FMP uses the following factors to determine the ABC:

1. *Biomass.* The estimated stock biomass of Pacific mackerel age one and above for the 2009–2010 management season is 282,049 mt.

2. *Cutoff.* This is the biomass level below which no commercial fishery is allowed. The FMP established this level at 18,200 mt.

3. *Distribution.* The portion of the Pacific mackerel biomass estimated in the U.S. EEZ off the Pacific coast is 70 percent and is based on the average historical larval distribution obtained from scientific cruises and the distribution of the resource according to the logbooks of aerial fish-spotters.

4. *Fraction.* The harvest fraction is the percentage of the biomass above 18,200 mt that may be harvested. The FMP established this at 30 percent.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the CPS FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

These proposed specifications are exempt from review under Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities as follows:

The purpose of this proposed rule is to implement the 2009–2010 HG for Pacific mackerel in the U.S. EEZ off the Pacific coast. The CPS FMP and its implementing regulations require NMFS to set an annual HG for the Pacific mackerel fishery based on the harvest formula in the FMP. The harvest formula is applied to the current stock biomass estimate to determine the ABC, from which the HG is then derived.

Pacific mackerel harvest is one component of CPS fisheries off the U.S. West Coast which primarily includes the fisheries for Pacific sardine, northern anchovy, jack mackerel and market squid. Pacific mackerel are principally caught off southern California within the limited entry portion (south of 39 N. latitude; Point Arena, California) of the fishery. Sixty vessels are currently permitted in the Federal CPS limited entry fishery off California. These vessels are considered small business entities by the U.S. Small Business Administration since the vessels do not have annual receipts in excess of $4.0

million. This proposed rule has an equal effect on all of these small entities. Therefore, there would be no disporportionate impacts on large and small business entities under the proposed action.

The profitability of these vessels as a result of this proposed rule is based on the average Pacific mackerel ex-vessel price per mt. NMFS used average Pacific mackerel ex-vessel price per mt to conduct a profitability analysis because cost data for the harvesting operations of CPS finfish vessels was unavailable.

During the 2007/2008 fishing year 6,200 mt of Pacific mackerel were landed with an estimated ex-vessel value of $900,000 and during the 2008/2009 fishing year approximately 4,000 mt were landed with an estimated exvessel value of $780,000. The proposed HG for the 2009/2010 Pacific mackerel fishing season (July 1, 2008 through June 30, 2009) is 10,000 mt. If the fleet were to take the entire 2009/2010 HG, and assuming no change in the coastwide average ex-vessel price per mt of $200, the potential revenue to the fleet would be approximately $2 million.

The amount of Pacific mackerel caught each year depends greatly on market forces within the fishery, as well as the other CPS fisheries, and on the regional availability of the species to the fleet and the fleets' ability to easily find schools relatively close to port. If there is no change in market conditions (i.e., a lack in demand for Pacific mackerel product), it is not likely that the full HG will be taken during the 2009–2010 fishing year, in which case profits will be lower than if the entire HG were taken. Additionally, the potential lack of regional availability of the resource to the fleet can cause a reduction in the amount of Pacific mackerel that is harvested, in turn, potentially reducing the total revenue to the fleet.

The annual average U.S. Pacific mackerel harvest from 2001/2002 to 2008/2009 is 5,584 mt with an average annual exvessel revenue of $929,419. Based on this catch and revenue history for Pacific mackerel over the last nine years NMFS does not anticipate a drop in profitability based on this rule, as the 2009/2010 available harvest (10,000 mt) is nearly twice the average catch during that time.

In addition, the revenue derived from harvesting Pacific mackerel is only one factor determining the overall revenue of the CPS fleet and therefore the economic impact to the fleet from the proposed action cannot be viewed in isolation. CPS vessels typically harvest a number of other species, including Pacific sardine, market squid, northern anchovy, and tuna, with the focus on Pacific sardine, which had an estimated ex-vessel of $14.5 million in 2008 and market squid which had an estimated ex-vessel of $26 million in 2008. Therefore Pacific mackerel is only a small component of this multi-species CPS fishery.

Based on the disproportionality and profitability analysis above, this rule if adopted, will not have a significant economic impact on a substantial number of these small entities.

As a result, an Initial Regulatory Flexibility Analysis is not required and none has been prepared.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 23, 2009.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. E9–23463 Filed 9–28–09; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 74, No. 187
Tuesday, September 29, 2009

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Determination of Total Amounts of Fiscal Year 2010 Tariff-Rate Quotas for Raw Cane Sugar and Certain Sugars, Syrups and Molasses

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: The Office of the Secretary of the U.S. Department of Agriculture is providing notice of the establishment of the Fiscal Year (FY 2010) in-quota aggregate quantity of the raw, as well as, refined and specialty sugar Tariff-Rate Quotas (TRQ) as required under the U.S. World Trade Organization (WTO) commitments. The FY 2010 raw cane sugar TRQ is established at 1,117,195 metric tons raw value (MTRV) that may be entered under subheading 1701.11.10 of the U.S. Harmonized Tariff Schedule (HTS) during FY 2010 (October 1, 2009–September 30, 2010). In addition in-quota aggregate quantity of the refined and specialty sugar TRQ is established at 90,039 MTRV for certain sugars, syrups, and molasses (collectively referred to as refined sugar) that may be entered under subheadings 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10, and 2106.90.44 of the HTS during FY 2010.

DATES: *Effective Date:* October 1, 2009.

FOR FURTHER INFORMATION CONTACT: Angel Gonzalez, Import Policies and Export Reporting Division, Foreign Agricultural Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., AgStop 1021, Washington, DC 20250–1021; by telephone (202) 720–2916; by fax (202) 720–0876; or by e-mail *angel.f.gonzalez@fas.usda.gov.*

SUPPLEMENTARY INFORMATION: The provisions of paragraph (a)(i) of the Additional U.S. Note 5, Chapter 17 in the HTS authorize the Secretary of Agriculture to establish the in-quota TRQ amounts (expressed in terms of raw value) for imports of raw cane sugar and certain sugars, syrups, and molasses that may be entered under the subheadings of the HTS subject to the lower tier of duties of the TRQs for entry during the fiscal year beginning October 1, 2009. The Office of the U.S. Trade Representative (USTR) is responsible for the allocation of these quantities among supplying countries and areas.

Section 359(k) of the Agricultural Adjustment Act of 1938, as amended requires that at the beginning of the quota year the Secretary of Agriculture establish the TRQ's for raw can sugar and refined sugars at the minimum levels necessary to comply with obligations under international trade agreements, with the exception of specialty sugar.

Notice is hereby given that I have determined, in accordance with paragraph (a)(i) of the Additional U.S. Note 5, Chapter 17 in the HTS and section 359(k) of the 1938 Act, that an aggregate quantity of up to 1,117,195 MTRV of raw cane sugar described in subheading 1701.11.10 of the HTS may be entered or withdrawn from warehouse for consumption during FY 2010 (October 1, 2009–September 30, 2010). This is the minimum amount to which the United States is committed under the WTO Uruguay Round Agreements. I have further determined that an aggregate quantity of 90,039 MTRV of sugars, syrups, and molasses described in subheadings 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10, and 2106.90.44 may be entered or withdrawn from warehouse for consumption during FY 2010. Of this quantity of 90,039 MTRV, the quantity of 69,695 MTRV is reserved for the importation of specialty sugars as defined by the USTR. This 90,039 MTRV quantity includes the 22,000 MTRV required WTO minimum amount of which 1,656 MTRV is reserved for specialty sugar.

The FY 2010 specialty sugar TRQ will be opened in five tranches. Because the specialty sugar TRQ is first-come, first-served, tranches are needed to allow for orderly marketing throughout the year. The first tranche, totaling 1,656 MTRV, will open October 1, 2009. All specialty sugars are eligible for entry under this tranche. The second tranche will open on November 10, 2009, and be equal to 25,000 MTRV. The remaining tranches will each be equal to 14,346 MTRV, with the third opening on January 12, 2010; the fourth, on May 17, 2010; and the fifth, on August 24, 2010. The second, third, fourth, and fifth tranches will be reserved for organic sugar and other specialty sugars not currently produced commercially in the United States or reasonably available from domestic sources.

Conversion factor: 1 metric ton = 1.10231125 short tons.

Signed at Washington, DC, the 23rd day of September 2009.

Thomas J. Vilsack,

Secretary of Agriculture.

[FR Doc. E9–23447 Filed 9–28–09; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Land Exchanges

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension with no revision of a currently approved information collection, OMB 0596–0105, Land Exchanges.

DATES: Comments must be received in writing on or before November 30, 2009 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Jeffrey Vail, Assistant Director, Lands, Mail Stop 1124, Forest Service, USDA, P.O. Box 96090, Washington, DC 20090–6090.

Comments also may be submitted via facsimile to (202) 205–1604 or by e-mail to: *landexchange@fs.fed.us.*

The public may inspect comments received at Office of the Assistant Director—Lands Staff, Yates Building, 201 14th Street, SW., Washington, DC during normal business hours. Visitors are encouraged to call ahead to 202–205–1248 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Jeffrey Vail, Assistant Director, Lands Staff, 202–205–2818 or Kim Berns, Land

Adjustment Program Manager, at 202–205–1248. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Land Exchanges.

OMB Number: 0596–0105.

Expiration Date of Approval: Three years from date of OMB approval.

Type of Request: Extension with no revision of a currently approved information collection.

Abstract: Land exchanges are discretionary, voluntary real estate transactions between the Secretary of Agriculture (acting by and through the Forest Service) and a non-Federal exchange party (or parties). Land exchanges can be initiated by a non-Federal party (or parties), an agent of a landowner, a broker, a third party, or a non-Federal public agency.

Each land exchange requires preparation of an Agreement to Initiate, as required by Title 36 Code of Federal Regulations (CFR), part 254, subpart C, clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including name and address when provided, will become a matter of public record. Comments will be summarized and included in the request section 254.4—Agreement to Initiate an Exchange. This document specifies the preliminary and non-binding intentions of the non-Federal land exchange party and the Forest Service in pursuing a land exchange. The Agreement to Initiate can contain such information as the description of properties being considered in the land exchange, an implementation schedule of action items, identification of the party responsible for each action item, as well as target dates for completion of each action item.

As the exchange proposal develops, the Forest Service and the non-Federal land exchange party may enter into binding Exchange Agreement, pursuant to Title 36 CFR part 254, subpart A, section 254.14—Exchange Agreement. The Exchange Agreement documents the conditions that must be met to complete the exchange. The Exchange Agreement can contain information such as identification of parties, description of lands and interests to be exchanged, identification of all reserved and outstanding interest, and all other terms and conditions necessary to complete the exchange.

The Forest Service collects the information from the non-Federal party (or parties) necessary to complete the Agreement to Initiate and the Exchange Agreement. The information is collected by Forest Service personnel from parties involved in the exchange via telephone or in person. Data from this information collection is unique to each land exchange and is not available from other sources. No standardized forms are associated with this information collection.

Estimate of Annual Burden:

Agreement to Initiate: 1.

Exchange agreement: 1.

Type of Respondents: Non-Federal party (or parties) that can include landowners, agents of landowners, brokers, a third party or a non-Federal public agency.

Estimated Annual Number of Respondents: 60.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 60.

Comment Is Invited

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

September 22, 2009.

Gloria Manning,

Associate Deputy Chief, National Forest Systems.

[FR Doc. E9–23385 Filed 9–28–09; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Lake Tahoe Basin Federal Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Lake Tahoe Basin Federal Advisory Committee will hold a meeting on October 14, 2009 at the US Forest Service Office, 35 College Drive, South Lake Tahoe, CA 96150. This Committee, established by the Secretary of Agriculture on December 15, 1998 (64 FR 2876), is chartered to provide advice to the Secretary on implementing the terms of the Federal Interagency Partnership on the Lake Tahoe Region and other matters raised by the Secretary.

DATES: The meeting will be held October 14, 2009, beginning at 1 p.m. and ending at 4 p.m.

ADDRESSES: The meeting will be held at the U.S. Forest Service Office, 35 College Drive, South Lake Tahoe, CA 96150.

FOR FURTHER INFORMATION OR TO REQUEST AN ACCOMMODATION (ONE WEEK PRIOR TO MEETING DATE) CONTACT: Arla Hams, Lake Tahoe Basin Management Unit, Forest Service, 35 College Drive, South Lake Tahoe, CA 96150, (530) 543–2773.

SUPPLEMENTARY INFORMATION: Items to be covered on the agenda: (1) Aquatic Invasive Species funding; (2) Southern Nevada Public Land Management Act (SNPLMA) Round 11 process update, (3) Environmental Improvement Program update, (4) Tahoe Regional Planning Agency Regional Plan update, and (5) public comment. All Lake Tahoe Basin Federal Advisory Committee meetings are open to the public. Interested citizens are encouraged to attend at the above address. Issues may be brought to the attention of the Committee during the open public comment period at the meeting or by filing written statements with the secretary for the Committee before or after the meeting.

Please refer any written comments to the Lake Tahoe Basin Management Unit at the contact address stated above.

Dated: September 23, 2009.

Terri Marceron,

Forest Supervisor.

[FR Doc. E9–23419 Filed 9–28–09; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

The Secretary of Agriculture's Determination of the Primary Purpose of the State of Florida's Agricultural Best Management Practices Program

AGENCY: Natural Resources Conservation Service, United States Department of Agriculture.

ACTION: Notice of Determination.

SUMMARY: The Natural Resources Conservation Service (NRCS) is providing public notice that the Secretary of Agriculture has determined that cost-share payments made under the State of Florida's Agricultural Best Management Practices Program are primarily for the purpose of conserving soil and water resources or protecting and restoring the environment. NRCS was assigned technical and administrative responsibility for reviewing the State of Florida's Agricultural Best Management Practices Program and making appropriate recommendations for the Secretary's determination of primary purpose. The Secretary made the determination for certain specific programs that are part of the State of Florida's Agricultural Best Management Practices Program (71 FR 76965).

This supplants the earlier determination and covers all cost-share components of the State of Florida's Agricultural Best Management Practices Program. This determination is in accordance with Section 126 of the Internal Revenue Code of 1954, as amended (26 U.S.C. 126), and permits recipients of cost-share payments to exclude such payments from gross income to the extent allowed by the Internal Revenue Service.

FOR FURTHER INFORMATION CONTACT: Charles H. Bronson, Commissioner of Agriculture, Florida Department of Agriculture and Consumer Services, The Capitol, Tallahassee, Florida 32399; or Gregory K. Johnson, Director, Financial Assistance Programs Division, Department of Agriculture, Natural Resources Conservation Service, 1400 Independence Avenue, SW., Room 5241 South Building, Washington, DC 20250.

SUPPLEMENTARY INFORMATION: Under Section 126(a)(10) of the Internal Revenue Code, gross income does not include the ''excludable portion'' of payments received under any program of a State under which payments are made to individuals primarily for the purpose of protecting or restoring the environment. In general, a cost-share payment for selected conservation practices is exempt from Federal taxation if it meets the following three tests: (1) It was for a capital expense, (2) it does not substantially increase the operator's annual income from the property for which it is made, and (3) the Secretary of Agriculture certified that the payment was made primarily for conserving soil and water resources, protecting or restoring the environment, improving forests, or providing habitat for wildlife.

The Secretary of Agriculture evaluates a conservation program on the basis of criteria set forth in 7 CFR part 14, and makes a ''primary purpose'' determination for the payments made under the program. The objective of the determinations made under part 14 is to provide maximum conservation, environmental, forestry improvement, and wildlife benefits to the general public from the operation of applicable programs. Final determinations are made on the basis of program, category of practices, or individual practices. Following a primary purpose determination by the Secretary of Agriculture, the Secretary of the Treasury determines if the payments made under the conservation program substantially increases the annual income derived from the property benefited by the payments.

Determination

As provided for by Section 126 of the Internal Revenue Code, the Secretary examined the authorizing legislation, regulations, and operating procedures regarding State of Florida's Agricultural Best Management Practices Program. In accordance with the criteria set out in 7 CFR part 14, the Secretary has determined the primary purpose of cost-share payments made under the State of Florida's Agricultural Best Management Practices Program is conserving soil and water resources, or protecting and restoring the environment.

The State of Florida uses the Agricultural Best Management Practices Program to provide overall water resources benefits and to protect the environment. The Florida Department of Agriculture and Consumer Services provides cost-share reimbursement for select Best Management Practices that have potential water conservation, sediment control, and water quality benefits. The objectives of the program are met through cost-shared construction of specific engineered structures, land treatment, management practices, and acquisition of specific equipment to meet environmental needs on private farmland.

A ''Record of Decision'' for the State of Florida's Agricultural Best Management Practices Program has been prepared and is available upon request from Gregory K. Johnson, Director, Financial Assistance Programs Division, Department of Agriculture, Natural Resources Conservation Service, 1400 Independence Avenue, SW., Room 5241 South Building, Washington, DC 20250.

Signed this 23rd day of September 2009, in Washington, DC.

Dave White,

Chief, Natural Resources Conservation Service.

[FR Doc. E9–23448 Filed 9–28–09; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF COMMERCE

Membership of the Departmental Performance Review Board

AGENCY: Department of Commerce.

ACTION: Notice of membership on the Departmental Performance Review Board.

SUMMARY: In accordance with 5 U.S.C., 4314(c)(4), Department of Commerce (DOC) announces the appointment of persons to serve as members of the Departmental Performance Review Board (DPRB). The DPRB provides an objective peer review of the initial performance ratings, performance-based pay adjustments and bonus recommendations, higher-level review requests and other performance-related actions submitted by appointing authorities for Senior Executive Service (SES) members whom they directly supervise, and makes recommendations based upon its review. The term of the new members of the DPRB will expire December 31, 2011.

DATES: *Effective Date:* The effective date of service of appointees to the Departmental Performance Review Board is based upon publication of this notice.

FOR FURTHER INFORMATION CONTACT: Denise A. Yaag, Director, Office of Executive Resources, Office of Human Resources Management, Office of the Director, 14th and Constitution Avenue, NW., Washington, DC 20230, (202) 482–3600.

SUPPLEMENTARY INFORMATION: The names and position titles of the members of the DPRB are set forth below by organization: Department of Commerce, Departmental Performance Review Board Membership, 2009–2011.

Office of the Secretary

Tene A. Dolphin, Director, Executive Secretariat.

Office of General Counsel

Michael A. Levitt, Assistant General Counsel for Legislation and Regulation.

Barbara S. Fredericks, Assistant General Counsel for Administration.

Chief Financial Officer and Assistant Secretary for Administration

William J. Fleming, Deputy Director for Human Resources Management.

Office of the Chief Information Officer

Earl B. Neal, Director of Information Technology, Security, Infrastructure and Technology.

Bureau of Industry and Security

Gay G. Shrum, Director of Administration.

Bureau of the Census

C. Harvey Monk, Associate Director for Economic Programs.

Economics and Statistics Administration

James K. White, Associate Under Secretary for Management.

Economics and Development Administration

Sandra Walters, Chief Financial Officer and Director of Administration.

International Trade Administration

Michelle O'Neill, Deputy Under Secretary for International Trade.

Stephen P. Jacobs, Deputy Assistant Secretary for Market Access and Compliance.

Minority Business Development Agency

Edith J. McCloud, Associate Director for Management.

National Oceanic and Atmospheric Administration

Robert J. Byrd, Chief Financial Officer/Chief Administrative Officer, NWS.

Joseph F. Klimavicz, Chief Information Officer and Director of High Performance Computing and Communications.

Maureen Wylie, Chief Financial Officer, NOAA.

Kathleen A. Kelly, Director, Office of Satellite Operations, NESDIS.

National Technical Information Service

Ellen Herbst, Director, National Technical Information Service.

National Telecommunications and Information Administration

Daniel C. Hurley, Director, Communications and Information Infrastructure Assurance Program.

National Institute of Standards and Technology

Richard F. Kayser, Jr., Special Assistant for Environment, Safety and Health.

Dated: September 16, 2009.

Denise A. Yang,

Director, Office of Executive Resources.

[FR Doc. E9–23345 Filed 9–28–09; 8:45 am]

BILLING CODE 3510–BS–M

DEPARTMENT OF COMMERCE

Membership of the Office of the Secretary Performance Review Board

AGENCY: Department of Commerce.

ACTION: Notice of Membership on the Office of the Secretary Performance Review Board.

SUMMARY: In accordance with 5 U.S.C., 4314(c)(4), Department of Commerce (DOC) announces the appointment of persons to serve as members of the Office of the Secretary (OS) Performance Review Board (PRB). The OS PRB is responsible for reviewing performance ratings, pay adjustments and bonuses of Senior Executive Service (SES) members. The term of the new members of the OS PRB will expire December 31, 2011.

DATES: *Effective Date:* The effective date of service of appointees to the Office of the Secretary Performance Review Board is upon publication of this notice.

FOR FURTHER INFORMATION CONTACT: Denise A. Yaag, Director, Office of Executive Resources, Office of Human Resources Management, Office of the Director, 14th and Constitution Avenue, NW., Washington, DC 20230, (202) 482–3600.

SUPPLEMENTARY INFORMATION: The names, position titles, and type of appointment of the members of the OS/PRB are set forth below by organization: Department of Commerce, Office of the Secretary, 2009–2011, Performance Review Board Membership.

Office of the Secretary

Tene A. Dolphin, Director, Executive Secretariat.

Earl B. Neal, Director, Office of Information Technology, Security, Infrastructure, and Technology.

Office of Assistant Secretary for Administration

Suzan J. Aramaki, Director, Office of Civil Rights.

Alfred J. Broadbent, Director, Office of Security.

National Institute of Standards and Technology

W. Todd Grams, Chief Financial Officer for NIST.

National Oceanic and Atmospheric Administration

Louisa Koch, Director, Office of Education.

Office of the General Counsel

Michael A. Levitt, Assistant General Counsel for Legislation and Regulation.

Barbara S. Fredericks, Assistant General Counsel for Administration (Alternate).

Dated: September 16, 2009.

Denise A. Yaag,

Director, Office of Executive Resources.

[FR Doc. E9–23344 Filed 9–28–09; 8:45 am]

BILLING CODE 3510–BS–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR88

Endangered Species; File No. 14655

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Jane Provancha, NASA, Ecological Program, Kennedy Space Center, FL, 32899, has applied in due form for a permit to take green (*Chelonia mydas*), loggerhead (*Caretta caretta*), and Kemp's ridley (*Lepidochelys kempii*) sea turtles for purposes of scientific research.

DATES: Written, telefaxed, or e-mail comments must be received on or before October 29, 2009.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the Features box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov*, and then selecting File No. 14655 from the list of available applications. These documents are also available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)713–0376; and

Southeast Region, NMFS, 263 13th Avenue, South, St. Petersburg, FL 33701; phone (727)824–5312; fax (727)824–5309.

Written comments or requests for a public hearing on this application should be mailed to the Chief, Permits, Conservation and Education Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

Comments may also be submitted by facsimile at (301)713–0376, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period.

Comments may also be submitted by e-mail. The mailbox address for providing e-mail comments is *NMFS.Pr1Comments@noaa.gov*. Include in the subject line of the e-mail comment the following document identifier: File No. 14655.

FOR FURTHER INFORMATION CONTACT: Kate Swails or Patrick Opay, (301)713–2289.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq*.) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant proposes to continue to monitor the abundance and distribution of sea turtles in the waters of Mosquito Lagoon in Volusia and Brevard Counties, Florida. Up to 40 green, 40 loggerhead, and 1 Kemp's ridley sea turtles would be captured, flipper and PIT tagged, blood sampled and/or tissue biopsied, lavaged, and released annually. Up to 12 green and 10 loggerhead turtles may be tracked using a sonic transmitter. The permit is requested for five years.

Dated: September 24, 2009.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E9–23471 Filed 9–28–09; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE28

Incidental Takes of Marine Mammals During Specified Activities; St. George Reef Light Station Restoration and Maintenance at Northwest Seal Rock, Del Norte County, California

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; proposed incidental take authorization; request for comments.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) regulations, NMFS has received an application from the St. George Reef Lighthouse Preservation Society (SGRLPS), for an Incidental Harassment Authorization (IHA) to take small numbers of marine mammals, by incidental harassment, incidental to conducting aircraft operations and restoration and maintenance work on the St. George Reef Light Station on Northwest Seal Rock (NWSR) in the northeast Pacific Ocean. Pursuant to the Marine Mammal Protection Act, as amended, NMFS requests comments on its proposal to authorize SGRLPS to incidentally take, by Level B harassment only, small numbers of marine mammals, incidental to conducting aircraft operations, and lighthouse renovation and light maintenance activities for one year. Since the proposed activities would occur in the vicinity of pinniped haul out sites, marine mammals could be disturbed as a result of helicopter landing/takeoff and human presence; therefore, SGRLPS has requested an IHA.

DATES: Comments and information must be received no later than October 29, 2009.

ADDRESSES: Comments on the application should be addressed to P. Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225. The mailbox address for providing email comments is *PR1.0648–XE28@noaa.gov*. Comments sent via e-mail, including all attachments, must not exceed a 10–megabyte file size.

All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

A copy of the application containing a list of the references used in this document may be obtained by writing to the address specified above, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications*.

Documents cited in this notice may be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Jeannine Cody, NMFS, Office of Protected Resources, NMFS, (301) 713–2289 or Monica DeAngelis, NMFS Southwest Regional Office, (562) 980–3232.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5)(D) of the MMPA (16 U.S.C. 1371 (a)(5)(D)) directs the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional, taking of marine mammals, for periods of not more than one year, by United States citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental taking of small numbers of marine mammals shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses. The authorization must set forth the permissible methods of taking, other means of effecting the least practicable adverse impact on the species or stock and its habitat and monitoring and reporting of such takings. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of

marine mammals by harassment. Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as:

any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [''Level A harassment'']; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [''Level B harassment''].

Section 101(a)(5)(D) of the MMPA establishes a 45–day time limit for NMFS' review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Not later than 45 days after the close of the public comment period, if the Secretary makes the findings set forth in Section 101(a)(5)(D)(i) of the MMPA, the Secretary shall issue the authorization with appropriate conditions to meet the requirements of clause 101(a)(5)(D)(ii) of the MMPA.

Summary of Request

On October 13, 2006, NMFS received an application from SGRLPS for the incidental taking by Level B harassment only, of small numbers of four species of marine mammals incidental to aircraft operations and restoration and maintenance activities on the St. George Reef Light Station (Station). Since the proposed activities would occur in the vicinity of a pinniped haul out site, marine mammals could be disturbed as a result of helicopter landings/takeoffs and human presence, therefore, SGRLPS has requested an IHA.

The United States Coast Guard (USCG) decommissioned the Station in 1975. In 1996, the United States Government Services Administration, and the government of Del Norte County transferred the management and upkeep of the Station to SGRLPS which aims to restore and restore and preserve the Station which is listed in the National Park Service's National Register of Historic Places (Reference Number 93001373).

In 2002, the SGRLPS applied for a Private Aid to Navigation (PATON) permit from the USCG to install a new solar- and wind-powered optic light system for the Station. A PATON is a buoy, light or day beacon owned and maintained by any individual or organization other than the USCG. The USGS issued the PATON permit to SGRLPS with the condition that, should repairs be necessary, they must be completed within a stipulated time period. However, the USCG revoked the PATON permit in 2003, when the optic light system experienced a failure and the SGRLPS was not able to repair it within the stipulated time period.

In order to renew the PATON permit to conduct annual maintenance of the Station's optical light system, as well as to conduct emergency maintenance in the event of equipment failure, the USCG recommended that the SGRLPS obtain an Endangered Species Act (ESA; 16 U.S.C. 1531 et. seq.) permit from the U.S. Fish and Wildlife Service (USFWS) for migratory birds and a MMPA incidental take authorization and ESA permit for marine mammals from NMFS.

Description of the Specified Geographic Region

The Station is located on a small, rocky islet known as Northwest Seal Rock (NWSR) (41° 50'24'' N, 124° 22'06'' W) approximately nine kilometers (km) (6.0 miles (mi)) offshore of Crescent City, California in the northeast Pacific Ocean. NWSR is a rocky formation approximately 91.4 meters (m) (300 feet (ft) in diameter that peaks at 5.18 meters (m) (17 feet (ft)) above mean sea level. The Station, built in 1892, rises 45.7 m (150 ft) above the sea, consists of hundreds of granite blocks, is topped with a cast iron lantern room, and covers much of the surface of the islet.

Description of the Specified Activity

SGRLPS proposes to conduct the proposed activities (aircraft operations, lighthouse restoration, and light maintenance activities) between November 1, 2009, and April 30, 2010, at a maximum frequency of one session per month. The proposed duration for each session would last no more than three days (e.g., Friday, Saturday, and Sunday).

Aircraft Operations

Because NWSR has no safe landing area for boats, the proposed restoration activities would require SGRLPS to transport personnel and equipment from the California mainland to NWSR by a small helicopter. SGRLPS plans to charter a Raven R44 helicopter, owned and operated by Air Shasta Rotor and Wing, LLC. The Raven R44, which seats three passengers and one pilot, is a compact-sized (1134 kilograms (kg), 2500 pounds (lbs)) helicopter with two-bladed main and tail rotors. Both sets of rotors are fitted with noise-attenuating blade tip caps that would decrease flyover noise. Helicopter landings take place on top of the engine room (caisson) which is approximately 15 m (48 ft) above the surface of the rocks on NWSR.

SGRLPS proposes to transport no more than 15 work crew members and equipment to NWSR for each session and estimates that each session would require no more than 30 helicopter landings/takeoffs per month. During landing, the helicopter would land on the caisson to allow the work crew members to disembark and retrieve their equipment located in a basket attached to the underside of the helicopter. The helicopter would then return to the mainland to pick up additional personnel and equipment. Even though SGRLPS would use the helicopter to transport work crew members and materials on the first and last days of the three-day activity, the helicopter would likely fly to and from the Station on all three days of the restoration and maintenance activities.

Proposed schedule: SGRLPS proposes a maximum of 12 flights (six arrivals and six departures) for the first day. The first flight would depart from Crescent City Airport (Latitude: 41°46′48″ N; Longitude: 124°14′11″ W) at 9 a.m. for a six-minute flight to NWSR. The helicopter would land and takeoff immediately after offloading personnel and equipment every 20 minutes (min). The total duration of the first day's aerial operations would last for approximately three hours (hrs) and 26 min and would end at approximately 12:30 p.m. Crew members would remain overnight at the Station and would not return to the mainland on the first day.

For the second day, the SGRLPS proposes a maximum of 2 flights (one arrival and one departure) to transport no more than three crew members off of NWSR. The first flight would depart from Crescent City Airport at 9 a.m. for a six-minute flight to NWSR. The total duration of the second day's aerial operations would last for approximately 26 min.

For the final day of operations, SGRLPS proposes to conduct a maximum of eight helicopter flights (four arrivals and four departures) to transport the remaining crew members and equipment/material back to the Crescent City Airport.

As a mean of funding support for the restoration activities, the SGRLPS will conduct public tours of the Station during the last day of the proposed restoration and maintenance activities. SGRLPS proposes to transport visitors to the Station during the Sunday work window period. Although some of these flights would be conducted solely for the transportation of tourists, those flights would be conducted at a later stage when no pinnipeds are expected

to be at the Station. No additional allowance is included for animals that might be affected by additional flights for the transportation of tourists. The total duration of the last day's aerial operations would last for approximately four hrs.

Lighthouse Restoration Activities

Restoration activities would include the removal of peeling paint and plaster, restoration of interior plaster and paint, refurbishing structural and decorative metal, reworking original metal support beams throughout the lantern room and elsewhere, replacing glass as necessary, and upgrading the present electrical system. SGRLPS expects to complete most of the major restoration work within two to three years.

Light Maintenance Activities

As required by the USCG, in order to maintain the beacon light as a PATON, the SGRLPS will need to conduct maintenance at least once or up to two times per year within the proposed work window. Scheduled light maintenance activities would coincide with lighthouse restoration activities conducted monthly during the period of November 1, 2009, through April 30, 2010. The SGRLPS expects that maintenance activities would not exceed three hrs per monthly session.

Emergency Light Maintenance

If the beacon light fails during the period November 1, 2009, through April 30, 2010, the SGRLPS proposes to send a crew of two to three people to the Station by helicopter to repair the beacon light. For each emergency repair event, the SGRLPS proposes to conduct a maximum of four flights (two arrivals and two departures) to transport equipment and supplies. The helicopter may remain on site or transit back to shore and make a second landing to pick up the repair personnel.

In the case of an emergency repair between November 1, 2009, and April 30, 2010, the SGRLPS would consult with the NMFS Southwest Regional Office (SWRO) to best determine the timing of the trips to the lighthouse, on a case-by-case basis, based upon the existing environmental conditions and the abundance and distribution of any marine mammals present on NWSR. The SWRO biologists would have the ultimate knowledge regarding the animal use and abundance of the NWSR at the time of the repair request and make a decision regarding when the trips to the lighthouse can be made during the emergency repair time window that would have the least practicable adverse impact to marine mammals. The SWRO would also ensure that the SGRLPS' request for incidental take during emergency repairs would not exceed the number of incidental take authorized in the IHA.

Complete automation of the light generating system and automatic backup system will minimize maintenance and emergency repair visits to the island. The light is solar powered using one solar panel; an installed second panel serves as a backup which is automatically activated if needed. A second smaller bulb in the lantern is activated if the primary bulb fails. Use of high quality, durable materials and thorough weatherproofing is planned to minimize trips for maintenance and repair in the future. All tools and supplies are stored on the island so that a minimal number of transport trips for emergency maintenance will be necessary.

Description of Marine Mammals in the Activity Area

The marine mammal species likely to be harassed incidental to helicopter operations, lighthouse restoration, and lighthouse maintenance on NWSR are the California sea lion (*Zalophus californianus*), the Pacific Harbor seal (*Phoca vitulina*), the eastern (Distinct Population Segment) U.S. stock of Steller sea lion (Eumetopias jubatus), and the and the eastern Pacific stock of northern fur seal (*Callorhinus ursinus*). General information of these species can be found in Caretta *et al.*, (2008) and Angliss and Allen (2009) and is available at the following URLs: *http://www.nmfs.noaa.gov/pr/pdfs/sars/po2008.pdf* and *http://www.nmfs.noaa.gov/pr/pdfs/sars/ak2008.pdf* respectively. Refer to these documents for information on these species. Additional information on these species is presented below this section.

California sea lion

California sea lions are not listed as threatened or endangered under the ESA, nor are they categorized as depleted under the MMPA. The California sea lion includes three subspecies: *Z. c. wollebaeki* (on the Galapagos Islands), *Z. c. japonicus* (in Japan, but now thought to be extinct), and *Z. c. californianus* (found from southern Mexico to southwestern Canada; herein referred to as the California sea lion). The subspecies is comprised of three stocks: (1) the U.S. stock, beginning at the U.S./Mexico border extending northward into Canada; (2) the western Baja California stock, extending from the U.S./Mexico border to the southern tip of the Baja California peninsula; and (3) the Gulf of California stock, which includes the Gulf of California from the southern tip of the Baja California peninsula and across to the mainland and extends to southern Mexico (Lowry *et al.*, 1992).

In 2008, the estimated population of the U.S. stock of California sea lion ranges from 141,842 to 238,000 animals and the maximum population growth rate was 6.52 percent when pup counts from El Nino years (1983, 1984, 1992, 1993, 1998, and 2003) were removed (Carretta *et al.*, 2008).

Major rookeries for the California sea lion exist on the Channel Islands off southern California and on the islands situated along the east and west coasts of Baja California. Males are polygamous, establishing breeding territories that may include up to fourteen females. They defend their territories with aggressive physical displays and vocalization. Sea lions reach sexual maturity at four to five years old and the breeding season lasts from May to August. Most pups are born from May through July and weaned at 10 months old.

Crescent Coastal Research (CCR) conducted a three-year (1998–2000) survey of the wildlife species on NWSR for the SGRLPS. They reported that counts of California sea lions on NWSR varied greatly (from six to 541) during the observation period from April 1997 through July 2000. CCR reported that counts for California sea lions during the spring (April - May), summer (June - August), and fall (September - October), averaged 25, 154, and 235, respectively (CCR, 2001).

Pacific harbor seal

Pacific harbor seals are not listed as threatened or endangered under the ESA, nor are they categorized as depleted under the MMPA. The animals inhabit near-shore coastal and estuarine areas from Baja California, Mexico, to the Pribilof Islands in Alaska. Pacific harbor seals are divided into two subspecies: *P. v. stejnegeri* in the western North Pacific, near Japan, and *P. v. richardsi* in the northeast Pacific Ocean. The latter subspecies, recognized as three separate stocks, inhabits the west coast of the continental United States, including: the outer coastal waters of Oregon and Washington states; Washington state inland waters; and Alaska coastal and inland waters. Two of these stocks, the California stock and Oregon/Washington coast stock, of Pacific harbor seals are identified off the coast of Oregon and California for management purposes under the MMPA. However, the stock boundary is difficult to distinguish because of the continuous distribution of harbor seals

along the west coast and any rigid boundary line is (to a greater or lesser extent) arbitrary, from a biological perspective (Carretta *et al.*, 2008). Due to the location of the proposed project which is situated near the border of Oregon and California, both stocks could be present within the proposed project area.

In 2008, the estimated population of the California of Pacific harbor seals ranged from 31,600 to 34,233 animals and the maximum population growth rate was 3.5 percent. The estimated population of the Oregon/Washington coast stocks was 22,380 animals and the maximum population growth rate was 4.0 percent. (Carretta *et al.*, 2008)

In California, over 500 harbor seal haulout sites are widely distributed along the mainland and offshore islands, and include rocky shores, beaches and intertidal sandbars (Lowry *et al.*, 2005). Harbor seals mate at sea and females give birth during the spring and summer, although, the pupping season varies with latitude. Pups are nursed for an average of 24 days and are ready to swim minutes after being born. Harbor seal pupping takes place at many locations and rookery size varies from a few pups to many hundreds of pups. The nearest harbor seal rookery relative to the proposed project site is at Castle Rock National Wildlife Refuge, located approximately located 965 m (0.6 mi) south of Point St. George, and 2.4 km (1.5 miles) north of the Crescent City Harbor in Del Norte County, California (USFWS, 2007).

CCR noted that harbor seal use of NWSR was minimal, with only one sighting of a group of six animals, during 20 observation surveys. They hypothesized that harbor seals may avoid the islet because of its distance from shore, relatively steep topography, and full exposure to rough and frequently turbulent sea swells.

Northern fur seal

Northern fur seals are not listed as threatened or endangered under the ESA. However, they are categorized as depleted under the MMPA. Northern fur seals occur from southern California north to the Bering Sea and west to the Sea of Okhotsk and Honshu Island of Japan. Two separate stocks of northern fur seals are recognized within U.S. waters: an Eastern Pacific stock distributed among sites in Alaska, British Columbia; and a San Miguel Island stock distributed along the west coast of the continental U.S.

Northern fur seals may temporarily haul out on land at other sites in Alaska, British Columbia, and on islets along the west coast of the continental United States, but generally this occurs outside of the breeding season (Fiscus, 1983).

In 2008, the estimated population of the San Miguel Island stock ranged from 5,096 to 9,424 animals and the maximum population growth rate was 8.6 percent (Carretta *et al.*, 2008).

Northern fur seals breed in Alaska and migrate along the west coast during fall and winter. Due to their pelagic habitat, they are rarely seen from shore in the continental U.S., but individuals occasionally come ashore on islands well offshore (i.e., Farallon Islands and Channel Islands in California). During the breeding season, approximately 74 percent of the worldwide population is found on the Pribilof Islands in Alaska, with the remaining animals spread throughout the North Pacific Ocean (Lander and Kajimura, 1982).

CCR observed one male northern fur seal on NWSR in October, 1998 (CCR, 2001). It is possible that a few animals may use the island more often that indicated by the CCR surveys, if they were mistaken for other otariid species (M. DeAngelis, NMFS, pers. comm.).

Steller sea lion

The Steller sea lion eastern stock is listed as threatened under the ESA and is categorized as depleted under the MMPA. Steller sea lions range along the North Pacific Rim from northern Japan to California (Loughlin *et al.*, 1984), with centers of abundance and distribution in the Gulf of Alaska and Aleutian Islands, respectively. Two separate stocks of Steller sea lions were recognized within U.S. waters: an eastern U.S. stock, which includes animals east of Cape Suckling, Alaska (144E W), and a western U.S. stock, which includes animals at and west of Cape Suckling (Loughlin, 1997). The species is not known to migrate, but individuals disperse widely outside of the breeding season (late May through early July), thus potentially intermixing with animals from other areas.

In 2008, the estimated population of the eastern U.S. stock ranged from 44,404 to 55,832 animals and the maximum population growth rate was 3.1 percent (Angliss and Allen, 2009).

The eastern U.S. stock of Steller sea lions breeds on rookeries located in southeast Alaska, British Columbia, Oregon, and California; there are no rookeries located in Washington state. Counts of pups on rookeries conducted near the end of the birthing season are nearly complete counts of pup production.

Despite the wide-ranging movements of juveniles and adult males in particular, exchange between rookeries by breeding adult females and males (other than between adjoining rookeries) appears low, although males have a higher tendency to disperse than females (NMFS 1995, Trujillo *et al.*, 2004, Hoffman et al., 2006). A northward shift in the overall breeding distribution has occurred, with a contraction of the range in southern California and new rookeries established in southeastern Alaska (Pitcher *et al.*, 2007).

CCR reported that Steller sea lion numbers at NWSR ranged from 20 to 355 animals. Counts of Steller sea lions during the spring (April - May), summer (June - August), and fall (September - October), averaged 53, 110, and 56, respectively (CCR, 2001). A more recent survey at NWSR between 2000 and 2004 showed Steller sea lion numbers ranged from 175 to 354 in July (M. Lowry, NMFS/SWFSC, unpubl. data). Winter use of NWSR by Steller sea lion is presumed to be minimal, due to inundation of the natural portion of the island by large swells.

Cetaceans

There are several endangered cetaceans that may be transiting near the project area: the blue (*Balaenoptera musculus*), fin (*Balaenoptera physalus*), humpback (*Megaptera novaeanliae*), sei (*Balaenoptera borealis*), north Pacific right (*Eubalena japonica*), sperm (*Physeter macrocephalus*), and southern resident killer (*Orcinus orca*) whales. Therefore, these species are typically found farther offshore than the proposed action area. However, this proposed IHA will only address requested take authorizations for pinnipeds.

Potential Effects of the Proposed Activity on Marine Mammals

Possible Effects of Aircraft Operations

The proposed helicopter operations have the potential to adversely impact Steller sea lions, California sea lions, Pacific harbor seals, and northern fur seals, hauled out on the rocky islet. Noise generated from helicopter activities may cause harassment of pinnipeds, both hauled out and in the water, at or directly below the surface.

The physical presence of aircraft could also lead to non-acoustic effects on marine mammals involving visual or other cues. Airborne sound from a low flying helicopter or airplane may be heard by marine mammals while at the surface or underwater. In general, helicopters tend to be noisier than fixed wing aircraft of similar size, and larger aircraft tend to be louder than those that are smaller. Underwater sounds from aircraft are strongest just below the surface and directly under the aircraft.

Noise from aircraft would not be expected to cause direct physical effects but have the potential to affect behavior. The primary factor that may influence abrupt movements of animals is engine noise, specifically changes in engine noise. Responses by mammals could include hasty dives or turns, change in course, or flushing and stampeding from a haul out site. There are few well documented studies of the impacts of aircraft overflight over pinniped haul out sites or rookeries, and many of those that exist, are specific to military activities (Efroymson *et al.*, 2001).

Several factors complicate the analysis of long- and short-term effects for aircraft overflights. Information on behavioral effects of overflights by military aircraft (or component stressors) on most wildlife species is sparse. Moreover, models that relate behavioral changes to abundance or reproduction, and those that relate behavioral or hearing effects thresholds from one population to another are generally not available. In addition, the aggregation of sound frequencies, durations, and the view of the aircraft into a single exposure metric is not always the best predictor of effects and it may also be difficult to calculate. Overall, there has been no indication that single or occasional aircraft flying above pinnipeds in water cause long term displacement of these animals (Richardson *et al.*, 1995). The Lowest Observed Adverse Effects Levels (LOAELs) are rather variable for pinnipeds on land, ranging from just over 150 m (492 ft) to about 2,000 m (6,562 ft) (Efroymson *et al.*, 2001). A conservative (90th percentile) distance effects level is 1,150 m (3,773 ft). Most thresholds represent movement away from the overflight. Bowles and Stewart (1980) estimated an LOAEL of 305 m (1,000 ft) for helicopters (low and landing) in California sea lions and harbor seals observed on San Miguel Island, CA; animals responded to some degree by moving within the haul out and entering into the water, stampeding into the water, or clearing the haul out completely. Both species always responded with the raising of their heads. California sea lions appeared to react more to the visual cue of the helicopter than the noise.

It is likely that a helicopter landing at the Station would cause 100 percent of the pinnipeds on NWSR to flush, however, they appear to show rapid habituation to helicopter landing and departure (Crescent Coastal Research, 2001; Guy Towers, SGRLPS, pers. com.). According to the CCR Report (2001), while up to 40 percent of the California and Steller sea lions present on the rock have been observed to enter the water on the first of a series of helicopter landings, as few as 0 percent have flushed on subsequent landings on the same date.

Noise testing performed on the R44 Raven Helicopter, as required for Federal Aviation Administration approval, required an overflight at 150 m (492 ft) above ground level, 109 knots and a maximum gross weight of 1,134 kg (2,500 lbs). The noise levels measured on the ground at this distance and speed were 81.9 decibels (dB) (A-weighted) for the model R44 Raven I, or 81.0 dB (A-weighted) for the model R44 Raven II (NMFS, 2007).

Level B behavioral harassment of pinnipeds may occur during helicopter landing and takeoff from NWSR due to the pinnipeds temporarily moving from the rocks and lower structure of the Station into the sea due to the noise and appearance of helicopter during approaches and departures. It is expected that all or a portion of the marine mammals hauled out on the island will depart the rock and move into the water upon initial helicopter approaches. The movement to the water is expected to be gradual due to the required controlled helicopter approaches (see Mitigation and Monitoring section), the small size of the aircraft, relatively quiet rotors, and behavioral habituation on the part of the animals as helicopter trips continue throughout the day. During the sessions of helicopter activity, some animals may be temporarily displaced from the island and either raft in the water or relocate to other haul-outs.

Sea lions have shown habituation to helicopter flight within a day at the project site and most animals are expected to return soon after helicopter activities cease for that day. By clustering helicopter arrival/departures within a short time period, animals are expected to show less response to subsequent landings. No impact on the population size or breeding stock of Steller sea lions, California sea lions, Pacific harbor seals, or northern fur seals is expected to occur.

Possible Effects of Restoration and Light Maintenance Activities

The proposed restoration activities have the potential to adversely impact Steller sea lions, California sea lions, Pacific harbor seals, and northern fur seals, hauled out on NWSR. Restoration and maintenance activities would involve the removal of peeling paint and plaster, restoration of interior plaster and paint, refurbishing structural and decorative metal, reworking original metal support beams throughout the lantern room and elsewhere, replacing glass as necessary, upgrading the present electrical system; and annual light beacon maintenance.

Any noise associated with these activities is likely to be from light construction (e.g., sanding, hammering, or use of hand drills) and the pinnipeds may be disturbed by human presence. Animals respond to disturbance from humans in the same way as they respond to the risk of predation, by avoiding areas of high risk, either completely or by using them for limited periods (Gill *et al.*, 1996). There is increasing recognition that the effect of human disturbance on wildlife is highly dependent on the nature of the disturbance (Burger *et al.*, 1995; Klein *et al.*, 1995; and Kucey, 2005). Disturbances resulting from human activity and can impact short- and long-term pinniped haul out behavior (Renouf *et al.*, 1981; Schneider and Payne, 1983; Terhune and Almon, 1983; Allen *et al.*, 1984; Stewart, 1984; Suryan and Harvey, 1999; Mortenson *et al.*, 2000; and Kucey and Trites, 2006). The apparent skittishness of both harbor seals and Steller sea lions raises concerns regarding behavioral and physiological impacts to individuals and populations experiencing high levels of human disturbance. It is well known that human activity can flush harbor seals off haul out sites (Allen et al., 1984; Calambokidis *et al.*, 1991; Suryan and Harvey, 1999; Mortenson *et al.*, 2000).

The Hawaiian monk seal (*Monachus schauinslandi*) has been shown to avoid beaches that have been disturbed often by humans (Kenyon, 1972). Stevens and Boness (2003) concluded that after the 1997-98 El Nino, when populations of the South American fur seal, Arctocephalus australis, in Peru declined dramatically, seals abandoned some of their former primary breeding sites, but continued to breed at adjacent beaches that were more rugged (i.e., less likely to be used by humans). Abandoned and unused sites were more likely to have human disturbance than currently used sites. In once case, human disturbance appeared to cause Steller sea lions to desert a breeding area at Northeast Point on St. Paul Island, Alaska (Kenyon, 1962). However, no impact on the population size or breeding stock of Steller sea lions, California sea lions, Pacific harbor seals, or northern fur seals is expected to occur.

The SGRLPS also expects that there will be no long- or short-term physical impacts to pinniped habitat on NWSR. The SGRLPS proposes to confine all restoration activities to the existing

structure which would occur on the upper levels of the Station which are not used by marine mammals. The SGRLPS would remove all waste, discarded materials, and equipment from the island after each visit.

Mortality

Sudden movement of large numbers of animals may cause a stampede. In order to prevent such stampedes from occurring within the sea lion colony, certain mitigation requirements and restrictions, such as controlled helicopter approaches and limited access period during the pupping season, will be imposed should an IHA be issued. As such, and because any pinnipeds nearby likely would avoid the approaching helicopter, the SGRLPS anticipates that there will be no instances of injury or mortality during the proposed project.

Proposed Monitoring

At least once during the period between November 1, 2009, and April 30, 2010, a qualified biologist shall be present during all three workdays at the Station. The biologist hired will be subject to approval of NMFS and this requirement may be modified depending on the results of the first year of monitoring.

The qualified biologist shall document use of the island by the Steller sea lions, frequency, (i.e., dates, time, tidal height, species, numbers present, and any disturbances), and note any responses to potential disturbances. In the event of any observed Steller sea lion injury, mortality, or the presence of newborn pup, the SGRLPS will notify the NMFS SWRO Administrator and the NMFS Director of Office of Protected Resources immediately.

Aerial photographic surveys may provide the most accurate means of documenting species composition, age and sex class of pinnipeds using the project site during human activity periods. Aerial photo coverage of the island shall be completed from the same helicopter used to transport the SGRLPS personnel to the island during restoration trips. Photographs of all marine mammals hauled out on the island shall be taken at an altitude greater than 300 m (984 ft) by a skilled photographer, prior to the first landing on each visit included in the monitoring program. Photographic documentation of marine mammals present at the end of each three-day work session shall also be made for a before and after comparison. These photographs will be forwarded to a biologist capable of discerning marine mammal species. Data shall be provided to NMFS in the form of a report with a data table, any other significant observations related to marine mammals, and a report of restoration activities (see Reporting). The original photographs can be made available to NMFS or other marine mammal experts for inspection and further analysis.

Proposed Mitigation

As a way to reduce potential Level B behavioral harassment to marine mammals that would result from the proposed project, NMFS proposes that the following mitigation measures would be required.

Time and Frequency: Lighthouse restoration activities are to be conducted at maximum once per month between November 1, 2009, and April 30, 2010. Each restoration session will last no more than three days. Maintenance of the light beacon will occur only in conjunction with restoration activities.

Helicopter Approach and Timing Techniques: The SGRLPS shall ensure that helicopter approach patterns to the lighthouse will be such that the timing techniques are least disturbing to marine mammals. Since the most severe impacts (stampede) are precipitated by rapid and direct helicopter approaches, initial approach to the Station must be offshore from the island at a relatively high altitude (e.g., 800 - 1,000 ft, or 244 - 305 m). Before the final approach, the helicopter shall circle lower, and approach from area where the density of pinnipeds is the lowest. If for any safety reasons (e.g., wind condition) such helicopter approach and timing techniques cannot be achieved, the SGRLPS must abort restoration and maintenance mission for that day.

Avoidance of Visual and Acoustic Contact with People on Island: The SGRLPS members and restoration crews shall be instructed to avoid making unnecessary noise and not expose themselves visually to pinnipeds around the base of the lighthouse. Although no impacts from these activities were seen during the CCR study, it is relatively simple to avoid this potential impact. The door to the lower platform (which is used at times by pinnipeds) shall remain closed and barricaded to all tourists and other personnel.

Proposed Reporting

The SGRLPS will submit interim monitoring reports to the NMFS SWRO Administrator and the NMFS Director of Office of Protected Resources no later than 30 days after the conclusion of each monthly session. The interim report will describe the operations that were conducted and sightings of marine mammals near the proposed project. The report will provide full documentation of methods, results, and interpretation pertaining to all monitoring. The interim report will summarize the dates and locations of restoration and maintenance activities, and all marine mammal sightings (dates, times, locations, activities, associated with the project). The interim report will also include estimates of the number and nature of exposures that could result in the takes of marine mammals by incidental harassment as well as a description of the implementation and effectiveness of the monitoring and mitigation measures of the IHA.

The SGRLPS will submit a draft Final Monitoring Report to NMFS no later than 90 days after the project is completed to the Regional Administrator and the Director of Office of Protected Resources at NMFS Headquarters. Within 30 days after receiving comments from NMFS on the draft Final Monitoring Report, the SGRLPS must submit a Final Monitoring Report to the Regional Administrator and the NMFS Director of Office of Protected Resources. If the SGRLPS receives no comments from NMFS on the draft Final Monitoring Report, the draft Final Monitoring Report will be considered to be the Final Monitoring Report.

Estimated Take by Incidental Harassment

It is estimated that approximately 204 California sea lions, 172 Steller sea lions, 36 Pacific harbor seals, and 6 northern fur seals could be potentially affected by Level B behavioral harassment over the course of the proposed IHA. Estimates of the numbers of marine mammals that might be affected are based on consideration of the number of marine mammals that could be disturbed appreciably by approximately 30 hours of aircraft operations during the course of the proposed activity. These estimates are also based on pinniped survey counts conducted by CCR on NWSR in the spring of 1997, 1998, 1999, and 2000 (CCR, 2001), calculated for the population variance or average monthly abundance for the six months of the proposed restoration and maintenance project between November 1, 2009, and April 30, 2010. These incidental harassment take numbers represent 0.14 percent of the U.S. stock of California sea lion, 0.42 percent of the eastern U.S. stock of Steller sea lion, 0.11 percent of the California stock of Pacific harbor seals, and 0.06 percent of the San Miguel Island stock of northern fur seal.

All of the potential takes are expected to be Level B behavioral harassment only. Because of the mitigation measures that will be required and the likelihood that some pinnipeds will avoid the area, no injury or mortality to pinnipeds is expected or requested.

Negligible Impact Determination

NMFS has preliminarily determined, provided that the aforementioned mitigation and monitoring measures are implemented, that the impact of conducting aircraft operations, restoration, and maintenance activities on St. George Reef Light Station on NWSR may result, at worst, in a temporary modification in behavior and/or low-level physiological effects (Level B Harassment) of small numbers of certain species of marine mammals. While behavioral and avoidance reactions may be made by these species in response to the resultant noise from the airguns, these behavioral changes are expected to have a negligible impact on the affected species and stocks of marine mammals. While the number of potential incidental harassment takes will depend on the distribution and abundance of marine mammals on NWSR, the number of potential harassment takings is estimated to be relatively small in light of the population size. In addition, no take by death and/or serious injury is anticipated.

Endangered Species Act (ESA)

Under section 7 of the ESA, the USCG has begun consultation on the proposed restoration, maintenance activities. NMFS will also consult internally on the issuance of an IHA under section 101(a)(5)(D) of the MMPA for this activity. Consultation will be concluded prior to a determination on the issuance of an IHA.

National Environmental Policy Act (NEPA)

NMFS is currently preparing an Environmental Assessment for the proposed activity. Before making a determination on the issuance of an IHA, NMFS will ensure compliance with NEPA and its implementing regulations. The EA will be available on the NMFS website upon completion.

Preliminary Conclusions

Based on the preceding information, and provided that the proposed mitigation and monitoring are incorporated, NMFS has preliminarily concluded that the impact of the proposed helicopter operations, Station restoration and maintenance activities on NWSR in Del Norte County, California would incidentally take, by level B behavioral harassment only, small numbers of Steller sea lions and California sea lions in the vicinity of the proposed activities.

While behavioral modifications, including temporarily vacating the area during the lighthouse restoration and maintenance period, may be made by these species to avoid the resultant helicopter landing/takeoff and visual disturbance from human presence, the availability of alternate areas within these areas and haul-out sites, and the short and sporadic duration of the restoration and maintenance activities, have led NMFS to preliminarily determine that this action will have a negligible impact on Steller sea lions, California sea lions, Pacific harbor seals, and northern fur seals.

There is no subsistence harvest of marine mammals on or near NWSR; therefore, there will be no impact of the activity on the availability of the species or stocks of marine mammals for subsistence uses. No take by Level A harassment (injury) or death is anticipated and harassment takes should be at the lowest level practicable due to incorporation of the mitigation measures proposed in this document.

Proposed Authorization

NMFS proposes to issue an IHA to the SGRLPS to conduct aircraft operations and restoration and maintenance work on the St. George Reef Light Station on Northwest Seal Rock in the northeast Pacific Ocean during November 1, 2009, through April 30, 2010, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: September 23, 2009.

Helen M. Golde,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E9–23489 Filed 9–28–09; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR87

Marine Mammals; File No. 1100–1849

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application for amendment.

SUMMARY: Notice is hereby given that Shane Moore, Moore & Moore Films, Box 2980, 1203 Melody Creek Lane, Jackson, Wyoming 83001, has applied for an amendment to Commercial Photography Permit No. 1100–1849.

DATES: Written, telefaxed, or e-mail comments must be received on or before October 29, 2009.

ADDRESSES: The application and related documents are available upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)713–0376; and

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907)586–7221; fax (907)586–7249.

Written comments or requests for a public hearing on this request should be submitted to the Chief, Permits, Conservation and Education Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular amendment request would be appropriate.

Comments may also be submitted by facsimile at (301)713–0376, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period.

Comments may also be submitted by e-mail. The mailbox address for providing e-mail comments is *NMFS.Pr1Comments@noaa.gov*. Include in the subject line of the e-mail comment the following document identifier: File No. 1100–1849.

FOR FURTHER INFORMATION CONTACT: Carrie Hubard or Amy Hapeman, (301)713–2289.

SUPPLEMENTARY INFORMATION: The subject amendment to Permit No. 1100–1849 is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

Permit No. 1100–1849, issued on March 22, 2007 (72 FR 14525), authorizes the permit holder to take 10 killer whales (*Orcinus orca*) of the Eastern North Pacific Transient stock, 10 gray whales (*Eschrichtius robustus*), and 10 minke whales (*Balaenoptera acutorostrata*) annually by close approach for filming in the Gulf of Alaska and Bering Sea. The purpose of the project is to document the behavior of marine animals in the presence of the carcass of a gray or minke whale that was killed by killer whales. The holder

is authorized to fix a remotely operated video camera in an underwater housing to the sea floor approximately 15 feet from the carcass. The camera is deployed after the killer whales have left the carcass and is controlled from a boat approximately 100 yards away. In addition, if killer whales, gray whales, or minke whales pass near the boat, the holder may submerge a small camera on a pole to take photographs of passing animals. Filming activities may occur between April 1 and August 31 of each year. The permit expires March 31, 2010.

The permit holder is requesting to extend the permit until March 31, 2012. Since the original permit was issued for three years, the proposed amendment would make the permit effective for five years. Funding constraints have prevented the permit holder from using the permit thus far and the extension would allow the project to be completed. No changes to the objectives, species, location, or methodologies would occur. The amended permit would authorize the same level of take for the two additional years as is currently authorized.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: September 23, 2009.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E9–23469 Filed 9–28–09; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Electroshock Weapons Measurement Methods and Issues Public Meeting

AGENCY: National Institute of Standards and Technology (NIST), United States Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: NIST invites manufacturers of electroshock weapons that deploy skin penetrating barbs for operation to attend a public meeting. The purpose of the meeting is for manufacturers to present to NIST nonproprietary information on their methods of measurement and test of the output of these weapons and associated lessons learned.

DATES: The public meeting will be held on Wednesday, October 21, 2009 from 9 a.m. to 12 p.m.

ADDRESSES: The public meeting will be held at NIST, 100 Bureau Drive, Gaithersburg, MD. Information on accommodations, location, and travel can be found at: *http://www.nist.gov/public_affairs/visitor/visitor.htm.* Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Cindy Stanley at 301–975–2756 or by e-mail at *cindy.stanley@nist.gov.*

SUPPLEMENTARY INFORMATION: To support the development of rigorous performance requirements for electroshock weapons, the Office of Law Enforcement Standards (OLES) at NIST, is developing methods to measure the current and high-voltage output of these weapons, to calibrate these measurement methods, and to compute measurement uncertainties. NIST is holding this public meeting to obtain individual input from workshop participants on their non-proprietary efforts in these areas.

All visitors to the NIST site are required to pre-register to be admitted. Anyone wishing to attend this meeting must register by close of business Monday, October 19, 2009 in order to attend. Please submit your name, time of arrival, e-mail address and phone number to Cindy Stanley and she will provide you with instructions for admittance. Non-U.S. citizens must also submit their country of citizenship, title, employer/sponsor, and address. Cindy Stanley's e-mail address is *cindy.stanley@nist.gov* and phone number is 301–975–2756.

Dated: September 23, 2009.

Patrick Gallagher,

Deputy Director.

[FR Doc. E9–23461 Filed 9–28–09; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Rulings

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* September 29, 2009.

SUMMARY: The Department of Commerce (''Department'') hereby publishes a list of scope rulings completed between April 1, 2009, and June 30, 2009. In conjunction with this list, the Department is also publishing a list of requests for scope rulings and anticircumvention determinations pending as of June 30, 2009. We intend to publish future lists after the close of the next calendar quarter.

FOR FURTHER INFORMATION CONTACT: Jennifer Moats or Julia Hancock, AD/CVD Operations, China/NME Group, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: 202–482–5047 or 202–482–1394, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department's regulations provide that the Secretary will publish in the **Federal Register** a list of scope rulings on a quarterly basis. *See* 19 CFR 351.225(o). Our most recent notification of scope rulings was published on August 27, 2009. *See Notice of Scope Rulings,* 74 FR 43680 (August 27, 2009). This current notice covers all scope rulings and anticircumvention determinations completed by Import Administration between April 1, 2009, and June 30, 2009, inclusive, and it also lists any scope or anticircumvention inquiries pending as of June 30, 2009. As described below, subsequent lists will follow after the close of each calendar quarter.

Scope Rulings Completed Between April 1, 2009, and June 30, 2009

Japan

A–588–804: Ball Bearings and Parts Thereof from Japan:

Requestor: NMB (USA), Inc. (''NMB''); tape guide assemblies imported and purchased for sale by NMB are outside the scope of the antidumping duty order; June 1, 2009.

A–588–602: Certain Carbon Steel Butt-Weld Pipe Fittings from Japan:

Requestor: Benex Corporation (''Benex''); Benex's tee blanks are within the scope of the antidumping duty order; June 25, 2009.

People's Republic of China

A–570–504: Petroleum Wax Candles from the People's Republic of China:

Requestor: America's Gardening Resource; its citronella rope candles are outside the scope of the antidumping duty order; April 29, 2009.

A–570–504: Petroleum Wax Candles from the People's Republic of China:
Requestor: ZNP Creative Co., Ltd.; the ''5 minute Candle Set'' is within the scope of the antidumping duty order; May 6, 2009.
A–570–504: Petroleum Wax Candles from the People's Republic of China:
Requestor: RAB Foods; the ''Yahrzeit'' candle is within the scope of the antidumping duty order; June 1, 2009.
A–570–827: Cased Pencils from the People's Republic of China:
Requestor: It's Academic, Inc. (''It's Academic''); certain It's Academic compasses with pencils (''Bow Compass'' (item number 01350), ''Metal Compass'' (item number 01341), ''Retractable Point Compass'' (item number 01330), ''Compass made of recycled products'' (item number 41360), and ''Regular Compass'' (item number 01302)) are outside the scope of the antidumping duty order; June 23, 2009.
A–570–868: Folding Metal Tables and Chairs from the People's Republic of China:
Requestor: New Tec Integration Co., Ltd. (''New Tec''); New Tec's chair using two U-shaped steel tubes to form the front and rear legs, and not utilizing the cross-bracing typically affixed to the leg frame by rivets, welds, and fasteners, is within the scope of the antidumping duty order; May 22, 2009.
A–570–890: Wooden Bedroom Furniture from the People's Republic of China:
Requestor: Target Corporation; the Shabby Chic secretary desk and mirror are outside the scope of the antidumping duty order; April 15, 2009.
A–570–891: Hand Trucks from the People's Republic of China:
Requestor: Safco Products Co.; the StowAway Cart (Model 4062) and Stow And Go Cart (Model 4049) are outside the scope of the antidumping duty order; June 10, 2009.
A–570–891: Hand Trucks from the People's Republic of China:
Requestor: E & B Giftware, LLC; the Samsonite Micro Mover Fold Away Carry-On Luggage Cart and the American Tourister Swing Wheel Luggage Cart are within the scope of the antidumping duty order; the Samsonite Compact Luggage Cart is outside the scope of the antidumping duty order; May 29, 2009.
A–570–899: Artist Canvas from the People's Republic of China:
Requestor: C2F, Inc.; framed artist canvas in two forms (*i.e.,* 65% polyester, 35% cotton bulk or 100% cotton bulk) woven in the Republic of Korea and cut and framed in the People's Republic of China are outside the scope of the antidumping duty order; May 25, 2009.
A–570–901: Lined Paper Products from the People's Republic of China:
Requestor: PlanAhead LLC; writing cases, writing portfolios, portfolios and padfolios, 70314 Professional Padfolio; 70689 Contour Padfolio; 72055 Urban Padfolio; 72537 Fashion Padfolio, are outside the scope of the antidumping duty order; April 2, 2009.
A–570–909: Certain Steel Nails from the People's Republic of China:
Requestor: Shanghai March Import & Export Co., Ltd.; the horseshoe nails exported by Shanghai March Import & Export Co., Ltd. are outside the scope of the antidumping duty order; June 5, 2009.

Anticircumvention Determinations Completed Between April 1, 2009, and June 30, 2009

A–570–894: Certain Tissue Paper Products from the People's Republic of China:
Requestor: Seaman Paper Company of Massachusetts, Inc.; imports of certain tissue paper products from Thailand made out of jumbo rolls and sheets of tissue paper from the People's Republic of China and completed or assembled in other foreign countries are circumventing the antidumping duty order; June 19, 2009.
A–570–868: Folding Metal Tables and Chairs from the People's Republic of China:
Requestor: Meco Corporation; the common leg table (a folding metal table affixed with cross bars that enable the legs to fold in pairs) produced in the People's Republic of China is a minor alteration that circumvents the antidumping duty order; May 6, 2009.

Scope Inquiries Terminated Between April 1, 2009, and June 30, 2009

Japan

A–588–046: Polychloroprene Rubber from Japan:
Requestor: Denka Corporation (''Denka''); whether Denka's solid polychloroprene product, known as DCR37, is within the scope of the antidumping duty order; May 5, 2009, request withdrawn.

Anticircumvention Inquiries Terminated between April 1, 2009, and June 30, 2009

None.

Scope Inquiries Pending as of June 30, 2009

Germany

A–428–801: Ball Bearings and Parts from Germany:
Requestor: The Schaeffler Group; whether certain ball roller bearings are within the scope of the antidumping duty order, requested April 28, 2009.

Norway

A–403–801 and C–403–802: Fresh and Chilled Atlantic Salmon from Norway:
Requestor: Changing Seas; whether its whole salmon steaks are within the scope of the antidumping and countervailing duty orders; requested February 5, 2009.

People's Republic of China

A–570–504: Petroleum Wax Candles from the People's Republic of China:
Requestor: Trade Associates Group, Ltd.; whether its candles (multiple designs) are within the scope of the antidumping duty order; requested June 11, 2009.
A–570–504: Petroleum Wax Candles from the People's Republic of China:
Requestor: Sourcing International, LLC; whether its flower candles are within scope of the antidumping duty order; requested June 24, 2009.
A–570–806: Silicon Metal from the People's Republic of China:
Requestor: Globe Metallurgical Inc.; whether certain silicon metal exported by Ferro-Alliages et Mineraux to the United States from Canada is within the scope of the antidumping duty order; requested October 1, 2008.
A–570–814: Certain Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China:
Requestor: King Architectural Metals (''King''); whether King's pipe fittings for structural use in handrails and fencing are within the scope of the antidumping duty order; April 17, 2009.
A–570–864: Pure Magnesium in Granular Form from the People's Republic of China:
Requestor: ESM Group Inc.; whether atomized ingots are within the scope of the antidumping duty order; initiated April 18, 2007; preliminary ruling issued August 27, 2008.
A–570–868: Folding Metal Tables and Chairs from the People's Republic of China:
Requestor: Lifetime Products, Inc. (''Lifetime''); whether Lifetime's fold-in-half adjustable height tables are outside the scope of the antidumping duty order; requested June 30, 2009.

A–570–886: Polyethylene Retail Carrier Bags from the People's Republic of China:

Requestor: Majestic International, LLC; whether its 120 gift bags are within the scope of the antidumping duty order; requested May 5, 2009.

A–570–886: Polyethylene Retail Carrier Bags from the People's Republic of China:

Requestor: Care Line Industries, Inc.; whether certain bags designed for hospital use, which are not printed with store names or logos and packed in consumer packaging with printing indicating specific end-uses other than packaging or carrying merchandise from retail establishments, are within the scope of the antidumping duty order; requested June 4, 2009.

A–570–890: Wooden Bedroom Furniture from the People's Republic of China:

Requestor: Target Corporation (''Target''); whether Target's White Toy Box is within the scope of the antidumping duty order; requested May 20, 2009.

A–570–891: Hand Trucks from the People's Republic of China:

Requestor: Northern Tool & Equipment Co.; whether a high-axle torch cart (item #164771) is within the scope of the antidumping duty order; requested March 23, 2007.

A–570–899: Artist Canvas from the People's Republic of China:

Requestor: Art Supplies Enterprises, Inc.; whether framed artist canvas woven and primed in the Socialist Republic of Vietnam and cut and framed in the People's Republic of China is within the scope of the antidumping duty order; requested December 22, 2008.

A–570–899: Artist Canvas from the People's Republic of China:

Requestor: Art Supplies Enterprises, Inc.; whether framed artist canvas woven and primed in India and cut and framed in the People's Republic of China is within the scope of the antidumping duty order; requested May 20, 2009.

A–570–901: Lined Paper Products from the People's Republic of China:

Requestor: Livescribe Inc., whether the patented dot-patterned paper (trademarked ''ANOTO'') is within the scope of the antidumping duty order; requested October 24, 2008; supplemented with additional information on July 14, 2009.

A–570–901: Lined Paper Products from the People's Republic of China:

Requestor: Wal-Mart Stores, Inc., whether the notebook component, when imported as part of the complete stationery set, is within the scope of the antidumping duty order; requested March 6, 2009.

A–570–901: Lined Paper Products from the People's Republic of China:

Requestor: Vera Bradley; whether its Clip Notes, which contain a standard sized clipboard measuring 10″; × 14″ with a hinged metal clip at the top and a single pad of lined paper measuring 8½″ × 11″, where the clip board and the single pad of paper are decorated with Vera Bradley's pattern design, are within the scope of the antidumping duty order; requested March 16, 2009.

A–570–904: Certain Activated Carbon from the People's Republic of China:

Requestor: Rolf C Hagen (USA) Corp; whether certain fish filter parts are within the scope of the antidumping duty order; requested November 14, 2008.

A–570–910 and C–570–911: Certain Welded Carbon Quality Steel Pipe from the People's Republic of China:

Requestor: Constantine N. Polites and Company; whether unfinished scaffolding pipe is within the scope of the antidumping duty order; requested March 30, 2009.

A–570–910 and C–570–911: Certain Welded Carbon Quality Steel Pipe from the People's Republic of China:

Requestor: Tubos California; whether its water pipes are within the scope of the antidumping duty order; requested May 27, 2009.

A–570–914: Light-Walled Rectangular Pipe and Tube from the People's Republic of China:

Requestor: MMI Products, Inc.; whether MMI Products, Inc.'s fence posts are within the scope of the antidumping duty order; requested June 19, 2009.

A–570–916 and C–570–917: Laminated Woven Sacks from the People's Republic of China:

Requestor: Shapiro Packaging; whether its ''Manna Pro Calf Manna,'' ''Manna Pro Horse Feed,'' and ''Red Head Deer Corn'' sacks are within the scope of the antidumping duty order; requested March 20, 2009.

A–570–918: Steel Wire Garment Hangers from the People's Republic of China:

Requestor: Econoco Corporation; whether chrome-plated hangers with a certain diameter are within the scope of the antidumping duty order; requested December 3, 2008.

A–570–918: Steel Wire Garment Hangers from the People's Republic of China:

Requestor: American Hanger; whether chrome-plated hangers with a certain diameter are within the scope of the antidumping duty order; requested December 1, 2008.

A–570–922: Raw Flexible Magnets from the People's Republic of China:

Requestor: It's Academic, Inc.; whether its seven packages of locker magnets are within the scope of the antidumping duty order, requested June 4, 2009.

A–570–924: Polyethylene Terephthalate (''PET'') Film from the People's Republic of China:

Requestor: Coated Fabrics Company; whether Amorphous PET (''APET''), Glycol-modified PET (''PETG''), and coextruded APET with PETG on its outer surfaces (''GAG Sheet'') are within the scope of the antidumping duty order; requested February 12, 2009.

Multiple Countries

A–570–922 and C–570–923: Raw Flexible Magnets from the People's Republic of China; A–583–842: Raw Flexible Magnets from Taiwan:

Requestor: Direct Innovations; whether certain decorative retail magnets are within the scope of the antidumping and countervailing duty orders; requested March 20, 2009.

Anticircumvention Rulings Pending as of June 30, 2009

People's Republic of China

A–570–849: Cut-to-Length Carbon Steel Plate from the People's Republic of China:

Requestor: Nucor Corporation, SSAB N.A.D., Evraz Claymont Steel, Evraz Oregon Steel Mills, and ArcelorMittal USA Inc.; whether adding metallurgically and economically insignificant amounts of boron is a minor alteration that circumvents the antidumping duty order; requested August 13, 2008; initiated October 10, 2008.

Interested parties are invited to comment on the completeness of this list of pending scope and anticircumvention inquiries. Any comments should be submitted to the Deputy Assistant Secretary for AD/CVD Operations, Import Administration, International Trade Administration, 14th Street and Constitution Avenue, NW., APO/Dockets Unit, Room 1870, Washington, DC 20230.

This notice is published in accordance with 19 CFR 351.225(o).

Dated: September 22, 2009.

John M. Andersen,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. E9–23473 Filed 9–28–09; 8:45 am]

BILLING CODE 3510–DS–P

COMMISSION OF FINE ARTS

Notice of Meeting

The next meeting of the U.S. Commission of Fine Arts is scheduled for 15 October 2009, at 10 a.m. in the Commission offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street, NW., Washington DC, 20001–2728. Items of discussion may include buildings, parks and memorials.

Draft agendas and additional information regarding the Commission are available on our Web site: *http://www.cfa.gov.* Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address or call 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated: 22 September in Washington, DC.

Thomas Luebke,

Secretary.

[FR Doc. E9–23420 Filed 9–28–09; 8:45 am]

BILLING CODE 6330–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 09–25]

36(b)(l) Arms Sales Notification

AGENCY: Department of Defense. Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 09–25 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: September 15, 2009.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–M

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

SEP 8 2009

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515-6501

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 09-25, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Morocco for defense articles and services estimated to cost $187 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

Jeffrey A. Wieringa
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

Same ltr to:

House
Committee on Foreign Affairs
Committee on Armed Services
Committee on Appropriations

Senate
Committee on Foreign Relations
Committee on Armed Services
Committee on Appropriations

Transmittal No. 09-25

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act, as amended

(i) Prospective Purchaser: Morocco

(ii) Total Estimated Value:

Major Defense Equipment*	$ 42 million
Other	$145 million
TOTAL	$187 million

(iii) Description and Quantity or Quantities of Articles or Services under Consideration for Purchase: 40 LAU-129A Launchers; 20 AGM-65D MAVERICK Missiles; 4 AGM-65D MAVERICK Training Missiles; 4 AGM-65H MAVERICK Training Missiles; 60 Enhanced GBU-12 PAVEWAY II Kits; 28 M61 20mm Vulcan Cannons; 28 AN/ARC-238 Single Channel Ground and Airborne Radios with HAVEQUICK I/II or SATURN I/II; Also included: 1 Ground Based Simulator, 40 LAU-118A missile rails, 6 AN/AAQ-33 SNIPER Targeting Pods with Ground Station, 16 Air Combat Maneuvering Instrumentation (ACMI) Pods, 4 ACMI Ground Stations, 8 Joint Mission Planning Systems, 2 Remote Operated Video Enhanced Receivers, 30 AN/ALR-93 Radar Warning Receivers, 30 AN/AVS-9 Night Vision Goggles, containers, bomb components, support equipment, repair and return, spares and repair parts, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical, engineering, and logistics support services, and other related elements of logistics support.

(iv) Military Department: Air Force (SAY, Amd #4 and YAB, Amd #1)

(v) Prior Related Cases, if any: FMS Case SAY-$2.167B-19Apr08

(vi) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: none

(vii) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached.

(viii) Date Report Delivered to Congress: SEP 8 2009

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Morocco - F-16C/D Block 50/52 Aircraft

The Government of Morocco has requested a possible sale of 40 LAU-129A Launchers; 20 AGM-65D MAVERICK Missiles; 4 AGM-65D MAVERICK Training Missiles; 4 AGM-65H MAVERICK Training Missiles; 60 Enhanced GBU-12 PAVEWAY II Kits; 28 M61 20mm Vulcan Cannons; 28 AN/ARC-238 Single Channel Ground and Airborne Radios with HAVEQUICK I/II or SATURN I/II; Also included: 1 Ground Based Simulator, 40 LAU-118A missile rails, 6 AN/AAQ-33 SNIPER Targeting Pods with Ground Station, 16 Air Combat Maneuvering Instrumentation (ACMI) Pods, 4 ACMI Ground Stations, 8 Joint Mission Planning Systems, 2 Remote Operated Video Enhanced Receivers, 30 AN/ALR-93 Radar Warning Receivers, 30 AN/AVS-9 Night Vision Goggles, containers, bomb components, support equipment, repair and return, spares and repair parts, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical, engineering, and logistics support services, and other related elements of logistics support. The estimated cost is $187 million.

The proposed sale will contribute to the foreign policy and national security objectives of the United States by enhancing Morocco's capacity to support U.S. efforts in the Overseas Contingency Operations, as well as supporting Morocco's legitimate need for its own self-defense. Morocco is one of the most stable and pro-Western of the Arab states, and the U.S. remains committed to a long-term relationship with Morocco.

The proposed sale will allow the Moroccan Air Force to modernize its aging fighter inventory, thereby enabling Morocco to support both its own air defense needs and coalition operations. Morocco is a Major Non-NATO ally. Delivery of this weapon system will greatly enhance Morocco's interoperability with the U.S. and other NATO nations, making it a more valuable partner in an increasingly important area of the world.

The proposed sale of this weapon system will not alter the basic military balance in the region.

The principal contractors will be:

Lockheed Martin Aeronautics Company	Fort Worth, Texas
Raytheon Missile Systems	Tucson, Arizona
L3 Communications	Arlington, Texas
Advanced Night Vision System Inc.	North Salt Lake, Utah

Marvin Industries	Inglewood, CA
L3 Communications	Arlington, TX
Raytheon Missile Systems	Tucson, AZ
BAE Advanced Systems	Greenland, NY
Boeing Corporation	Seattle, WA
Boeing Integrated Defense Systems	St Lewis, MO
Boeing IDS	Long Beach, CA
Boeing IDS	San Diego, CA
Raytheon Company	Lexington, MA
Raytheon Company	Goleta, CA
Lockheed Martin Missile and Fire Control	Dallas, TX
Northrop-Grumman Electro-Optical Systems	Garland, TX
Northrop-Grumman Electronic Systems	Baltimore, MD

There are no known offset agreements in connection with this proposed sale.

Implementation of this sale will not require the assignment of any additional U.S. Government personnel or contractor representatives to Morocco.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 09-25

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

Annex
Item No. vii

(vii) Sensitivity of Technology:

1. The AGM-65G/H MAVERICK air-to-ground missile has an overall classification of Secret. The Secret aspects of the Maverick system are tactics, information revealing its vulnerability to countermeasures, and counter-countermeasures. Manuals and technical documents, which are necessary for operational use and organizational maintenance have portions that are classified Confidential. Performance and operating logic of the countermeasures circuits are Secret.

2. The PAVEWAY II/III series of laser guided bombs consists of a guidance kit that converts existing unguided free-fall bombs into precision-guided "smart" munitions. At the core of each PAVEWAY II/III Munition Kit is a dumb bomb. A laser guidance kit is integrated with each dumb bomb to add the requisite level of accuracy. The kit consists of a computer-controlled group at the front end of the weapon and an airfoil group at the back. When a target is illuminated by a laser, either airborne or ground-based, the guidance fins react to signals from the control group and steer the weapon to the target. This precision-guided munition offers improved accuracy over free-fall bombs, thus providing the potential for reduced collateral damage.

3. The AN/AAQ-33 SNIPER targeting system is Unclassified but contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is classified Secret. Software (object code) is classified Confidential. Sensitive elements include the forward looking infrared (FLIR) sensors, Laser Pulse Interval Modulation (PIM) and doublet coding, and the AGM-65 Missile Boresight Correlator (MBC), and ECCM features that increase capability in a jamming environment. The SNIPER system to be released will not include laser PIM, laser doublet coding, or the Lockheed Martin (LM)-proprietary XR image processing algorithm (no extended range capability).

4. If a technologically advanced adversary were to obtain knowledge of the specific hardware or software in this proposed sale, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of systems with similar or advance capabilities.

[FR Doc. E9–22949 Filed 9–28–09; 8:45 am]
BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

Office of the Secretary

Class Tuition Waiver

AGENCY: Department of Defense Education Activity (DoDEA), DoD.

ACTION: Notice.

SUMMARY: On August 3, 2009, the Deputy Under Secretary of Defense (Plans), Performing the Duties of the Under Secretary of Defense (Personnel and Readiness), signed a memorandum to the Director, Department of Defense Education Activity, designating for enrollment on a space-available, tuition-free basis, classes of dependents of military and diplomatic personnel whose nations participated in the Partnership for Peace (PfP) Program in Brussels and Mons, Belgium; Naples, Italy; London, United Kingdom; Brunssum, the Netherlands; and Oberammergau, Germany, prior to gaining status as full members of NATO during the period between January 2009 and January 2014. Subject to the availability of space, this waiver may be applied for the duration of the sponsor's tour not to exceed a total of three years for each eligible dependent. This class waiver is effective immediately.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Lynch, 4040 North Fairfax Drive, Arlington, VA 22203–1635.

SUPPLEMENTARY INFORMATION: Please note that the availability of space in the Defense Dependents' Education System varies from year to year and is not guaranteed. Commanders should ensure that enrollments are timely and do not disrupt the dependent's or school's educational program.

Dated: September 23, 2009.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E9–23416 Filed 9–28–09; 8:45 am]
BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2009–0028]

Proposed Collection; Comment Request

AGENCY: Office of the Administrative Assistant to the Secretary of the Army, (OAA–RPA), DoD.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Department of the Army announces the extension of a proposed public information collection and seeks public comment on the provisions thereof. *Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by November 30, 2009.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Department of the Army, Corps of Engineers, Institute for Water Resources, 7701 Telegraph Road, (CEIWR–MD), Alexandria, Virginia 22315–3868. ATTN: (Stuart A. Davis), or call Department of the Army Reports Clearance Officer at (703) 428–6440.

Title and OMB Number: Corps of Engineers Civil Works Questionnaire—Generic Clearance; OMB Control Number 0710–0001.

Needs and Uses: The U.S. Army Corps of Engineer utilizes the data collected from the questionnaire items for planning data to formulate and evaluate alternative water resources development plans, to determine the effectiveness and evaluate the impacts of Corps projects, and in the case of the flood damage mitigation, to obtain information on flood damage incurred, whether or not a project is being considered or exists. All survey questionnaires are administered either by face-to-face, mail, or telephone methods. Public surveys are used to gather data for planning and operating Corps projects and facilities and to determine public preferences and satisfaction.

Affected Public: Individuals or households; business or other for-profit; not-for-profit institutions; farms; State, local or tribal government.

Annual Burden Hours: 21,642.

Number of Respondents: 185,500.

Responses per Respondent: 1.

Average Burden per Response: 7 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

All survey questionnaires are carefully selected to minimize undue burden on the public and are subject to internal controls and pre-testing before actual use. Duplication is avoided by close coordination with state and local agencies as well as other Federal agencies and, whenever possible, participation in joint data collection efforts. Most of the Corps of Engineers civil works survey information is collected for very unique circumstances, such as visitor information at Corps recreation areas or flood damage information related to the Corps evaluation procedures. Much of this information is required to be very current and must be updated every one to two years.

Dated: September 21, 2009.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E9–23417 Filed 9–28–09; 8:45 am]
BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before November 30, 2009.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: September 23, 2009.

Angela C. Arrington,

Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management.

Office of Special Education and Rehabilitative Services

Type of Review: Revision.

Title: Report on IDEA part B Maintenance of Effort Reduction and Coordinated Early Intervening Services.

Frequency: Annually.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 60.

Burden Hours: 1,032,480.

Abstract: This package provides instructions and forms necessary for States to report the provisions of coordinated early intervening services (CEIS) and maintenance of effort (MOE) reduction in IDEA. The form satisfies reporting requirements and is used by OSEP to monitor SEAs and for Congressional reporting.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 4146. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E9–23444 Filed 9–28–09; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

National Assessment Governing Board; Public Hearings

AGENCY: U.S. Department of Education, National Assessment Governing Board.

ACTION: Notice of public hearing.

SUMMARY: The National Assessment Governing Board is announcing a public hearing on November 9, 2009 to obtain comment on expert panel recommendations on uniform national rules for testing of Students with Disabilities (SD) and English Language Learners (ELL) on the National Assessment of Educational Progress (NAEP).

Public and private parties and organizations are invited to present written and/or oral testimony. The hearing will be held in the Phoenix Park Hotel, 520 North Capitol Street, NW., Washington, DC 20001 from 9:30 a.m. to 3 p.m. EST.

This notice sets forth the schedule and proposed agenda of a forthcoming public hearing of the National Assessment Governing Board. This notice also describes the functions of the Board. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify members of the general public of their opportunity to provide comment. Individuals who will need special accommodations in order to attend the hearing (such as interpreting services, assistive listening devices, materials in alternative format) should notify Munira Mwalimu at 202–357–6938 or at *Munira.Mwalimu@ed.gov* no later than November 4, 2009. We will attempt to meet requests after this date, but cannot guarantee availability of the requested accommodation. The meeting site is accessible to individuals with disabilities.

DATES: November 9, 2009.

Location: Phoenix Park Hotel, 520 North Capitol Street, NW., Washington, DC 20001. The hotel may be reached via the Union Station Metro.

Time: 9:30 a.m. to 3 p.m. EST.

Background

Under Public Law 107–279, the National Assessment Governing Board (NAGB) is responsible for determining the content and methodology of the National Assessment of Educational Progress (NAEP). The assessment is required to provide a fair and accurate measurement of student academic achievement through a random sampling process that produces representative data for the nation, the States, and other participating jurisdictions.

Despite changes in policy during the past decade, variations in inclusion and accommodation rates continue for students with disabilities and English language learners among States and urban districts participating in the National Assessment. These differences—both between jurisdictions and over time—continue to prompt concern about the fairness and comparability of NAEP results.

The Governing Board has established an Ad Hoc Committee of Board members to conduct a comprehensive examination of NAEP testing and reporting of these two student groups. The Committee appointed two technical advisory panels to recommend uniform national rules for NAEP testing of SD and ELL students to better assure that NAEP samples are fully representative and produce comparable results. These panels reported to the Board at its meeting on August 6 and 7, 2009. The Board plans to consult widely before deciding whether or not to adopt the expert panel recommendations.

The reports and recommendations being considered are available under

supplementary information in this notice and on the website of the Governing Board at *http://www.nagb.org.* Other related material on the Governing Board and NAEP may be found at this Web site and at *http://www.nces.ed.gov/nationsreportcard.*

The Board is seeking comment from policymakers, teachers, researchers, State and local school administrators, specialists in SD and ELL students, parents of children in elementary and secondary schools, representatives of interested organizations, and members of the public. Representatives of the Governing Board will conduct the hearing to receive testimony, and may ask clarifying questions or respond to presentations. Oral presentations should not exceed ten minutes. Testimony will become part of the public record.

All views will be considered by the Ad Hoc Committee and the full Board. It is anticipated that the Committee will make recommendations to the Governing Board at the Governing Board meetings on November 19–21, 2009 and March 4–6, 2010.

To register to present oral testimony on November 9, 2009 at the Phoenix Park Hotel in Washington, DC, please call Tessa Regis, of the National Assessment Governing Board staff, at 202–357–7500 or send an e-mail to tessa.regis@ed.gov by 4 p.m. (Eastern Time) on Friday, November 6, 2009. Written testimony should be sent by mail, fax or e-mail for receipt in the Board office by November 10, 2009.

The Board will make an effort to hear testimony from all persons who wish to address it at the hearing without prior registration. Speakers are encouraged to bring written statements for distribution at the hearing.

Testimony should be sent to: National Assessment Governing Board, 800 North Capitol Street, NW. — Suite 825, Washington, DC 20002, Attention: Tessa Regis, FAX: (202) 357–6945, E-mail: *tessa.regis@ed.gov.*

FOR FURTHER INFORMATION CONTACT: Tessa Regis or Lawrence Feinberg, National Assessment Governing Board, 800 North Capitol Street, NW., Suite 825, Washington, DC 20002–4233, Telephone: (202) 357–6938.

SUPPLEMENTARY INFORMATION: The National Assessment Governing Board is established under section 412 of the National Education Statistics Act of 1994, as amended. The Board formulates policy guidelines for the National Assessment of Educational Progress (NAEP). The Board's responsibilities include selecting subject areas to be assessed, developing assessment specifications and frameworks, designing the methodology of the assessment, developing appropriate student achievement levels for each grade and subject tested, developing standards and procedures for interstate and national comparisons, developing guidelines for reporting and disseminating results, and releasing initial NAEP results to the public.

The expert panel recommendations being considered by the Governing Board are summarized below. They are not mutually exclusive. Some could go into effect quickly while others would be for medium-term or long-range implementation. NAEP is a representative-sample survey, designed to produce valid, comparable data on the academic achievement of large groups of students. It is prohibited by law from providing results for individual children or schools. The recommendations are being considered because of concern that variations in exclusion and accommodation practices may jeopardize the fairness and comparability of NAEP results.

The recommendations on which public comment is sought are summarized as follows:

By Expert Panel on Uniform National Rules for NAEP Testing of Students With Disabilities

(1) Encourage as many students as possible to participate in NAEP, and provide for the use of allowable accommodations that are necessary to enable students with disabilities to participate.

(2) Clarify and expand NAEP's guidance to schools, encouraging maximum participation of students with disabilities so at least 95 percent of those drawn for the NAEP sample participate.

(3) Report separately on students who have individualized education programs (IEPs) and those with Section 504 plans, but (except to maintain trend) only count the students with IEPs as students with disabilities.

(4) Provide incentives for schools to include students with disabilities, including additional outreach and public reporting of participation rates below 95 percent of students with disabilities.

(5) Support research efforts to develop targeted testing for students at both the top and bottom levels of achievement, with sound procedures to identify students to receive targeted test booklets on the basis of their performance on some standard indicator of achievement.

(6) Encourage and review research on the identification and progress of students who have a significant cognitive disability but in the short term do not test this 1% of students on NAEP.

(7) Assess the English language proficiency of students with disabilities who are English language learners and are drawn for the NAEP sample and provide linguistically appropriate accommodations for those who need them before determining whether additional accommodations may be needed to address any disabilities those students may have.

By Expert Panel on Uniform National Rules for NAEP Testing of English Language Learners

(1) ELLs in all States and districts selected for the NAEP sample who have been in United States schools for one year or more should be included in the National Assessment. This policy should be implemented with the disaggregated reporting of ELL test results by detailed information on students' English language proficiency and the availability of accommodations that maximize meaningful participation.

(2) Students should be offered ELL-responsive accommodations that maintain the constructs in the NAEP framework, including items and directions in plain language, side-by-side bilingual Spanish-English test booklets, word-to-word bilingual glossaries without definitions, as well as other accommodations currently allowed by NAEP. The accommodations for each student should be selected at the local level by school personnel who are qualified to make judgments regarding the inclusion of the ELL in NAEP, including knowledge of his or her level of English language proficiency.

(3) NAEP results for ELL students should be disaggregated and reported by the best available standardized assessment data on the level of English language proficiency.

(4) To attain comparable participation rates across States and districts, special efforts should be made to inform and solicit the cooperation of State and local officials who decide upon the participation of individual students, including joint planning sessions and targeted information sharing. A high common goal for 95 percent or more of ELL students sampled to participate should be established.

(5) NAEP should adopt an aggressive timeline for innovation and research, including (a) the development of test items written in plain language; (b) a short test of English language proficiency; (c) targeted testing with blocks of items at low and high levels of difficulty; and (d) computerized

administration of the assessment when feasible.

The full reports and recommendations of the technical advisory panels are available at *http://nagb.org/newsroom/PressReleasePDFs/SD–Panel-Report.pdf* and *http://nagb.org/newsroom/PressReleasePDFs/ELL–Panel-Report.pdf*. PowerPoint summaries are available at *http://nagb.org/newsroom/PressReleasePDFs/PPt-SD–Panel-Report.pdf* and *http://nagb.org/newsroom/PressReleasePDFs/PPt-ELL–Panel-Report.pdf.*

A detailed summary of the hearing that is informative to the public and consistent with the policy of section 5 U.S.C. 552b(c) will be available to the public within 14 days of the meeting. Records are kept of all Board proceedings and are available for public inspection at the U.S. Department of Education, National Assessment Governing Board, Suite #825, 800 North Capitol Street, NW., Washington, DC, from 9 a.m. to 5 p.m. Eastern Time, Monday through Friday.

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister/index.html*. To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register.** Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: September 24, 2009.

Cornelia S. Orr,

Executive Director, National Assessment Governing Board, U. S. Department of Education.

[FR Doc. E9–23467 Filed 9–28–09; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP09–465–000]

Northern Natural Gas Company; Notice of Application

September 22, 2009.

Take notice that on September 14, 2009, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124, filed with the Federal Energy Regulatory Commission an application under Section 7 of the Natural Gas Act to expand the existing certificated storage boundary of the Cunningham storage field located in Pratt and Kingman counties, Kansas, to include the Viola and Simpson formations in the Extension Area (including Northern's acquisition of all property interests), all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In its application, Northern asserts the need to acquire additional storage acres to control and mitigate storage gas migration from the Cunningham storage field that is occurring to the north of Northern's existing certificated storage boundary.

Any questions regarding this application should be directed to Michael T. Loeffler, Senior Director of Certificates and External Affairs for Northern, 1111 South 103rd Street, Omaha, Nebraska 68124, (402) 398–7103; or Bret Fritch, Senior Regulatory Analyst, at (402) 398–7140.

The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site Web at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@gerc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the eLibrary link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail

notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: October 13, 2009.

Kimberly D. Bose,

Secretary.

[FR Doc. E9–23404 Filed 9–28–09; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–31–004]

Transcontinental Gas Pipe Line Corporation; Notice of Application

September 22, 2009.

Take notice that on September 11, 2009, Transcontinental Gas Pipe Line Corporation (Transco), 2800 Post Oak Boulevard, Houston, Texas 77056–6106 filed an application pursuant to section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations, to amend its certificate granted by Commission Order issued on August 14, 2008 [1] and as amended by Commission Order issued on October 23, 2008.[2] Transco proposes to revise its Exhibit K, cost of facilities in order to reflect increases in the cost of facilities for the Sentinel Expansion Project (Project) and to revise the initial recourse rates for Phase 2 of the Project. Transco states that the overall impact of the adjustments will be an increase of $59.6 million to the estimated cost of the Project facilities which is attributable to higher than anticipated expenses for construction and restoration.

This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Any questions regarding the application are to be directed to Scott Turkington, Director, Rates & Regulatory, Transcontinental Gas Pipe Line Corporation, Post Office Box 1396, Houston, Texas 77251–1396, telephone: (713) 215–3391 or e-mail: *scott.c.turkington@williams.com.*

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit the original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

Comment Date: October 2, 2009.

Kimberly D. Bose,

Secretary.

[FR Doc. E9–23405 Filed 9–28–09; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. DI09–14–000]

Hawken LLC; Notice of Declaration of Intention and Soliciting Comments, Protests, and/or Motions To Intervene

September 22, 2009.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Declaration of Intention.

b. *Docket No:* DI09–14–000.

c. *Date Filed:* September 11, 2009.

d. *Applicant:* Hawken LLC.

e. *Name of Project:* Baranof Chinook Hydroelectric Project.

f. *Location:* The proposed Baranof Chinook Hydroelectric Project will be located on Baranof Lake and Baranof River, on Baranof Island, Sitka Borough, near Baranof, Alaska, affecting T. 55 S, R. 66 E, sec. 24, and T. 55 S, R. 67 E, sec. 19, Copper River Meridian.

g. *Filed Pursuant to:* Section 23(b)(1) of the Federal Power Act, 16 U.S.C. 817(b).

h. *Applicant Contact:* Dale Young, 9720 Trappers Lane, Juneau, AK 99801; telephone: (907) 789–0740; e-mail: *http://www.hawken@mac.com.*

i. *FERC Contact:* Any questions on this notice should be addressed to Henry Ecton, (202) 502–8768, or email address: *henry.ecton@ferc.gov.*

j. *Deadline for filing comments, protests, and/or motions:* October 22, 2009.

All documents (original and eight copies) should be filed with: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and/or interventions may be filed electronically via the Internet in lieu of paper. Any questions, please contact the Secretary's Office. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing link.

Please include the docket number (DI09–14–000) on any comments, protests, and/or motions filed.

k. *Description of Project:* The proposed Baranof Chinook Hydropower Project is part of a proposed three-phase project to build and operate a salmon research enhancement and rehabilitation facility. There are no proposed dams for this project, because Baranof Lake is a natural lake. Phase One will involve the construction of multiple intakes and penstocks, designed to withdraw water from separate locations on Baranof Lake. Phase Two will use the water from the penstocks to supply a bank of 14 Cornel Pump Turbines with a combined output of 600 kW. Phase Three will either use a bank of 28 Cornell Pump Turbines with a combined output of 1200 kW, or a pair of Francis turbines with an output between 900 kW and 1680 kW. The purpose of the project is to supply energy for the salmon facility and associated support infrastructure. The proposed project will not be connected to an interstate grid, and will not occupy federal lands.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether or not the project: (1) Would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize

[1] 124 FERC ¶ 61,160 (2008).

[2] 125 FERC ¶ 61,086 (2008).

surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. *Locations of the Application:* Copies of this filing are on file with the Commission and are available for public inspection. This filing may be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link, select ''Docket#'' and follow the instructions. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3372, or TTY, contact (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''PROTESTS'', AND/OR ''MOTIONS TO INTERVENE'', as applicable, and the Docket Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E9–23403 Filed 9–28–09; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL09–71–000]

Resale Power Group of Iowa; WPPI Energy; Notice of Petition for Declaratory Order

September 14, 2009.

Take notice that on September 3, 2009, Resale Power Group of Iowa (''RPGI'') and WPPI Energy (''WPPI'') (collectively, ''Petitioners''), filed a Petition For Declaratory Order, Request for Exemption In Lieu Of the Applicable Fee, and Request for Expedited Consideration (''Petition''), requesting a declaratory order by the Commission determining that the transmission rate that Petitioners pay to the Midwest Independent Transmission System Operator, Inc. (''MISO'') under its Open Access Transmission Tariff (''OATT'') and applicable service agreements is the only transmission service charge that Petitioners can be required to pay for such transmission service.

Any person desiring to participate in this filing must file a motion to intervene or a protest in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time Wednesday, October 5, 2009.

Kimberly D. Bose,

Secretary.

[FR Doc. E9–22702 Filed 9–28–09; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD09–11–000]

Natural Gas Infrastructure and Opportunities for Improved Efficiency; Notice of Public Conference

September 21, 2009.

Take notice that a public conference will be held on December 2, 2009, from approximately 9 a.m. until 12 p.m. Eastern Time, in the Commission Meeting Room on the second floor of the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC. All interested persons may attend; there is neither registration nor a registration fee. Commissioners are expected to participate.

The conference will focus on waste heat recovery efforts as well as other efficiency measures in the natural gas industry.

Transcripts of the conference will be immediately available from Ace Reporting Company (202–347–3700 or 1–800–336–6646) for a fee. A free webcast of this event is available through *http://www.ferc.gov.* Anyone with internet access who desires to view this event can do so by navigating to the Calendar of Events at *http://www.ferc.gov* and locating this event in the Calendar. The event will contain a link to its webcast. The Capitol Connection provides technical support for the free webcasts. It also offers access to this event via television in the Washington, DC area and via phone-bridge for a fee. If you have any questions, visit *http://www.CapitolConnection.org* or call (703) 993–3100.

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to *accessibility@ferc.gov* or call toll free 866–208–3372 (voice) or (202)–208–1659 (TTY), or send a FAX to (202)–

208–2106 with the required accommodations. Additional details and the agenda for this conference will be included in a subsequent notice. For more information about the conference, please contact Pamela Romano at (202) 502–6854 (*pamela.romano@ferc.gov*).

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E9–23346 Filed 9–28–09; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8960–5; Docket ID No. EPA–HQ–ORD–2009–0217]

Draft Toxicological Review of Chloroprene: In Support of the Summary Information in the Integrated Risk Information System (IRIS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: EPA is announcing a public comment period for the external review draft document titled, ''Toxicological Review of Chloroprene: In Support of Summary Information on the Integrated Risk Information System (IRIS)''. EPA intends to consider comments and recommendations from the public and the expert peer-review workshop, which will be scheduled at a later date and announced in the **Federal Register**, when EPA finalizes the draft document. The public comment period will provide opportunities for all interested parties to comment on the document. EPA intends to forward public comments submitted in accordance with this notice to the external peer-review panel prior to the meeting for their consideration.

EPA is releasing this draft document solely for the purpose of pre-dissemination public review under applicable information quality guidelines. This document has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency policy or determination.

The draft document and EPA's peer-review charge are available via the Internet on the National Center for Environmental Assessment's (NCEA) home page under the Recent Additions and the Data and Publications menus at *http://www.epa.gov/ncea*. When finalizing the draft document, EPA intends to consider any public comments that EPA receives in accordance with this notice.

DATES: The 60-day public comment period begins September 29, 2009, and ends November 30, 2009. Technical comments should be in writing and must be received by EPA by November 30, 2009. EPA intends to submit comments from the public received by this date for consideration by the external peer review panel.

ADDRESSES: The draft ''Toxicological Review of Chloroprene: In Support of Summary Information on the Integrated Risk Information System (IRIS)'' is available via the Internet on the NCEA's home page under the Recent Additions and the Data and Publications menus at *http://www.epa.gov/ncea*. A limited number of paper copies are available from NCEA's Technical Information Staff, telephone: 703–347–8561; facsimile: 703–347–8691. If you are requesting a paper copy, please provide your name, mailing address, and the document title, ''Toxicological Review of Chloroprene: In Support of Summary Information on the Integrated Risk Information System (IRIS)''.

Comments may be submitted electronically via *http://www.regulations.gov*, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions as provided in the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, contact the Office of Environmental Information Docket; telephone: 202–566–1752; facsimile: 202–566–1753; or e-mail: *ORD.Docket@epa.gov*.

If you have questions about the document, contact Allen Davis, Hazardous Pollutant Assessment Group (HPAG), National Center for Environmental Assessment, 109 T.W. Alexander Dr., Research Triangle Park, NC 27709; telephone: 919–541–3789; facsimile: 919–541–0245; or e-mail: *davis.allen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Summary of Information About the Integrated Risk Information System (IRIS)

IRIS is a database that contains potential adverse human health effects information that may result from chronic (or lifetime) exposure to specific chemical substances found in the environment. The database (available on the Internet at *http://www.epa.gov/iris*) contains qualitative and quantitative health effects information for more than 540 chemical substances that may be used to support the first two steps (hazard identification and dose-response evaluation) of a risk assessment process. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Combined with specific exposure information, government and private entities can use IRIS data to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

II. How To Submit Technical Comments to the Docket at http://www.regulations.gov

Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2009–0217 by one of the following methods:

- *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.
- *E-mail: ORD.Docket@epa.gov*.
- *Fax:* 202–566–1753.
- *Mail:* Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The phone number is 202–566–1752.
- *Hand Delivery:* The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202–566–1744. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

If you provide comments by mail or hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions: Direct your comments to Docket ID No. EPA–HQ–ORD–2009–0217. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *http://www.regulations.gov*, including any personal information provided, unless a comment includes information

claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: June 15, 2009.

Rebecca Clark,

Director, National Center for Environmental Assessment.

[FR Doc. E9–23504 Filed 9–28–09; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 92–237; DA 09–2096]

Next Meeting of the North American Numbering Council

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: On September 23, 2009, the Commission released a public notice announcing the October 15, 2009 meeting and agenda of the North American Numbering Council (NANC). The intended effect of this action is to make the public aware of the NANC's next meeting and agenda.

DATES: Thursday, October 15, 2009, 9:30 a.m.

ADDRESSES: Competition Policy Division, Wireline Competition Bureau, Federal Communications Commission, Portals II, 445 Twelfth Street, SW., Suite 5–C162, Washington, DC 20554. Requests to make an oral statement or provide written comments to the NANC should be sent to Deborah Blue.

FOR FURTHER INFORMATION CONTACT: Deborah Blue, Special Assistant to the Designated Federal Officer (DFO) at (202) 418–1466 or *Deborah.Blue@fcc.gov*. The fax number is: (202) 418–1413. The TTY number is: (202) 418–0484.

SUPPLEMENTARY INFORMATION: *Released:* September 23, 2009. The North American Numbering Council (NANC) has scheduled a meeting to be held Thursday, October 15, 2009, from 9:30 a.m. until 5 p.m. The meeting will be held at the Federal Communications Commission, Portals II, 445 Twelfth Street, SW., Room TW–C305, Washington, DC. This meeting is open to members of the general public. The FCC will attempt to accommodate as many participants as possible. The public may submit written statements to the NANC, which must be received two business days before the meeting. In addition, oral statements at the meeting by parties or entities not represented on the NANC will be permitted to the extent time permits. Such statements will be limited to five minutes in length by any one party or entity, and requests to make an oral statement must be received two business days before the meeting.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty). Reasonable accommodations for people with disabilities are available upon request. Include a description of the accommodation you will need, including as much detail as you can. Also include a way we can contact you if we need more information. Please allow at least five days advance notice; last minute requests will be accepted, but may be impossible to fill.

Proposed Agenda: Thursday, October 15, 2009, 9:30 a.m.*

1. Announcements and Recent News;
2. Approval of Transcript —Meeting of July 16, 2009;
3. Report of the North American Numbering Plan Administrator (NANPA);
4. Report of the National Thousands Block Pooling Administrator (PA);
5. *Local Number Portability Administration (LNPA) Working Group:* Recommendation to NANC on Implementation of FCC Local Number Portability Interval Order, FCC 09–41;
6. Report of North American Portability Management LLC (NAPM LLC);
7. Report of the Numbering Oversight Working Group;
8. Status of the Industry Numbering Committee (INC) activities;
9. Report from the North American Numbering Plan Billing and Collection (NANP B&C) Agent;
10. Report of the Billing & Collection Working Group (B&C WG);
11. Report of the Future of Numbering Working Group (FoN WG);
12. Summary of Action Items;
13. Public Comments and Participation (5 minutes per speaker);
14. Other Business.

Adjourn no later than 5 p.m.

*The Agenda may be modified at the discretion of the NANC Chairman with the approval of the DFO.

Federal Communications Commission.

Marilyn Jones,

Attorney, Wireline Competition Bureau.

[FR Doc. E9–23495 Filed 9–28–09; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Radio Broadcasting Services; AM or FM Proposals To Change the Community of License

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The following applicants filed AM or FM proposals to change the community of license: CEDAR COVE BROADCASTING, INC., Station KMPB, Facility ID 94204, BPED–20090902AAR, From FRISCO, CO, To MINTURN, CO; COCHISE BROADCASTING LLC, Station KCDC, Facility ID 166049, BPH–20090828AEA, From MILFORD, UT, To LA VERKIN, UT; EDUCATIONAL MEDIA FOUNDATION, Station KRLP,

Facility ID 91900, BPED–20090831ADE, From WINDOM, MN, To FAIRMONT, MN; GEOS COMMUNICATIONS, Station WNKZ, Facility ID 66715, BPH–20090908AAW, From LAPORTE, PA, To DUSHORE, PA; ROY E. HENDERSON TR/AS NEW ULM BROADCASTING CO., Station KNRG, Facility ID 15113, BPH–20090827ACZ, From NEW ULM, TX, To SMITHVILLE, TX.

DATES: Comments may be filed through November 30, 2009.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Tung Bui, 202–418–2700.

SUPPLEMENTARY INFORMATION: The full text of these applications is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW., Washington, DC 20554 or electronically via the Media Bureau's Consolidated Data Base System, *http://svartifoss2.fcc.gov/prod/cdbs/pubacc/prod/cdbs_pa.htm*. A copy of this application may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*.

Federal Communications Commission.

James D. Bradshaw,

Deputy Chief, Audio Division, Media Bureau.

[FR Doc. E9–23498 Filed 9–28–09; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than October 14, 2009.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Robert D. Fleming and Phyllis A. Fleming, both of Ipava, Illinois, as a group acting in concert, and Joseph J. Dietz, Lewistown, Illinois; to retain voting shares of ISB Bancshares, Inc., and thereby indirectly retain voting shares of Ipava State Bank, both of Ipava, Illinois.

Board of Governors of the Federal Reserve System, September 24, 2009.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E9–23462 Filed 9–28–09; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; HIT Standards Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting.

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public.

Name of Committee: HIT Standards Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the HIT Policy Committee.

Date and Time: The meeting will be held on October 14, 2009, from 9 a.m. to 3 p.m./ Eastern Time.

Location: The Omni Shoreham Hotel, 2500 Calvert Street, NW., Washington, DC. The hotel telephone number is 202–234–0700.

Contact Person: Jonathan Ishee, Office of the National Coordinator, HHS, 200 Independence Ave, SW., Room 729–G, Washington, DC 20201, 202–205–8493, Fax: 202–690–6079, e-mail: *jonathan.ishee@hhs.gov.* Please call the contact person for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The Committee will discuss reports from its Clinical Operations, Clinical Quality, and Privacy and Security Workgroups. The Committee will also take testimony from invited experts in the field of security as it relates to health information technology. ONC intends to make background material available to the public no later than two (2) business days prior to the meeting. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at *http://healthit.hhs.gov.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 6, 2009. Oral comments from the public will be scheduled between approximately 2:30 p.m. to 3 p.m. Time allotted for each presentation may be limited. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public hearing session, ONC will take written comments after the meeting until close of business.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Judy Sparrow at least seven (7) days in advance of the meeting.

ONC is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://healthit.hhs.gov* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: September 24, 2009.

Jonathan Ishee,

Office of Policy and Research, Office of the National Coordinator for Health Information Technology.

[FR Doc. E9–23440 Filed 9–28–09; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

President's Advisory Council for Faith-Based and Neighborhood Partnerships

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the President's Advisory Council for Faith-based and Neighborhood Partnerships announces the following meeting:

Name: President's Advisory Council for Faith-based and Neighborhood Partnerships Council Meeting.

Time and Date: Tuesday, October 13th, 9 a.m.–1 p.m. and 2 p.m.–6 p.m. Eastern.

Place: Meetings will be held in person. Location TBD.

Status: Open to the public, limited only by the space available. Conference call line will be available.

Purpose: The Council brings together leaders and experts in fields related to the work of faith-based and neighborhood organizations in order to: Identify best practices and successful modes of delivering social services; evaluate the need for improvements in the implementation and coordination of public policies relating to faith- based and other neighborhood organizations; and make recommendations for changes in policies, programs, and practices.

Contact Person for Additional Information: Mara Vanderslice, 202–260–1931, *mara.vanderslice@hhs.gov.*

Supplementary Information: Please contact Mara Vanderslice for more information about how to attend the meeting or join via conference call line.

Agenda: Topics to be discussed include deliberation on draft recommendations for Council report.

Dated: September 24, 2009.

Mara Vanderslice,

Special Assistant.

[FR Doc. E9–23483 Filed 9–28–09; 8:45 am]

BILLING CODE 4154–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request

The Impact of Continuing Medical Education on Physician Practice

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Clinical Center, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 14, 2009, page 22749 and allowed 60-days for public comment. One comment was received:

'These meetings should be on computer software and the general population of this nation should be able to attend. This is a very cheap way to distribute information, the general public can have some understanding of what you are telling doctors to do and the open ness of the project will help all americans. It is time to stop secret meetings. They cost more for taxpayers, they don't get the message through when videotapes can be made of the information transmitted. This 1935 style of getting out information is seriously expensive and a stupid way to do business in 2009. Obama said to open up the process—its time to do that.'

The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Impact of Continuing Medical Education on Physician Practice. *Type of information Collection Request:* New. *Need and Use of Information Collection:* This study will assess the value of the training programs administered by the Office of Clinical research Training and Medical Education. The primary objective of the survey is to determine if training programs have had an impact on whether the trainees are performing clinical research, hold an academic appointment, have National Institutes of Health funding sources as well as to obtain information from the trainees as to what part of the National Institutes of Health medical education program they feel could be improved upon, the quality of the mentoring program, and how their National Institutes of Health training has contributed to their current clinical competence. *Frequency of Response:* On occasion. *Affected Public:* Individuals and businesses. *Type of Respondents:* Physicians, dentists, medical students, dental students, nurses, PhDs, and other Health Care Providers. *The annual reporting burden is as follows: Estimated Number of Respondents:* 10,000. *Estimated Number of Responses per Respondent:* 2. *Average Burden Hours per Response:* 0.017; and *Estimated Total Annual Burden Hours Requested:* 340.

Request For Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Linda Wisniewski, Office of Clinical Research Training and Medical Education, Clinical Center, Building 10, Room: 1N252B, 9000 Rockville Pike, Bethesda, MD 20892, or call 301–496–9425 or E-mail your request, including your address to: *wisniewskil@cc.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: September 15, 2009.

Laura Lee,

Project Clearance Liaison, Warren Grant Magnuson Clinical Center, National Institutes of Health.

[FR Doc. E9–23334 Filed 9–28–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Submission for OMB Review; Comment Request; The Sister Study PHASE 2: Environmental and Genetic Risk Factors for Breast Cancer

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on 10 July 2009 on page 33259 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after

October 1, 1995, unless it displays a currently valid OMB control number.

5 CFR 1320.5: Reporting and Recordkeeping Requirements: Final Rule: Respondents to this collection of information are not required to respond unless the data collection instruments display a currently valid OMB control number.

Proposed Collection: Title: The Sister Study PHASE 2: Environmental and Genetic Risk Factors for Breast Cancer. *Type of Information Collection Request:* Revision of OMB No. 0925–0522 and expiration date 30 September 2009. *Need and Use of Information Collection:* The purpose of the Sister Study is to study genetic and environmental risk factors for the development of breast cancer in a high-risk cohort of sisters of women who have had breast cancer. In the United States, approximately 192,370 new cases of invasive breast cancer are anticipated in 2009. The etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible. Sisters of women with breast cancer are one group at increased risk for breast cancer; we would expect at least 2 times as many breast cancers to accrue in a cohort of sisters as would accrue in a cohort identified through random sampling or other means. In addition, a cohort of sisters should be enriched with regard to the prevalence of relevant genes and/or exposures, further enhancing the ability to detect gene-environment interactions. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. We have enrolled a cohort of 50,000 women who have not had breast cancer. Recruitment took place from August 2003 through July 2009. We estimate that in the cohort of 50,000 sisters, aged 35–74 at enrollment, approximately 300 new cases of breast cancer will be diagnosed during each year of follow-up. *Frequency of Response:* For the remainder of the study, women will be contacted once each year to update contact information and health status (5–10 minutes per response); and asked to complete short (60–75 minutes, total) updates every two-to-three years. Women diagnosed with breast cancer or other health outcomes of interest are asked to provide additional information about their diagnosis (20 minutes per response) and their doctors will be contacted to provide medical records related to diagnosis and treatments (15 minutes per response). *Affected Public:* Study participants; medical office staff. *Type of Respondents:* Participants enrolled in high-risk cohort study of risk factors for breast cancer. The annual reporting burden is as follows: *Estimated Number of Respondents:* 50,000 study participants and 2100 medical office staff. *Estimated Number of Responses per Respondent:* See table below:

Activity (3-yrs)	Estimated number of respondents	Estimated responses per respondent	Average burden hours per response	Estimated total burden hours requested
Annual Updates	50,000	2	0.085	8,500
Bi/Trienniel Follow-Up	50,000	1	1.25	62,500
Incident BC Case Follow-Up	1800	1	0.33	594
Incident Other Case Follow-Up	300	1	0.33	99
Incident Case Medical Office Contact	2100	1	0.25	525
Total				72,218

Average Burden Hours Per Response: 0.7 hour; and *Estimated Total Burden Hours Requested:* 72,218 (over 3 years). The average annual burden hours requested is 24,073. The annualized cost to respondents is estimated at $14 (assuming $20 hourly wage × 0.7 hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3–05, PO Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541–4668 or E-mail your request, including your address to: ''*sandler@niehs.nih.gov.*''

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: September 22, 2009.

Marc Hollander,

NIEHS, Associate Director for Management.

[FR Doc. E9–23510 Filed 9–28–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Immunology Integrated Review Group, Innate Immunity and Inflammation Study Section.
Date: October 15–16, 2009.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Key Bridge Marriott, 1401 Lee Highway, Arlington, VA 22209.
Contact Person: Tina McIntyre, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, 301–594–6375, *mcintyrt@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict.
Date: October 15, 2009.
Time: 1 p.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)
Contact Person: Jose Fernando Arena, PhD, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–435–1735, *arenaj@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Microcirculation, Hypertension and Atherosclerosis.
Date: October 20–21, 2009.
Time: 11 a.m. to 9 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)
Contact Person: Anshumali Chaudhari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210, *chaudhaa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Investigations on Primary Immunodeficiency Diseases.
Date: October 20, 2009.
Time: 11 a.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)
Contact Person: Jin Huang, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095G, MSC 7812, Bethesda, MD 20892, 301–435–1230, *jh377p@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Eukaryotic Pathogens and Their Vectors.
Date: October 20, 2009.
Time: 3:30 p.m. to 5:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)
Contact Person: Richard G. Kostriken, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC, 7808 Bethesda, MD 20892, 301–402–4454, *kostrikr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PARO8–224: System Dynamics Methodologies.
Date: October 26, 2009.
Time: 11 a.m. to 12:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)
Contact Person: Fungai Chanetsa, MPH, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–435–1262, *fungai.chanetsa@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Cell Death and Neurodegeneration.
Date: October 26, 2009.
Time: 12 p.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)
Contact Person: Alexander Yakovlev, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, 301–435–1254, *yakovleva@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 22, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–23336 Filed 9–28–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Reproductive Sciences and Development.
Date: October 14–15, 2009.
Time: 10 a.m. to 1 p.m.
Agenda: To review and evaluate grant Applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)
Contact Person: Krish Krishnan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435–1041, *krishnak@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Mental Health and Neurodegenerative Disorders Members. Conflict.
Date: October 26–27, 2009.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)
Contact Person: Suzan Nadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 521 7B, MSC 7846, Bethesda, MD 20892, 301–435–1259, *nadis@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflicts: Hepatobiliary Pathophysiology, Toxicology and Pharmacology.
Date: October 26–27, 2009.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant Applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)
Contact Person: Bonnie L. Burgess-Beusse, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301–435–1783, *beusseb@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Ethical, Legal and Societal Implications of Genetics.
Date: October 29, 2009.
Time: 2 p.m. to 4:30 p.m.
Agenda: To review and evaluate grant Applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)
Contact Person: Diane L. Stassi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200,

MSC 7890, Bethesda, MD 20892, 301–435–2514, *stassid@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 21, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–23240 Filed 9–28–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0443]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 26, 2009, from 8:30 a.m. to 4 p.m.

Addresses: Electronic comments should be submitted to *http://www.regulations.gov*. Enter ''FDA–2009–N–0443'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. Comments received on or before October 5, 2009, will be provided to the committee before the meeting.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Minh Doan, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Minh.Doan@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code 3014512530. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss updating susceptibility test information in systemic antibacterial drug product labeling.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 16, 2009. Oral presentations from the public will be scheduled between approximately 12:45 p.m. and 1:45 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 9, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 12, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Minh Doan at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 9/23/09.

David Horowitz,

Assistant Commissioner for Policy

[FR Doc. E9–23437 Filed 9–28–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 16, 2009, from 8 a.m. to 5:30 p.m. and on November 17, 2009, from 8 a.m. to 5 p.m.

Location: Bethesda Marriott Hotel, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike (HFM–71), Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 16, 2009, in the morning the Committee will hear updates on the following topics: the HHS Advisory Committee on Blood Safety and Availability, Dengue virus outbreak, and 2009 A/H1N1 Pandemic and the impact on blood safety and availability. The Committee will then discuss blood donor deferral for malaria risk associated with travel to Mexico. In the afternoon the Committee will discuss the design of a new phase III study of pathogen inactivation of human platelets using the Cerus, INTERCEPT Blood System. On November 17, 2009, in the morning the Committee will discuss blood pressure and pulse as blood donor eligibility criteria, and in the afternoon the committee will discuss the public health need and performance characteristics of over-the-counter home-use HIV test kits.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background

material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: On November 16, 2009, from 8 a.m. to 5:30 p.m. and on November 17, 2009, from 8 a.m. to 3:15 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 9, 2009. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. and between 4 p.m. and 4:30 p.m. on November 16, 2009, and between approximately 10:30 a.m. and 11 a.m., and 2:15 and 2:45 p.m. on November 17, 2009. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 30, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 2, 2009.

Closed Committee Deliberations : On November 17, 2009, from approximately 3 p.m. until 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). The committee will hear presentations and discuss sponsor, trade secret and confidential information.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Pearline K. Muckelvene at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23434 Filed 9–28–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

''CORRECTED Version of Request for Information Regarding Development and Operation of a Transplantation Sentinel Network''

AGENCY: Office of Blood, Organ and Other Tissue Safety, Division of Healthcare Quality Promotion, Center for Preparedness, Detection, and Control of Infectious Diseases, Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Request for information notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking information on development and operation of a national transplantation sentinel network (TSN) for the United States, including resources needed for management of such a system. The purpose of the network is to detect and prevent disease transmission from organ and tissue allografts recovered for transplantation.

In June 2005, the CDC announced a Request for Application (RFA) through a cooperative agreement for development of a TSN for organizations that recover, process, distribute, and implant organs and tissues. The overall goal of the system was to improve patient safety for organ and tissue recipients. The RFA objectives were to: (1) Identify and track organs and tissues to facilitate intervention following recognition of infections among recipients or donors; (2) improve communication among those in the transplant community, healthcare facilities and public health agencies concerning potential risks for transmission of infections; and (3) improve pathologic and microbiologic capabilities on cadaveric donor specimen samples through shared resources. Development and field testing of the prototype was completed in 2008.

For this RFI, respondents are asked to describe experiences, plans or opinions regarding aspects of completing and operating a TSN system; system governance, security, and marketing; user training; and operational and infrastructure management. Responses need not address every aspect of this RFI; responses may be limited to address specific components or portions of a section. The specific sections requested for comments are: (1) Transition of Transplantation Transmission Sentinel Network (TTSN) Prototype to Full Production; (2) Standardization and Compatibility Issues; (3) Reporting Criteria; (4) Interoperability and Interfacing with Existing Data Sources; (5) System Operation and Infrastructure Management; (6) Analysis Plan including Feedback to Users; (7) Patient Health Information Privacy and Security; and (8) System Governance.

DATES: Comments must be submitted on or before December 11, 2009.

ADDRESSES: The entire TSN RFI can be accessed at *http://www.cdc.gov/ncidod/dhqp/pdf/ttsn/RFI_TSN_FedRegDoc_9909.pdf*. Electronic responses are preferred and should be sent to *TransplantRFI@cdc.gov*. Responses sent in hard copy format must be securely bound and sent to Debbie Seem, Office of Blood, Organ and Other Tissue Safety, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Building 16, MS–A07, 1600 Clifton Road, NE., Atlanta, GA 30329–4018, Telephone number: 404–639–3234, E-mail Address: *gqi4@cdc.gov*.

SUPPLEMENTARY INFORMATION: Each year in the United States, more than 28,000 solid organs and 2 million tissues are transplanted, including heart, lung, liver, kidneys, pancreas, intestine, bone, skin, heart valves, tendons, fascia and corneas. Donor-derived infections have been identified as a source of morbidity and mortality among both solid organ and tissue transplant recipients.

Infectious transmission identified in the past few years among solid organs have reflected a broad array of viruses, bacteria, and parasites, resulting in a high proportion of mortality amongst infected recipients; examples include HIV, hepatitis C virus (HCV), lymphocytic choriomeningitis virus, *Mycobacterium tuberculosis, Pseudomonas aeruginosa, Strongyloides* spp, and *Trypanosoma cruzi,* the etiologic agent of Chagas Disease. Malignancies also have been transmitted by solid organs. The Health Resources and Services Administration (HRSA) oversees the transplantation of solid organs through the Organ Procurement and Transplantation Network (OPTN) administered by the United Network for Organ Sharing (UNOS). OPTN policy requires reporting of all potential donor-derived infections to UNOS and

notification of institutions that recovered organs and tissues from that donor.

For tissues, disease transmission reports are less frequent but include transmission of HCV, Group A streptococcus, *Clostridium* spp, and *Chryseobacterium meningosepticum.* Unlike solid organs, risk of disease transmission depends on multiple factors related to the graft, including the feasibility and effectiveness of processing, which may vary according to tissue type and specific processing or manipulation procedures. The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research, regulates articles containing or consisting of human cells or tissues intended for implantation, transplantation, infusion, or transfer into a human recipient as human cells, tissues, or cellular or tissue-based products (HCT/Ps). HCT/P establishments are required to report to FDA all serious infections following graft transplantation. However, healthcare providers are not required to report adverse events, and healthcare facilities that do not perform any steps in tissue manufacture (recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing) are not subject to any FDA regulation for HCT/Ps.

Because organs and tissues can come from the same donor, a TSN should provide the mechanism for standardizing allograft identifiers, tracking of organ and tissue receipt, rapid notification of and response to potential disease transmissions, benchmarking of sentinel events and integration into a national biovigilance network. Specifically utilizing these system characteristics, all relevant recovery, processing, distributing and implanting institutions could rapidly communicate when a possible disease transmission is identified. This may prevent any further use of allografts with transmissible diseases in additional recipients after a problem is recognized and allow for earlier initiation of treatment or prophylaxis of recipients, potentially resulting in reduction of transmission events or resulting morbidity and mortality.

A national TSN needs to avoid duplication of the OPTN or of FDA reporting mechanisms; however, interfacing with these existing systems is critical. A national TSN could be coordinated by CDC in collaboration with other agencies of the Department of Health and Human Services (HHS) and external partners. In addition, HHS has recognized health information technology (IT) data and exchange standards to promote the exchange of health information across the healthcare landscape. The National Health IT activities initiated by the HHS Office of the National Coordinator for Health IT (ONC) has examined incorporating reporting criteria into Electronic Health Records (EHRs) which could assist in the possible identification and reporting of public health cases and adverse events. Reporting criteria which are incorporated and utilized by EHRs may include: general and specific reporting considerations, as well as the identification of data and events that may trigger a report, additional questions that may need to be asked of reporters, and the identification of specific data that may need to be reported. Integrating these requirements into a national TSN system is vital to the long term viability of the program.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–23427 Filed 9–28–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2009–0038]

Privacy Act of 1974; Department of Homeland Security/ALL–004 General Information Technology Access Account Records System of Records

AGENCY: Privacy Office; DHS.

ACTION: Notice of Privacy Act system of records update.

SUMMARY: In accordance with the Privacy Act of 1974 the Department of Homeland Security proposes to update and reissue a Department of Homeland Security system of records notice titled, Department of Homeland Security/ALL–004 General Information Technology Access Account Records System of Records. As a result of the biennial review of this system, the Department proposes to include the addition of social security numbers in the categories of records covered by the system for the purpose of identifying an individual for system access. Additionally, a new routine use has been added for the purpose of sharing with the media where appropriate. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Written comments must be submitted on or before October 29, 2009.

ADDRESSES: You may submit comments, identified by Docket Number DHS–2009–0038 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 703–483–2999.
- *Mail:* Mary Ellen Callahan, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.
- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions and for privacy issues please contact: Mary Ellen Callahan (703–235–0780), Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

As part of its efforts to maintain its Privacy Act record systems, the Department of Homeland Security (DHS) is updating and reissuing a Department-wide system of records under the Privacy Act (5 U.S.C. 552a) for DHS/ALL–004 General Information Technology Access Account Records System of Records (73 FR 28139, May 15, 2008). This will ensure that all components of DHS follow the same privacy rules for collecting and handling information technology access account records. The collection and maintenance of this information will assist DHS in managing the Department's information technology access account records.

This system of records is part of DHS' ongoing record integration and management efforts. This system consists of information collected in order to provide authorized individuals with access to DHS information technology resources. This information includes user name, business affiliation, account information and passwords.

In accordance with the Privacy Act of 1974, DHS is giving notice that it proposes to update and reissue a DHS system of records notice titled, DHS/ALL–004 General Information Technology Access Account Records System of Records. As a result of the biennial review of this system, the

Department proposes to include the addition of social security numbers in the categories of records covered by the system for the purpose of identifying an individual for system access. Additionally, a new routine use has been added for the purpose of sharing with the media where appropriate. This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information principles in a statutory framework governing the means by which the United States Government collects, maintains, uses, and disseminates individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency for which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass United States citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of DHS by complying with DHS Privacy Act regulations, 6 CFR Part 5.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, and the routine uses that are contained in each system in order to make agency record keeping practices transparent, to notify individuals regarding the uses to which their records are put, and to assist individuals to more easily find such files within the agency. Below is the description of DHS/ALL–004 General Information Technology Access Account Records System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM OF RECORDS:

DHS/ALL–004.

SYSTEM NAME:

Department of Homeland Security General Information Technology Access Account Records System of Records.

SECURITY CLASSIFICATION:

Sensitive but unclassified.

SYSTEM LOCATION:

Records are maintained at several Headquarters locations and in component offices of the Department of Homeland Security, in both Washington, DC and field locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include:

All persons who are authorized to access DHS information technology resources, including employees, contractors, grantees, private enterprises and any lawfully designated representative of the above and including representatives of Federal, State, territorial, tribal, local, international, or foreign government agencies or entities, in furtherance of the DHS mission. Also covered by this system are individuals who serve on DHS boards and committees; individuals who have business with DHS and who have provided personal information in order to facilitate access to DHS information technology resources; and individuals who are points of contact provided for government business, operations, or programs, and the individual(s) they list as emergency contacts.

CATEGORIES OF RECORDS IN THE SYSTEM:

- Name;
- Social Security Number;
- Business and affiliations;
- Facility positions held;
- Business telephone numbers;
- Cellular phone numbers;
- Pager numbers;
- Numbers where individuals can be reached while on travel or otherwise away from the office;
- Citizenship;
- Level of access;
- Home addresses;
- Electronic mail addresses of senders and recipients;
- Records on access to DHS computers and networks including user ID and passwords;
- Date and time of access;
- IP address of access;
- Logs of internet activity and records on the authentication of the access request;
- Records on the names and phone numbers of other contacts; and
- Positions or titles of contacts, their business/organizational affiliations and other contact information provided to the Department that is derived from other sources to facilitate authorized access to DHS Information Technology resources.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 44 U.S.C. 3101; and EO 9397 (SSN).

PURPOSE(S):

This system will collect a discreet set of personally identifiable information in order to provide authorized individuals access to or interact with DHS information technology resources. The information collected by the system will include full name, user name, account information, citizenship, business/organizational affiliation, contact information, and passwords. Directly resulting from the use of DHS information technology resources is the collection, review, and maintenance of any logs, audits, or other such security data regarding the use of such information technology resources.

The system enables DHS to maintain: Account information required for approved access to information technology; lists of individuals who are appropriate organizational points of contact; and lists of individuals who are emergency points of contact. The system will also enable DHS to provide individuals access to certain programs and meeting attendance and where appropriate allow for sharing of information between individuals in the same operational program to facilitate collaboration.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3), limited by privacy impact assessments, data sharing, or other agreements, as follows:

A. To the Department of Justice (including United States Attorney Offices) or other Federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. Any employee of DHS in his/her official capacity;

3. Any employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and DHS determines that the records are both relevant and necessary to the litigation and the use of such records is

compatible with the purpose for which DHS collected the records.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration or other Federal government agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and § 2906.

D. To an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. The Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) or harm to the individual that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate Federal, State, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To sponsors, employers, contractors, facility operators, grantees, experts, and consultants in connection with establishing an access account for an individual or maintaining appropriate points of contact and when necessary to accomplish a DHS mission function or objective related to this system of records.

I. To other individuals in the same operational program supported by an information technology system, where appropriate notice to the individual has been made that his or her contact information will be shared with other members of the same operational program in order to facilitate collaboration.

J. To Federal agencies such as Office of Personnel Management, the Merit Systems Protection Board, the Office of Management and Budget, Federal Labor Relations Authority, Government Accountability Office, and the Equal Employment Opportunity Commission in the fulfillment of these agencies' official duties.

K. To international, Federal, State and local, tribal, private and/or corporate entities for the purpose of the regular exchange of business contact information in order to facilitate collaboration for official business.

L. To appropriate agencies, entities, and persons when: It is suspected or confirmed that the security or confidentiality of information in the system of records has been compromised; DHS has determined that, as a result of the suspected or confirmed compromise, there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and the disclosure is made to such agencies, entities, and persons who are reasonably necessary to assist in DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

M. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are on paper and/or in digital or other electronic form. Digital and other electronic images are stored on a storage area network in a secured environment. Records, whether paper or electronic, may be stored at the DHS Headquarters or at the component level.

RETRIEVABILITY:

Information may be retrieved, sorted, and/or searched by an identification number assigned by computer, social security number, by facility, by business affiliation, e-mail address, or by the name of the individual, or other employee data fields previously identified in this SORN.

SAFEGUARDS:

Information in this system is safeguarded in accordance with applicable laws, rules and policies, including the DHS Information Technology Security Program Handbook and DHS Information Security Program Policy and Handbook. Further, Department of Homeland Security/ALL–004 General Information Technology Access Account Records system of records security protocols will meet multiple National Institute of Standards and Technology (NIST) Security Standards from Authentication to Certification and Accreditation. Records in the Department of Homeland Security/ALL–004 General Information Technology Access Account Records system of records will be maintained in a secure, password protected electronic system that will utilize security hardware and software to include: multiple firewalls, active intruder detection, and role-based access controls. Additional safeguards will vary by component and program. All records are protected from unauthorized access through appropriate administrative, physical, and technical safeguards. These safeguards include: restricting access to authorized personnel who have a ''need to know;'' using locks; and password protection identification features. Classified information is appropriately stored in accordance with applicable requirements. DHS file areas are locked

after normal duty hours and the facilities are protected from the outside by security personnel.

RETENTION AND DISPOSAL:

Records are securely retained and disposed of in accordance with the National Archives and Records Administration's General Records Schedule 24, section 6, ''User Identification, Profiles, Authorizations, and Password Files.'' Inactive records will be destroyed or deleted 6 years after the user account is terminated or password is altered, or when no longer needed for investigative or security purposes, whichever is later.

SYSTEM MANAGER AND ADDRESS:

For Headquarters and components of DHS, the System Manager is the Chief Privacy Officer and Chief Freedom of Information Act Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528. For components of DHS, the System Manager can be found at *http://www.dhs.gov/foia* under ''contacts.''

NOTIFICATION PROCEDURE:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Headquarters' or component's FOIA Officer, whose contact information can be found at *http://www.dhs.gov/foia* under ''contacts.'' If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Privacy Office, Department of Homeland Security, 245 Murray Drive, SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR Part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, *http://www.dhs.gov* or 1–866–431–0486. In addition you should provide the following:

- An explanation of why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created;
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records; and
- If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

A request for access to records in this system may be made by writing to the System Manager, identified above, in conformance with 6 CFR Part 5, which provides the rules for requesting access to Privacy Act records maintained by DHS.

CONTESTING RECORD PROCEDURES:

Same as ''Records Access Procedures'' above.

RECORD SOURCE CATEGORIES:

Information contained in this system is obtained from affected individuals/organizations/facilities, public source data, other government agencies and/or information already in other DHS records systems.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: September 23, 2009.

Mary Ellen Callahan

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. E9–23513 Filed 9–28–09; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–129F; Extension of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review; Form I–129F, Petition for Alien Fiance(e); OMB Control No. 1615–0001.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until November 30, 2009.

During this 60 day period, USCIS will be evaluating whether to revise the Form I–129F. Should USCIS decide to revise Form I–129F we will advise the public when we publish the 30-day notice in the **Federal Register** in accordance with the Paperwork Reduction Act. The public will then have 30 days to comment on any revisions to the Form I–129F.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Products Division, Clearance Officer, 111 Massachusetts Avenue, NW., Washington, DC 20529–2210. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov* When submitting comments by e-mail, please make sure to add OMB Control No. 1615–0001 in the subject box. Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Petition for Alien Fiancé.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–129F; U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–129F must be filed with U.S. Citizenship and Immigration Services (USCIS) by a citizen of the United States in order to petition for an alien spouse, fiancé, or child.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 200,000 responses at 1 hour and 30 minutes (1.50) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 300,000 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov/.*

We may also be contacted at: USCIS, Regulatory Products Division, 111 Massachusetts Avenue, NW., Washington, DC 20529–2210, Telephone number 202–272–8377.

Dated: September 24, 2009.

Sunday Aigbe,

Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. E9–23484 Filed 9–28–09; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form N–336, Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form N–336, Application Request for Hearing on a Decision in Naturalization Proceedings Under Section 336; OMB Control No. 1615–0050.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on June 2, 2009, at 74 FR 26418, allowing for a 60-day public comment period. USCIS did not receive any comments.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until October 29, 2009. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, Clearance Office, 111 Massachusetts Avenue, Washington, DC 20529–2210. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov,* and to the OMB USCIS Desk Officer via facsimile at 202–395–5806 or via e-mail at *oira_submission@omb.eop.gov.*

When submitting comments by e-mail, please make sure to add OMB Control No. 1615–0050 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Request for Hearing on a Decision in Naturalization Proceedings under Section 336.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N–366. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals and households. This form provides a method for applicants, whose applications for naturalization are denied, to request a new hearing by an Immigration Officer of the same or higher rank as the denying officer, within 30 days of the original decision.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 7,669 responses at 2 hours and 45 minutes (2.75) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 21,090 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov/.*

We may also be contacted at: USCIS, Regulatory Products Division, 111 Massachusetts Avenue, NW., Washington, DC 20529–2210, Telephone number 202–272–8377.

Dated: September 24, 2009.

Stephen Tarragon,

Deputy Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services.

[FR Doc. E9–23485 Filed 9–28–09; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–290B; Extension of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review; Form I–290B, Notice of Appeal or Motion; OMB Control No. 1615–0095.

* * * * *

The Department of Homeland Security, U.S. Citizenship and

Immigration Services (USCIS) has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until November 30, 2009.

During this 60-day period, USCIS will be evaluating whether to revise the Form I–290B. Should USCIS decide to revise Form I–290B we will advise the public when we publish the 30-day notice in the **Federal Register** in accordance with the Paperwork Reduction Act. The public will then have 30 days to comment on any revisions to the Form I–290B.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Products Division, Clearance Officer, 111 Massachusetts Avenue, NW., Washington, DC 20529–2210. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov.* When submitting comments by e-mail, please make sure to add OMB Control No. 1615–0095 in the subject box. Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Notice of Appeal or Motion.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–290B; U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–290B is necessary for USCIS to make a determination that appeal or motion to reopen or reconsider meet eligibility requirements, and for the Administrative Appeals Office to adjudicate the merits of the appeal, or reopen the motion.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 30,000 responses at 1 hour and 30 minutes (1.50) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 45,000 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov/.*

We may also be contacted at: USCIS, Regulatory Products Division, 111 Massachusetts Avenue, NW., Washington, DC 20529–2210, Telephone number 202–272–8377.

Dated: September 24, 2009.

Sunday Aigbe,

Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. E9–23486 Filed 9–28–09; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Grassland Bypass Project, Merced and Fresno Counties, CA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of Availability of the Final Environmental Impact Statement and Environmental Impact Report (Final EIS/EIR).

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) and the California Environmental Quality Act (CEQA), the Bureau of Reclamation (Reclamation), the Federal lead agency, and the San Luis & Delta-Mendota Water Authority (Authority), the State lead agency, have prepared a Final Environmental Impact Statement (EIS) and a Final Environmental Impact Report (EIR) for the continuation of the Grassland Bypass Project until December 31, 2019 (Project). Reclamation proposes to enter a Use Agreement with the Authority for the continued use of a portion of the San Luis Drain after 2009 to convey subsurface agricultural irrigation water to Mud Slough (North). The Central Valley Regional Water Quality Control Board would need to revise their Basin Plan Amendment to delay compliance with selenium objectives for 2010 and amend the existing Waste Discharge Requirements for the Project in order to allow for anticipated drainage discharge into Mud Slough, and the Authority and the California Department of Fish and Game will need to amend their existing Memorandum of Understanding for the portion of Mud Slough North in the State's China Island Wildlife Area. Reclamation and the Authority would need to remove existing and future sediments from the affected portion of the San Luis Drain.

A Notice of Availability of the joint Draft EIS/EIR was published in the **Federal Register** on Thursday, January 15, 2009 (74 FR 2615). The written comment period on the Draft EIS/EIR ended March 16, 2009. The Final EIS/EIR contains responses to all comments received and reflects comments and any additional information received during the review period.

DATES: Reclamation will not make a decision on the proposed action until at least 30 days after release of the Final EIS/EIR. After the 30-day waiting period, Reclamation will complete a Record of Decision (ROD). The ROD will state the action that will be implemented and will discuss all factors leading to the decision.

ADDRESSES: A compact disk or a copy of the Final EIS/EIR may be requested from Ms. Shauna McDonald, Bureau of Reclamation, 1243 'N' Street, Fresno, CA 93721–1831 by calling 559–487–5202, TDD 559–487–5933, or via e-mail at *SMcDonald@usbr.gov.* The Final document is also available on the following Web site: at *http://www.usbr.gov/mp/nepa/nepa_projdetails.cfm?Project_ID=3513.*

See **SUPPLEMENTARY INFORMATION** section for locations where copies of the Final EIS/EIR are available.

FOR FURTHER INFORMATION CONTACT: Ms. Shauna McDonald, Bureau of Reclamation at the phone number or e-mail address above.

SUPPLEMENTARY INFORMATION: The Project and the Grassland Drainage Area are located in Merced and Fresno Counties in the Central Valley of California. Prior to 1996 when the interim project was implemented, subsurface agricultural drainage water was conveyed through channels used to deliver water to wetland habitat areas which limited Reclamation's ability to deliver fresh water to the wetlands. The Project now consolidates subsurface drainage flows on a regional basis (from the 97,000 acre Grassland Drainage Area [GDA]) after source control measures, applies the drainage to salt tolerant crops to reduce the volume, utilizes a 4-mile channel to place it into the Federal San Luis Drain (Drain) at a point near Russell Avenue, (Milepost 105.72, Check 19) and then utilizes a 28-mile segment of the Drain to convey the remaining drainage flows around wetland habitat areas, after which it is discharged to Mud Slough and subsequently reaches the San Joaquin River. The Project has reduced the volume of agricultural drainage water discharged from the GDA, resulting in significant environmental improvements to wetlands water supply channels and the San Joaquin River.

The original Grassland Bypass Project was implemented in November 1995 through an ''Agreement for Use of the San Luis Drain'' (Agreement No. 6–07–20-w1319) between Reclamation and the Authority. A Finding of No Significant Impact (FONSI No. 96–1–MP) was adopted by Reclamation for the original project and environmental commitments set forth in the FONSI were made an integral component of the initial Use Agreement. The Use Agreement allowed use of the Drain for a 5-year period that concluded September 30, 2001. A new Use Agreement (Agreement No. 01–WC–20–2075) was completed on September 28, 2001, for the period through December 31, 2009. The Project also includes a monitoring program with biological, water quality, and sediment components. Results of the monitoring program are reviewed by an Oversight Committee quarterly, or as necessary, to implement the Use Agreement.

The Draft EIS/EIR considered the direct, indirect, and cumulative effects on the physical, natural, and human environment that may result from the continued use of the Grassland Bypass Channel and a 28-mile segment of the San Luis Drain; continued discharges to Mud Slough; sediment management options within that Drain segment; ongoing drainwater reuse and expansion of the San Joaquin River Water Quality Improvement Project reuse area to 6,900 acres, and programmatic consideration of future phases of the treatment and disposal program.

The Draft EIS/EIR addressed potentially significant environmental issues and recommends adequate and feasible mitigation measures to reduce or eliminate significant environmental impacts. The Draft EIS/EIR examined two other alternatives: No Action and the 2001 Requirements Alternative. This other action alternative would continue the selenium load reductions and incentive fees of the 2001 Use Agreement.

A public meeting was held on February 10, 2009, in Los Banos, CA. Copies of the Final EIS/EIR are available for public review at the following locations:

- Bureau of Reclamation, South-Central California Area Office, 1243 'N' Street, Fresno, CA 93721–1831.
- Bureau of Reclamation, Mid-Pacific Regional Office Library, 2800 Cottage Way, Sacramento, CA 95825.
- San Luis & Delta-Mendota Water Authority, 842 Sixth Street, Suite 7, Los Banos, CA 93635.
- Fresno County Public Library Government Publications, 2420 Mariposa Street, Fresno, CA 93721.
- San Francisco Public Library Government Documents, 100 Larkin Street, San Francisco, CA 94012.
- Stanislaus County Library, 1500 I Street, Modesto, CA 95354.
- Merced County Public Library, 1312 South 7th Street, Los Banos, CA 93635.
- University of California-Berkeley, Water Resources Archive, 410 O'Brien Hall, Berkeley, CA 94720.
- University of California Davis, Shields Library, Documents Department, 100 NW Quad, Davis, CA 95616.
- California State Library, 914 Capitol Mall, Suite E–29, Sacramento, CA 95814.

Before including your name, address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: August 7, 2009.

Brian Person,

Acting Deputy Regional Director, Mid-Pacific Region.

[FR Doc. E9–23428 Filed 9–28–09; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–09–L19100000–BJ0000–LRCM08RS3472]

Filing of Plat of Survey—Montana

AGENCY: Bureau of Land Management, Montana State Office, Interior.

ACTION: Notice of filing of plat of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, thirty (30) days from the date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Marvin Montoya, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5124 or (406) 896–5009.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the Bureau of Indian Affairs, Rocky Mountain Region, Billings, Montana, and was necessary to determine Individual and Tribal Trust lands.

The lands we surveyed are:

Principal Meridian, Montana

T. 26 N., R. 45 E.

The plat, in 6 sheets, representing the dependent resurvey of a portion of the east boundary, the corrective dependent resurvey of the lines between sections 2 and 11 and sections 8 and 17, the dependent resurvey of a portion of the subdivisional lines, a portion of the subdivision of sections 2, 3, 8, 10, 11, 13, and 16, the adjusted original meanders of the former left bank of the Missouri River, downstream, through sections 10, 11, 13, 15, 16, and 17, and the subdivision of sections 2, 3, 8, 10, 11, 13, and 16, and the survey of the meanders of the present left bank of the Missouri River, downstream, through sections 2, 3, 8, 10, 11, 13, 15, 16, and 17, the limits of erosion, downstream, through section 10, the meanders of the left bank of two relicted channels of the Missouri River, downstream, through sections 3, 8, 10, and 17, the medial lines of two relicted channels of the Missouri River, certain division of accretion and partition lines, and certain islands (Tracts 37 through 44), Township 26 North, Range 45 East, Principal Meridian, Montana, was accepted September 8, 2009. We will place a copy of the plat, in 6 sheets, and related field notes we described in the open files. They will be available to the public as a matter of information. If BLM receives a protest against this survey, as shown on this plat, in 6 sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in 6 sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Dated: September 16, 2009.

Steven G. Schey,

Acting Chief Cadastral Surveyor, Division of Resources.

[FR Doc. E9–23430 Filed 9–28–09; 8:45 am]

BILLING CODE 4310–$$–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–468 and 731–TA–1166–1167 (Preliminary)]

Certain Magnesia Carbon Bricks From China and Mexico

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (Commission) determines, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 19 U.S.C. 1673b(a)) (the Act), that there is a reasonable indication that an industry in the United States is materially injured,[2] or threatened with material injury [3] by reason of imports from China and Mexico of certain magnesia carbon bricks, provided for in subheadings 6902.10.10, 6902.10.50, 6815.91.00, and 6815.99.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (LTFV) and subsidized by the Government of China.

Commencement of Final Phase Investigation

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce (Commerce) of affirmative preliminary determinations in these investigations under sections 703(b) and 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) and 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On July 29, 2009, a petition was filed with the Commission and Commerce by Resco Products Inc., Pittsburgh, PA, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of certain magnesia carbon bricks from China and LTFV imports of certain magnesia carbon bricks from China and Mexico. Accordingly, effective July 29, 2009, the Commission instituted countervailing duty investigation No. 701–TA–468 (Preliminary) and antidumping duty investigation Nos. 731–TA–1166–1167 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of August 10, 2009 (74 FR 39969). The conference was held in Washington, DC, on August 19, 2009, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on September 14, 2009. The views of the Commission are contained in USITC Publication 4100 (September 2009), entitled *Certain Magnesia Carbon Bricks from China and Mexico: Investigation Nos. 701–TA–468 and 731–TA–1166–1167 (Preliminary).*

By order of the Commission.

Issued: September 22, 2009.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E9–23388 Filed 9–28–09; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioner Charlotte R. Lane, Commissioner Irving A. Williamson, and Commissioner Dean A. Pinkert determine that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of certain magnesia carbon bricks from China and Mexico.

[3] Chairman Shara L. Aranoff, Vice Chairman Daniel R. Pearson, and Commissioner Deanna Tanner Okun determine that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports of certain magnesia carbon bricks from China and determine that there is no reasonable indication that an industry in the United States is materially injured or threatened with material injury, or that the establishment of an industry in the United States is materially retarded, by reason of imports from Mexico of certain magnesia carbon bricks.

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–472 and 731–TA–1171–1172 (Preliminary)]

Certain Standard Steel Fasteners From China and Taiwan

AGENCY: United States International Trade Commission.

ACTION: Institution of antidumping and countervailing duty investigations and scheduling of preliminary phase investigations.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigations Nos. 701–TA–472 and 731–TA–1171–1172 (Preliminary) under sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)) (the Act) to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from China and/or Taiwan of certain standard steel fasteners (''fasteners''), provided for in subheadings 7318.15.20, 7318.15.80, and 7318.16.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce extends the time for initiation pursuant to sections 702(c)(1)(B) or 732(c)(1)(B) of the Act (19 U.S.C. 1671a(c)(1)(B) or 1673a(c)(1)(B)), the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by November 9, 2009. The Commission's views are due at Commerce within five business days thereafter, or by November 17, 2009.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

DATES: *Effective Date:* September 23, 2009.

FOR FURTHER INFORMATION CONTACT: Joshua Kaplan (202–205–3184), Office of Investigations, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov)*. The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted in response to a petition filed on September 23, 2009, by Nucor Fastener Division, St. Joe, IN.

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Commission's Director of Investigations has scheduled a conference in connection with these investigations for 9:30 a.m. on October 14, 2009, at the U.S. International Trade Commission Building, 500 E Street, SW., Washington, DC. Parties wishing to participate in the conference should contact Joshua Kaplan (202–205–3184) not later than October 9, 2009, to arrange for their appearance. Parties in support of the imposition of antidumping and/or countervailing duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written submissions.—As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before October 19, 2009, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (November 8, 2002). Even where electronic filing of a document is permitted, certain documents must also be filed in paper form, as specified in II (C) of the Commission's Handbook on Electronic Filing Procedures, 67 FR 68168, 68173 (November 8, 2002).

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

By order of the Commission.

Issued: September 24, 2009.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E9–23501 Filed 9–28–09; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–636]

In the Matter of Certain Laser Imageable Lithographic Printing Plates: Notice of Commission Determination To Review in Part an Initial Determination Finding Respondents in Violation of Section 337 and on Review To Affirm the Administrative Law Judge's Determination That There Is a Violation of Section 337; Schedule for Briefing on the Issues on Review and on Remedy, Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: The United States International Trade Commission hereby provides notice that it has determined to review in part the final initial determination (''ID'') issued by the presiding administrative law judge (''ALJ'') finding a violation of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) by the remaining respondents in the above-captioned investigation. Specifically, the Commission has determined to modify the ALJ's claim construction analysis, but to affirm the ALJ's determination of violation of section 337. Notice is further given that the Commission is requesting briefing on remedy, the public interest, and bonding with respect to the respondents found in violation.

FOR FURTHER INFORMATION CONTACT: Paul M. Bartkowski, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–5432. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired

persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on March 7, 2008, based on a complaint filed by Presstek, Inc. (''Presstek'') of Hudson, New Hampshire. The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain laser imageable lithographic printing plates that infringe certain claims of U.S. Patent Nos. 5,339,737 (''the '737 patent'') and 5,487,338 (''the '338 patent'') and U.S. Trademark Reg. No. 1,711,005 (''the '005 trademark''). All assertions relating to the '005 trademark were subsequently terminated from the investigation. Certain respondents have been terminated from the investigation, and the remaining respondents are VIM Technologies, Ltd., Hanita Coatings RCA, Ltd., AteCe Canada, Guaranteed Service & Supplies, Inc., Recognition Systems, Inc., and Spicers Paper, Inc. (hereinafter referred to collectively as ''Respondents'').

On July 24, 2009, the ALJ issued the subject ID finding that a violation of section 337 has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain laser imageable lithographic printing plates by reason of infringement of one or more of claims 1, 10, and 27 of the '737 patent and by reason of infringement of one or more of claims 20, 21, and 23 of the '338 patent.

Respondents filed a combined petition for review of the ID, which Presstek and the Commission investigative attorney opposed. Having reviewed the record of this investigation, including Respondents' petition for review and the responses thereto, the Commission has determined to review certain aspects of the ID relating to claim construction. On review, the Commission has determined to modify the ID by supplementing the ALJ's claim construction analysis for reasons that will be provided in the Commission's opinion on remedy, the public interest, and bonding, and has determined to affirm the ALJ's determination of violation of section 337.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease-and-desist orders that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see In the Matter of Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease-and-desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Complainants and the IA are also requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the dates that the patents expire and the HTSUS numbers under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than close of business on October 6, 2009. Reply submissions, if any, must be filed no later than the close of business on October 13, 2009. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.42).

By order of the Commission.

Issued September 24, 2009.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E9–23499 Filed 9–28–09; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–643]

In the Matter of Certain Cigarettes and Packaging Thereof: Notice of Commission Final Determination of Violation of Section 337; Termination of Investigation; Issuance of General Exclusion Order

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined that there is a violation of 19 U.S.C. 1337 by Alcesia SRL (''Alcesia'') of Moldova in the above-captioned investigation and has issued a general exclusion order. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Daniel E. Valencia, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–1999. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On April 4, 2008, the Commission instituted this investigation, based on a complaint filed by Philip Morris USA Inc. (''PM USA'') of Richmond, VA, naming Alcesia; Emarket Systems Ltd. (d.b.a. all-discount-cigarettes.com); Jamen Chong (d.b.a. asiadfs.com); Tri-kita (d.b.a. cheapcigarettes4all.com); Mr. Eduard Lee (d.b.a. cigarettesonlineshop.com); Zonitech Properties Limited (d.b.a. cigline.net); Zonitech Properties Limited (d.b.a. shopping-heaven.com); Cendano (d.b.a. galastore.com); Ms. Svetlana Trevinska (d.b.a. save-on-cigarettes.com); LMB Trading SA (d.b.a. k2smokes.ch); G.K.L. International SRL (d.b.a. all-cigarettes-brandsxom); G.K.L. International SRL (d.b.a. smokerjim.net); and Best Product Solution Ltd. as respondents. The complaint alleges violations of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, in the importation into the United States of certain cigarettes and packaging thereof that infringe registered trademarks owned by PM USA. Subsequent to institution all respondents but Alcesia were found in default.

On February 3, 2009, the ALJ issued Order No. 19, a summary initial determination (''ID'') granting PM USA's motion for summary determination that Alcesia has violated section 337 with respect to three trademarks: U.S. Trademark Registration Nos. 68,502; 378,340; and 894,450. On February 17, 2009, Alcesia petitioned for review of the ID. On February 24 and 25, 2009, PM USA and the Commission Investigative Attorney (''IA''), respectively, opposed Alcesia's petition for review.

On April 9, 2009, the Commission determined to review the ID and requested written submissions on the issues under review, remedy, the public interest, and bonding. On May 8, 2009, the parties filed opening submissions, and on May 29, 2009, the parties filed response submissions. Several non-parties also filed submissions addressing issues related to remedy and the public interest.

Having examined the record of this investigation, including the ALJ's summary ID, the Commission has determined to affirm the ALJ's finding that Alcesia has violated section 337 by selling for importation into the United States gray market cigarettes that infringe PM USA's Marlboro®, Parliament®, and Virginia Slims® trademarks. In particular, the Commission has adopted the ALJ's finding that a lack of English-language warning labels from the Surgeon General on the gray market cigarette packages makes them materially different from the U.S. market cigarettes. The Commission, however, has declined to adopt the ID's finding that the gray market cigarettes' susceptibility to seizure under the Imported Cigarette Compliance Act makes them materially different from U.S. market cigarettes. The Commission also takes no position on the ID's finding that a material difference exists between the gray market and U.S. market cigarettes because PM USA exercises quality control over procedures for distribution, storage, and transportation of the U.S. market cigarettes, while it does not exercise this control over the gray market cigarettes.

The Commission has determined that the appropriate form of relief is a general exclusion order prohibiting the unlicensed entry of Marlboro®, Parliament®, or Virginia Slims® branded cigarettes that (a) infringe one or more of the following U.S. Trademark Reg. Nos. 68,502, 378,340, and 894,450 and (b) are materially different from cigarettes manufactured by or under authority of PM USA for sale and use in the United States.

The Commission further determined that the public interest factors enumerated in section 337(d) (19 U.S.C. 1337(d)) do not preclude issuance of the general exclusion order. Finally, the Commission determined that the amount of bond during the Presidential review period (19 U.S.C. 1337(j)) shall be 100 percent of the entered value of the article that is subject to the order. The Commission's order was delivered to the President and the United States Trade Representative on the day of its issuance.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in sections 210.42–50 of the Commission's Rules of Practice and Procedure (19 CFR 210.42–50).

By order of the Commission.

Issued: September 21, 2009.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E9–23389 Filed 9–28–09; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Office of Information Policy; Attorney General Memorandum for Executive Departments and Agencies Concerning the Freedom of Information Act

AGENCY: Department of Justice.

ACTION: Notice.

SUMMARY: On January 21, 2009, the President issued a memorandum for the heads of executive departments and agencies on the Freedom of Information Act (FOIA). That memorandum required that the Attorney General issue new guidelines governing the FOIA to the heads of executive departments and agencies, reaffirming the commitment to accountability and transparency, and to publish such guidelines in the **Federal Register**. Pursuant to the President's directive, the Attorney General issued new FOIA guidelines on March 19, 2009. Those guidelines are now published here.

FOR FURTHER INFORMATION CONTACT: Melanie Ann Pustay, Director, Office of Information Policy, U.S. Department of Justice, 1425 New York Avenue, NW., Suite 11050, Washington, DC 20009, telephone (202) 514–3642.

SUPPLEMENTARY INFORMATION: In his January 21, 2009 memorandum on the Freedom of Information Act (FOIA) the President stated that ''[a]ll agencies should adopt a presumption in favor of disclosure, in order to renew their commitment to the principles embodied in FOIA, and to usher in a new era of open Government.'' This memorandum is published in the **Federal Register** at 74 FR 4683–84 and is available at *http://www.whitehouse.gov/thepress_office/FreedomofInformationAct/.*

The President also directed the Attorney I General ''to issue new guidelines governing the FOIA to the heads of executive departments and agencies, reaffirming the commitment to accountability and transparency.'' Pursuant to this instruction, the

Attorney General issued new FOIA guidelines on March 19, 2009; The purpose of the Attorney General's memorandum is to underscore the FOIA's purpose of providing an open government and to help ensure that it is realized in practice. The guidelines provided by the Attorney General stress the important implications of the President's call for a presumption of openness, emphasize that the FOIA is everyone's responsibility, and direct agencies to work proactively and promptly. A full text of these guidelines is available on the Department of Justice's Web site at *http://www.usdoj.gov/ag/foia-memo-march2009.pdf.* Pursuant to the President's instruction, the Attorney General's guidelines are also published here.

Dated: September 17, 2009.

Melanie Ann Pustay,

Director, Office of Information Policy.

[FR Doc. E9–23375 Filed 9–28–09; 8:45 am]

BILLING CODE M

DEPARTMENT OF LABOR

Employment and Training Administration

Request for Comments on the Proposed Information Collection for Trade Adjustment Assistance (TAA) Reserve Funding Request Form. 1205–0275, Extension With No Revisions

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, ETA is soliciting comments concerning the proposed extension of data collection for the ETA Form 9117 (formerly ETA–9023), Trade Adjustment Assistance (TAA) Reserve Funding Request Form (1205–0275, expires 1/31/2010).

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee's section below on or before November 30, 2009.

ADDRESSES: Submit written comments to Chris Meservy, Program Analyst, Room C–5428, Employment and Training Administration, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone number: 202–693–2806 (this is not a toll-free number). Fax: 202–693–3584. E-mail: *meservy.chris.h@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Trade Adjustment Assistance (TAA) program provides assistance to workers that have been adversely affected by foreign trade. Under the Trade Act of 1974, as amended by the American Recovery and Reinvestment Act of 2009, the statutory training cap is $575 million each year, with additional funding available for job search and relocation allowances and State administration. To be eligible for TAA benefits and services, a group of workers, a company official, a union or other duly authorized representative, or a One Stop Operator or partner must file a petition with the Department of Labor. If the Department determines that the workers meet the statutory criteria, it issues a certification of eligibility for the workers in the group to apply for benefits and services through partnerships between the State Workforce Agencies (SWAs) and the One Stop Career Center system.

II. Review Focus

The Department of Labor is particularly interested in comments which:

* Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

* Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

* Enhance the quality, utility, and clarity of the information to be collected; and

* Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions

Type of Review: Extension with no revisions.

Title: Trade Adjustment Assistance (TAA) Reserve Funding Request.

OMB Number: 1205–0275.

Affected Public: State, local or Tribal government.

Total Respondents: 25.

Frequency: On occasion.

Forms: ETA 9117, ETA 9023.

Average Time per Response: 3 hours.

Estimated Total Burden Hours: 75.

Comments submitted in response to this ICR will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: This 23rd day of September 2009.

Jane Oates,

Assistant Secretary, Employment and Training Administration.

[FR Doc. E9–23361 Filed 9–28–09; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Materials Research; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463 as amended), the National Science Foundation announces the following meeting:

Name: Site visit review of the Materials Research Science and Engineering Center (MRSEC) at the University of Wisconsin, #1203.

Dates & Times:

October 25, 2009; 5 p.m.–7 p.m.
October 26, 2009; 7:30 a.m.–8 p.m.
October 27, 2009; 8 a.m.–3 p.m.

Place: University of Wisconsin, Madison, WI.

Type of Meeting: Part-open.

Contact Person: Dr. Charles Ying, Program Director, Materials Research Science and Engineering Centers Program, Division of Materials Research, Room 1065, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone (703) 292–8428.

Purpose of Meeting: To provide advice and recommendations concerning further support of the MRSEC at the University of Wisconsin.

Agenda:

Sunday, October 25, 2009

5 p.m.–5:15 p.m.: Closed—Executive Session.
5:15 p.m.–7 p.m.: Open—Review of the Wisconsin MRSEC.

Monday, October 26, 2009

7:30 a.m.–8:45 a.m.: Closed—Executive Session.
8:45 a.m.–4:30 p.m.: Open—Review of the Wisconsin MRSEC.
4:30 p.m.–8 p.m.: Closed—Executive Session and Dinner Meeting.

Tuesday, October 27, 2009

8 a.m.–9 a.m.: Closed—Executive session.
9 a.m.–10 a.m.: Open—Review of the Wisconsin MRSEC.
10 a.m.–3 p.m.: Closed—Executive Session, Draft and Review Report.

Reason for Closing: The work being reviewed may include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552 b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: September 24, 2009.

Susanne Bolton,

Committee Management Officer.

[FR Doc. E9–23415 Filed 9–28–09; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Polar Programs; Notice of Meeting

In accordance with Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Advisory Committee for Polar Programs (1130).

Date/Time:

November 9, 2009, 8 a.m. to 5 p.m.
November 10, 2009, 8 a.m. to 3 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Room 1235.

Type of Meeting: Open.

Contact Person: Sue LaFratta, Office of Polar Programs (OPP). National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. (703) 292–8030.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To advise NSF on the impact of its policies, programs, and activities on the polar research community, to provide advice to the Director of OPP on issues related to long-range planning.

Agenda: Staff presentations and discussion on opportunities and challenges for polar research, education and infrastructure; discussion of Committee of Visitors meetings; transformative research.

Dated: September 24, 2009.

Susanne Bolton,

Committee Management Officer.

[FR Doc. E9–23408 Filed 9–28–09; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of Permit Modification Received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 part 670 of the Code of Federal Regulations. This is the required notice of a requested permit modification.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by October 29, 2009. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy at the above address or (703) 292–7405.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Description of Permit Modification Requested: The Foundation issued a permit (2007–003) to Dr. Rennie S. Holt, Direct of the Antarctic Marine Living Resources Program, on December 26, 2006. Dr. Holt has retired and the permit is now under the name of the new Director, Dr. George Watters. The issued permit allows the applicant to conduct census surveys, attendance, diving, foraging, diet, age determination, pathology, and long term monitoring (tagging) of pennipeds and seabirds.

The applicant requests the following modifications to his permit to:

(1) Capture to instrument, tag (flipper and PIT), collect blood, vibrissae, muscle/blubber biopsy, milk (if lactating), DNA sample, weight and measure 30 adult and 30 juvenile Weddell seals.

(2) Increase the total allowable tagged Leopard seals from 20 to 40. To avoid capture and limit the amount of impact on individual seals, the applicant would opportunistically tag Leopard seals on a rear flipper without capture.

(3) The applicant would like to deploy up to 110 microprocessors attached to existing flipper tags. No additional takes requested as the GLS tags will be added while implementing other protocols permitted elsewhere in the permit. Tags will be recovered the following season.

(4) Increase the already permitted number of takes from 50 to 100 juvenile Antarctic Fur seals to replace lost tags.

(5) Increase the number takes of adult Antarctic Fur seals from 20 to 100 to collect DNA samples (2mm biopsy punch on the end of a jab stick (ski pole).

(6) PIT (Passive Integrated Transponders) tags will be placed subcutaneously between the tail and pelvis on the mid-line of each animal.

Location: Cape Shirreff and San Telmo Island, Livingston Island, South Shetland Islands.

Dates: October 1, 2009 to April 20, 2011.

Nadene G. Kennedy,

Permit Officer, Office of Polar Programs.

[FR Doc. E9–23379 Filed 9–28–09; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of Permit Applications Received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by October 29, 2009. This application may be inspected by

interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy at the above address or (703) 292–7405.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

The applications received are as follows:

1. *Applicant:* Permit Application No. 2010–016. Philip R. Kyle, Department of Earth & Environmental Science, New Mexico Institute of Mining and Technology, Socorro, NM 87801.

Activity for Which Permit Is Requested

Enter Antarctic Specially Protected Area. The applicant plans to enter Tramway Ridge, Mount Erebus (ASPA 130) measure soil temperatures and fluxes of CO_2 and CO gases as part of the on-going surveillance of the active volcano. In addition, the applicant will undertake a survey of the geothermal features in the summit area of Mount Erebus.

Location

Tramway Ridge, Mount Erebus (ASPA 130).

Dates

December 1, 2009 to January 31, 2012.

Nadene G. Kennedy,

Permit Officer, Office of Polar Programs.

[FR Doc. E9–23380 Filed 9–28–09; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2009–0425]

Draft Regulatory Guide: Issuance, Availability

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Issuance and Availability of Draft Regulatory Guide, DG–8039, ''Methods for Estimating Effective Dose Equivalent from External Exposure.''

FOR FURTHER INFORMATION CONTACT: Roger Pedersen, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: (301) 415–3162, e-mail to *Roger.Pedersen@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft guide in the agency's ''Regulatory Guide'' series. This series was developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

The draft regulatory guide (DG), entitled, ''Methods for Estimating Effective Dose Equivalent from External Exposure,'' is temporarily identified by its task number, DG–8039, which should be mentioned in all related correspondence. DG–8039 will be a new regulatory guide.

This regulatory guide describes dosimetry methods that the NRC considers acceptable for determining effective dose equivalent for external (EDEX) radiation exposures. These methods provide a conservative estimate of EDEX and may be used to calculate TEDE in demonstrating compliance with TEDE-based regulatory requirements consistent with the provisions in 10 CFR 20.1201(c).

Title 10, section 20.1003, ''Definitions,'' of the *Code of Federal Regulations* (10 CFR 20.1003) defines total effective dose equivalent (TEDE) as the sum of the effective dose equivalent (EDE) (for external exposures) and the committed EDE (for internal exposures). In 10 CFR 20.1201(a), the NRC provides an annual dose limit of 0.05 sievert (5 rem) TEDE and in 10 CFR 20.1201(c) requires that when an external personal monitoring device is used to measure external exposure, the deep-dose equivalent (DDE) must be used as an estimate of the EDE unless the EDE is determined more directly by a dosimetry method approved by the NRC. In using the DDE to estimate the EDE, the assigned DDE must be for the part of the body receiving the highest radiation exposure.

II. Further Information

The NRC staff is soliciting comments on DG–8039. Comments may be accompanied by relevant information or supporting data and should mention DG–8039 in the subject line. Comments submitted in writing or in electronic form will be made available to the public in their entirety through the NRC's Agencywide Documents Access and Management System (ADAMS).

Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed. You may submit comments by any of the following methods:

1. *Mail comments to:* Rulemaking and Directives Branch, Mail Stop: TWB–05–B01M, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

2. *Federal e-Rulemaking Portal:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2009–0425. Address questions about NRC dockets to Carol Gallagher, 301–492–3668; e-mail *Carol.Gallagher@nrc.gov.*

3. *Fax comments to:* Rulemaking and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission at (301) 492–3446.

Comments would be most helpful if received by November 26, 2009. Comments received after that date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Requests for technical information about DG–8039 may be directed to the NRC contact, Roger Pedersen at (301) 415–3162 or e-mail to *Roger.Pedersen@nrc.gov.*

Electronic copies of DG–8039 are available through the NRC's public Web site under Draft Regulatory Guides in the ''Regulatory Guides'' collection of the NRC's Electronic Reading Room at

http://www.nrc.gov/reading-rm/doc-collections/. Electronic copies are also available in ADAMS *(http://www.nrc.gov/reading-rm/adams.html),* under Accession No. ML091390066.

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR) located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555–0001. The PDR can also be reached by telephone at (301) 415–4737 or (800) 397–4205, by fax at (301) 415–3548, and by e-mail to *pdr.resource@nrc.gov.*

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 3rd day of September 2009.

For the Nuclear Regulatory Commission.

Andrea D. Valentin,

Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. E9–23433 Filed 9–28–09; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2009–0427; Docket No. 030–10491]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment to Byproduct Materials License No. 29–16145–01, for Unrestricted Release of Robert Wood Johnson University Hospital at Hamilton's Clinical Pharmacology Unit Located at #3 Hamilton Health Place, Hamilton, NJ

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Environmental Assessment and Finding of No Significant Impact for license amendment.

FOR FURTHER INFORMATION CONTACT: Héctor Bermúdez, Sr. Health Physicist, Medical Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406; telephone (404) 562–4734; fax number (610) 337–5269; or by e-mail: *Hector.Bermudez@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to byproduct materials License No. 29–16145–01. This license is held by Robert Wood Johnson University Hospital at Hamilton (the Licensee), for one of its facilities located at #3 Hamilton Health Place (the Facility). Issuance of the amendment would authorize release of the Facility for unrestricted use. The Licensee requested this action in a letter dated December 10, 2008. The NRC has prepared an Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of Title 10, *Code of Federal Regulations* (CFR), Part 51 (10 CFR Part 51). Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The amendment will be issued to the Licensee following the publication of this FONSI and EA in the **Federal Register**.

II. Environmental Assessment

Identification of Proposed Action

The proposed action would approve the Licensee's December 18, 2008, license amendment request, resulting in release of the Facility for unrestricted use. License No. 29–16145–01 was issued on September 19, 1974, to Hamilton Hospital (now Robert Wood Johnson University Hospital at Hamilton) pursuant to 10 CFR Part 30, and has been amended periodically since that time. This license authorizes the Licensee to use unsealed byproduct materials for the purposes of medical diagnosis and treatment of humans.

The building that houses the Facility is a single story building located in a mixed residential/commercial area. The licensee occupied approximately 12,000 square feet of space in part of the building, consisting of office space and laboratories. Within the Facility, use of licensed materials was confined to Rooms 102, 103, 104, 126, 154, 180, 195C, 216, 217, 220, 221, and 242.

Routine licensed activities ceased in 2008 and the licensee initiated a survey of the Facility. Based on the Licensee's historical knowledge of the site and the conditions of the Facility, the Licensee determined that only routine decontamination activities, in accordance with the NRC-approved operating radiation safety procedures, would be required. The Licensee was not required to submit a decommissioning plan to the NRC because worker cleanup activities and procedures are consistent with those approved for routine operations. The Licensee conducted surveys of the Facility and provided information to the NRC to demonstrate that it meets the criteria in Subpart E of 10 CFR Part 20 for unrestricted release and for license termination.

Need for the Proposed Action

The Licensee has ceased conducting licensed activities at the Facility, and seeks the unrestricted use of its Facility.

Environmental Impacts of the Proposed Action

The historical review of licensed activities conducted at the Facility shows that such activities involved use of the following radionuclide with a half-life greater than 120 days in unsealed form: Carbon-14. The Licensee conducted a final status survey in April 2009. This survey covered all the areas of use at the Facility. The final status survey report was attached to the Licensee's letter dated April 30, 2009. The Licensee elected to demonstrate compliance with the radiological criteria for unrestricted release as specified in 10 CFR 20.1402 by using the screening approach described in NUREG–1757, ''Consolidated NMSS Decommissioning Guidance,'' Volume 2. The Licensee used the radionuclide-specific derived concentration guideline levels (DCGLs), developed there by the NRC, which comply with the dose criterion in 10 CFR 20.1402. These DCGLs define the maximum amount of residual radioactivity on building surfaces, equipment, and materials, and in soils, that will satisfy the NRC requirements in Subpart E of 10 CFR Part 20 for unrestricted release. The Licensee's final status survey results were below these DCGLs and are in compliance with the As Low As Reasonably Achievable (ALARA) requirement of 10 CFR 20.1402. The NRC thus finds that the Licensee's final status survey results are acceptable.

Based on its review the staff has determined that the affected environment and any environmental impacts associated with the proposed action are bounded by the impacts evaluated by the ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC–Licensed Nuclear Facilities'' (NUREG–1496) Volumes 1–3 (ML042310492, ML042320379, and ML042330385). The staff finds there were no significant environmental impacts from the use of radioactive material at the Facility. The NRC staff reviewed the docket file records and the final status survey report to identify any non-radiological hazards that may have impacted the environment surrounding the Facility. No such hazards or impacts to the environment were identified. The NRC has identified no other radiological or non-radiological activities in the area

that could result in cumulative environmental impacts.

The NRC staff finds that the proposed release of the Facility for unrestricted use is in compliance with 10 CFR 20.1402. Based on its review, the staff considered the impact of the residual radioactivity at the Facility and concluded that the proposed action will not have a significant effect on the quality of the human environment.

Environmental Impacts of the Alternatives to the Proposed Action

Due to the largely administrative nature of the proposed action, its environmental impacts are small. Therefore, the only alternative the staff considered is the no-action alternative, under which the staff would leave things as they are by simply denying the amendment request. This no-action alternative is not feasible because it conflicts with 10 CFR 30.36(d), requiring that decommissioning of byproduct material facilities be completed and approved by the NRC after licensed activities cease. The NRC's analysis of the Licensee's final status survey data confirmed that the Facility meets the requirements of 10 CFR 20.1402 for unrestricted release. Additionally, denying the amendment request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are therefore similar, and the no-action alternative is accordingly not further considered.

Conclusion

The NRC staff has concluded that the proposed action is consistent with the NRC's unrestricted release criteria specified in 10 CFR 20.1402. Because the proposed action will not significantly impact the quality of the human environment, the NRC staff concludes that the proposed action is the preferred alternative.

Agencies and Persons Consulted

NRC provided a draft of this Environmental Assessment to the State of New Jersey, Department of Environmental Protection, Bureau of Radiological Health for review on August 18, 2009. The State of New Jersey responded by e-mail on September 11, 2009. The State agreed with the conclusions of the EA and otherwise had no comments.

The NRC staff has determined that the proposed action is of a procedural nature, and will not affect listed species or critical habitat. Therefore, no further consultation is required under Section 7 of the Endangered Species Act. The NRC staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act.

III. Finding of No Significant Impact

The NRC staff has prepared this EA in support of the proposed action. On the basis of this EA, the NRC finds that there are no significant environmental impacts from the proposed action, and that preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

IV. Further Information

Documents related to this action, including the application for license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents related to this action are listed below, along with their ADAMS accession numbers.

1. Amendment request dated December 10, 2008 (ML083640174);
2. Additional information on amendment request dated April 30, 2009 (ML091240536);
3. Additional information on amendment request dated June 29, 2009 (ML091820556);
4. NUREG–1757, ''Consolidated NMSS Decommissioning Guidance;'' Title 10, *Code of Federal Regulations,* Part 20, Subpart E, ''Radiological Criteria for License Termination;''
5. Title 10, *Code of Federal Regulations,* Part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;'' and
6. NUREG–1496, ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC–Licensed Nuclear Facilities.''

If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.* These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Region I, 475 Allendale Road, King of Prussia, PA this 23rd day of September 2009.

For the Nuclear Regulatory Commission.

James P. Dwyer,

Chief, Commercial & R&D Branch, Division of Nuclear Materials Safety, Region I.

[FR Doc. E9–23455 Filed 9–28–09; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2009–0430; Docket No. 030–33542]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment to Byproduct Materials License No. 29–30152–01, for Unrestricted Release of the Ligand Pharmaceuticals Facility in Cranbury, NJ

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of environmental assessment and finding of no significant impact for license amendment.

FOR FURTHER INFORMATION CONTACT: Betsy Ullrich, Senior Health Physicist, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406; telephone (610) 337–5040; fax number (610) 337–5269; or by e-mail: *elizabeth.ullrich@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Byproduct Materials License No. 29–30152–01. This license is held by Ligand Pharmaceuticals (the Licensee), for its Ligand Pharmaceuticals facility (the Facility), located at 3000 Eastpark Boulevard in Cranbury, New Jersey. Issuance of the amendment would authorize release of the East Wing of the Facility for unrestricted use. The Licensee requested this action in a letter dated July 29, 2009. The NRC has prepared an Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of Title 10, *Code of Federal Regulations* (CFR), Part 51 (10 CFR Part 51). Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The amendment will be issued to the Licensee following

the publication of this FONSI and EA in the **Federal Register.**

II. Environmental Assessment

Identification of Proposed Action

The proposed action would approve the Licensee's July 29, 2009, license amendment request, resulting in release of the East Wing of the Facility for unrestricted use. License No. 29–30152–01 was issued on July 21, 1994, pursuant to 10 CFR Part 30, and has been amended periodically since that time. This license authorized the Licensee to use unsealed byproduct material for purposes of conducting research and development activities on laboratory bench tops and in hoods.

The Facility contains approximately 58,000 square feet of office space, laboratories, and hallways. The Facility is located in a research park in a commercial area. Within the East Wing of the Facility, use of licensed materials was confined to nine laboratories and one room used for waste storage.

In winter 2009, the Licensee ceased licensed activities and initiated a survey and decontamination of the East Wing of the Facility. Based on the Licensee's historical knowledge of the site and the conditions of the East Wing of the Facility, the Licensee determined that only routine decontamination activities, in accordance with their NRC-approved, operating radiation safety procedures, were required. The Licensee was not required to submit a decommissioning plan to the NRC because worker cleanup activities and procedures are consistent with those approved for routine operations. The Licensee conducted surveys of the East Wing of the Facility and provided information to the NRC to demonstrate that it meets the criteria in Subpart E of 10 CFR Part 20 for unrestricted release.

Need for the Proposed Action

The Licensee has ceased conducting licensed activities in the East Wing of the Facility, and seeks the unrestricted use of the East Wing of its Facility.

Environmental Impacts of the Proposed Action

The historical review of licensed activities conducted in the East Wing of the Facility shows that such activities involved use of the following radionuclides with half-lives greater than 120 days: Hydrogen-3, carbon-14, and calcium-45. Prior to performing the final status survey, the Licensee conducted decontamination activities, as necessary, in the areas of the East Wing of the Facility affected by these radionuclides.

The Licensee conducted a final status survey between April 13 and May 1, 2009. This survey covered Laboratories 110, 120, 130, 140, 150, 175, 185, and 187; the waste room; and the connecting hallways. The final status survey report was attached to the Licensee's amendment request dated July 29, 2009. The Licensee elected to demonstrate compliance with the radiological criteria for unrestricted release as specified in 10 CFR 20.1402 by using the screening approach described in NUREG–1757, ''Consolidated NMSS Decommissioning Guidance,'' Volume 2. The Licensee used the radionuclide-specific derived concentration guideline levels (DCGLs), developed there by the NRC, which comply with the dose criterion in 10 CFR 20.1402. These DCGLs define the maximum amount of residual radioactivity on building surfaces, equipment, and materials, and in soils, that will satisfy the NRC requirements in Subpart E of 10 CFR Part 20 for unrestricted release. The Licensee's final status survey results were below these DCGLs and are in compliance with the As Low As Reasonably Achievable (ALARA) requirement of 10 CFR 20.1402. The NRC thus finds that the Licensee's final status survey results are acceptable.

Based on its review, the staff has determined that the affected environment and any environmental impacts associated with the proposed action are bounded by the impacts evaluated by the ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC–Licensed Nuclear Facilities'' (NUREG–1496) Volumes 1–3 (ML042310492, ML042320379, and ML042330385). The staff finds there were no significant environmental impacts from the use of radioactive material in the East Wing of the Facility. The NRC staff reviewed the docket file records and the final status survey report to identify any non-radiological hazards that may have impacted the environment surrounding the East Wing of the Facility. No such hazards or impacts to the environment were identified. The NRC has identified no other radiological or non-radiological activities in the area that could result in cumulative environmental impacts.

The NRC staff finds that the proposed release of the East Wing of the Facility for unrestricted use is in compliance with 10 CFR 20.1402. Although the Licensee will continue to perform licensed activities at other parts of the Facility, the Licensee must ensure that this decommissioned area does not become recontaminated. Before the license can be terminated, the Licensee will be required to show that the entire Facility, including previously-released areas, complies with the radiological criteria in 10 CFR 20.1402. Based on its review, the staff considered the impact of the residual radioactivity in the East Wing of the Facility and concluded that the proposed action will not have a significant effect on the quality of the human environment.

Environmental Impacts of the Alternatives to the Proposed Action

Due to the largely administrative nature of the proposed action, its environmental impacts are small. Therefore, the only alternative the staff considered is the no-action alternative, under which the staff would leave things as they are by simply denying the amendment request. This no-action alternative is not feasible because it conflicts with 10 CFR 30.36(d), requiring that decommissioning of byproduct material facilities be completed and approved by the NRC after licensed activities cease. The NRC's analysis of the Licensee's final status survey data confirmed that the East Wing of the Facility meets the requirements of 10 CFR 20.1402 for unrestricted release. Additionally, denying the amendment request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are therefore similar and the no-action alternative is accordingly not further considered.

Conclusion

The NRC staff has concluded that the proposed action is consistent with the NRC's unrestricted release criteria specified in 10 CFR 20.1402. Because the proposed action will not significantly impact the quality of the human environment, the NRC staff concludes that the proposed action is the preferred alternative.

Agencies and Persons Consulted

NRC provided a draft of this Environmental Assessment to the New Jersey Department of Environmental Protection for review on August 10, 2009. On September 10, 2009, the New Jersey Department of Environmental Protection responded by letter. The State agreed with the conclusions of the EA, and otherwise had no comments.

The NRC staff has determined that the proposed action is of a procedural nature, and will not affect listed species or critical habitat. Therefore, no further consultation is required under Section 7 of the Endangered Species Act. The

NRC staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act.

III. Finding of No Significant Impact

The NRC staff has prepared this EA in support of the proposed action. On the basis of this EA, the NRC finds that there are no significant environmental impacts from the proposed action, and that preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

IV. Further Information

Documents related to this action, including the application for license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents related to this action are listed below, along with their ADAMS accession numbers.

[1] Letter dated July 29, 2009 with the ''Decommissioning Survey for Ligand Pharmaceuticals'' ML092170692;

[2] NUREG–1757, ''Consolidated NMSS Decommissioning Guidance;''

[3] Title 10, *Code of Federal Regulations*, Part 20, Subpart E, ''Radiological Criteria for License Termination;''

[4] Title 10, *Code of Federal Regulations*, Part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;'' and

[5] NUREG–1496, ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC–Licensed Nuclear Facilities.''

If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.* These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Region I, 475 Allendale Road, King of Prussia, PA this 23rd day of September 2009.

For the Nuclear Regulatory Commission.

James Dwyer,

Chief, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I.

[FR Doc. E9–23459 Filed 9–28–09; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2009–0429; Docket No. 030–05249]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment to Byproduct Materials License No. 29–01035–01, for Unrestricted Release of the FMC Corporation Facility Located In Princeton, NJ

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Environmental Assessment and Finding of No Significant Impact for license amendment.

FOR FURTHER INFORMATION CONTACT: Betsy Ullrich, Senior Health Physicist, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406; telephone (610) 337–5040; fax number (610) 337–5268; or by e-mail: *Elizabeth.ullrich@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Byproduct Materials License No. 29–01035–01. This license is held by FMC Corporation (the Licensee), for its FMC Corporation Princeton Chemical Research and Development Center (the Facility), located at U. S. Route 1 and Plainsboro Road in Princeton, New Jersey. Issuance of the amendment would authorize release of the Facility for unrestricted use. The Licensee requested this action in a letter dated August 5, 2009. The NRC has prepared an Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of Title 10, *Code of Federal Regulations* (CFR), part 51 (10 CFR part 51). Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The amendment will be issued to the Licensee following the publication of this FONSI and EA in the **Federal Register.**

II. Environmental Assessment

Identification of Proposed Action

The proposed action would approve the Licensee's August 5, 2009, license amendment request, resulting in release of the Facility for unrestricted use. License No. 29–01035–01 was issued on August 24, 1956, pursuant to 10 CFR part 30, and has been amended periodically since that time. This license authorized the Licensee to use unsealed byproduct material for purposes of conducting research and development activities on laboratory bench tops and in hoods.

The Facility is situated on 114 acres and consists of multiple buildings housing office space and laboratories. The Facility is located in a mixed industrial/commercial area. Within the Facility, use of licensed materials was confined to Building 2 and Building 22.

In 2008, the Licensee ceased licensed activities at the Facility and initiated a survey and decontamination of the Facility. Based on the Licensee's historical knowledge of the site and the conditions of the Facility, the Licensee determined that only routine decontamination activities, in accordance with their NRC-approved, operating radiation safety procedures, were required. The Licensee was not required to submit a decommissioning plan to the NRC because worker cleanup activities and procedures are consistent with those approved for routine operations. The Licensee conducted surveys of the Facility and provided information to the NRC to demonstrate that it meets the criteria in subpart E of 10 CFR part 20 for unrestricted release.

Need for the Proposed Action

The Licensee has ceased conducting licensed activities at the Facility, and seeks the unrestricted use of its Facility.

Environmental Impacts of the Proposed Action

The historical review of licensed activities conducted at the Facility shows that such activities involved use of the following radionuclides with half-lives greater than 120 days: hydrogen-3, carbon-14, and chlorine-36. Prior to performing the final status survey, the Licensee conducted decontamination activities, as necessary, in the areas of the Facility affected by these radionuclides.

The Licensee conducted a final status survey on June 15–17, and August 6, 2009. This survey covered Building 2, Laboratories 2–1130, 2–1135, 2–1140, 2–1150, 2–1155, 2–1160, 2–1162, 2–1165, 2–1175, 2–1205, 2–1210, 2–1230, 2–1245, 2–1250, 2–1255, 2–14742–2135,

2–2240, 2–2260, and 2–2265; Growth Chambers 8, 10, 15, and 19; Greenhouse #5; 2–1465 waste storage area; and the 2–Basement. The survey also covered Building 22, a small storage shed used for temporary storage of containers of low-level radioactive waste prior to disposal. The final status survey report for Building 2 was submitted July 31, 2009, and for Building 22 on August 7, 2009. The Licensee elected to demonstrate compliance with the radiological criteria for unrestricted release as specified in 10 CFR 20.1402 by using the screening approach described in NUREG–1757, ''Consolidated NMSS Decommissioning Guidance,'' Volume 2. The Licensee used the radionuclide-specific derived concentration guideline levels (DCGLs), developed there by the NRC, which comply with the dose criterion in 10 CFR 20.1402. These DCGLs define the maximum amount of residual radioactivity on building surfaces, equipment, and materials, and in soils, that will satisfy the NRC requirements in subpart E of 10 CFR part 20 for unrestricted release. The Licensee's final status survey results were below these DCGLs and are in compliance with the As Low As Reasonably Achievable (ALARA) requirement of 10 CFR 20.1402. The NRC thus finds that the Licensee's final status survey results are acceptable.

Based on its review, the staff has determined that the affected environment and any environmental impacts associated with the proposed action are bounded by the impacts evaluated by the ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC–Licensed Nuclear Facilities'' (NUREG–1496) Volumes 1–3 (ML042310492, ML042320379, and ML042330385). The staff finds there were no significant environmental impacts from the use of radioactive material at the Facility. The NRC staff reviewed the docket file records and the final status survey report to identify any non-radiological hazards that may have impacted the environment surrounding the Facility. No such hazards or impacts to the environment were identified. The NRC has identified no other radiological or non-radiological activities in the area that could result in cumulative environmental impacts.

The NRC staff finds that the proposed release of the Facility for unrestricted use and the termination of the NRC materials license is in compliance with 10 CFR 20.1402. Based on its review, the staff considered the impact of the residual radioactivity at the Facility and concluded that the proposed action will not have a significant effect on the quality of the human environment.

Environmental Impacts of the Alternatives to the Proposed Action

Due to the largely administrative nature of the proposed action, its environmental impacts are small. Therefore, the only alternative the staff considered is the no-action alternative, under which the staff would leave things as they are by simply denying the amendment request. This no-action alternative is not feasible because it conflicts with 10 CFR 30.36(d), requiring that decommissioning of byproduct material facilities be completed and approved by the NRC after licensed activities cease. The NRC's analysis of the Licensee's final status survey data confirmed that the Facility meets the requirements of 10 CFR 20.1402 for unrestricted release. Additionally, denying the amendment request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are therefore similar, and the no-action alternative is accordingly not further considered.

Conclusion

The NRC staff has concluded that the proposed action is consistent with the NRC's unrestricted release criteria specified in 10 CFR 20.1402. Because the proposed action will not significantly impact the quality of the human environment, the NRC staff concludes that the proposed action is the preferred alternative.

Agencies and Persons Consulted

NRC provided a draft of this Environmental Assessment to the New Jersey Department of Environmental Protection (NJDEP) for review on August 10, 2009. On September 4, 2009, NJDEP responded by letter. The State agreed with the conclusions of the EA, and otherwise had no comments.

The NRC staff has determined that the proposed action is of a procedural nature, and will not affect listed species or critical habitat. Therefore, no further consultation is required under section 7 of the Endangered Species Act. The NRC staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act.

III. Finding of No Significant Impact

The NRC staff has prepared this EA in support of the proposed action. On the basis of this EA, the NRC finds that there are no significant environmental impacts from the proposed action, and that preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

IV. Further Information

Documents related to this action, including the application for license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents related to this action are listed below, along with their ADAMS accession numbers.

[1] ''Multi-Agency Radiation Survey and Site Investigation Manual Final Status Survey, FMC Corporation, Building 2, Princeton, New Jersey, July 2009'' submitted July 31, 2009 [ML092160141];

[2] Letter dated August 5, 2009 [ML092190317];

[3] Survey results for Building 22 dated August 7, 2009 [ML092230184] and letter dated August 11, 2009 [ML092250111];

[4] NUREG–1757, ''Consolidated NMSS Decommissioning Guidance;''

[5] Title 10, *Code of Federal Regulations,* part 20, subpart E, ''Radiological Criteria for License Termination;''

[6] Title 10, *Code of Federal Regulations,* part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;'' and

[7] NUREG–1496, ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities.''

If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.* These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Region I, 475 Allendale Road, King of Prussia, PA this 23rd day of September 2009.

For the Nuclear Regulatory Commission.

James Dwyer,

Chief, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I.

[FR Doc. E9–23454 Filed 9–28–09; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2009–0428; Docket No. 030–29879]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment to Byproduct Materials License No. 29–28005–01 Partial Unrestricted Release of the Sarnoff Corporation's Facility in Princeton, NJ

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Environmental Assessment and Finding of No Significant Impact for license amendment.

FOR FURTHER INFORMATION CONTACT: Dennis Lawyer, Health Physicist, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania; telephone 610–337–5366; fax number 610–337–5269 or by e-mail: *dennis.lawyer@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Byproduct Materials License No. 29–28005–01. This license is held by The Sarnoff Corporation (the Licensee), for its facility located at 201 Washington Road in Princeton, New Jersey (the Facility). Issuance of the amendment would authorize release of Rooms EN–302, EN–307, and the Pond Building for unrestricted use. The amendment would also remove tritium from the materials authorized on the license as the licensee has provided surveys for the one laboratory which used tritium and will be used for other materials in the future. The Licensee requested this action in a letter dated April 14, 2009 and clarified its request in the additional information letter dated June 25, 2009. The NRC has prepared an Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of Title 10, Code of Federal Regulations (CFR), Part 51 (10 CFR Part 51). Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The amendment will be issued to the Licensee following the publication of this FONSI and EA in the **Federal Register**.

II. Environmental Assessment

Identification of Proposed Action

The proposed action would approve the Licensee's April 14, 2009, license amendment request, resulting in release of Rooms EN–302, EN–307, and the Pond Building for unrestricted use and removal of tritium from the material authorization. License No. 29–28005–01 was issued on June 16, 1987, pursuant to 10 CFR Part 30, and has been amended periodically since that time. This license authorized the Licensee to use unsealed byproduct material for purposes of conducting research and development activities on laboratory bench tops and in hoods.

The Facility is situated on 254 acres in a 600,000 square foot building, and consists of office space and laboratories. The Facility is located in a residential area. The use of unsealed radioactive materials with a half life of greater than 120 days was confined to 1,413 square feet within the Facility.

The Licensee ceased licensed activities in Room EN–307 about July 1, 1998; Room EN–302 on February 6, 1996; and the Pond Building in 2001 and initiated a survey and decontamination of the respective rooms. Based on the Licensee's historical knowledge of the site and the conditions of the Facility, the Licensee determined that only routine decontamination activities, in accordance with their NRC-approved, operating radiation safety procedures were required. The Licensee was not required to submit a decommissioning plan to the NRC because worker cleanup activities and procedures are consistent with those approved for routine operations. The Licensee conducted surveys of Rooms EN–302, EN–307, and the Pond Building and provided information to the NRC to demonstrate that it meets the criteria in Subpart E of 10 CFR Part 20 for unrestricted release. The licensee also conducted a survey on July 7, 2009, of the laboratory that had used hydrogen 3 and will be used for other materials in the future but the survey demonstrates that it could meet the criteria in Subpart E of 10 CFR Part 20 for unrestricted release if it were being released at this time.

Need for the Proposed Action

The Licensee has ceased conducting licensed activities in Rooms EN–302, EN–307, and the Pond Building at the Facility, and seeks the unrestricted use of these areas. The licensee seeks the removal of hydrogen 3 material from their license.

Environmental Impacts of the Proposed Action

The historical review of licensed activities conducted at the Facility shows that such activities involved use of the following radionuclides with half-lives greater than 120 days: hydrogen-3. Prior to performing the final status survey, the Licensee conducted decontamination activities, as necessary, in the areas of the Facility affected by these radionuclides. The Licensee conducted a final status survey on February 8, 1996, for Room EN–302; July 15, 1998, for EN–307; and April 16, 2002, for the Pond Building. The final status survey report was attached to the Licensee's additional information letter dated July 16, 2009. The Licensee elected to demonstrate compliance with the radiological criteria for unrestricted release as specified in 10 CFR 20.1402 by using the screening approach described in NUREG–1757, ''Consolidated NMSS Decommissioning Guidance,'' Volume 2. The Licensee used the radionuclide-specific derived concentration guideline levels (DCGLs), developed there by the NRC, which comply with the dose criterion in 10 CFR 20.1402. These DCGLs define the maximum amount of residual radioactivity on building surfaces, equipment, and materials that will satisfy the NRC requirements in Subpart E of 10 CFR Part 20 for unrestricted release. The Licensee's final status survey results were below these DCGLs and are in compliance with the As Low As Reasonably Achievable (ALARA) requirement of 10 CFR 20.1402. The NRC thus finds that the Licensee's final status survey results are acceptable.

Based on its review, the staff has determined that the affected environment and any environmental impacts associated with the proposed action are bounded by the impacts evaluated by the ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC–Licensed Nuclear Facilities'' (NUREG–1496) Volumes 1–3 (ML042310492, ML042320379, and ML042330385). The staff finds there were no significant environmental impacts from the use of radioactive material at the Facility. The NRC staff reviewed the docket file records and the final status survey report to identify any non-radiological hazards that may have impacted the environment surrounding the Facility. No such hazards or impacts

to the environment were identified. The NRC has identified no other radiological or non-radiological activities in the area that could result in cumulative environmental impacts.

The NRC staff finds that the proposed release of the portion of the Facility described above for unrestricted use is in compliance with 10 CFR 20.1402. Although the Licensee will continue to perform licensed activities at other parts of the Facility, the Licensee must ensure that this decommissioned area does not become recontaminated. Before the license can be terminated, the Licensee will be required to show that the entire Facility, including previously-released areas, complies with the radiological criteria in 10 CFR 20.1402. Based on its review, the staff considered the impact of the residual radioactivity at the Facility and concluded that the proposed action will not have a significant effect on the quality of the human environment.

Environmental Impacts of the Alternatives to the Proposed Action

Due to the largely administrative nature of the proposed action, its environmental impacts are small. Therefore, the only alternative the staff considered is the no-action alternative, under which the staff would leave things as they are by simply denying the amendment request. This no-action alternative is not feasible because it conflicts with 10 CFR 30.36(d), requiring that decommissioning of byproduct material facilities be completed and approved by the NRC after licensed activities cease. The NRC's analysis of the Licensee's final status survey data confirmed that the Rooms EN–302, EN–307, and the Pond Building meet the requirements of 10 CFR 20.1402 for unrestricted release. Additionally, denying the amendment request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are therefore similar, and the no-action alternative is accordingly not further considered.

Conclusion

The NRC staff has concluded that the proposed action is consistent with the NRC's unrestricted release criteria specified in 10 CFR 20.1402. Because the proposed action will not significantly impact the quality of the human environment, the NRC staff concludes that the proposed action is the preferred alternative.

Agencies and Persons Consulted

NRC provided a draft of this Environmental Assessment to the New Jersey Department of Environmental Protection for review on August 11, 2009. On September 10, 2009, New Jersey Bureau of Environmental Radiation responded by letter. The State agreed with the conclusions of the EA, and otherwise had no comments.

The NRC staff has determined that the proposed action is of a procedural nature, and will not affect listed species or critical habitat. Therefore, no further consultation is required under Section 7 of the Endangered Species Act. The NRC staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act.

III. Finding of No Significant Impact

The NRC staff has prepared this EA in support of the proposed action. On the basis of this EA, the NRC finds that there are no significant environmental impacts from the proposed action, and that preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

IV. Further Information

Documents related to this action, including the application for license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents related to this action are listed below, along with their ADAMS accession numbers.

1. NUREG–1757, ''Consolidated NMSS Decommissioning Guidance;''

2. Title 10, *Code of Federal Regulations,* Part 20, Subpart E, ''Radiological Criteria for License Termination;''

3. Title 10, *Code of Federal Regulations,* Part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;''

4. NUREG–1496, ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities;''

5. The Sarnoff Corporation Amendment requested dated April 14, 2009 [ML091110218];

6. The Sarnoff Corporation additional information letter dated June 25, 2009 [ML092010369];

7. The Sarnoff Corporation additional information letter dated July 16, 2009 [ML092010261]; and

8. The Sarnoff Corporation additional Information letter dated July 17, 2009 [ML092080374].

If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *PDR.Resource@nrc.gov.* These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Region I, 475 Allendale Road, King of Prussia, PA this 23rd day of September 2009.

For the Nuclear Regulatory Commission.

James P. Dwyer,

Chief, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I.

[FR Doc. E9–23456 Filed 9–28–09; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2009–0431; Docket No. 030–05210]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment to Byproduct Materials License No. 29–00018–02, Unrestricted Release of Building 43 at the Hoffman-La Roche Inc. Facility in Nutley, NJ

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Environmental Assessment and Finding of No Significant Impact for license amendment.

FOR FURTHER INFORMATION CONTACT: Betsy Ullrich, Senior Health Physicist, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406; telephone (610) 337–5040; fax number (610) 337–5269; or by e-mail: *elizabeth.ullrich@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the

issuance of a license amendment to Byproduct Materials License No. 29–00018–02. This license is held by Hoffman-La Roche Inc. (the Licensee), for its Hoffman-La Roche Inc. facilities (the Facility), located at 340 Kingsland Street in Nutley, New Jersey. Issuance of the amendment would authorize release of Building 43, the medical waste incinerator facility, for unrestricted use. The Licensee requested this action in a letter dated July 28, 2009. The NRC has prepared an Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of Title 10, *Code of Federal Regulations* (CFR), Part 51 (10 CFR Part 51). Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The amendment will be issued to the Licensee following the publication of this FONSI and EA in the **Federal Register**.

II. Environmental Assessment

Identification of Proposed Action

The proposed action would approve the Licensee's July 28, 2009, license amendment request, resulting in release of Building 43 for unrestricted use. License No. 29–00018–02 was issued on March 10, 1959, pursuant to 10 CFR Part 30, and has been amended periodically since that time. This license authorized the Licensee to use unsealed byproduct material for purposes of conducting research and development activities on laboratory bench tops and in hoods, and incineration of waste.

Building 43, the medical waste incinerator facility, is situated on 5,250 square feet, and consists of a multi-level incinerator room, control room, and support areas. The Facility is located in a mixed residential/commercial area. Licensed materials were used in most areas of Building 43.

On September 27, 2007, the Licensee ceased licensed activities and initiated a survey and decontamination of Building 43. Based on the Licensee's historical knowledge of the site and the conditions of Building 43, the Licensee determined that only routine decontamination activities, in accordance with their NRC-approved, operating radiation safety procedures, were required. The Licensee was not required to submit a decommissioning plan to the NRC because worker cleanup activities and procedures are consistent with those approved for routine operations. The Licensee conducted surveys of Building 43 and provided information to the NRC to demonstrate that it meets the criteria in Subpart E of 10 CFR Part 20 for unrestricted release.

Need for the Proposed Action

The Licensee has ceased conducting licensed activities at Building 43, and seeks the unrestricted use of Building 43.

Environmental Impacts of the Proposed Action

The historical review of licensed activities conducted at Building 43 shows that such activities involved use of the following radionuclides with half-lives greater than 120 days: Hydrogen-3 and carbon-14. Prior to performing the final status survey, the Licensee conducted decontamination activities, as necessary, in the areas of Building 43 affected by these radionuclides.

The Licensee conducted a final status survey on June 8–12, 2009. This survey covered all areas of Building 43. The final status survey report was attached to the Licensee's amendment request dated July 28, 2009. The Licensee elected to demonstrate compliance with the radiological criteria for unrestricted release as specified in 10 CFR 20.1402 by using the screening approach described in NUREG–1757, ''Consolidated NMSS Decommissioning Guidance,'' Volume 2. The Licensee used the radionuclide-specific derived concentration guideline levels (DCGLs), developed there by the NRC, which comply with the dose criterion in 10 CFR 20.1402. These DCGLs define the maximum amount of residual radioactivity on building surfaces, equipment, and materials, and in soils, that will satisfy the NRC requirements in Subpart E of 10 CFR Part 20 for unrestricted release. The Licensee's final status survey results were below these DCGLs and are in compliance with the As Low As Reasonably Achievable (ALARA) requirement of 10 CFR 20.1402. The NRC thus finds that the Licensee's final status survey results are acceptable.

Based on its review, the staff has determined that the affected environment and any environmental impacts associated with the proposed action are bounded by the impacts evaluated by the ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities'' (NUREG–1496) Volumes 1–3 (ML042310492, ML042320379, and ML042330385). The staff finds there were no significant environmental impacts from the use of radioactive material in Building 43. The NRC staff reviewed the docket file records and the final status survey report to identify any non-radiological hazards that may have impacted the environment surrounding Building 43. No such hazards or impacts to the environment were identified. The NRC has identified no other radiological or non-radiological activities in the area that could result in cumulative environmental impacts.

The NRC staff finds that the proposed release of the portion of the Facility described above for unrestricted use is in compliance with 10 CFR 20.1402. Although the Licensee will continue to perform licensed activities at other parts of the Facility, the Licensee must ensure that this decommissioned area does not become recontaminated. Before the license can be terminated, the Licensee will be required to show that the entire Facility, including previously-released areas, complies with the radiological criteria in 10 CFR 20.1402. Based on its review, the staff considered the impact of the residual radioactivity at Building 43 and concluded that the proposed action will not have a significant effect on the quality of the human environment.

Environmental Impacts of the Alternatives to the Proposed Action

Due to the largely administrative nature of the proposed action, its environmental impacts are small. Therefore, the only alternative the staff considered is the no-action alternative, under which the staff would leave things as they are by simply denying the amendment request. This no-action alternative is not feasible because it conflicts with 10 CFR 30.36(d), requiring that decommissioning of byproduct material facilities be completed and approved by the NRC after licensed activities cease. The NRC's analysis of the Licensee's final status survey data confirmed that Building 43 meets the requirements of 10 CFR 20.1402 for unrestricted release. Additionally, denying the amendment request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are therefore similar, and the no-action alternative is accordingly not further considered.

Conclusion

The NRC staff has concluded that the proposed action is consistent with the NRC's unrestricted release criteria specified in 10 CFR 20.1402. Because the proposed action will not significantly impact the quality of the human environment, the NRC staff concludes that the proposed action is the preferred alternative.

Agencies and Persons Consulted

NRC provided a draft of this Environmental Assessment to the State of New Jersey Department of Environmental Protection (NJDEP) for review on August 3, 2009. On September 4, 2009, NJDEP responded by letter. The State agreed with the conclusions of the EA, and otherwise had no comments.

The NRC staff has determined that the proposed action is of a procedural nature, and will not affect listed species or critical habitat. Therefore, no further consultation is required under Section 7 of the Endangered Species Act. The NRC staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act.

III. Finding of No Significant Impact

The NRC staff has prepared this EA in support of the proposed action. On the basis of this EA, the NRC finds that there are no significant environmental impacts from the proposed action, and that preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

IV. Further Information

Documents related to this action, including the application for license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents related to this action are listed below, along with their ADAMS accession numbers.

[1] NUREG–1757, ''Consolidated NMSS Decommissioning Guidance;''

[2] Title 10, *Code of Federal Regulations,* Part 20, Subpart E, ''Radiological Criteria for License Termination;''

[3] Title 10, *Code of Federal Regulations,* Part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;''

[4] NUREG–1496, ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC–Licensed Nuclear Facilities;'' and

[5] Licensee letter dated July 28, 2009, with ''Building 43, Medical Waste Incinerator, Decommissioning Final Status Report'' dated July, 2009 [ML092120369].

If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.* These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Region I, 475 Allendale Road, King of Prussia, PA this 23rd day of September 2009.

For the Nuclear Regulatory Commission.

James Dwyer,

Chief, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I.

[FR Doc. E9–23457 Filed 9–28–09; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act; Notice of Meeting

DATES: Weeks of September 28, October 5, 12, 19, 26, November 2, 2009.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of September 28, 2009

Tuesday, September 29, 2009

1:30 p.m. NRC All Employees Meeting (Public Meeting), Marriott Bethesda North Hotel, 5701 Marinelli Road, Rockville, MD 20852.

Wednesday, September 30, 2009

9:30 a.m. Discussion of Management Issues (Closed Ex. 2).

Week of October 5, 2009—Tentative

There are no meetings scheduled for the week of October 5, 2009.

Week of October 12, 2009—Tentative

Tuesday, October 13, 2009

9:30 a.m. Discussion of Security Issues (Closed Ex. 3).

Week of October 19, 2009—Tentative

There are no meetings scheduled for the week of October 19, 2009.

Week of October 26, 2009—Tentative

There are no meetings scheduled for the week of October 26, 2009.

Week of November 2, 2009—Tentative

There are no meetings scheduled for the week of November 2, 2009.

* * * * *

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording) (301) 415–1292. Contact person for more information: Rochelle Bavol, (301) 415–1651.

* * * * *

Additional Information

By a vote of 3–0 on September 22, 2009, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that Affirmation of: a. South Texas Project Nuclear Operating Company (South Texas Project, Units 3 and 4), Request for Extension of Time to File Appeal and b. Pa'ina Hawaii, LLC (Materials License Application) Applicant's Motion to Transfer Case to the Commission) be held on September 23, 2009, with less than one week notice to the public. Both items were affirmed.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/about-nrc/policy-making/schedule.html*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify the NRC's Disability Program Coordinator, Rohn Brown, at 301–492–2279, TDD: 301–415–2100, or by e-mail at *rohn.brown@nrc.gov* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed electronically to subscribers. If you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969), or send an e-mail to *darlene.wright@nrc.gov.*

Dated: September 24, 2009.

Rochelle C. Bavol,

Office of the Secretary.

[FR Doc. E9–23560 Filed 9–25–09; 4:15 pm]

BILLING CODE 7590–01–P

SMALL BUSINESS ADMINISTRATION

Gulf Opportunity Pilot Loan Program (GO Loan Pilot)

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of extension of waiver of regulatory provisions.

SUMMARY: This notice announces the extension of the ''Notice of waiver of regulatory provisions'' for SBA's GO Loan Pilot until September 30, 2010. Due to the scope and magnitude of the devastation to Presidentially-declared disaster areas resulting from Hurricanes Katrina and Rita, the Agency is extending its full guaranty and streamlined and centralized loan processing available through the GO Loan Pilot to small businesses in the eligible parishes/counties through September 30, 2010.

DATES: The waiver of regulatory provisions published in the **Federal Register** on November 17, 2005, is extended under this Notice until September 30, 2010.

FOR FURTHER INFORMATION CONTACT: Gail Hepler, Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416; *gail.hepler@sba.gov.*

SUPPLEMENTARY INFORMATION: On November 8, 2005, SBA initiated the GO Loan Pilot program which was designed to provide expedited small business financial assistance to businesses located in those communities severely impacted by Hurricanes Katrina and Rita. Under this unique initiative, SBA provides its full (85%) guaranty and streamlined and centralized loan processing to all eligible lenders that agree to make expedited SBA 7(a) loans available to small businesses located in, locating to or re-locating in the parishes/counties that have been Presidentially-declared as disaster areas resulting from Hurricanes Katrina and Rita, plus any contiguous parishes/counties.

To maximize the effectiveness of the GO Loan Pilot, on November 17, 2005, SBA published a notice in the **Federal Register** waiving for the GO Loan Pilot certain Agency regulations for the 7(a) Business Loan Program. (70 FR 69645). Because the pilot was designed as a temporary program scheduled to expire on September 30, 2006, and was extended to September 30, 2009, the waiver of certain Agency regulations also is due to expire on September 30, 2009. However, the Agency believes that there is a continuing, substantial need for the specific SBA assistance provided by this pilot in the affected areas.

When compared to other similarly-sized Section 7(a) loans in the same States, the GO Loan portfolio is performing very well, at about one-half the rates of delinquency and loan purchase. In addition, the demand for GO Loans has significantly increased in FY2009 in response to the continued need to rebuild the Gulf Coast areas devastated by Hurricanes Katrina and Rita. The annualized disbursement of GO Loans approved in FY2009 was 21% higher than disbursements of GO Loans approved in FY2008. Furthermore, on August 24, 2009, the Federal Emergency Management Agency (FEMA) issued a news release announcing additional funding for projects throughout the New Orleans, LA area. These additional funds bring the total public assistance funds obligated for Louisiana recovery projects since January 20, 2009 to more than $1 billion. The extension of the GO Loan pilot program, combined with additional FEMA funding, form a continuing, comprehensive Federal response to support the recovery of these highly devastated communities.

Thus, the Agency believes it is appropriate to extend this unique and vital program through September 30, 2010. Accordingly, the SBA is also extending its waiver of the Agency regulations identified in the **Federal Register** notice at 70 FR 69645 through September 30, 2010. SBA's waiver of these provisions is authorized by regulations. These waivers apply only to those loans approved under the GO Loan Pilot and will last only for the duration of the Pilot, which expires September 30, 2010. As part of the GO Loan Pilot, these waivers apply only to those small businesses located in, locating to, or relocating in the parishes/counties that have been Presidentially-declared as disaster areas resulting from Hurricanes Katrina or Rita, plus any contiguous parishes/counties. A list of all eligible parishes/counties is located at *http://www.sba.gov/idc/groups/public/documents/sba_homepage/serv_goloan_3.pdf.*

Authority: 15 U.S.C. 636(a)(24); 13 CFR 120.3.

Eric R. Zarnikow,

Associate Administrator, Office of Capital Access.

[FR Doc. E9–23406 Filed 9–28–09; 8:45 am]

BILLING CODE 8025–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 30e–2, SEC File No. 270–437, OMB Control No. 3235–0494.

Notice is hereby given that, under the Paperwork Reduction Act of 1995 (44 U.S.C. 350l *et seq.*), (the ''Paperwork Reduction Act'') the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Section 30(e) of the Investment Company Act of 1940 (15 U.S.C. 80a–29(e)) (the ''Investment Company Act'') and Rule 30e–2 [1] (17 CFR 270.30e–2) thereunder require registered unit investment trusts (''UITs'') that invest substantially all of their assets in securities of a management investment company [2] (''fund'') to send to shareholders at least semi-annually a report containing certain financial statements and other information. Specifically, Rule 30e–2 requires that the report contain the financial statements and other information that Rule 30e–1 under the Investment Company Act (17 CFR 270.30e–1) requires to be included in the report of the underlying fund for the same fiscal period. Rule 30e–1 requires that the underlying fund's report contain, among other things, the financial statements and other information that is required to be included in such report by the fund's registration form.

The purpose of this requirement is to apprise current shareholders of the operational and financial condition of the UIT. Absent the requirement to disclose all material information in reports, investors would be unable to obtain accurate information upon which to base investment decisions and consumer confidence in the securities

[1] Rule 30e–2 was originally adopted as Rule 30d–2, but was redesignated as Rule 30e–2 effective February 15, 2001. See Role of Independent Directors of Investment Companies, Investment Company Act Release No. 24816 (Jan. 2, 2001) (66 FR 3734 (Jan. 16, 2001)).

[2] Management investment companies are defined in Section 4 of the Investment Company Act as any investment company other than a face-amount certificate company or a unit investment trust, as those terms are defined in Section 4 of the Investment Company Act. See 15 U.S.C. 80a–4.

industry might be adversely affected. Requiring the submission of these reports to the Commission permits us to verify compliance with securities law requirements. In addition, Rule 30e–2 permits, under certain conditions, delivery of a single shareholder report to investors who share an address (''householding''). Specifically, Rule 30e–2 permits householding of annual and semi-annual reports by UITs to satisfy the delivery requirements of Rule 30e–2 if, in addition to the other conditions set forth in the rule, the UIT has obtained from each applicable investor written or implied consent to the householding of shareholder reports at such address. The rule requires UITs that wish to household shareholder reports with implied consent to send a notice to each applicable investor stating that the investors in the household will receive one report in the future unless the investors provide contrary instructions. In addition, at least once a year, UITs relying on the rule for householding must explain to investors who have provided written or implied consent how they can revoke their consent. Preparing and sending the initial notice and the annual explanation of the right to revoke consent are collections of information under the Paperwork Reduction Act. The purpose of the notice and annual explanation requirements associated with the householding provisions of the rule is to ensure that investors who wish to receive individual copies of shareholder reports are able to do so.

The Commission estimates that as of 2009, approximately 820 UITs were subject to the provisions of Rule 30e–2. The Commission further estimates that the annual burden associated with Rule 30e–2 is 121 hours for each UIT, including an estimated 20 hours associated with the notice requirement for householding and an estimated 1 hour associated with the explanation of the right to revoke consent to householding, for a total of 99,220 burden hours.

In addition to the burden hours, the Commission estimates that the cost of contracting for outside services associated with complying with Rule 30e–2 is $20,000 per respondent (80 hours times $250 per hour for independent auditor services), for a total of $16,400,000 ($20,000 per respondent times 820 respondents).

These estimates are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.

The collection of information under Rule 30e–2 is mandatory. The information provided under Rule 30e–2 is not kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

Please direct general comments regarding the above information to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or send an e-mail to Shagufta Ahmed at *Shagufta_Ahmed@omb.eop.gov;* and (ii) Charles Boucher, Director/CIO, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: September 23, 2009.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9–23496 Filed 9–28–09; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 17Ad–4(b) and (c), OMB Control No. 3235–0341, SEC File No. 270–264.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information provided for in Rule 17Ad–4(b) and (c) (17 CFR 240.17Ad–4(b) and (c)) of the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17Ad–4(b) and (c) is used to document when transfer agents are exempt or no longer exempt from some of the Commission's transfer agent rules. Depending on which federal government organization is the transfer agent's appropriate regulatory agency (''ARA''), Rule 17Ad–4(b)(3) requires an exempt transfer agent to either prepare and maintain or file a document that certifies that the transfer agent qualifies as exempt under Rule 17Ad–4(b)(1) or when the transfer agent loses such exemption.

The ARAs use the information contained in the notice to determine whether a registered transfer agent qualifies for the exemption, to determine when a registered transfer agent no longer qualifies for the exemption, and to determine the extent that transfer agent is subject to the Commission's rules.

The Board of Governors of the Federal Reserve System (''the Fed'') receives approximately two notices of exempt status and two notices of loss of exempt status annually. The Federal Deposit Insurance Corporation (''FDIC'') also receives approximately two notices of exempt status and two notices of loss of exempt status annually. The Commission and the Office of the Comptroller of the Currency (''OCC'') do not require transfer agents to file a notice of exempt status or loss of exempt status. Instead, transfer agents whose ARA is the Commission or OCC need only to prepare and maintain these notices. The Commission estimates that approximately ten notices of exempt status and ten notices of loss of exempt status are prepared annually by transfer agents whose ARA is the Commission. We estimate that the transfer agents for whom the OCC is their ARA prepare and maintain approximately five notices of exempt status and five notices of loss of exempt status annually. Thus, a total of approximately thirty-eight notices of exempt status and loss of exempt status are prepared and maintained by transfer agents annually. Of these thirty-eight notices, approximately eight are filed with an ARA. Any additional costs associated with filing such notices would be limited primarily to postage, which would be minimal. Since the Commission estimates that no more than one-half hour is required to prepare each notice, the total annual burden to transfer agents is approximately nineteen hours. The average cost per hour is approximately $30. Therefore, the total cost of compliance to the transfer agent industry is about $570.

Please note that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by

sending an e-mail to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Charles Boucher, Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to *PRA_Mailbox@sec.gov*. Comments must be submitted within 30 days of this notice.

Dated: September 23, 2009.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9–23494 Filed 9–28–09; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–60712; File No. SR–NYSE–2009–97]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by New York Stock Exchange LLC Extending Until October 4, 2009, the Operation of Interim NYSE Rule 128 Which Permits the Exchange To Cancel or Adjust Clearly Erroneous Executions If They Arise Out of the Use or Operation of Any Quotation, Execution or Communication System Owned or Operated by the Exchange, Including Those Executions That Occur in the Event of a System Disruption or System Malfunction

September 23, 2009.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 22, 2009, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. NYSE has designated the proposed rule change as constituting a rule change under Rule 19b–4(f)(6) under the Act,[3] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend until October 4, 2009, the operation of interim NYSE Rule 128 (''Clearly Erroneous Executions for NYSE Equities'') which permits the Exchange to cancel or adjust clearly erroneous executions if they arise out of the use or operation of any quotation, execution or communication system owned or operated by the Exchange, including those executions that occur in the event of a system disruption or system malfunction. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend until October 4, 2009, the operation of interim NYSE Rule 128 (''Clearly Erroneous Executions for NYSE Equities'') which permits the Exchange to cancel or adjust clearly erroneous executions if they arise out of the use or operation of any quotation, execution or communication system owned or operated by the Exchange, including those executions that occur in the event of a system disruption or system malfunction.

Prior to the implementation of NYSE Rule 128 on January 28, 2008,[4] the NYSE did not have a rule providing the Exchange with the authority to cancel or adjust clearly erroneous trades of securities executed on or through the systems and facilities of the NYSE.

In order for the NYSE to be consistent with other national securities exchanges which have some version of a clearly erroneous execution rule, the Exchange is drafting an amended clearly erroneous rule which will accommodate such other exchanges but will be appropriate for the NYSE market model.

The NYSE notes that the Commission approved an amended clearly erroneous execution rule for Nasdaq in May 2008.[5] On July 28, 2008, the Exchange filed with the SEC a request to extend the operation of interim Rule 128 until October 1, 2008[6] in order to review the provisions of Nasdaq's clearly erroneous rule and to consider integrating similar standards into its own amendment to Rule 128. On October 1, 2008,[7] the Exchange filed with the SEC a further request to extend the operation of interim Rule 128 until January 9, 2009 in order to consider integrating similar standards into the amendment to Rule 128. On January 9, 2009,[8] the Exchange filed with the SEC a request to extend the operation of interim Rule 128 until March 9, 2009, indicating that the Exchange was still in the process of reviewing the Nasdaq rule with a view towards incorporating certain provisions into the amendment of interim Rule 128.

On February 10, 2009, NYSE Arca submitted a proposal to the SEC to amend its clearly erroneous rule. The NYSE Arca proposed rule differed in certain respects from the Nasdaq clearly erroneous rule. On March 9, 2009, the Exchange filed with the SEC a request to extend the operation of interim Rule 128 until June 9, 2009[9] to finalize review of NYSE Arca's proposed amended CEE rule, which included market wide CEE initiatives, to determine if it was appropriate to incorporate such provisions into the Rule 128 amendment.

Thereafter, on April 24, 2009, NYSE Arca filed a revised rule change with the Commission to amend its clearly erroneous rule (NYSE Arca Rule 7.10).[10] The Exchange was in the process of finalizing its review of NYSE Arca's revised CEE rule change, which also included market wide CEE initiatives, to determine if it was appropriate to incorporate all such provisions into NYSE's interim Rule 128 amendment. On June 9, 2009, the Exchange filed with the SEC a request to extend the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] *See* Securities Exchange Act Release No. 57323 (February 13, 2008), 73 FR 9371 (February 20, 2008) (SR–NYSE–2008–09).

[5] *See* Securities Exchange Act Release No. 57826 (May 15, 2008), 73 FR 29802 (May 22, 2008) (SR–NASDAQ–2007–001).

[6] *See* Securities Exchange Act Release No. 58328 (August 8, 2008), 73 FR 47247 (August 13, 2008) (SR–NYSE–2008–63).

[7] *See* Securities Exchange Act Release No. 58732 (October 3, 2008), 73 FR 61183 (October 15, 2008) (SR–NYSE–2008–99).

[8] *See* Securities Exchange Act Release No. 59255 (January 15, 2009) 74 FR 4496 (January 26, 2009) (SR–NYSE–2009–02).

[9] *See* Securities Exchange Act Release No. 59581 (March 9, 2009) 74 FR 12431 (March 24, 2009) (SR–NYSE–2009–26).

[10] *See* Securities Exchange Act Release No. 59838 (April 28, 2009) 74 FR 20767 (May 5, 2009) (SR–NYSEArca-2009–36) (*See* NYSE Arca Rule 7.10).

operation of interim Rule 128 until July 15, 2009[11] to finalize review of NYSE Arca's proposed amended CEE rule. On July 15, 2009[12] the Exchange filed with the SEC a request to extend the operation of interim Rule 128 until August 1, 2009 to finalize review of NYSE Arca's proposed amended CEE rule. On July 31, 2009 the Exchange filed with the SEC a request to extend the operation of interim Rule 128 until August 10, 2009[13] to finalize review of NYSE Arca's proposed amended CEE rule. On August 11, 2009 the Exchange filed with the SEC a request to extend the operation of interim Rule 128 until August 21, 2009[14] to finalize review of NYSE Arca's proposed amended CEE rule. On August 21, 2009 the Exchange filed with the SEC a request to extend the operation of interim Rule 128 until August 31, 2009[15] to finalize review of NYSE Arca's proposed amended CEE rule. On August 31, 2009 the Exchange filed with the SEC a request to extend the operation of interim Rule 128 until September 8, 2009[16] to finalize review of NYSE Arca's proposed amended CEE rule. On September 8, 2009 the Exchange filed with the SEC a request to extend the operation of interim Rule 128 until September 15, 2009[17] to finalize review of NYSE Arca's proposed amended CEE rule. On September 15, 2009 the Exchange filed with the SEC a request to extend the operation of interim Rule 128 until September 22, 2009[18] to finalize review of NYSE Arca's proposed amended CEE rule.

The Exchange anticipates finalizing proposed rule text of its clearly erroneous execution rule shortly, and is, therefore, requesting to extend the operation of interim Rule 128 until October 4, 2009. Prior to October 4, 2009, the Exchange intends to formally file a 19b–4 rule change amending interim Rule 128.

1. Statutory Basis

The basis under the Securities Exchange Act of 1934 (the ''Act'')[19] for this proposed rule change is the requirement under Section 6(b)(5)[20] that an Exchange have rules that are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

As articulated more fully in the ''Purpose'' Section above, the proposed rule would place the NYSE on equal footing with other national securities exchanges. This will promote the integrity of the market and protect the public interest, since it would permit all exchanges to cancel or adjust clearly erroneous trades when such trades occur, rather than canceling them on all other markets, but leaving them standing on only one market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[21] and Rule 19b–4(f)(6) thereunder.[22]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[23] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)[24] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. NYSE requests that the Commission waive the 30-day operative delay because the Exchange believes that the absence of such a rule in an automated and fast-paced trading environment poses a danger to the integrity of the markets and the public interest. NYSE notes that immediate effectiveness of the proposed rule change will immediately and timely enable NYSE to cancel or adjust clearly erroneous trades that may present a risk to the integrity of the equities markets and all related markets. The Commission believes that waiving the 30-day operative delay[25] is consistent with the protection of investors and the public interest because such waiver will permit the Exchange to continue operation of interim NYSE Rule 128 on an uninterrupted basis, and therefore designates the proposal operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2009–97 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission,

[11] *See* Securities Exchange Act Release No. 60131 (June 17, 2009) 74 FR 30196 (June 24, 2009) (SR–NYSE–2009–57).

[12] *See* Securities Exchange Act Release No. 60312 (July 15, 2009) 74 FR 36298 (July 22, 2009) (SR–NYSE–2009–70).

[13] *See* Securities Exchange Act Release No. 60419 (August 7, 2009) 74 FR 39987 (August 10, 2009) (SR–NYSE–2009–79).

[14] *See* Securities Exchange Act Release No. 60478 (August 11, 2009) 74 FR 41769 (August 18, 2009) (SR–NYSE–2009–81).

[15] *See* Securities Exchange Act Release No. 60563 (August 21, 2009) 74 FR 44423 (August 28, 2009) (SR–NYSE–2009–87).

[16] *See* Securities Exchange Act Release No. 60597 (August 31, 2009) 74 FR 46281 (September 8, 2009) (SR–NYSE–2009–92).

[17] *See* Securities Exchange Act Release No. 60649 (September 10, 2009) 74 FR 47846 (September 17, 2009) (SR–NYSE–2009–93).

[18] *See* Securities Exchange Act Release No. 60678 (September 16, 2009) 74 FR 48330 (September 22, 2009) (SR–NYSE–2009–95).

[19] 15 U.S.C. 78f(a) [sic].

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has determined to waive the five-day pre-filing period in this case.

[23] 17 CFR 240.19b–4(f)(6).

[24] 17 CFR 240.19b–4(f)(6).

[25] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2009–97. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filings also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–NYSE–2009–97 and should be submitted on or before October 20, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9–23491 Filed 9–28–09; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF STATE

[Public Notice 6773]

Waiver of Restriction on Assistance to the Central Government of Uzbekistan Related to Budget Transparency

Pursuant to section 7088(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2009 (Division H, Pub. L. 111–8) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of section 7088(c)(1) of the Act with respect to the Government of Uzbekistan, and I hereby waive such restriction.

This determination shall be reported to the Congress and published in the **Federal Register**.

Dated: September 17, 2009.

Jacob J. Lew,

Deputy Secretary of State for Management and Resources, Department of State.

[FR Doc. E9–23493 Filed 9–28–09; 8:45 am]

BILLING CODE 4710–46–P

[26] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Proposed Collection: Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A). Currently the Bureau of the Public Debt within the Department of the Treasury is soliciting comments concerning the Release.

DATES: Written comments should be received on or before November 16, 2009, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Public Debt, Judi Owens, 200 Third Street, A4–A, Parkersburg, WV 26106–1328, or e-mail to *Judi.Owens@bpd.treas.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Judi Owens, Bureau of the Public Debt, 200 Third Street, A4–A, Parkersburg, WV 26106–1328, (304) 480–8150.

SUPPLEMENTARY INFORMATION:

Title: Release.

OMB Number: 1535–0114.

Form Number: PD F 2001.

Abstract: The information is requested to ratify payment of savings bonds/notes and release the United States of America from any liability.

Current Actions: None.

Type of Review: Extension.

Affected Public: Individuals or households.

Estimated Number of Respondents: 200.

Estimated Time per Respondent: 6 minutes.

Estimated Total Annual Burden Hours: 20.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. *Comments are invited on:* (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: September 15, 2009.

Judi Owens,

Manager, Information Management.

[FR Doc. E9–23424 Filed 9–28–09; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1138

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1138, Extension of Time for Payment of Taxes by a Corporation Expecting a New Operating Loss Carryback.

DATES: Written comments should be received on or before November 30, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, at (202) 622–6665, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Extension of Time for Payment of Taxes by a Corporation Expecting a New Operating Loss Carryback.

OMB Number: 1545–1035.

Form Number: 1138.

Abstract: Form 1138 is filed by corporations to request an extension of time for the payment of taxes for a prior tax year when the corporation believes that it will have a net operating loss in the current tax year. The IRS uses Form 1138 to determine if the request should be granted.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 2,033.

Estimated Time per Respondent: 4 hr., 49 min.

Estimated Total Annual Burden Hours: 9,800.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 22, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9–23400 Filed 9–28–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for the MeF Letter

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning the MeF letter, Mondernized e-File—Non-compliance with Mandate for Large Corporations to file electronically.

DATES: Written comments should be received on or before November 30, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, (202) 622–6665, at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Allan.M.Hopkins@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Mondernized e-File—Non-compliance with Mandate for Large Corporations to file electronically.

OMB Number: 1545–2023.

Form Number: MeF letter.

Abstract: Service will contact those taxpayers who file paper income tax returns to determine if these taxpayers should have filed electronic returns under the Mandate, Treasury Regulation section 301.6011–5T.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 20,250.

Estimated Time per Respondent: 5 minutes.

Estimated Total Annual Burden Hours: 2,080.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 22, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9–23399 Filed 9–28–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for the Health Coverage Tax Credit (HCTC) Reimbursement Request Form

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning the Health Coverage Tax Credit (HCTC) Reimbursement Request Form.

DATES: Written comments should be received on or before November 30, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, (202) 622–6665, at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Allan.M.Hopkins@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Health Coverage Tax Credit (HCTC) Reimbursement Request Form.

OMB Number: 1545–2152.

Abstract: This form will be used by HCTC participants to request reimbursement for health plan premiums paid prior to the commencement of advance payments.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 3,058.

Estimated Time per Respondent: 40 minutes.

Estimated Total Annual Burden Hours: 2,039.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 22, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9–23398 Filed 9–28–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Notice 97–45

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Notice 97–45, Highly Compensated Employee Definition.

DATES: Written comments should be received on or before November 30, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the notice should be directed to Evelyn J. Mack, at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6665, or through the Internet at *Evelyn.J.Mack@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Highly Compensated Employee Definition.

OMB Number: 1545–1550.

Notice Number: Notice 97–45.

Abstract: Notice 97–45 provides guidance on the definition of highly compensated employee(HCE) within the meaning of section 414(q) of the Internal Revenue Code, as simplified by section 1431 of the Small Business Job Protection Act of 1996, including an employer's option to make a top-paid group election under section 414(q)(1)(B)(ii). The notice requires qualified retirement plans that contain a definition of HCE to be amended to reflect the statutory changes to section 414(q).

Current Actions: There are no changes being made to the notice at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and not-for-profit institutions.

Estimated Number of Respondents: 218,683.

Estimated Time per Respondent: 18 minutes.

Estimated Total Annual Burden Hours: 65,605.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All

comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 16, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9–23397 Filed 9–28–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for ADA Accommodations Request Packet

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning the ADA Accommodations Packet.

DATES: Written comments should be received on or before November 30, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the packet should be directed to Allan Hopkins, at (202) 622–6665, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: ADA Accommodations Request Packet.

OMB Number: 1545–2027.

Abstract: Information is collected so that ADA applicants may receive reasonable accommodation, as needed, to take the Special Enrollment Examination.

Current Actions: There are no changes being made to the packet at this time.

Type of Review: This is an extension of a previously approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 300.

Estimated Average Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 300.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 22, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9–23395 Filed 9–28–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 2000–37 (Modified by Revenue Procedure 2004–51)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Revenue Procedure 2000–37; Reverse Like-Kind Exchanges (modified by Revenue Procedure 2004–51).

DATES: Written comments should be received on or before November 30, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of revenue procedure should be directed to Allan Hopkins at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6665, or through the Internet at *Allan.M.Hopkins@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Reverse Like-Kind Exchanges.

OMB Number: 1545–1701.

Revenue Procedure Number: Revenue Procedure 2000–37 (modified by RP 2004–51).

Abstract: Revenue Procedure 2000–37 provides a safe harbor for reverse like-kind exchanges in which a transaction using a ''qualified exchange accommodation arrangement'' will qualify for non-recognition treatment under section 1031 of the Internal Revenue Code. Revenue Procedure 2004–51 modifies sections 1 and 4 of Rev. Proc. 2000–37, 2000–2 C.B. 308, to provide that Rev. Proc. 2000–37 does not apply if the taxpayer owns the property intended to qualify as replacement property before initiating a qualified exchange accommodation arrangement (QEAA).

Current Actions: There are no changes being made to burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, and farms.

Estimated Number of Respondents: 1,600.

Estimated Time per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 3,200.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 22, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9–23394 Filed 9–28–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–130477–00: REG–130481–00; (TD 8987)]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG–130477–00; REG–130481–00 (TD 8987) Required Distributions From Retirement Plans (§§ 1.401(a)(9)-1 and 1.401(a)(9)-4).

DATES: Written comments should be received on or before November 30, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Allan Hopkins at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6665, or through the Internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Required Distributions From Retirement Plans.

OMB Number: 1545–1573.

Regulation Project Number: REG–130477–00 and REG–130481–00 (8987).

Abstract: This regulation permits a taxpayer to name a trust as the beneficiary of the employee's benefit under a retirement plan and use the life expectancies of the beneficiaries of the trust to determine the required minimum distribution, if certain conditions are satisfied.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 1,000.

Estimated Time per Respondent: 20 minutes.

Estimated Total Annual Burden Hours: 333.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 22, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9–23393 Filed 9–28–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 9117

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed

and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 9117, Excise Tax Program Order Blank for Forms and Publications.

DATES: Written comments should be received on or before November 30, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, (202) 622–6665, at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Excise Tax Program Order Blank for Forms and Publications.

OMB Number: 1545–1096.

Form Number: Form 9117.

Abstract: Form 9117 allows taxpayers who must file Form 720 returns a systemic way to order additional tax forms and informational publications.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 15,000.

Estimated Time per Respondent: 3 minutes.

Estimated Total Annual Burden Hours: 500.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 22, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9–23392 Filed 9–28–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8554, 8554–EP

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8554, Application for Renewal of Enrollment To Practice Before the Internal Revenue Service, and Form 8554–EP, Application for Renewal of Enrollment to Practice Before the Internal Revenue Service as an Enrolled Retirement Plan Agent (ERPA).

DATES: Written comments should be received on or before November 30, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Allan Hopkins, at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6665, or through the internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application for Renewal of Enrollment To Practice Before the Internal Revenue Service.

OMB Number: 1545–0946.

Form Number: 8554.

Abstract: The information obtained from Form 8554 relates to the approval of continuing professional education programs and the renewal of the enrollment status for those individuals admitted (enrolled) to practice before the Internal Revenue Service. The information will be used by the Director of Practice to determine the qualifications of individuals who apply for renewal of enrollment.

Title: Application for Renewal of Enrollment to Practice Before the Internal Revenue Service as an Enrolled Retirement Plan Agent (ERPA).

Form Number: 8554–EP.

Abstract: This form is used to renew your Enrolled Retirement Plan Agent (ERPA) status. You must renew your enrollment status every 3 years. For additional information on renewals, see Circular 230 or visit the Office of Professional Responsibility Web site at *http://www.irs.gov.*

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 39,500.

Estimated Time per Response: 1 hour, 12 minutes.

Estimated Total Annual Burden Hours: 47,400.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is

necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 22, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9–23391 Filed 9–28–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Proposed Collection: Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A). Currently the Bureau of the Public Debt within the Department of the Treasury is soliciting comments concerning the extension of information collections under the regulations which were issued pursuant to the Government Securities Act.

DATES: Written comments should be received on or before November 16, 2009, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Public Debt, Judi Owens, 200 Third Street, A4–A Parkersburg, WV 26106–1328, or *Judi.Owens@bpd.treas.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Judi Owens, Bureau of the Public Debt, 200 Third Street, A4–A, Parkersburg, WV 26106–1328, (304) 480–8150.

SUPPLEMENTARY INFORMATION: *Title:* Government Securities Act Regulations.

OMB Number: 1535–0089.

Abstract: The information collections are contained within the regulations issued pursuant to the Government Securities Act (GSA), as amended (15 U.S.C. 780–5), which require government securities brokers and dealers to make and keep certain records concerning their business activities and their holdings of securities, to submit financial reports, and to make certain disclosures to investors. The regulations also require depository institutions to keep certain records of non-fiduciary custodial holdings of government securities. The regulations and associated collections are fundamental to customer protection and dealer financial responsibility.

Current Actions: None.

Type of Review: Extension.

Affected Public: Government securities brokers and dealers and depository institutions.

Estimated Number of Respondents: 4,767.

Estimated Total Annual Responses: 9,081.

Estimated Total Annual Burden Hours: 369,664.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. *Comments are invited on:* (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: September 15, 2009.

Judi Owens,

Manager, Information Management.

[FR Doc. E9–23425 Filed 9–28–09; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF THE TREASURY

United States Mint

Notification of United States Mint 2009 Braille Education Set Pricing

ACTION: Notice.

SUMMARY: The United States Mint is announcing the price of the United States Mint 2009 Braille Education Set.

Public Law 109–247, the Louis Braille Bicentennial-Braille Literacy Commemorative Coin Act, authorizes the United States Mint to mint and issue 2009 Louis Braille Bicentennial Silver Dollars. In addition to these commemorative coins, the United States Mint is offering a limited edition collectible product capturing the life and legacy of Louis Braille and the importance the Braille system plays in the literacy and independence of blind people. This product will consist of a Louis Braille Bicentennial Uncirculated Silver Dollar presented in a folder designed to highlight the life of Louis Braille.

The United States Mint 2009 Braille Education Set will be offered for sale on October 8, 2009, at a price of $44.95.

FOR FURTHER INFORMATION CONTACT: B.B. Craig, Associate Director for Sales and Marketing, United States Mint, 801 Ninth Street, NW., Washington, DC 20220; or call 202–354–7500.

Authority: 31 U.S.C. 5111, 5112 & 9701.

Dated: September 23, 2009.

Edmund C. Moy,

Director, United States Mint.

[FR Doc. E9–23382 Filed 9–28–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0691]

Proposed Information Collection (Learner's Perception (LP) Survey); Comment Request

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Health Administration (VHA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to identify areas for improvement in clinical training programs.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before November 30, 2009.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov*; or to Mary Stout, Veterans Health Administration (193E1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *mary.stout@va.gov*. Please refer to ''OMB Control No. 2900–0691'' in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Mary Stout (202) 273–8664 or FAX (202) 273–9381.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Learner's Perception (LP) Survey, VA Form 10–0439.

OMB Control Number: 2900–0691.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 10–0439 will be use to obtain health care trainees perception of their clinical experience with VA versus non-VA facilities. VA will use the data to identify strengths and opportunities for improvement in VA clinical training programs.

Affected Public: Individuals or households.

Estimated Annual Burden: 3,500 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 14,000.

Dated: September 24, 2009.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. E9–23409 Filed 9–28–09; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0523]

Proposed Information Collection (Loan Analysis) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information to determine the veteran-borrower's ability to qualify for guaranteed loan.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before November 30, 2009.

ADDRESSES: Submit written comments on the collection of information through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail to *nancy.kessinger@va.gov*. Please refer to ''OMB Control No. 2900–0523'' in any correspondence. During the comment period, comments may be viewed online through at FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461–9769 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Loan Analysis, VA Form 26–6393.

OMB Control Number: 2900–0523.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 26–6393 is used to determine a veteran-borrower qualification for a VA-guaranteed loan. Lenders complete and submit the form to provide evidence of their decision to submit a prior approval loan application or close a loan on the automatic basis is based upon appropriate application of VA credit standards.

Affected Public: Federal Government.

Estimated Annual Burden: 62,500 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 125,000.

Dated: September 24, 2009.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. E9–23410 Filed 9–28–09; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0001]

Proposed Information Collection (Veteran's Application for Compensation and/or Pension) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an

opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each revision of a currently approved collection and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to determine a veteran's eligibility, dependency, and income, as applicable, for compensation and/or pension benefits and to assist veterans in reopening a previously denied disability compensation claim or to request an increase in benefit and/or claim for a new service-connected condition.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before November 30, 2009.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0001'' in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461–9769 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Titles:

a. Veteran's Application for Compensation and/or Pension, VA Form 21–526.

b. Veteran's Supplemental Claim Application, VA Form 21–526b.

c. Authorization and Consent Release Information to the Department of Veterans Affairs (VA), VA Form 21–4142.

OMB Control Number: 2900–0001.

Type of Review: Revision of a currently approved collection.

Abstracts:

a. Veterans complete VA Form 21–526 to apply for compensation and/or pension benefits.

b. Veterans who previously filed a claim using VA Form 21–526, Application for Compensation or Pension, and who wish to request an increase in a service connected condition, reopen their claim for a previously denied claim, and/or file a claim for a new service-connected condition must complete VA Form 21–526b. VA Form 21–526b will be used for supplemental claims for disability compensation.

c. Veterans who need VA's assistance in obtaining non-VA medical records must complete VA Form 21–4142.

Affected Public: Individuals or households.

Estimated Annual Burden:

a. VA Form 21–526—391,708.
b. VA Form 21–526b—50,000.
c. VA Form 21–4142—274.

Estimated Average Burden Per Respondent:

a. VA Form 21–526—1 hour.
b. VA Form 21–526b—15 minutes
c. VA Form 21–4142—5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents:

a. VA Form 21–526—391,708
b. VA Form 21–526b—200,000
c. VA Form 21–4142—3,292.

Dated: September 24, 2009.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. E9–23481 Filed 9–28–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0376]

Proposed Information Collection (Agent Orange Registry Code Sheet); Comment Request

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Health Administration (VHA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on the information needed to maintain an up-to-date Agent Orange Registry.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before November 30, 2009.

ADDRESSES: Submit written comments on the collection of information through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov;* or to Mary Stout, Veterans Health Administration (193E1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: mary.stout@va.gov. Please refer to ''OMB Control No. 2900–0376'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Mary Stout at (202) 461–5867 or FAX (202) 273–9381.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Agent Orange Registry Code Sheet, VA Form 10–9009.

OMB Control Number: 2900–0376.

Type of Review: Extension of a currently approved collection.

Abstract: VA in an on-going effort to maintain an Agent Orange Registry (AOR) developed a reporting format to facilitate the collection of information obtained from veterans during the Agent Orange registry examination process. VA is required to organize and update the information contained in AOR to be able to notify Vietnam era veterans who served in the Republic of Vietnam of any increased health risks resulting from exposure to dioxin or other toxic agents. VA may also provide, upon request, a health examination, consultation, and counseling veterans who are eligible for listing or inclusion in any health-related registry administrated by VA that is similar to the Persian Gulf War Veterans Health Registry. Registry examinations is provided to veterans who served in Korea in 1968 or 1969, and/or any U.S. veteran who may have been exposed to dioxin, or other toxic substance in a herbicide or defoliant, during the conduct of, or as a result of, the testing, transporting, or spraying of herbicides, and who requests an Agent Orange Registry examination. VA will enter the information obtained from the veteran during the interview on VA Form 10–9009, Agent Orange Registry Code Sheet. The registry will provide a mechanism that will catalogue prominent symptoms, reproductive health, and diagnoses and to communicate with Agent Orange veterans. VA will inform the veterans on research finding or new compensation policies through periodic newsletters. The registry is not designed or intended to be a research tool and therefore the results cannot be generalized to represent all Agent Orange veterans.

Affected Public: Individuals or Households.

Estimated Total Annual Burden: 6,667 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 6,667.

Dated: September 24, 2009.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. E9–23411 Filed 9–28–09; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0335]

Proposed Information Collection (Dental Record Authorization and Invoice for Outpatient Services) Activity: Comment Request

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Health Administration (VHA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on the information needed to determine a veteran's dental treatment needs, and the fees associated for these services.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before November 30, 2009.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *http://www.Regulations.gov;* or to Mary Stout, Veterans Health Administration (193E1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *mary.stout@va.gov*. Please refer to ''OMB Control No. 2900–0335'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Mary Stout (202) 461–5867 or FAX (202) 273–9381.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Dental Record Authorization and Invoice for Outpatient Services, VA Form 10–2570d.

OMB Control Number: 2900–0335.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 10–2570d is essential to the proper administration of VA outpatient fee dental program. The associated instructions make it possible to communicate with clarity the required procedures, peculiarities, and precautions associated with VA authorizations for contracting with private dentists for the provision of dental treatment for eligible veteran beneficiaries. Since most of the veterans who are authorized fee dental care are geographically inaccessible to VA dental clinics, it is necessary to request information as to the veteran's oral condition, treatment needs and the usual customary fees for these services from the private fee dentist whom the veteran has selected. The form lists the dental treatment needs of the veteran patient, the cost to VA to provide such services, and serves as an invoice for payment. VA uses the data collected to verify the veteran's eligibility to receive dental benefits.

Affected Public: Business and other for profit.

Estimated Total Annual Burden: 3,666 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 11,000.

Dated: September 24, 2009.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. E9–23412 Filed 9–28–09; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–New (HEC)]

Agency Information Collection (Health Eligibility Center (HEC) Activities Under OMB Review

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Health Administration (VHA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and includes the actual data collection instrument.

DATES: Comments must be submitted on or before October 29, 2009.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–New (HEC)'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 273–0443 or e-mail *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–New (HEC).''

SUPPLEMENTARY INFORMATION:

Titles:

a. Health Eligibility Center (HEC) Correspondence Satisfaction Letter, FL 10–491.

b. Customer Modality Satisfaction Survey, VA Form 10–0151.

OMB Control Number: 2900–New (HEC).

Type of Review: New collection.

Abstract: The HEC goal is to respond to Veterans correspondence, addressing their concerns in a concise and understandable manner. The correspondence letter will allow Veterans an opportunity to provide anonymous feedback on how well the HEC addressed their concerns. HEC will use Veterans feedback to improve the correspondence process. The Customer Modality Survey will be used to focus on how VA employees assess the needs of Veterans and outline internal processes to improve services prior to Veterans receiving care such as preregistration support and claim processing.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on July 24, 2009, at page 36828.

Affected Public: Individuals and households.

Estimated Annual Burden:

a. VA FL 10–0151—11,551 hours.

b. VA Form 10–491—83,677 hours.

Estimated Average Burden per Respondent:

a. VA FL 10–0151—4.2 minutes.

b. VA Form 10–491—23 minutes.

Frequency of Response:

a. VA FL 10–0151—1.53.

b. VA Form 10–491—1.9.

Estimated Number of Respondents:

a. VA FL 10–0151—107,851.

b. VA Form 10–491—114,889.

Total Annual Responses:

a. VA FL 10–0151—165,012.

b. VA Form 10–491—218,289.

Dated: September 24, 2009.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. E9–23413 Filed 9–28–09; 8:45 am]

BILLING CODE 8320–01–P



Federal Register

Tuesday,
September 29, 2009

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 413 and 414

Medicare Programs; End-Stage Renal Disease Prospective Payment System; Town Hall Meeting on End-Stage Renal Disease Prospective Payment System; Proposed Rule and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 413 and 414

[CMS–1418–P]

RIN 0938–AP57

Medicare Programs; End-Stage Renal Disease Prospective Payment System

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a case-mix adjusted bundled prospective payment system (PPS) for Medicare outpatient end-stage renal disease (ESRD) dialysis facilities beginning January 1, 2011, in compliance with the statutory requirement of the Medicare Improvements for Patients and Providers Act (MIPPA), enacted July 15, 2008. The proposed ESRD PPS would replace the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 16, 2009.

ADDRESSES: In commenting, please refer to file code CMS–1418–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.*

Follow the instructions under the ''More Search Options'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–*1418*–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–*1418*–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: William Cymer, (410) 786–4533. Lynn Riley, (410) 786–1286, (ESRD Quality Incentive Program.)

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

Act The Social Security Act
BIPA Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554)
BMI Body mass index
BN Budget neutrality
BSA Body surface area
CBSA Core-Based Statistical Area
CDC Centers for Disease Control and Prevention
CFR Code of Federal Regulations
CMS Centers for Medicare & Medicaid Services
CPM Clinical performance measure
CR Composite rate
CROWN Consolidated Renal Operations in a Web-Enabled Network
CY Calendar year
DME Durable medical equipment
EDB Enrollment Data Base
EPO Epoetin alfa
ESA Erythropoiesis stimulating agent
ESRD End stage renal disease
FI Fiscal intermediary
FY Fiscal year
GAO Government Accountability Office
HD Hemodialysis
IHS Indian Health Service
Kt/V A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
LDO Large dialysis organization
MAC Medicare Administrative Contractor
MAP Medicare allowable payment
MCP Monthly capitation payment
MedPAC Medicare Payment Advisory Commission
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MSA Metropolitan Statistical Area
NEC Not elsewhere classified
NIH National Institutes of Health
NOS Not otherwise specified
NQF National Quality Forum
OMB Office of Management and Budget
OSCAR Online State Certification and Reporting System
PD Peritoneal dialysis
PFS Physician fee schedule
PPS Prospective payment system
PDE Prescription drug event
PVD Peripheral vascular disease
REMIS Renal Management Information System
RRB Railroad Retirement Board
RRT Renal replacement therapy
SB Separately billable
SIMS ESRD Standard Information Management System
SSA Social Security Administration
UM–KECC University of Michigan, Kidney Epidemiology & Cost Center
URR Urea reduction ratio

I. Background

A. Origins of the Composite Payment System

Section 299I of the Social Security Amendments of 1972, Public Law 92–603, established the end-stage renal disease (ESRD) program under Medicare. That law extended Medicare coverage to individuals regardless of age who have permanent kidney failure, requiring either dialysis or kidney transplantation to maintain life, and meet certain other eligibility criteria. On July 1, 1973, the Medicare program extended benefits to about 11,000 beneficiaries with ESRD. In calendar year 1974, the program paid benefits of about $229 million for dialysis, transplant, and other services. By 1979, the number of beneficiaries had grown to 42,500, with payments reaching $985 million.

Because of concern over the rapid escalation in expenditures for the ESRD program, the Congress enacted legislation in 1978 (Pub. L. 95–292, ''ESRD Program Amendments of 1978''), which amended title XVIII of the Social Security Act (the Act) to add new section 1881, which governs Medicare payment for ESRD benefits. In particular, section 1881(b)(2)(B) of the Act directed us to publish regulations establishing methods and procedures to determine the costs incurred by ESRD providers and renal dialysis facilities in

furnishing covered services to individuals with ESRD, and to determine, on a cost-related or other equitable and economically efficient basis, payment amounts for part B services furnished by such providers and facilities to individuals with ESRD. Section 1881(b)(2)(B) of the Act also provided that we establish a prospective reimbursement method for those services with incentives for encouraging facilities to be more efficient and provide cost-effective care.

The enactment of the Omnibus Budget Reconciliation Act of 1981, Public Law 97–35, resulted in a further directive for implementing changes to the ESRD payment system. Section 2145 of Public Law 97–35 amended section 1881 of the Act by requiring the Secretary to provide by regulation a method for determining prospectively the amounts of payments for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility, and to such individuals at home. In particular, the law required that such method be based on a single composite weighted formula (''composite rate'') (which takes into account the mix of patients who receive services at a facility or at home and the relative costs for furnishing such services) for hospital-based facilities and such a single composite rate for other renal dialysis facilities, or that payment be based on such other method or combination of methods which differentiate between hospital-based and other renal dialysis facilities, and which would more effectively encourage more efficient delivery of dialysis services and would provide greater incentives for increased use of home dialysis.

As a result of these statutory requirements, on February 12, 1982, we published a proposed rule on reimbursement for outpatient dialysis services (47 FR 6556) to implement section 1881 of the Act, as amended by section 2145 of Public Law 97–35. The regulations provided that each facility would receive a payment rate per dialysis treatment (''composite rate''), that is adjusted for geographic differences in area wage levels for the treatment furnished in the facility or at home. We refer to the methodology for payment of outpatient maintenance dialysis services on a per-treatment basis as the ''composite payment system''.

Final regulations implementing the composite payment system were published on May 11, 1983 (48 FR 21254). The initial payment rates, which were developed from Medicare cost reports for fiscal years ending in 1977, 1978, and 1979, were established at $127 per treatment for independent facilities and $131 for hospital-based facilities. The composite payment system was effective August 1, 1983. It was limited to payments for the costs incurred by dialysis facilities furnishing outpatient maintenance dialysis, including some routinely provided drugs, laboratory tests, and supplies, whether furnished by hospital-based and independent facilities in a facility or at home. We established separate rates for hospital-based and independent dialysis facilities, and provided a process under which facilities with costs in excess of their payment rates could seek exceptions to those rates under specified circumstances.

With regard to home dialysis, this system was the basis for reimbursing home dialysis furnished by hospital-based and independent facilities (''Method I''). (The other is ''Method II,'' under which the beneficiary works directly with a durable medical equipment supplier to obtain the supplies and equipment needed.) For further information on the distinctions between Method I and Method II, see section III.E of this proposed rule.

The composite payment system implemented in 1983 was relatively comprehensive with respect to the renal dialysis services included as part of the composite payment bundle. However, a substantial portion of expenditures for renal dialysis services are excluded from the composite payment system and reimbursed in accordance with the respective fee schedules or other payment methodologies. For example, payment for erythropoiesis stimulating agents (ESAs) such as epoetin alfa (EPO, for example, Epogen®) and darbepoetin alfa (ARANESP®) used to treat anemia, and vitamin D analogues (paracalcitol, doxercalciferol, calcitriol), is made outside of the composite payment system as separately billable services. These separately billable services currently comprise about 40 percent of total spending for outpatient maintenance dialysis. The present payment for outpatient maintenance dialysis under Medicare represents a mix of prospective payment, fee-for-service, and other payment rules.

Subsequent inflation increases to the composite payment system applied only in response to specific statutory directives. For example, between 1983 and 2001, the payment rates were increased only three times. A $1.00 increase per treatment was effective January 1, 1991 as a result of the enactment of the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508. The rates were not revised again until the enactment of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Public Law 106–113, which increased the payments by 1.2 percent effective January 1, 2000 and January 1, 2001, respectively.

During the last few years, policymakers and other interested parties, including the Medicare Payment Advisory Commission (MedPac) and the Government Accountability Office (GAO), have examined the Medicare outpatient maintenance dialysis payment system and suggested a bundled prospective payment approach. See *Medicare Payment Advisory Commission (MedPAC): Report to the Congress: Medicare Payment Policy,* March 2001, March 2005, and March 2007, and GAO Report GAO–07–77, *End Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility,* November 2006. We believe that a fully bundled PPS would combine composite rate dialysis services with separately billable services under a single payment, adjusted to reflect patient differences in resource needs or case-mix. As in any PPS, dialysis facilities would keep the difference if Medicare payments exceeded costs for the bundled services, and would be liable for the difference if costs exceeded Medicare payments.

Aside from resulting in a single comprehensive payment for all services included in the bundle, we believe a bundled ESRD PPS would have several objectives. These include eliminating incentives to overuse profitable separately billable drugs, particularly EPO, the targeting of greater payments to ESRD facilities with more costly patients to promote both equitable payment and access to services, and the promotion of operational efficiency. Because of the increased flexibility a bundled PPS would provide in the delivery of outpatient maintenance dialysis services, we believe that it could also increase desirable clinical outcomes, resulting in an enhanced quality of care.

B. Statutory Authority for a Bundled ESRD PPS

1. BIPA

The Congress has twice required studies on the bundling of additional services into the composite payment system. In section 422(c)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106–554, the Congress required the Secretary

to issue a report on a bundled system that would include separately billable drugs and clinical laboratory services routinely used in furnishing dialysis. The Secretary submitted this report, *Toward a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System,* to Congress in May 2003. That report contained three major findings that would form the basis for the subsequent development of a bundled ESRD PPS:

1. Currently available administrative data are adequate for proceeding with the development of an expanded outpatient ESRD PPS.

2. Case-mix adjustment is potentially feasible based on available clinical information for ESRD patients in order to pay facilities appropriately for treating more costly resource intensive patients.

3. Current quality review initiatives provide a basis for monitoring the impact of a bundled ESRD PPS after implementation, to ensure quality of care does not deteriorate in response to the system's efficiency incentives.

The Secretary's May 2003 report contained recommendations and conclusions drawn from research, which CMS had initiated on its own prior to the enactment of the law. In September 2000, the Kidney Epidemiology and Cost Center of the University of Michigan (UM–KECC) was awarded a multi-phased research contract. That research led to UM–KECC's August 2002 report, *An Expanded Medicare Outpatient End Stage Renal Disease Prospective Payment System, Phase I Report.* This report provided useful information on many of the issues that would need to be addressed before a bundled ESRD PPS could be implemented, and formed the foundation for the Secretary's May 2003 report.

2. MMA

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, also required the Secretary to submit to the Congress a report detailing the elements and features for the design and implementation of a bundled ESRD PPS. Section 623(f)(1) of the MMA specified that such a system should include the bundling of separately billed drugs, clinical laboratory tests, and other items ''to the maximum extent feasible''. That section also required the report to include a description of the methodology to be used to establish payment rates and that the report, detailing the design of an appropriate bundled payment system, be submitted to the Congress by October 1, 2005. Section 623(e) of the MMA also required a demonstration project testing the feasibility of using a fully bundled case-mix adjusted ESRD PPS.

In addition to requiring a report on a bundled ESRD PPS, section 623 of the MMA amended section 1881(b) of the Act, by requiring significant revisions to the composite payment system. Specifically, section 623 of the MMA required:

- An increase of 1.6 percent to the composite payment rates effective January 1, 2005.
- An add-on to composite rate payments to account for the difference in payments for separately billable drugs based on a revised drug pricing methodology compared to the previous method.
- A ''basic'' case-mix adjustment to an ESRD facility's composite payment rate reflecting a ''limited number of patient characteristics.''
- That total payments under the basic case-mix adjusted composite payment system be budget neutral.
- An annual increase to the basic case mix adjusted payment amounts based on projected growth in expenditures for separately billed drugs (the ''growth update'').
- That payment rates be adjusted by a geographic index, as determined appropriate by the Secretary (and phased-in to the extent such index differed from the previous payment system).
- Reinstatement of the composite rate exceptions process, eliminated for most dialysis facilities beginning December 31, 2000 under BIPA, for ESRD pediatric facilities, effective October 1, 2002.

On August 5, 2004 and November 15, 2004, we published a proposed rule and final rule (69 FR 47487 through 47730 and 69 FR 66235 through 66915), respectively, implementing the provisions affecting the composite payment system effective January 1, 2005, as set forth in section 623 of the MMA. We refer to the modified composite payment system as the ''basic case-mix adjusted composite payment system''. The development and application of the basic case-mix adjustments, using regression based adjustment factors for the patient variables of age, body surface area, and low body mass index, are explained in each of those rules. (For more information, we refer readers to 69 FR 47529 and 69 FR 66323, respectively.) The product of the specific adjusters for each patient, multiplied by the otherwise applicable composite payment rate, yielded the basic case-mix adjustment required by the MMA. The basic case-mix adjusted composite payment system was effective April 1, 2005, and was derived from UM–KECC's research summarized in its report, *Methodology for Developing a Basic Case-Mix Adjustment for the Medicare ESRD Prospective Payment System* (May 19, 2004 report and April 1, 2005 addendum).

Subsequent to our implementation of the MMA requirements discussed above, UM–KECC continued its research to develop a case-mix adjusted ESRD PPS that would combine composite rate and separately billable services. UM–KECC reported its findings and recommendations in a final report submitted to CMS in February 2008, *End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle.* That report is available on the Internet at: *http://www.sph.umich.edu/kecc/assets/documents/UM-KECC_Expanded_ESRD_Bundle.pdf.* Individuals requiring special assistive technology may contact CMS at 410–786–4533 between the hours of 8:30 a.m. and 5 p.m. e.d.t. for assistance. UM–KECC's final report formed the basis for the Secretary's February 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System,* mandated under section 623(f)(1) of the MMA.

The aspects of the basic case-mix adjusted composite payment system implemented as a result of section 1881(b)(12) of the Act, as added by section 623(d)(1) of the MMA, are important because they provide a foundation for the development of the case-mix adjusted bundled ESRD PPS required under Public Law 110–275, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Accordingly, we briefly describe below the basic case-mix adjustment under the current composite payment system before turning to the relevant provisions of MIPPA and the development of the proposed ESRD PPS.

3. The Basic Case-Mix Adjustment

Resources required to furnish routine dialysis such as staff and equipment time vary by patient. For example, all other things being equal, larger patients cost more to deliver the same dose of dialysis than do smaller patients. Also, severely debilitated or aged patients may require more staff time than do younger healthier patients. Because of the variation in resources required to furnish routine dialysis to individuals with varying patient characteristics, facilities that treat a greater than average proportion of resource-intensive patients could be economically disadvantaged if they are paid a rate

based on average resources. In addition, patients who are costlier than average to dialyze may face difficulties gaining access to care because a fixed composite payment rate could create a disincentive to treat such patients. The purpose of a case-mix adjustment based on patient characteristics is to make higher payments to ESRD facilities treating more resource-intensive patients, according to objective quantifiable criteria. Such an adjustment also would reduce the disincentives to treat or provide the optimal dose of dialysis to such patients.

The costs of providing the routine maintenance dialysis services that are paid under the composite rate are reported on the Medicare cost reports for hospital-based and independent ESRD facilities (Forms CMS 2552–96 and CMS 265–94, respectively). Patient-specific data related to the costs of furnishing composite rate services are not collected because these costs are included as part of the composite rate and are not separately billed. However, earlier UM–KECC research revealed considerable variability in costs and patient characteristics among dialysis facilities, and that several patient characteristics predicted facility costs. See Wolfe, R. *et al., An expanded Medicare outpatient end stage renal disease prospective payment system, Phase I report,* University of Michigan, Kidney Epidemiology and Cost Center, August 2002; Hirth, R.A., *et al., Is case-mix adjustment necessary for an expanded dialysis bundle?* Health Care Financing Review, Summer 2003, 24, pp. 77–88; *Kidney Epidemiology and Cost Center: Methodology for developing a basic case-mix adjustment for the Medicare ESRD prospective payment system,* May 19, 2004 report and April 1, 2005 addendum, prepared under contract no. N–12004–11–504200 for the Centers for Medicare and Medicaid Services.

In order to determine a basic case-mix adjustment that could be applied to each ESRD facility's composite rate, UM–KECC further examined the relationship between facility-level costs for composite rate services based on the Medicare cost reports for hospital-based and independent facilities, and the average characteristics of patients treated by the facility. The research used data from Medicare cost reports for 3,254 independent and hospital-based ESRD facilities for 2000 to 2002, patient characteristics/co-morbidity data from CMS's Medical Evidence Form 2728 for 1995 through 2002, and Medicare claims for approximately 360,000 ESRD patients. See Hirth, R.A., *et al., Economic impact of case-mix adjusting the dialysis composite rate,* Journal of the American Society of Nephrology, 16, 2005, pp. 1172–1176, and Wheeler, John R. C., *et al., Understanding the basic case-mix adjustment for the composite rate,* American Journal of Kidney Diseases, 47, No. 4, April 2006, pp. 666–671. Based on standard techniques of multiple regression analysis, UM–KECC found that age and body size had significant relationships to composite rate costs. The body size variables were body surface area (BSA) and low body mass index (BMI), calculated based on a patient's height and weight.

A BMI less than 18.5 kg/m^2 is considered a clinical measure of underweight status and is an indicator of patients who are malnourished or suffering from co-morbidities such as wasting syndrome. BSA is closely associated with the duration and intensity of dialysis required to achieve targets for dialysis adequacy. Facilities with a larger proportion of patients with a greater than average BSA, or with a BMI lower than 18.5, were found to have greater composite rate costs. The research also revealed a U-shaped relationship between age and composite rate costs, with the youngest and oldest age groups incurring greater costs for composite rate services due to resource needs.

Although several co-morbidities were found to have statistically significant relationships to composite rate costs, CMS did not adopt them to develop the basic case-mix system mandated by the MMA for a number of reasons. For instance, the relationship of some co-morbidities to the composite rate costs was not stable over time. In addition, establishment of the diagnostic criteria used in connection with specific co-morbidities required further study.

A few findings were surprising. For example, several patient characteristics, notably type 1 or type 2 diabetes, which generally are important with regard to the etiology of ESRD, did not show statistically significant relationships to composite rate costs for renal dialysis services. While the result that facilities with the greatest number of oldest patients incurred greater composite rate costs was expected, the finding that facilities with a higher proportion of patients in the youngest age group (a group that excludes pediatric patients or those less than age 18) incurred greater composite rate costs as well, was unexpected.

The outcome of UM–KECC's research was a set of basic case-mix adjusters or multipliers for ESRD patients based on three variables. These variables were: (1) The patient's age (five groups), (2) BSA (a patient-specific value based on incremental differences from the national patient average), and (3) BMI category (two groups, value either less than, or equal to/greater than 18.5 kg/m^2). CMS also developed a special adjuster for pediatric patients outside of UM–KECC's research methodology based on analysis of a sample of Medicare cost reports. The adjuster for each of these three variables is multiplied by the facility's composite rate to yield the current ''basic'' case-mix adjustment for each ESRD patient according to the specified patient characteristics.

These adjusters were as follows:

Age group	Composite rate multiplier
< 18	*1.62
18–44	1.223
45–59	1.055
60–69 (reference group)	1.000
70–79	1.094
80+	1.174
Body Surface Area (BSA):	
(per 0.1m^2 change in BSA from national average of 1.84)	1.037
Low Body Mass Index (BMI):	
(<18.5kg/m^2)	1.112

*Developed by CMS. The age, BSA, and BMI multipliers do not apply under the basic case-mix adjustments for patients under age 18.

The above multipliers were derived from the coefficients of the regression model used to predict facility differences in composite rate costs based on UM–KECC's research. For example, the case-mix adjuster for a 47 year old ESRD patient who is underweight (BMI < 18.5 kg/m^2) and has a BSA of 2.0 m^2 would be calculated as follows:

Age Adjuster	1.055
BSA Adjuster	$1.037^{(2.0-1.84)/0.1} = 1.060$
Low BMI Adjuster	1.112
Case-Mix Adjuster	$1.055 \times 1.060 \times 1.112 = 1.244$

The resulting case-mix adjustment factor of 1.244 for this patient would be multiplied by the facility's otherwise applicable wage adjusted composite payment rate.

The basic case-mix adjustment mandated under the MMA only affects the composite rate. It does not reflect costs associated with separately billable services. Separately billable services, particularly injectable drugs, are a significant component of the total dialysis resources used for each patient. Prior to the enactment of MIPPA on July 15, 2008, however, CMS did not have authority to bundle those services into a case-mix adjusted PPS.

4. MIPPA

The implementation of the basic case-mix adjustments to the composite payment system effective April 1, 2005, and the Secretary's February 2008 Report to Congress, suggested that an expanded or bundled ESRD PPS which combined composite rate and separately billable services to yield case-mix adjusted payments was technically feasible. The report defined a payment bundle of dialysis-related services, described the methodology used to develop the regression based case-mix adjusters and the base period payment rates to which the case-mix adjusters would be applied, and discussed numerous other issues relevant to the bundling of outpatient dialysis services under a system of prospective payments. As a result of the July 15, 2008 enactment of MIPPA, section 153(b) of MIPPA amended section 1881(b) of the Act to require the implementation of an ESRD bundled payment system effective January 1, 2011 (herein referred to as the ''ESRD PPS''). Consistent with the language under the statute, we will refer to hospital-based and independent renal dialysis facilities as ''providers'' and ''facilities'', respectively, and when addressing both types of facilities, we will collectively refer to such entities as ''ESRD facilities'', as set forth in proposed § 413.171. Section 153(b) of MIPPA specifies the following:

- The Secretary must implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for ''renal dialysis services'' in lieu of any other payment, and for such services and items furnished for home dialysis and self-care home dialysis support services.
- A definition for the ''renal dialysis services'' that are included in the bundle.
- The estimated amount of total payments under the ESRD PPS for 2011 must be equal to 98 percent of the estimated total amount of payments for renal dialysis services paid under Medicare, including payments for drugs, that would have been made with regard to services in 2011 if the new system was not implemented. Such estimate must be made based on per patient utilization data from 2007, 2008, or 2009, whichever year has the lowest per patient utilization.
- The ESRD PPS must include adjustments for case-mix variables, high cost outlier payments, and low-volume facilities and provide for a four-year transition (phase-in) period, with all facilities transitioned into the bundled ESRD PPS on January 1, 2014. ESRD facilities may make a one-time election before January 1, 2011, to be paid under the ESRD PPS and not go through the transition period.
- The ESRD PPS may include other payment adjustments, as the Secretary determines appropriate, including the use of a geographic index, and potential adjustments for pediatric patients and rural dialysis centers, and may provide for a unit of payment as the Secretary specifies (for example, per treatment or per unit of time).
- The ESRD PPS payment amounts must be annually increased by an ESRD bundled market basket beginning in 2012, and during the transition.
- Section 623(e) of the MMA, which requires a demonstration project of the use of a case-mix adjusted bundled ESRD PPS, be repealed.

Section 153(a)(1) of MIPPA also requires that the composite payment rates be increased by 1.0 percent effective for services furnished on or after January 1, 2009, and before January 1, 2010, and increased by 1.0 percent for services furnished on or after January 1, 2010. In addition, section 153(a)(2) of MIPPA requires that the payment rate for dialysis services furnished on or after January 1, 2009, by ESRD providers of services, be the same as the payment rate for such services furnished by renal dialysis facilities. On November 19, 2008, we published the CY 2009 Physician Fee Schedule final rule (73 FR 69754), implementing the site neutral composite rate for ESRD facilities, and the CY 2009 1.0 percent increase to the composite rate. We expect to publish the CY 2010 1.0 percent increase to the composite rate in the CY 2010 Physician Fee Schedule final rule.

In the following sections of this notice of proposed rulemaking, we describe the ESRD PPS we are proposing to implement effective January 1, 2011, in compliance with the statutory requirements of MIPPA.

II. Overview of the Proposed ESRD PPS

This proposed rule would implement a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis patients beginning January 1, 2011, in accordance with the statutory provisions set forth in section 153(b) of MIPPA. We propose to implement this new system as described in proposed § 413.172 and § 413.215. The proposed ESRD PPS would replace the current basic case-mix adjusted composite payment system and methodologies for the reimbursement of separately billable outpatient ESRD services. Specifically, we propose that the ESRD PPS would combine payments for composite rate and separately billable services into a single base rate of $198.64 developed from CY 2007 claims data. Under the proposed rule, the base rate would be subsequently adjusted using patient-specific case-mix adjustment factors developed from separate equations for composite rate and separately billable services. The case-mix adjusters would include variables for age, body surface area (BSA), low body mass index (BMI), gender, eleven co-morbidity categories, and the onset of renal dialysis. These proposed adjustment factors were developed using standard techniques of multiple regression to yield case-mix adjusted payments per treatment. The per treatment payment amounts would also be adjusted to reflect urban and rural differences in area wage levels using an area wage index developed from Core Based Statistical Areas (CBSAs definitions). The proposed rule also provides that ESRD facilities treating patients with unusually high resource requirements as measured through their utilization of identified services beyond a specified threshold would be entitled to outlier payments, that is, additional payments beyond the otherwise applicable case-mix adjusted bundled prospective payment amount. The proposed ESRD PPS also provides for special adjustments for pediatric patients and for facilities treating a low volume of ESRD patients, as well as a 4-year transition (phase-in) period under which facilities would receive a blend of payments under the prior case-mix adjusted composite payment system and the new ESRD PPS.

III. The Proposed ESRD PPS Bundle

Section 1881(b)(14)(A)(i) of the Act, as added by section 153(b) of MIPPA, specifies that the ESRD PPS must represent a single payment to ESRD facilities for ''renal dialysis services'' in lieu of any other payment, and home dialysis supplies, equipment, and support services furnished pursuant to section 1881(b)(4) of the Act. Section 1881(b)(14)(B) of the Act, which identifies the renal dialysis services that are to be included in the ESRD PPS payment bundle, provides the following:

* * * the term ''renal dialysis services'' includes—

(i) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(ii) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;

(iii) Other drugs and biologicals that are furnished to individuals for the treatment of

end stage renal disease and for which payment was(before application of this [new ESRD PPS]) made separately under this title, and any oral equivalent form of such drug or biological; and

(iv) Diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

The methodology, which we subsequently describe, for the development of the proposed ESRD PPS, generally identifies the renal dialysis services that we propose to include in the proposed payment bundle in accordance with our interpretation of the statute. We also discuss in more detail below the definition for renal dialysis services under section 1881(b)(14)(B) of the Act.

A. Composite Rate Services

Section 1881(b)(14)(B)(i) of the Act requires that the ESRD PPS payment bundle include composite rate services. As we indicated previously, the current case-mix adjusted composite payment system represents a limited PPS for a bundle of outpatient renal dialysis services that includes maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies, and staff time. It applies to Medicare beneficiaries receiving dialysis in ESRD facilities and to patients who have elected Method I home dialysis. (Under Method I, the ESRD facility with which the home patient is associated assumes responsibility for furnishing all home dialysis equipment, supplies, and home support services included in the provision of composite rate services. (See section 2740 of CMS Pub. 15–1.)) The ESRD facility receives reimbursement under the current case-mix adjusted composite payment system. For all other ESRD outpatient services not included in the composite payment rate under the current system, such items and services are billed separately in accordance with Medicare fee schedules and other payment methodologies under Part B and Part D. We propose to include in the proposed ESRD PPS those items and services included in the composite rate for renal dialysis services as of December 31, 2010, including self-dialysis training services, such as labor, supplies, and equipment(for greater detail, see discussion on self-dialysis training sessions in section E.2). Therefore, these costs for such composite rate services would be included in our computation of the proposed ESRD PPS base rate as explained in section VII. of this proposed rule. This not only would include payments for the costs of services directly related to dialysis, including payments for the costs of self-dialysis training sessions, but also payments authorized in accordance with the composite payment rate exception provisions set forth in 42 CFR 413.180 through 413.186. The costs for composite rate services are also included in our development of the composite rate regression model used to create the two equation patient specific case-mix adjusters that would be applied to the base rate. Composite rate services are defined in proposed § 413.171.

B. ESAs and Their Oral Forms

Section 1881(b)(14)(B)(ii) of the Act requires that ESAs and any oral form of such agents that are furnished to individuals for the treatment of ESRD be included in the ESRD PPS payment bundle. Epoetin alfa (EPO, for example, Epogen®) and darbepoetin (ARANESP®) are injectable ESAs, which are currently separately billable outside of the case-mix adjusted composite payment system. Payments for EPO® and ARANESP® would be included in the calculation of the proposed ESRD PPS base rate. These agents would also be included in the separately billable regression model used to create the two equation patient specific case-mix adjusters for the proposed ESRD PPS. We are currently unaware of any other injectable ESAs or oral forms of such ESAs used for the treatment of ESRD. However, should such agents become available subsequent to the implementation of the ESRD PPS on January 1, 2011, these agents would be considered renal dialysis services and subject to payment under the ESRD PPS. That is, consistent with the statute, we propose that no additional payment would be provided for such agents outside of the bundle of renal dialysis services included in the ESRD PPS. The inclusion of ESA's and their oral forms as renal dialysis services in the ESRD PPS payment bundle is set forth in proposed Medicare regulation 413.171.

C. Other Drugs and Biologicals and Their Oral Equivalents

Section 1881(b)(14)(B)(iii) of the Act specifies that other drugs and biologicals that were furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, prior to the implementation of the ESRD PPS, and their oral equivalent forms, must be included in the ESRD PPS payment bundle. Given the reference to ''this title,'' we interpret clause (iii) as requiring the inclusion in the ESRD PPS payment bundle all drugs and biologicals that were separately billable prior to the implementation of MIPPA under title XVIII of the Act. Therefore, we believe the ESRD PPS payment bundle would include all drugs and biologicals formerly separately payable under Medicare Part B and Part D. We recognize that an alternative reading of the last part of clause (iii) with respect to the phrase ''and any oral equivalent form of such drug or biological'' could be interpreted to limit the scope of the drugs and biologicals included in the bundle to only oral versions of injectables (or other non-oral routes of administration). However, we believe that this reading of the statute is unduly constrained. Therefore, our view is that the intent of clause (iii) is to include all drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat ESRD, regardless of the route of administration.

We believe that the exclusion of oral drugs and biologicals for which there is no injectable equivalent (or other non-oral form of administration) from the ESRD PPS would defeat one of the very purposes of the new system—the inclusion of all renal dialysis services furnished to ESRD patients in a comprehensive payment bundle to which a reasonable payment amount can be attached empirically. In addition, the exclusion of oral drugs and biologicals for which there is no injectable (or other non-oral) version does not make sense from a payment policy perspective. Such a policy would result in the gradual growth of excluded services from the ESRD PPS payment bundle, and the progressive erosion of the payment system, as new oral-only drugs and biologicals for the treatment of ESRD emerge. Moreover, we believe the inclusion of such drugs and biologicals is supportable under clause (iv). That is, we believe the language under clause (iv) addressing ''other items and services not covered in clause (i),'' provides sufficient authority to include all drugs and biologicals, including oral-only drugs and biologicals, used to treat ESRD in the ESRD PPS payment bundle. Therefore, we are proposing that drugs and biologicals used to treat ESRD that were separately payable prior to January 1, 2011, be included as part of the proposed ESRD PPS payment bundle. Accordingly, we propose to include such drugs and biologicals in the development of the proposed patient-specific case-mix adjusters and in the calculation of the proposed ESRD base rate to which the adjusters would be

applied. We identified specific National Drug Codes (NDCs) for drugs and biologicals previously payable under part D that we propose to include in the payment bundle. However, we propose that the ESRD PPS will apply, regardless of the emergence of new drugs or biologicals, or different NDCs for the classes of drugs and biologicals included in the ESRD PPS bundle. Finally, section 1881(b)(14)(B) of the Act specifically excludes vaccines from the payment bundle and, therefore, vaccines will not be included in the proposed ESRD PPS. We are seeking comments on our proposals above.

We have found that eleven drugs and biologicals accounted for 99.7 percent of the payments under Part B for all injectable drugs and biologicals that were furnished to outpatient ESRD patients in CY 2007. These drugs and biologicals are epoetin alfa (EPO®), darbepoetin alfa (ARANESP®), calcitriol, doxercalciferol, paracalcitol, iron sucrose, sodium ferric gluconate, levocarnitine, alteplase recombinant, vancomycin, and daptomycin. These drugs and biologicals, as well as the others comprising 0.3 percent of the total payments for drugs and biologicals under Part B in CY 2007, would be included in the proposed ESRD PPS payment bundle. Of the top eleven injectable drugs and biologicals, several have oral versions. For example, levocarnitine, and the vitamin D analogues calcitriol, doxercalciferol, and paricalcitol are also available in oral form. The oral versions of these drugs are currently covered under Medicare Part D. Other drugs used to treat ESRD are available only in oral form and are currently payable under Part D. These include cinacalcet hydrochloride, lanthanum carbonate, calcium acetate, sevelamer hydrochloride, and sevelamer carbonate. Consistent with our interpretation of section 1881(b)(14)(B)(iii) of the Act, we propose that payments for all drugs and biologicals furnished to ESRD patients and separately billable prior to January 1, 2011, would be included under the proposed ESRD PPS payment bundle as renal dialysis services. Under this proposal, separate billing for these services would be prohibited. The proposed ESRD PPS methodology, both with respect to the computation of the case-mix adjusters and the calculation of the proposed ESRD base rate to which the adjusters would be applied, includes payments for these services. The inclusion of other drugs and biologicals and their oral equivalents as renal dialysis services in the ESRD PPS payment bundle is set forth in proposed § 413.171.

D. Diagnostic Laboratory Tests and Other Items and Services

Section 1881(b)(14)(B)(iv) of the Act requires that diagnostic laboratory tests not included under the composite payment rate (that is, currently separately billable laboratory tests) must be included as part of the ESRD PPS payment bundle. We propose to define such laboratory tests as laboratory tests that are separately billed by ESRD facilities as of December 31, 2010, and laboratory tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients that are separately billed by independent laboratories. Because many of the same diagnostic laboratory tests can be performed for both ESRD and non-ESRD patients, we believe that this approach for including laboratory services appropriately captures tests for inclusion in the payment bundle. We propose that payments for these laboratory services would be included in the development of the proposed patient-specific case-mix adjusters and in the proposed ESRD base rate to which the adjusters would be applied.

Section 1881(b)(14)(B)(iv) of the Act also requires that the ESRD PPS payment bundle include ''other items and services not described in clause (i)''. We believe that this language can be reasonably interpreted to include other separately billable items and services used in the treatment of ESRD, such as supplies. Examples of such items and services would include, but not be limited to, items such as syringes, specialized tubing, as well as blood and blood products, which facilities may furnish during the dialysis treatment. We also believe that the language also can be interpreted to include the cost of other self-dialysis training services in the ESRD PPS (for further detail on self-dialysis training, see section E.2. below). We propose that such items and services be included in the ESRD PPS bundle. The inclusion of diagnostic laboratory tests and other items and services as renal dialysis services in the ESRD PPS payment bundle is set forth in proposed § 413.171.

E. Home Dialysis Patients (Method I and II) and Self-Dialysis Training

Section 1881(b)(4) of the Act authorizes the Secretary to make payment to providers of services and renal dialysis facilities, and to suppliers of home dialysis supplies and equipment, for the cost of home dialysis supplies and equipment and self-care home dialysis support services furnished to patients for self-care home dialysis. As a result of section 153(b) of MIPPA, as explained above, section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made under this title to an ESRD facility for renal dialysis services and for such services and items furnished pursuant to section 1881(b)(4) of the Act. As we explained above, we also believe that self-dialysis training services would be considered renal dialysis services as defined in section 1881(b)(14)(B) of the Act. As a result, we are proposing that the costs of home dialysis services furnished to both Method I and Method II home dialysis patients under the current basic case-mix adjusted payment system, as well as self-dialysis training services, must be combined into a single payment under the proposed ESRD PPS.

1. Payment for Home Dialysis

Currently, Hemodialysis, Continuous Cycling Peritoneal Dialysis (CCPD), Intermittent Peritoneal Dialysis (IPD) and Continuous Ambulatory Peritoneal Dialysis (CAPD) treatment modalities may be performed at home by appropriately trained patients. Medicare beneficiaries dialyzing at home must complete a Medicare Beneficiary Form (CMS–382) selecting between two methods of payment (Method I or Method II) as described below.

a. Method I—The Composite Rate

If a Medicare home dialysis patient chooses Method I, the ESRD facility with which the patient is associated must assume responsibility for providing all home dialysis equipment and supplies as well as providing home support services and receives the composite payment rate for such services. Support services needed to furnish home dialysis services include, but are not limited to: (1) Periodic monitoring of a patient's adaptation to home dialysis and performance of dialysis; (2) visits by trained technical personnel made in accordance with a plan prepared by a professional team; (3) unscheduled visits on an as needed basis; and (4) providing, installing, repairing, testing, and maintaining home dialysis equipment including appropriate water testing and treatment. For these services, the ESRD facility receives, in accordance with § 414.330(a), the same Medicare dialysis payment rate as it would receive for an in-facility patient under the basic case-mix adjusted composite payment system. Under Method I, the ESRD facility bills the Medicare Administrative Contractor/Fiscal

Intermediary (MAC/FI) and the beneficiary is responsible for paying the Medicare Part B deductible and the 20 percent coinsurance on the Medicare rate to the facility.

b. Method II—Dealing Directly With Suppliers

In accordance with regulations at § 414.330(a)(2), a Medicare ESRD beneficiary can elect to obtain home dialysis equipment and supplies from a supplier, that is not a Medicare approved dialysis facility (Method II). If a beneficiary elects Method II, the beneficiary will deal directly with a single Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier to secure the necessary supplies and equipment to dialyze at home. The selected DMEPOS supplier (not a dialysis facility) must accept assignment and bills the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). The beneficiary is financially responsible to the supplier for any unmet Medicare Part B deductible and for the 20 percent Medicare Part B coinsurance requirement. The amount of Medicare payment under Method II for home dialysis equipment and supplies may not exceed $1,974.25 per month for CCPD and $1,490.85 per month (57 FR 54186, published November 17, 1992) for all other modalities of home dialysis.

For each beneficiary it serves, the supplier is required to maintain a written agreement with an approved ESRD facility to provide backup and support services. An ESRD facility that has a written agreement to supply backup and support services bills the MAC/FI for services provided under the agreement. Under Method II, an ESRD facility may be paid up to $121.15 (57 FR 54186, published November 17, 1992) per month for home dialysis support services, such as arranging for the provision of all ESRD related laboratory tests and billing for the laboratory tests that are included in the composite payment rate. An ESRD facility may not be paid for home dialysis equipment or supplies under Method II.

Based on 2004–2006 data, only 3.1 percent of renal facilities report support service costs furnished to Medicare Method II home dialysis patients. The data also show that the number of Method II patients is small and has significantly declined over the study period (that is, 2004–2006) as shown below.

Patients	Year
5289	2004
4465	2005
2635	2006

We are proposing that payment for all home dialysis services excluding physicians' services (See section III.F. below regarding the exclusion of physicians' services) would be included in the bundled payment to the ESRD facility, under the proposed ESRD PPS.

In addition, as we indicated, section 1881(b)(14)(A)(i) of the Act requires that a single payment for renal dialysis services and items and services under section 1881(b)(4) be made to an ESRD facility. Therefore, since we are proposing that the costs of home dialysis services furnished under Method I and Method II (see section V Data Sources), regardless of home treatment modality, would be included in the proposed ESRD PPS, we also are proposing that the Method II home dialysis approach in its present form would no longer exist under the proposed ESRD PPS. With regard to payment limits for home dialysis services, in accordance with 6203(b) of Public Law 101–239, we published a final rule on November 17, 1992 implementing (57 FR 54179), Medicare program payment changes for home dialysis. In section 413.330(c), we set payment limits on what Medicare would pay for home dialysis supplies, equipment, and home support services as explained above. Accordingly, effective January 1, 2011, we propose to revise § 414.330 to reflect that payment as established in section 1881(b)(14) of the Act will be the basis for home dialysis supplies, equipment, and home support services and therefore, Medicare would pay for home dialysis equipment, supplies and support services only under the prospective payment rate established in proposed 413.210 and payment limits previously established for such would no longer apply. We also note, that this proposal would not eliminate Method I in its present form. Therefore, effective January 1, 2011, a supplier could only furnish, under an arrangement with the ESRD facility, home dialysis equipment and supplies to a Medicare home dialysis beneficiary, and then the supplier would need to look to the ESRD facility for payment. We believe that this would reduce the administrative burden of maintaining two payment methods for home dialysis patients, since we believe that section 1881(b)(14)(A)(i) requires that all Medicare home dialysis patients would be paid under the ESRD PPS. We invite public comments on this proposal.

2. Self-Dialysis Training

Currently, Medicare covers home hemodialysis training and two forms of PD training programs. Home dialysis and self-dialysis can only be performed after an ESRD patient has completed an appropriate course of training. The scope of training services that a certified facility provides to ESRD patients is described in § 494.100(a). Medicare pays the ESRD facility its case-mix adjusted composite rate plus $12 per training treatment for CAPD and $20 per training treatment for CCPD. For hemodialysis training, Medicare pays the ESRD facility its case-mix adjusted composite rate plus $20 per training treatment (Medicare Claims Processing Manual, Chapter 8, Outpatient ESRD Hospitals, Independent Facility, and Physician/Supplier Claims, Section 50.8, Training and Retraining). We point out that effective January 1, 2011, under the proposed ESRD PPS, ESRD facilities would no longer receive an add-on of $12 for CAPD and $20 for hemodialysis and CCPD to the otherwise applicable payment amount per treatment for the costs of training. In addition, ESRD facility training expenses are included in the base period payment rate to which the combined rate and payment multiplier in the proposed two-equation model is applied.

As we indicated, section 1881(b)(14)(B) of the Act, as added by section 153(b) of MIPPA, specifies the renal dialysis services that must be included in the ESRD PPS. Since self-dialysis training is used to train patients for the treatment modality of home dialysis with little or no help, we believe that these services would be considered ''renal dialysis services.'' As we indicated above, services related to self-training would meet the definition under clauses (i) and (iv) of section 1881(b)(14)(B) of the Act. As such, we propose to include the cost of self-dialysis training in the proposed ESRD PPS. We evaluated the current training cost reported by ESRD facilities (see section V Data Sources) to train ESRD patients for home dialysis. Training costs have been included in the composite rate payment adjusters in the proposed ESRD PPS. In section VIII.A. of this proposed rule, we point out that total composite rate costs included in the per treatment calculation include costs incurred for training expenses, as well as all home dialysis costs. We used the ESRD facilities cost reports to identify provider costs for training rather than payments. Therefore, in this proposed rule we propose to include

these costs in the composite rate portion of the two-equation ESRD PPS model described in section VI of this proposed rule. We believe that including training and home dialysis costs in the ESRD PPS would provide increased flexibility to dialysis centers for greater use of less costly PD and alternative treatment regimens such as nocturnal dialysis, home hemodialysis using compact portable dialysis machines, and shorter but more frequent dialysis sessions. For these reasons, we are proposing to include training and home dialysis costs in the proposed ESRD PPS, as set forth in proposed § 413.217. Training costs were included in the calculation of the composite rate costs used to develop the regression-based adjustment factors for the composite rate portion of the two-equation model described in section VIII. In addition, the base rate to which the patient-specific case-mix adjustment factors are applied includes payments to ESRD facilities for training expenses. Because we are proposing that training costs under the ESRD PPS would be treated no differently than any other overhead expense, an explicit adjustment to the bundled payment amount for HD and PD training expenditures would not be necessary. We are seeking comments on our proposal to include home dialysis training services in the proposed ESRD PPS.

F. Physicians' Services

Section 1881(b)(14)(A)(i), as added by MIPPA, states as follows in pertinent part:

''* * * the Secretary shall implement a payment system under which a single payment is made under this title to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment * * * and for such services and items furnished pursuant to [section 1881(b)(4)].''

We believe this provision generally governs payment to ESRD facilities. With regard to physicians' services related to renal dialysis, such services are addressed in section 1881(b)(3) of the Act. At this time, we do not intend to significantly modify payment for physicians' services. Any changes with regard to the payment for physicians' services related to renal dialysis would be addressed in future rulemaking. Therefore, the scope of this proposed rule generally will be limited to payment for home dialysis and renal dialysis services furnished by ESRD facilities.

IV. Unit of Payment

Under section 1881(b)(14)(C) of the Act, as added by section 153(b) of MIPPA, the ESRD PPS may provide for payment on the basis of renal dialysis services furnished during a week, or month, or such other appropriate unit of payment as the Secretary specifies. Approximately 92 percent of ESRD beneficiaries requiring outpatient dialysis undergo hemodialysis (HD), usually furnished in a facility. A small but increasing number of patients perform HD at home. The most typical schedule is 3 treatments per week, with each treatment averaging 3 to 4 hours. The remaining 8 percent of patients use peritoneal dialysis (PD). PD is usually done at home, with or without machine assistance. Unlike HD, which involves the circulation of the patient's blood and filtration of toxins using an artificial kidney machine, PD removes blood toxins through the draining of the dialysate from the lining of the abdomen or peritoneum several times a day. A form of PD, sometimes referred to as continuous cycling PD, is done with machine assistance while the patient sleeps, either at home or in specially designated areas at the ESRD facility.

Since the inception of the composite payment system in 1983, ESRD facilities have been reimbursed the applicable payment per treatment, with a maximum of 3 treatments for each full week a patient undergoes outpatient dialysis, unless additional treatments are justified by medical necessity. The 3-times weekly payment approach has applied regardless of whether the mode of dialysis is HD or PD. For example, an ESRD facility's payment for a Method I home patient on PD for 21 days would be equal to $21/7 \times 3$ or 9 times the composite rate per treatment.

Both the Secretary's May 2003 and February 2008 reports on the development of a bundled ESRD PPS discussed the limitations of the per treatment method of payment under the composite payment system. For example, some have charged that the composite payment system's 3 times weekly payment structure, regardless of dialysis modality, has discouraged innovative treatment approaches that could lead to better clinical outcomes and an enhanced quality of life for patients. We believe that the argument is two-fold. First, the reliance on separately billable services as a source of revenue growth for ESRD facilities has potentially impeded the greater use of less costly PD (which typically uses fewer separately billable drugs and less provider and facility overhead expense). Second, others argue that constraining payment based on number of treatments may reduce the use of alternative treatment regimens such as increased frequency nocturnal dialysis, home HD using compact portable dialysis machines, and shorter but more frequent dialysis sessions (for example, 1.5 to 2 hours, five or six days per week).

These critics have maintained that combining composite rate and separately billable services during a specified interval of time would provide ESRD facilities the financing flexibility to use whatever forms of dialysis were in the best interests of the patient. Because ESRD facilities generally submit to Medicare a bill for all outpatient dialysis services furnished to a patient during the month, an ESRD PPS based on monthly payments was suggested as an alternative in the Secretary's February 2008 Report to Congress. As we indicated above, section 1881(b)(14)(C) of the Act, as added by section 153(b) of MIPPA, gives the Secretary the discretion to establish an ESRD PPS based on an interval of time, or other appropriate unit of payment. In this notice we are proposing to establish an ESRD PPS which relies on a per treatment unit of payment. We propose to continue the present per treatment basis of payment in which ESRD facilities would be paid for up to three treatments per week, unless medical necessity justified more than three weekly treatments. ESRD facilities treating patients on PD or home HD would also receive payments for up to three treatments for each week of dialysis, unless medical necessity justified the furnishing of additional treatments. Our reasons for continuing the present per treatment method of payment under the proposed ESRD PPS are set forth below.

A. Administrative Complexity Due to Phase-In

Section 1881(b)(14)(E)(i) of the Act provides for a 4-year phase-in (transition), in equal increments for the implementation of the ESRD PPS. That is, the payments beginning January 1, 2011, must consist of a blend of the payment amounts under the new system and the prior payment rates in the following proportions:

Effective	New PPS (percent)	Prior payment amounts (percent)
1/1/2011	25	75
1/1/2012	50	50
1/1/2013	75	25
1/1/2014	100	0

Although ESRD facilities could elect to be excluded from the phase-in, in accordance with section 1881(b)(14)(E)(ii) of the Act, application of the phase-in under a monthly ESRD PPS would mean that a portion of each ESRD facility's total payments, would be based on a monthly payment methodology, while a portion would be based on the current per treatment system. We believe that combining a monthly ESRD PPS with the current per treatment methodology during the transition period would unduly complicate billing and increase the likelihood of payment errors and processing delays.

B. Administrative Complexity Due to Interruptions in Service

A monthly payment approach under the ESRD PPS likely would not pose a problem for patients who receive their dialysis treatments at a single ESRD facility throughout the month with no interruptions in service. However, we note that this situation applies to about 81 percent of patient months. Approximately 19 percent of outpatient dialysis patients incur an interruption of service or receive their treatments at more than one facility during a month. The combination of intervening events in the available data for CYs 2004–2006 is shown in Table 1.

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Table 1

Distribution of Medicare dialysis patient months by patient event, 2004-06

Patient events during month	2004 n=2,779,893	2005 n=2,878,259	2006 n=2,954,931
No events*	81.67	81.72	82.07
Start of dialysis	0.35	0.35	0.34
Hospitalization	15.17	15.15	14.89
Transplant	0.01	0.01	0.01
Transplant failure	0.02	0.02	0.02
Recovered renal function	0.05	0.05	0.05
Death or withdrawal from dialysis	0.51	0.50	0.49
Start of dialysis + hospitalization	0.94	0.93	0.88
Transplant + hospitalization	0.26	0.26	0.26
Transplant failure + hospitalization	0.05	0.05	0.05
Death/withdrawal + hospitalization	0.92	0.91	0.89
Other combination of events	0.05	0.06	0.05
No facility transfer or other event	78.54	78.45	79.05
Facility transfer only***	3.14	3.28	3.02
Facility transfer and other event	0.83	0.83	0.75
Other event only	17.50	17.45	17.18

*Patient events were identified using the following sources: the ESRD Medical Evidence Form (CMS Form 2728), the ESRD Death Notification Form (CMS Form 2746), and other data from the ESRD Network Standard Information Management System (SIMS); Medicare outpatient dialysis facility claims; Medicare inpatient claims; data from the Organ Procurement Transplant Network (OPTN); and the Social Security System Death Master File.

**This category is based on the definition used for the 2008 UM-KECC report, and includes months with a facility transfer only.

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To properly account for events which interrupt a patient's outpatient dialysis, the days associated with these intervening events would have to be tracked and counted so that a pro rata reduction to the otherwise applicable monthly payment amount could be determined. This becomes especially cumbersome if a patient receives treatments at more than one facility and an interruption in service occurs (for example, due to hospitalization). Although Table 1 reveals that this circumstance occurs in less than 1 percent of patient months, the administrative complexity involved in monitoring events, which cause an interruption in the patient's normal schedule of receiving dialysis treatments, particularly where multiple

facilities are involved, would be considerable.

Table 1 shows that for CY 2006, 79.05 percent of patient months did not involve an intervening event and did not include transfer to another facility. These patient months, when included with CY 2006 events that also account for an interruption of dialysis due to hospitalization, start of dialysis later in the month, or death/withdrawal from dialysis, account for 94.09 percent of CY 2006 patient months. One option that we considered for the approximately 15 percent of patient months in which a patient did not undergo a full month of dialysis due to hospitalization, onset of dialysis later in the month, or death/withdrawal from dialysis, was applying a prorated monthly payment rate to cover these situations, and reverting to a per treatment payment methodology for all other situations. However, we believe that this approach would be too administratively complex. For example, under this approach a facility could find that some of its patients would be paid a full monthly ESRD PPS rate, those with an interruption in service would be paid a prorated monthly rate, and others would be paid based on a per treatment method.

C. No Incentive To Discourage Skipped Treatments

A monthly ESRD PPS would afford facilities the maximum degree of clinical flexibility in treating patients. Facilities could provide whatever mode and frequency of dialysis, were in the best interests of the patient. However, under a monthly ESRD PPS, we believe that facilities may make less of an effort to discourage patients from skipping treatments. Because facilities do not receive reimbursement for skipped sessions under the current per treatment payment system, we are very concerned that a monthly ESRD PPS would provide no incentives for discouraging skipped treatments. Therefore, implementation of a monthly ESRD PPS would require either a stringent monitoring system to ensure the skipping of treatments does not become a byproduct of the new PPS's incentives, or require that a minimum number of treatments must be furnished to each patient in a month to ensure quality of care does not deteriorate. Both options would undercut two of the principles, which are part of the foundation of the new ESRD PPS, administrative simplicity and clinical flexibility.

Given the difficulties of implementing a monthly ESRD PPS during a transition period in which a per treatment methodology applies, we are proposing to continue the present per treatment payment methodology in connection with the proposed ESRD PPS, as set forth in proposed § 413.215. We may reconsider this decision after the transition period has ended. Some of the factors that we may evaluate at that time are whether the ESRD PPS has resulted in improved clinical outcomes, the degree to which facilities have increased the utilization of other modes of dialysis such as home PD, and whether interested stakeholders at that time would favor a monthly or other per unit of time payment methodology. We especially encourage comments from the industry and from organizations representing dialysis patients on our proposal to continue the per treatment methodology under the proposed ESRD PPS. In the following sections, we describe the data sources and analytical techniques used to develop the proposed per treatment ESRD PPS.

V. Data Sources

As discussed above, section 1881(b)(14)(B) of the Act, as added by section 153(b) of MIPPA, defines the renal dialysis services that must be included in the ESRD PPS. Based on our interpretation of the statute, we are proposing to construct the payment bundle using the following Medicare cost and payment information:

- Composite rate services as measured using composite rate costs as calculated from the Medicare cost reports;
- Drugs and biologicals (for example, injectables) that are separately billed by ESRD facilities on Medicare outpatient institutional claims;
- Drugs and biologicals (for example, oral) used to treat ESRD patients obtained from claims submitted by Part D stand-alone prescription drug plans;
- Laboratory tests that are separately billed by ESRD facilities on Medicare outpatient institutional claims;
- Laboratory tests ordered by a physician who receives MCPs for treating ESRD patients that are separately billed by independent laboratories;
- Other items and services separately billed by ESRD facilities that are used in conjunction with injectable medications or laboratory tests, such as blood products, syringes, and other dialysis supplies that are billed on Medicare outpatient institutional claims.

While cost information for composite rate services is available from the Medicare cost reports, the cost report does not contain information on the costs of the separately billable categories of services noted above. Accordingly, the methodology described in this notice of proposed rulemaking applicable to separately billable services relies on separately billable payment information from Medicare claims.

The descriptive statistics, case-mix model, and other analyses presented in this proposed rule are based primarily on CMS claims files for Medicare ESRD patients, and the Medicare cost reports for hospital-based ESRD outpatient dialysis providers and independent ESRD facilities. Resource utilization for separately billable services was based on patient-level Medicare outpatient claims for CYs 2004 through 2006. Since composite rate cost information is available only at the facility level, resource utilization for composite rate services was measured using the Medicare cost reports for each outpatient dialysis provider and facility (that is, hospital-based and independent facility). For the case-mix model for the proposed ESRD PPS, we relied on Medicare claims and cost reports for CY 2004 through CY 2006, because those years represented the latest most complete data available for the preparation of this proposed rule.

With regard to the budget neutrality requirement under section 1881(b)(14)(A)(ii) of the Act, which requires that the estimated total amount of payments for 2011 for renal dialysis services be equal to 98 percent of the estimated total amount of payments for renal dialysis services, that would have been made for services furnished in 2011 if the ESRD PPS had not been implemented, we are required to use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization. To comply with this provision of the statute, we plan to evaluate available claims for Medicare ESRD beneficiaries for CYs 2007, 2008, and 2009 to determine which year resulted in the lowest average payment amount per treatment. Because the lowest payment amount per treatment would reflect the lowest utilization of outpatient ESRD services among patients absent evidence that per unit prices for those services declined, we believe that selection of the CY with the lowest payment per treatment for calculation of the ESRD base rate would comply with section 1881(b)(14)(A)(ii) of the Act.

Currently, the latest payment information from Medicare claims that is available in sufficient time for the preparation of this proposed rule is for CY 2007. Cost report information subsequent to CY 2006, and Medicare claims data subsequent to CY 2007, could not be evaluated given the necessary lead time required to prepare this proposed rule. We plan to examine

available Medicare cost report information for CYs subsequent to 2006 in developing the case-mix adjusters to ensure use of the latest available data, and available payment data from Medicare claims for CY 2008 and CY 2009 to comply with the lowest per patient utilization requirement of section 1881(b)(14)(a)(ii) of the Act, in preparing the final rule. Any later payment data used in developing the ESRD PPS published in the final rule, would be updated in accordance with the methodology explained elsewhere in this proposed rule. (See Section VII., Development of Budget-Neutral ESRD Bundled Base Rate.)

We used several data sources for evaluating the patient and facility characteristics that were also used with the case-mix analyses. Patient demographic information was obtained from the Renal Management Information System (REMIS)/Consolidated Renal Operations in a Web-Enabled Network (CROWN), and the ESRD Standard Information Management System (SIMS). These data sources include the Medical Evidence Report Form (Form 2728), which is completed at the onset of renal replacement therapy (RRT), which is either dialysis or transplantation to sustain life at the onset of kidney failure. Patient body size measures were developed from the height and weight values reported on the Form 2728. Beginning April 1, 2005, these values were obtained from the patient claims for outpatient dialysis. Patient co-morbidities were measured using the Form 2728, supplemented with diagnoses reported on Medicare hospital inpatient, skilled nursing facility, hospital outpatient, hospice, home health agency, and physician claims. The claims diagnoses were used to identify co-morbidities that were not abstracted using the Form 2728, and to capture changes in patient condition subsequent to the onset of kidney failure. Because diagnoses reported on laboratory claims may represent a suspected condition subject to testing rather than an established diagnosis, laboratory claims were not used to identify co-morbidities in the case-mix models.

We measured dialysis facility characteristics using a combination of SIMS (ownership type and geographic location), the Medicare cost reports (facility size), the Online State Certification and Reporting System or OSCAR (hospital affiliation for satellite units), and other available information (for example, identifying facilities with composite payment rate exceptions).

A. Patient Claims Data

The outpatient facility paid claims file is the primary source of information for payments ESRD facilities receive for the treatment of ESRD patients. The ''type 72X'' bills provided the detailed data for dialysis payments. The claims files used for the analyses in this proposed rule are based on patients with at least one claims record for dialysis. We used carrier claims and durable medical equipment claims to track dialysis-related payments to other providers such as independent laboratories.

The case-mix models were based on claims from CYs 2004, 2005, and 2006. These were the most complete CY records available for use with the Medicare cost reports from the same periods to develop the payment methodology, given the lead time necessary for the preparation of this proposed rule. We plan to use available CY data subsequent to 2006 data in developing the payment methodology in connection with the final rule. The number of Medicare claims, patients, dialysis sessions, and ESRD facilities represented in the source claims data are shown in Table 2. We have also provided the same information for CY 2003 for comparison purposes.

TABLE 2—MEDICARE DIALYSIS PATIENTS, TREATMENTS, ESRD FACILITIES, AND CLAIMS BY YEAR, 2003–2007

	2003	2004	2005	2006	2007
Medicare Dialysis Patients[1]	298,617	308,561	318,531	324,836	328,841
Hemodialysis Equivalent Dialysis Treatments[2,3]	32,692,581	34,088,570	35,097,820	35,948,738	36,667,669
ESRD Facilities	4,365	4,523	4,668	4,810	4,955
Patient Month Claims	2,830,215	2,934,505	3,037,965	3,095,996	3,155,553

[1] Includes home dialysis patients for whom payments were made under Method II.
[2] Hemodialysis-equivalent treatments were capped at 20 per month. The number of dialysis treatments for Method II patients was estimated using the average number of hemodialysis-equivalent treatments per month reported for Method I peritoneal dialysis patients during that year (which ranged from 12.50 to 12.66 during 2003–07).
[3] Includes PD in which one week of PD is considered equivalent to 3 HD treatments.

B. Medicare Cost Reports

We obtained facility-level cost and treatment data from the CMS Medicare Hospital Cost Report (Form CMS 2552–96) and the CMS Medicare Independent Renal Dialysis Facility Cost Report (Form CMS 265–94). The number of available cost reports for CYs 2004 through 2006 that contained necessary cost and treatment data for purposes of the composite rate cost analyses are shown in Table 3.

TABLE 3—AVAILABLE COST REPORTS BY ESRD FACILITY TYPE, 2003–2006 [1]

ESRD facility type	2003	2004	2005	2006
Facilities (Independent)	3,689	3,852	4,025	4,140
Providers (Hospital Based)	455	451	448	433
Total	4,144	4,303	4,471	4,573

[1] Based on the June 2008 quarterly update of HCRIS. Includes cost reports with composite rate cost and treatment fields greater than 0.

For most ESRD facilities, a single cost report encompassed the entire calendar year. For FY cost reports that spanned two CYs, we used a weighted average based on the proportion falling in each CY.

C. Patient Claim and Cost Report Summary Data, 2004–2006

The case-mix models were based on data sets that linked claims and cost

report records for each year from CY 2004 through CY 2006. The claims data for patients treated in hospital satellite facilities were matched to the parent hospital using OSCAR, since cost reports are only submitted by the parent facility. Table 4 shows the resulting analysis files that included both claims and cost report data for measuring separately billable and composite rate resource utilization.

TABLE 4—MEDICARE DIALYSIS PATIENTS, TREATMENTS, ESRD FACILITIES, AND CLAIMS FOR PATIENTS AND FACILITIES WITH MEASURED COSTS PER TREATMENT, BY YEAR, 2004–2006 [1]

	2004	2005	2006
Medicare Dialysis Patients	301,625	311,787	317,734
Hemodialysis Equivalent Dialysis Treatments	33,056,812	34,062,969	34,963,270
ESRD Facilities	4,228	4,376	4,489
Patient Month Claims	2,732,001	2,826,580	2,897,424

[1] Includes patient months and ESRD facilities with Medicare hemodialysis-equivalent treatments >0 from the outpatient dialysis facility claims and measured composite rate costs from the cost reports.

D. Data for the Case-Mix Analyses, 2004–2006

The case-mix analyses required data for several patient and facility characteristics. After the exclusion of statistical outliers or otherwise unusable records, the data shown in Table 4 were reduced to yield the data set used in the primary analyses for both composite rate and separately billable services. Table 5 summarizes these records.

TABLE 5—MEDICARE DIALYSIS PATIENTS, TREATMENTS, ESRD FACILITIES, AND CLAIMS FINAL ANALYSIS SAMPLE BY YEAR, 2004–2006 [1]

	2004	2005	2006	Pooled, 2004–2006
Medicare Dialysis Patients	290,102	298,314	303,967	453,789
Hemodialysis Equivalent Dialysis Treatments	31,450,123	32,303,018	33,148,355	96,901,496
ESRD Facilities	3,794	3,948	4,072	4,250
Patient Month Claims	2,604,033	2,685,413	2,751,735	8,041,181

[1] Based on the sample of dialysis patients and ESRD facilities included in the case-mix analyses for both composite rate and separately billable services.

The primary case-mix analyses relied on pooled data from CY 2004 through CY 2006, which included a total of 8,041,181 Medicare ESRD patient months. The case-mix analyses included 95.4 percent of patients with Medicare outpatient dialysis claims during CYs 2004–2006. Over the 3-year period, the case-mix analyses included data for 453,789 Medicare ESRD patients treated in 4,250 ESRD facilities.

E. Prescription Drug Event Data, CY 2007

We obtained the total CY 2007 payments for Medicare Part D drugs from Part D claims submitted by prescription drug plans (drugs formerly covered under Part D prior to the ESRD PPS). The claims were restricted to Part D claims submitted on behalf of Medicare ESRD beneficiaries with valid type 72X claims in CY 2007 and Part D coverage. We used claims for the following classes of drugs to calculate the estimated Part D payments for drugs used to treat ESRD (formerly covered under Part D) for inclusion in the ESRD PPS payment bundle:

Drug class	Ingredient name
Vitamin D analogue	Calcitriol.
	Paracalcitol.
	Doxercalciferol.
Calcimimetic	Cinacalcet hydrochloride.
Oral phosphate binder.	Lanthanum carbonate.
	Calcium acetate.
	Sevelamer hydrochloride.
	Sevelamer carbonate.

The National Drug Codes (NDCs) used to identify the above drugs in the Part D claims are shown below in Table 6.

TABLE 6—LIST OF NATIONAL DRUG CODES USED TO IDENTIFY FORMER PART D DRUGS FOR THE ESRD PPS

Ingredient name	NDC	Strength	Trade name
Drug Class: Vitamin D Analogues			
Calcitriol	260530051	0.25 MCG	Calcitriol Capsules.
	540007	0.25 MCG	Calcitriol Capsules.
	930657	0.25 MCG	Calcitriol Capsules.
	930658	0.5 MCG	Calcitriol Capsules.
	1791578	0.25 MG	Calcitriol Capsules.
	1791603	0.5 MCG	Calcitriol Capsules.
	4800657	0.25 MCG	Calcitriol Capsules.
	4800658	0.5 MCG	Calcitriol Capsules.
	110140011	0.25 MCG	Calcitriol Capsules.
	142880007	0.25 MCG	Calcitriol Capsules.
	178560007	0.25 MCG	Calcitriol Capsules.

TABLE 6—LIST OF NATIONAL DRUG CODES USED TO IDENTIFY FORMER PART D DRUGS FOR THE ESRD PPS—Continued

Ingredient name	NDC	Strength	Trade name
	548684584	0.25 MCG	Calcitriol Capsules.
	551548251	0.25 MCG	Calcitriol Capsules.
	647250048	0.25 MG	Calcitriol Capsules.
	647250049	0.5 MG	Calcitriol Capsules.
	543120	1 MCG/ML ...	Calcitriol Oral Solution.
	682589030	0.5 MCG	Calcitriol Capsules.
	548683461	0.25 MCG	Rocaltrol Capsules.
	604910562	0.5 MCG	Rocaltrol Capsules.
	49115	1 MCG/ML ...	Rocaltrol Oral Solution.
Paricalcitol	744314	2 MCG	Zemplar Capsules.
	744315	4 MCG.	
	744317	1 MCG.	
	110140056	2 MCG.	
	110140057	4 MCG.	
	242360664	1 MCG.	
	511294272	1 MCG.	
	551540001	1 MCG.	
	551546971	1 MCG.	
Doxercalciferol	110140017	0.5 MCG	Hectorol Capsules.
	110140018	2.5 MCG.	
	511293550	2.5 MCG.	
	584680120	0.5 MCG.	
	584680122		
	584680121	2.5 MCG.	
Drug Class: Calcimimetic			
Cinacalcet Hydrochloride	682589225	30 MG	Cinacalcet HCL Tablet.
	632850074	66 MG	Sensipak Tablets.
	1791845	30 MG	Sensipar Tablets.
	548685616	30 MG	Sensipar Tablets.
	555130073	33 MG	Sensipar Tablets.
	555130074	66 MG	Sensipar Tablets.
	555130075	99 MG	Sensipar Tablets.
	632850073	30 MG	Sensipar Tablets.
	632850075	K99 MG	Sensipar Tablets.
Drug Class: Oral Phosphate Binder			
Lanthanum Carbonate	540920252	500 MG	Fosrenol Chewable Tablets.
	540920253	750 MG.	
	540920254	1000 MG.	
	635520250	750 MG.	
	635520251	1000 MG.	
	635520252	500 MG.	
Calcium Acetate	540026	667 MG	Calcium Acetate Capsules.
	142880954	667 MG	Calcium Acetate Capsules.
	597306402	667 MG	PhosLo Gelcaps.
	1791371	667 MG	PhosLo Tablets.
	1791934	.....	PhosLo Tablets.
	522680200	667 MG	PhosLo Tablets.
	548683460	667 MG	PhosLo Tablets.
	548685691	.....	PhosLo Tablets.
	647250260	667 MG	PhosLo Tablets.
Sevelamer Hydrochloride	178560020	400 MG	Crenagel Tablets.
	260530308	800 MG	Renagel Tablet.
	260530394	400 MG	Renagel Tablet.
	6155613	800 MG	Renagel Tablets.
	178560021	800 MG	Renagel Tablets.
	242360660	400 MG	Renagel Tablets.
	511293461	800 MG	Renagel Tablets.
	548685615	800 MG	Renagel Tablets.
	551549726	400 MG	Renagel Tablets.
	551549727	800 MG	Renagel Tablets.
	580160778	800 MG	Renagel Tablets.
	584680020	400 MG	Renagel Tablets.
	584680021	800 MG	Renagel Tablets.
	613920721	400 MG	Renagel Tablets.
	647250284	400 MG	Renagel Tablets.
	647250285	800 MG	Renagel Tablets.
	654970020	400 MG	Renagel Tablets.

TABLE 6—LIST OF NATIONAL DRUG CODES USED TO IDENTIFY FORMER PART D DRUGS FOR THE ESRD PPS—Continued

Ingredient name	NDC	Strength	Trade name
	654970021	800 MG	Renagel Tablets.
	675440656	800 MG	Renagel Tablets.
	682990002	400 MG	Renagel Tablets.
	682990021	800 MG	Renagel Tablets.
	584680130	800 MG	Renvela Tablets.
	711144207	403 MG	Sevelamer Hydrochloride Capsules.
	68258–9013	800 MG	Sevelamer Hydrochloride Tablets.
	68258–9070	400 MG	Sevelamer Hydrochloride Tablets.
Sevelamer Carbonate	68299–0130	800 MG	Renvela Tablets.

Table 7 shows the number of Medicare ESRD beneficiaries for which valid type 72X claims were filed in CY 2007, number of ESRD beneficiaries with Part D drug coverage from PDP plans, and number of beneficiaries with Part D claims for the above oral drugs. CY 2006 data are shown for comparison purposes only, as they were not used to calculate the ESRD base rate.

TABLE 7—MEDICARE DIALYSIS PATIENTS WITH PAYMENTS FOR PART D DRUGS, 2006 AND 2007

	2006		2007	
	Patients	%	Patients	%
ESRD patients with Medicare payments on outpatient dialysis facility claims *	324,836	.....	328,841	.....
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs	207,035	63.74	219,451	66.73
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs included in the ESRD PPS **	159,570	49.12	175,132	53.26

** Includes "type 72X" outpatient institutional claims.
** Includes Vitamin D Analogs (Calcitriol, Paracalcitol, and Doxercalciferol), Calcimimetics (Cinacalcet Hydrochloride), and Oral Phosphate Binders (Lanthanum Carbonate, Calcium Acetate, Sevelamer Hydrochloride, and Sevelamer Carbonate).

VI. Analytical Approach

In this proposed rule, we are presenting a case-mix model that UM–KECC has developed using standard techniques of multivariate regression. In multivariate or multiple regression, a set of independent or predictor variables are tested to determine the extent they can predict or ''explain'' the variation in a related dependent or predicted variable. The unit of analysis in such models is important because the level at which resource use can be measured differs for composite rate and separately billable services. We can measure separately billable services for individual patients using the payment information obtained from Medicare claims. However, the available measure of resource use for composite rate services consists of costs from the Medicare cost reports. These costs do not distinguish patient-specific differences within ESRD facilities, because they combine treatment costs for all ESRD patients.

In the Secretary's February 2008 report to Congress, we described two approaches for developing the case-mix models using multivariate regression. Under the first approach, referred to as the one-equation model, composite rate costs and separately billable payments for all patients treated in each ESRD facility are added together. When the result is divided by the number of corresponding ESRD treatments, the predicted or dependent variable of bundled services reflects a facility-level model of combined composite rate and separately billable services. This approach has the relative simplicity of having the case-mix adjustments based on a single statistical model estimated at the facility level.

The other approach, which we refer to as the two-equation model, relies on two separate regression equations, one to predict variation in composite rate costs at the facility level, and the other to predict variation in separately billable payments at the patient level. This approach has the advantage of measuring patient-level variation in the utilization of separately billable services available from the Medicare claims. It also permits combining separate composite rate and separately billable regression equations into a single payment equation.

The case-mix model, which we have adopted in developing the proposed ESRD PPS, is based on the two-equation model. The basis for our selection of the two-equation model was set forth in the Secretary's February 2008 report to Congress:

> In an extensive series of analyses, UM–KECC determined that application of the one-equation bundled PPS model (that is, a facility-level model) yielded very different regression coefficients for a number of potential case-mix adjusters compared to the two-equation bundled PPS model. These differences were attributed to the correlation between the tested case-mix variables and unobserved facility characteristics. UM–KECC concluded that a patient-level model would have the advantage of reducing potential bias related to unobserved facility characteristics, would result in more precise coefficient estimates, and yield greater stability in these estimates over time. A patient-level model for the separately billable services can be combined with a facility-level model for composite rate services to yield a single payment equation.

This is the approach adopted to develop the case-mix adjusters for the ESRD PPS described in this proposed rule.

For those interested, a more extensive and detailed mathematical explanation of the two-equation model used to develop the case-mix adjusters is contained in UM–KECC's February 2008 report, *End Stage Renal Disease Payment System: Results of Research on*

Case-Mix Adjustment for an Expanded Bundle (see pp. 38–44 and Technical Appendix C).

II. Development of ESRD PPS Base Rate

The patient-specific case-mix adjustments developed from the two-equation regression model for composite rate and separately billable services, which we have described in section VIII. of this proposed rule, would be applied to a base payment rate per treatment (''base rate''). The base rate would also be adjusted to reflect ESRD facility differences in area wage levels using a proposed wage index as described in section VIII.C. In this section, we describe the calculation of the proposed ESRD base rate, as set forth in proposed § 413.220, and the computation of the reduction factors used to adjust the base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act. The base rate presented in this proposed rule, and defined in proposed § 413.171, was calculated entirely from CY 2007 Medicare claims data. The proposed base rate, which represents the average Medicare allowable payment (MAP) for composite rate and separately billable services, was developed from CY 2007 claims data. We used claims data for CY 2007 in connection with the preparation of this proposed rule because such data were the latest available. We expect to have claims data for CY 2008 and partial claims information for CY 2009 in connection with our preparation of the final rule. Comparing per treatment payment amounts developed from available claims data for CYs 2007, 2008, and 2009 would permit a determination as to which year resulted in the ''lowest per patient utilization'' of dialysis services as required in accordance with section 1881(b)(14)(A)(ii) of the Act. The components of the proposed base rate based on CY 2007 claims data and the methodology used to project the base rate to CY 2011 (the first year of the ESRD PPS), are described below.

A. Calculation of the CY 2007 Unadjusted Rate per Treatment

Sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act, as added by MIPPA, specify the renal dialysis services, and other items and services, which must be included in the payment bundle of the ESRD PPS. Table 8 shows the payments for the various components which comprise the renal dialysis services which we propose to include in our development of the base rate using available CY 2007 claims data, in accordance with our interpretation of the statute. We first describe each of the components of the ESRD PPS payment bundle included in the CY 2007 unadjusted rate per treatment. Thereafter, we describe the adjustments used to calculate the ESRD PPS base rate from the CY 2007 unadjusted rate per treatment.

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Table 8
Medicare Allowable Payments (MAP) for composite rate and separately billable services, 2007

Description	Actual MAP for 2007, as reported on claims[1]
Total Medicare Allowable Payments by service category	
Outpatient dialysis and other composite rate services^	$5,705,412,338
Dialysis support services^	$1,447,484
Part B drugs and biologicals^	
Epogen*	$1,846,771,009
Darbepoetin	$167,776,951
Vitamin D	$402,447,416
Calcitriol	$3,116,590
Doxercalciferol	$76,770,839
Paricalcitol	$322,559,988
Iron	$234,031,283
Iron Sucrose	$165,992,904
NA Ferric Gluconate	$68,038,379
Levocarnitine	$5,025,914
Alteplase	$26,682,197
Vancomycin	$3,578,996
Daptomycin	$1,234,405
Other injectables	$7,467,546
Laboratory tests billed by dialysis facilities or ordered by physicians receiving monthly capitation payments for treating ESRD patients**	$319,165,724
DME supplies and equipment	
DME supplies	$15,039,695
DME equipment	$3,358,535
Supplies and other services billed by dialysis facilities^	$44,864,130
Part D drugs	$455,683,740
Total Medicare Allowable Payments for Composite Rate (CR) and Separately Billable (SB) Services	$9,239,987,362
Total Medicare Hemodialysis-equivalent sessions***	36,523,791
Average Medicare Allowable Payment per Session for CR and SB services	$252.99

Based on payment amounts reported on Medicare claims for 2007. Excludes facilities without a valid county code for determining the CBSA wage index and patients with an unknown birthdate.

^Billed by dialysis facilities.

*Monthly payments for EPO were capped to reflect no more than 30,000 units per session.

**Includes lab tests billed by dialysis facilities on outpatient institutional claims and lab tests ordered by physicians receiving monthly capitation payment (MCP) amounts and billed on carrier claims. Labs ordered by physicians receiving MCP amounts were determined using a list of MCP physicians from 2006. The estimates for total lab payments will be updated when the list of MCP physicians for 2007 is available.

***Hemodialysis-equivalent sessions were capped at 20 per patient per month and include both sessions reported on dialysis facility claims and an estimate for Method II patients. The estimated sessions for Method II patients were based on the average number of sessions per month reported for Method I peritoneal dialysis patients (12.5 in 2007).

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1. Composite Rate Services

The first component of the ESRD PPS payment bundle shown in Table 8 is ''Outpatient dialysis and other composite rate services''. This line item refers to total CY 2007 payments for composite rate services as obtained from ESRD facility claims (bill type 72X claims). This total includes all composite rate payments to ESRD facilities, including exception payments made in accordance with § 413.182 through § 413.186. Claims from ESRD facilities that did not have a valid county code, such that the relevant CBSA-based wage index (see section VIII.C.) could not be determined, were excluded. In addition, claims for patients with a missing birth date, which is necessary in order to calculate the basic case-mix adjustment under the composite payment system, were also excluded.

2. Dialysis Support Services

We computed a total amount for the next component of the ESRD PPS payment bundle shown in Table 8, ''Dialysis support services''. This total represents total payments for support services furnished to Method II home dialysis patients, and reported under subcategory 5 of revenue codes 082X through 085X on the type 72X claims.

3. Part B Drugs and Biologicals

The next component of the ESRD PPS bundle shown in Table 8 is ''Part B drugs and biologicals''. We found that total payments for the top 11 Part B drugs and biologicals reported on the type 72X claims, accounted for 99.7 percent of total spending for Part B drugs. Monthly payments for Epogen were capped to reflect no more than 30,000 units per treatment, as amounts in excess of this value were considered clinically implausible.

4. Laboratory tests

Another component of the ESRD PPS bundle shown in Table 8 is ''Laboratory tests billed by dialysis facilities or ordered by physicians receiving monthly capitation payments for treating ESRD patients''. Payments for laboratory tests represent the total amount paid to dialysis facilities for outpatient laboratory tests billed on the type 72X claims, as well as payments for laboratory tests ordered by physicians receiving MCP amounts and billed on carrier claims. We identified laboratory tests ordered by physicians receiving MCP using the list of physicians for CY 2006, which was the latest available list at the time of this proposed rule. The estimates for total laboratory payments will be updated using the list of CY 2007 MCP physicians in connection with the publication of the final rule.

5. DME Supplies and Equipment

''DME supplies and equipment'' is another component of the ESRD PPS payment bundle. Payments for these items and services were obtained from the CMS 1500 claims for Method II home patients.

6. Supplies and Other Services Billed by Dialysis Facilities

This category of the ESRD PPS payment bundle primarily includes payments for syringes used in the administration of intravenous drugs during the provision of outpatient dialysis. These supplies and services were billed by the dialysis facilities on the type 72X claims.

7. Former Part D Drugs

This amount represents total payments on behalf of the ESRD beneficiaries with Part D coverage in CY 2007 for Part D drugs and biologicals which we consider furnished for the treatment of ESRD. These drugs and biologicals, which are identified by class below, were obtained from CY 2007 Part D claims submitted on behalf of the Medicare ESRD beneficiaries with valid type 72X claims in CY 2007 with Part D coverage, using the NDC codes for the following drugs and biologicals:

Vitamin D Analogues
Calcitriol
Paracalcitol
Doxercalciferol

Calcimimetic
Cinacalcet hydrochloride

Oral phosphate binder
Lanthanum carbonate
Calcium acetate
Sevelamer hydrochloride
Sevelamer carbonate

The NDC codes used to identify the above drugs and biologicals are shown in the Appendix in Table C.

The number of Medicare ESRD beneficiaries for which valid type 72X claims were filed in CY 2007, number of ESRD beneficiaries with Part D drug coverage, and number of beneficiaries with Part D claims for the specified drugs and biologicals noted above, are shown in Table 9. CY 2006 data are also shown in Table 9 for comparison purposes.

TABLE 9—MEDICARE DIALYSIS PATIENTS WITH PAYMENTS FOR PART D DRUGS, 2006 AND 2007

	2006		2007	
	Patients	%	Patients	%
ESRD patients with Medicare payments on outpatient dialysis facility claims *	324,836	.....	328,841	.....
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs	207,035	63.74	219,451	66.73
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs included in the ESRD PPS **	159,570	49.12	175,132	53.26

* Includes ''type 72X'' outpatient institutional claims.
** Includes Vitamin D Analogs (Calcitriol, Paracalcitol, and Doxercalciferol), Calcimimetics (Cinacalcet Hydrochloride), and Oral Phosphate Binders (Lanthanum Carbonate, Calcium Acetate, Sevelamer Hydrochloride, and Sevelamer Carbonate).

The payment total for former Part D drugs includes payments by Medicare prescription drug plans, and all payments made by or on behalf of ESRD beneficiaries for the specified drugs. As noted in Table 9, the payment total for former Part D drugs only includes data for the 66.73 percent of ESRD beneficiaries who were enrolled in Part D. As a result, we do not have patient-specific information on the cost of drugs (part D equivalent drugs) for the remaining third of ESRD beneficiaries who do not have Part D coverage. To the extent these beneficiaries have drug coverage through their employer or other insurance, we do not have access to specific usage or payment information for these medications. Nonetheless, when the ESRD PPS is implemented January 1, 2011, former

Part D drugs would become renal dialysis services in accordance with section 1881(b)(14)(ii)(B) of the Act. As such, ESRD facilities would be responsible for providing ESRD-related oral drugs formerly covered under Part D to their patients.

We are considering use of a proxy to capture the costs associated with ESRD-related drugs for those patients without Part D coverage. One possible approach would be for us to include payments under the Retiree Drug Subsidy (RDS) program which is described below. We believe that as the RDS payments could be made for ESRD-related drugs under title XVIII of the Act, use of RDS data would be consistent with section 1881(b)(14)(A)(ii) which requires that in implementing the ESRD PPS, the Secretary must ensure that the estimated total amount of payments under this title for 2011 for renal dialysis services equals 98 percent of the estimated total amount of payments that would have been made under this title if the ESRD PPS were not implemented.

The RDS program was enacted in December 2003 by section 101 of the MMA. The program, which was effective January 1, 2006, was designed to support existing retiree benefit arrangements by providing subsidy payments to plan sponsors (that is, employers and unions). Subsidy payments to qualifying drug plan sponsors (for example, employers, unions) equal 28 percent of each qualifying retiree's allowable costs for prescription drugs otherwise covered by Medicare Part D, that are attributable to such drug costs between an applicable cost threshold and cost limit. For plan years ending in 2007, the applicable cost threshold is $265 and the cost limit is $5350.

Based on CMS' Office of the Actuary's most recent CY 2007, we provided subsidy payments totaling $3.8 billion on behalf of 7.0 million beneficiaries. Plans submit aggregate qualifying cost data and a list of eligible beneficiaries. We could determine the number of ESRD qualifying covered retirees under the RDS as a percentage of all qualifying covered retirees under RDS. We could further estimate the ESRD-related percentage of the $3.8 billion in subsidy payments and add this amount to the estimated aggregate payments in 2007. We note that since we do not receive patient-specific information on drug usage under the RDS program, it would not be possible to capture the effect of these drugs on the patient and facility-level adjustment factors. We refer readers to 42 CFR § 423.880 through § 423.894 for more information on the RDS provisions. We invite public comment on this approach and other possible approaches to enable us to capture drug payment information for all Medicare ESRD patients.

8. Total MAP

The total MAP amount represents the total payments made in CY 2007 for the composite rate and separately billable categories described above (that is, the sum of the payments for the items and services described in 1. through 7.) We propose to use the total MAP amount as the ESRD PPS base rate amount.

9. Total Medicare Hemodialysis-Equivalent Sessions

In order to calculate the proposed ESRD PPS base rate per treatment, it was necessary to divide the total MAP amount described above by the number of Medicare HD-equivalent sessions. The number of Medicare HD-equivalent sessions represents the total Medicare treatments for outpatient dialysis as reported on the type 72X claims submitted by dialysis facilities. PD patient weeks were converted to HD-equivalent sessions. For this purpose one week of PD was considered equivalent to three HD treatments. Accordingly, a patient on PD for 21 days would have (21/7) x 3 or 9 HD-equivalent sessions. In determining the total number of Medicare treatments, the number of HD-equivalent sessions were capped at 20 per patient per month. We propose to use the total number of CY 2007 Medicare HD-equivalent dialysis sessions, 36,523,791, to calculate the ESRD PPS base rate.

10. Average MAP per Treatment

We divided the total MAP in item 8, $9,239,987,362, by the total Medicare hemodialysis-equivalent sessions in item 9, 36,523,791, to yield an unadjusted rate per treatment for renal dialysis services in CY 2007. This unadjusted rate per treatment is $252.99. We propose to update this per treatment amount to reflect CY 2011 prices, and to standardize it to eliminate the effects of the case-mix and wage index adjustments in order to ensure duplicate payments do not occur under the ESRD PPS through the subsequent introduction of these variables in the payment formula. We also propose to further reduce the projected CY 2011 payment rate for estimated outlier payments, and the budget neutrality offset as set forth in sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. This is the proposed amount per treatment that would be multiplied under the ESRD PPS to reflect patient-specific differences in case-mix, and other adjustments as set forth in section 1881(b)(14)(D) of the Act. We refer to this projected CY 2011 payment rate, after application of the standardization, outlier, and budget neutrality offsets, as the ESRD PPS base rate. The proposed definition of the base rate is set forth in proposed § 413.171. Our proposed methodology for calculating the base rate to reflect the standardization, outlier, and budget neutrality reductions is explained in the sections that follow.

B. Determining the Update Factors for the Budget-Neutrality Calculation

In order to estimate payments under the current payment system for each facility in CY 2011, the first year of the ESRD PPS, the components of the CY 2007 unadjusted per treatment rate were updated to reflect estimated 2011 prices, using the methodology as described in greater detail below. It is necessary to estimate 2011 payments under the current ESRD payment system (including all separately billable items) for each facility in order to meet the statutory budget-neutrality requirement for the ESRD PPS. Section 1881(b)(14)(A)(ii) of the Act requires that the ESRD PPS payment system be 98 percent budget neutral in 2011. In other words, the estimated total amount of payments under the ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented. Therefore, we must first estimate what ESRD facilities would have been paid under the current system in CY 2011, by updating the 2007 payments to reflect 2011 prices. We then divide the total estimated CY 2011 payments by the number of CY 2007 treatments to determine the CY 2011 average payment per treatment. We do not make adjustments for future changes in treatments as this would require us to make assumptions about patient specific characteristics. If we were to project CY 2011 treatments we would increase the current basic case-mix adjusted composite payments by the same amount. This would in effect have no impact on the calculation of the per treatment amount. This CY 2011 unadjusted per treatment payment amount becomes the basis for meeting the budget neutrality requirement. Below we describe the update factors used to estimate CY 2011 payments for each component.

1. Composite Rate Services

In order to update the basic case-mix adjusted composite payments to 2011,

we began with the CY 2009 base composite rate ($133.81) and the CY 2009 drug add-on percentage of 15.2 percent. In accordance with section 153(a) of MIPPA and 1881(b)(14) of the Act, we updated the composite rate by 1.0 percent for CY 2010 and by the estimated ESRD bundled market basket percentage increase minus 1 percentage point (1.5 percent) for CY 2011 resulting in a 2011 composite rate of $137.18. A full description of the ESRD bundled (ESRDB) market basket is presented in section XII. of this proposed rule. We are proposing to use this base composite rate for CY 2011, which includes ESRD bundled market basket minus 1 percentage point, to update the CY 2010 composite rate for purposes of establishing the ESRD PPS base rate, given that we interpret section 1881(b)(14)(F)(ii) to require us to update the composite rate portion of the blend by the market basket percentage minus 1.0 percentage point in all years of the transition (which includes CY 2011). Therefore, using the market basket in this way would be a consistent approach. As described in section XII. of this preamble, we are proposing a market basket increase of 2.5 percent for CY 2011. Therefore, we are proposing a 1.5 percent update to the composite rate for CY 2011, resulting in a CY 2011 composite rate of $137.18 ($135.15 * 1.015). We note that the drug add-on percentage is reduced from 15.2 to 14.8 as a result of the increases to the composite rate in CYs 2010 and 2011. Since the drug add-on is calculated as percentage of the base composite rate, the drug add-on percentage decreases with increases in the composite rate. The CY 2009 Physician Fee Schedule final rule provides details on why increases to the base composite rate require decreases to the drug add-on percentage to ensure that the total drug add-on dollar amount remains the same (73 FR 69755). We intend to update the drug add-on, if necessary, for the ESRD PPS final rule.

We used the applicable facility-level and patient-level basic case-mix adjustments from the CY 2007 claims to re-compute payment using the applicable basic case-mix adjustments applied to a 100 percent CBSA wage-adjusted composite rate using the most recently available ESRD wage index, which is the CY 2009 final rule ESRD wage index with a 0.60 floor. We did this to use the most recent wage indexes available in estimating 2011 payments. The other components of the bundle, which are discussed below do not have payments which are computed with wage indexes. We used a 0.60 floor because we anticipate that floor will be in effect in CY 2011. We have been reducing the wage index floor by .05 every year and we expect to continue this policy. (More information on CBSAs and the wage index floor is presented in section VIII.C.1 of this proposed rule).

In addition, payment rates to facilities that have chosen to retain their exceptions under the basic case-mix composite payment system are not updated because, once approved, the exception amounts were fixed payment amounts, and hence the 2007 amounts represent the 2011 amounts. See the CY 2005 PFS final rule for a discussion regarding the application of statutory increases to exception amounts (69 FR 66332).

2. Self-Dialysis Support Services for Method II Patients

The allowance per month under Method II for home dialysis support services may not exceed $121.15 per month for all forms of dialysis. Since home dialysis support services for Method II patients are subject to a monthly capitation payment that is not increased, the CY 2007 amounts represent the CY 2011 amounts.

3. Part B Drugs and Biologicals

Under the current system, payments for ESRD drugs and biologicals under Part B are paid on average sales price plus 6 percent (ASP+6 percent) methodology. We reviewed ASP prices for four quarters of 2006, 2007, 2008 and two quarters of 2009 for the top eleven separately billable drugs. Given the variability shown in the prices over the last several years and the lack of a clear pattern, we propose to use the 2009 prices as proxy for 2011 values. At the time of the final rule, we will reevaluate this decision based on additional quarters of ASP drug pricing data. Thus, we used the growth from the average of the quarters for 2007 to the average of the two available quarters of 2009. For other ESRD-related Part B drugs, we used a weighted average of the top eleven Part B drugs to update those drug prices to 2011. Since the top eleven drugs represent 99.7 percent of total separately billable Part B drug payments, we believe that the overall weighted average was representative for the remaining 0.3 percent. See Table 10 for the growth factor that was applied to the 2007 drug payment levels.

TABLE 10

Drugs and biologicals	Price updates (percent)
EPO	1.7
Paricalcitol	−2.8
Sodium_ferric_glut	−0.5
Iron_sucrose	4.8
Levocarnitine	−19.0
Doxercalciferol	17.8
Calcitriol	−14.1
Vancomycin	−11.1
Alteplase	2.3
Aranesp	−8.2
Daptomycin	13.9
Other injectables	1.1

4. Laboratory Tests

We updated payments for laboratory tests paid through the laboratory fee schedule to 2011 using projected CPI–U increases and any legislative adjustments that would be applied to this fee schedule. This is the statutory update required for lab services. This amount totaled a growth of 5.1 percent from 2007 to 2011.

5. DME Supplies and Equipment

Since payments for supplies and equipment for Method II patients are subject to a monthly capitation payment that has not increased, the CY 2007 amount represents the 2011 amounts.

6. Supplies and Other Services

This category primarily includes the $0.50 administration fee for separately billable Part B drugs. Since this fee has not increased, there was no price update.

7. Former Part D Drugs

Former Part D drugs were updated by the growth rates for overall prescription drug prices that were used in the National Health Expenditure Projections. See *http://www.cms.hhs.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp#TopOfPage* for further reference on the National Health Expenditure Projections. Since we do not currently have enough data to establish a trend for Part D prices and since we use this price growth in the overall Part D projections, we believe it is an adequate proxy. This amount totaled a growth of 12.2 percent from 2007 to 2011.

Once we determined updated CY 2011 payments for each component of the items and services discussed above, we added the components together to determine each ESRD facility's total payments under the current payment system in CY 2011. These estimated total 2011 MAPs divided by the total 2007 Medicare HD-equivalent sessions

yield the unadjusted per treatment base rate for renal dialysis services in CY 2011 of $261.58.

We used $261.58 as the starting point for further adjustments in determining the proposed ESRD PPS per treatment base rate. The 2011 unadjusted average payment per treatment of $261.58 was then used in the payment model to estimate total payments under the proposed ESRD PPS in CY 2011. These CY 2011 ESRD PPS estimated payments were based on treatment data from the CY 2007 claims file.

C. Standardization Adjustment

CY 2011 payments under the proposed ESRD PPS were initially estimated without a budget-neutrality adjustment, using the unadjusted CY 2011 average payment per treatment amount of $261.58. We calculated the PPS payments using treatment counts from the 2007 claims file. The wage index and all applicable proposed patient-level and facility-level adjustments were applied to the unadjusted CY 2011 average payment per treatment to determine the estimated payment amount under the proposed ESRD PPS for each treatment and ESRD facility. We note that to simulate payments, we used the latest available final CY 2009 ESRD wage indexes, with no floor. While we anticipate a 0.60 floor for the ESRD wage index for the current basic case-mix composite payment system, we are proposing to eliminate the wage index floor for the ESRD wage index to be used for the proposed ESRD PPS in CY 2011 (see section VIII.C.1 for a detailed discussion of the ESRD wage index).

Next, we standardized the ESRD PPS payments in order to account for the overall positive effects of the proposed ESRD PPS case-mix patient and facility adjustment factors and wage indexes. We must standardize payments in order to ensure that total projected PPS payments are equal to the payments under the current basic case-mix adjusted composite payment system. In order to standardize the ESRD PPS payments, we compared the proposed ESRD PPS amounts calculated from the treatment counts in the 2007 claims file to the current system payments from the 2007 Medicare claims file updated to 2011 (as explained in greater detail in section VII.B. above). A standardization factor was calculated by dividing total estimated payments in 2011 under the current payment system by estimated payments under the proposed ESRD PPS in 2011. The standardization factor was calculated to be 0.7827, or a reduction of 21.73 percent. As a result, the CY 2011 unadjusted per treatment base rate of $261.58 was reduced by 21.73 percent to $204.74.

We are proposing that the base rate per treatment be further modified by the adjustments described below.

D. Calculation of the Budget-Neutrality Adjustments

a. Outlier Adjustment

Section 1881(b)(14)(D)(ii) of the Act provides that the ESRD PPS shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis-stimulating agents necessary for anemia management. We believe the payment adjustment under section 1881(b)(14)(D)(ii) of the Act for outlier cases should be applied in a budget neutral manner, as doing so will ensure that estimated total payments under the proposed ESRD PPS equals 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented.

To ensure that the proposed outlier policy under the ESRD PPS is budget neutral, we propose to reduce the base rate by the proposed outlier percentage, or 1 percent. Specifically, we propose to reduce the base rate from $204.74 to $202.69. We did this to account for the 1 percent of aggregate ESRD PPS payments estimated to be made as outlier payments. We then re-estimated the prospective payment amounts with the new reduced base rate of $202.69, allowing 1 percent of payments to be outliers. The appropriate outlier payment amount for each treatment was determined as described in greater detail in section X.A.2 of this proposed rule. The outlier amount was computed for all treatments, and the total outlier payment, across all treatment amounts was added to the prospective payment amount for all treatments.

In summary, we are proposing an outlier percentage of 1 percent; therefore, the proposed base rate per treatment must include a reduction of 1 percent. Thus the proposed standardized base rate of $204.74 was reduced by 1 percent to yield a proposed base rate of $202.69.

b. 98 Percent Budget Neutrality Adjustment

Section 1881(b)(14)(A)(ii) of the Act requires that the proposed ESRD PPS payment system be 98 percent budget neutral. In other words, the estimated total amount of payments under the ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS had not been implemented. Therefore, we reduced the 2011 standardized base rate per treatment, which was already adjusted for 1 percent outlier payments, by an additional two percent, from $202.69, to yield a proposed base rate of $198.64.

To summarize, the proposed base rate per treatment with an outlier adjustment and budget neutrality was calculated to be $198.64. This amount includes a 21.73-percent reduction from $261.58 to account for standardization to the projected CY 2011 current system payment per treatment, a 1-percent reduction to account for proposed outlier payments, and a 2-percent reduction for the required 98-percent budget neutrality. The outlier policy we are proposing is set forth at proposed § 413.237.

E. Calculation of Transition Budget-Neutrality Adjustment

Section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide ''a four-year phase-in'' of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, with payments under the ESRD PPS ''fully implemented for renal dialysis services furnished on or after January 1, 2014.'' Although the statute uses the term ''phase-in,'' for purposes of the proposed ESRD PPS, we will use the term ''transition'' to be consistent with other Medicare payment systems.

Section 1881(b)(14)(E)(ii) of the Act permits ESRD facilities to make a one-time election to be excluded from the transition. An ESRD facility that elects to be excluded from the transition receives payments for renal dialysis services provided on or after January 1, 2011 based on 100 percent of the payment rate under the ESRD PPS, rather than a blended payment based in part on the payment rate with regard to the current basic case-mix adjusted composite payment system and in part on the payment rate under the ESRD PPS. The implementation of the transition is discussed in section XIII.A of this proposed rule. The transition period policy is set forth in proposed § 413.239.

Section 1881(b)(14)(E)(iii) of the Act also requires that we make an adjustment to payments for renal dialysis services provided by ESRD facilities during the transition so that the estimated total amount of payments under the ESRD PPS, including payments under the transition, equals

the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. The transition budget neutrality adjustment would be comprised of two parts. First, we would make a payment adjustment under the basic case-mix adjusted composite payment system portion of the blended rate during the transition, in addition to computing a factor that would make the estimated total amount of payments under the ESRD PPS including payments under the transition equal the estimated total amount of payments that would otherwise occur without such a transition. We describe each part in detail in the paragraphs that follow.

First, to ensure that estimated total payments during the transition equal the estimated total amount of payments that would otherwise occur without such a transition, in addition to accounting for payments for composite rate services and items and services that are separately billable under Part B, it is necessary to reflect payments for ESRD-related Part D drugs that are currently separately payable under Title XVIII. Specifically, as we discussed in section III. of this proposed rule, section 1881(b)(14)(B) of the Act defines renal dialysis services to include, among other things, certain drugs and biologicals, including drugs and biologicals that were separately payable under Parts B and D. Under the current ESRD basic case-mix adjusted composite payment system, ESRD facilities generally do not furnish oral drugs and biologicals to their ESRD patients. ESRD patients currently acquire these drugs and biologicals either through Medicare Part D, private insurance, or independently.

As described in section III. of this proposed rule, we are proposing to include renal dialysis service drugs formerly covered under Part D under the proposed ESRD PPS. As a result, we are further proposing that ESRD facilities would be required to furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement.

As further discussed in section VII. of this proposed rule, the cost of the drugs and biologicals currently separately payable under Part D that we propose to be designated as Part B renal dialysis services for purposes of the proposed ESRD PPS, would be reflected in the ESRD PPS portion of the blended payment. That is, once the ESRD PPS is implemented on January 1, 2011, ESRD-related Part D drugs would become Part B renal dialysis service drugs and would no longer be separately covered under Part D. This is due to section 1881(b)(14)(A)(1) of the Act, which specifies that after January 1, 2011, a single payment is made under title XVIII for renal dialysis services furnished by ESRD facilities in lieu of any other payment for such services, as well as the new statutory definition under section 1881(b)(14)(B) of the Act. In addition, we note that ESRD-related Part D drugs are not part of the basic case-mix adjusted composite payment system or otherwise covered under Part B (in contrast to other separately billable ESRD-related items and services). As a result, ESRD facilities that elect to go through the transition would have no mechanism by which to receive payment for former Part D drugs with regard to the basic case-mix adjusted composite payment system portion of the payment blend (though such services would be captured with regard to the portion of the blended payment for the ESRD PPS). Because ESRD-related Part D drug payments would not be included in the portion of the blend based on the basic case-mix adjusted composite payment system, payments to ESRD facilities that elect to go through the transition may be understated during the transition.

Additionally, as required by section 1881(b)(14)(A)(ii) of the Act and described in section VII.D.b of this preamble, the estimated total amount of payments under the proposed ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total amount of payments for renal dialysis services under title XVIII that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented. As we noted, Part D drugs are not part of the basic case-mix adjusted composite payment system or otherwise covered under part B as separately billable ESRD-related items or services. However, because the payments for the ESRD-related Part D drugs proposed for inclusion in the ESRD PPS were made under title XVIII, we are required to include such items in the 98 percent budget neutrality adjustment.

Thus, to be consistent with the 98 percent budget neutrality requirement and to make estimated payments during the transition equal payments without the transition, we propose to provide a $14.00 per treatment adjustment to the portion of the blend with regard to the basic case-mix adjusted composite payment system. This amount is based on the 2011 per treatment ESRD-related Part D drug payments included in the proposed ESRD PPS base rate. We first computed the 2007 per Part D payment per treatment described in section VII.A. We then updated this amount to 2011 by applying the 12.2 percent update factor described in section VII.B.

We further propose that the $14 per treatment adjustment that would be made to the portion of the blend with regard to the basic case-mix adjusted composite payment system would be made without regard to basic case-mix adjustments or wage index adjustments. This is because ESRD-related Part D drugs were not included in the development of the adjustments for the basic case-mix adjusted composite payment system.

We considered an alternative approach for meeting the statutory transition budget neutrality adjustment. Under this approach, we would exclude estimated payments for ESRD-related Part D drugs from the estimated 2011 payments related to the basic case-mix adjusted composite payment system. That is to say, we would not pay ESRD facilities for the ESRD-related Part D drug payment with regard to the basic case-mix adjusted composite payment system portion of the blended payment during the transition, and therefore, we estimate that ESRD facilities may receive smaller blended payment amounts during the transition. Excluding ESRD-related Part D drugs from the basic case-mix adjusted composite payment portion of the blended payment would likely lower blended payments under the transition and, as a result, we estimate that many more facilities would elect to be paid 100 percent of the ESRD PPS rather than electing to go through the transition. These facilities would have to give up their option to go through the transition in order to receive 100 percent ESRD PPS payments for ESRD-related Part D drugs. The transition provides a more gradual change to ESRD PPS for those facilities that would receive lower payments under the proposed ESRD PPS. We believe it is more equitable to provide a $14 per treatment adjustment the portion of the blend related to the basic case-mix adjusted composite payment system. In addition, we believe that the transition budget neutrality adjustment should not change facilities' incentives with respect to whether or not to opt out of the transition. This approach would change the incentives because excluding ESRD-related Part D drugs from portion of the blended payment related to the basic case-mix adjusted composite payment system might lower blended payments under the transition, thereby increasing the incentive to elect to be paid under 100 percent ESRD PPS. This approach also would skew the impact analysis because it compares payment amount related to the basic case-mix adjusted composite

payment system without Part D payments, while payments under the proposed ESRD PPS include payments for Part D drugs. For the impact analysis to accurately represent payments that are included in the proposed ESRD PPS and be consistent with the 98 percent budget neutrality requirement, we believe we need to include payments for ESRD-related Part D drugs in our estimate of what ESRD facilities would be paid in 2011 for both the basic case-mix adjusted composite payment system and the proposed ESRD PPS, had an ESRD PPS not been implemented. For these reasons we rejected this alternative.

Accordingly, in order to make ESRD PPS budget neutral during the transition with respect to ESRD-related Part D drugs, we propose to make a $14 per treatment adjustment to the portion of the blend related to the basic case-mix adjusted composite rate payment system.

The second part of the transition budget neutrality adjustment addresses the overall effect of the ESRD facilities' decision whether to be paid under the transition versus being paid under the ESRD PPS. In the absence of such an adjustment, total payments would be higher under the transition payment system (blended payment amount) than under a 100 percent fully implemented PPS payment system, as we presume that each provider would likely choose the option that is most beneficial to them. In other words, we believe ESRD facilities that estimate that their aggregate payments will be higher under the transition than under the ESRD PPS likely will elect to be paid under the transition. This in turn would increase the total payments paid by CMS, with total payments then likely to exceed the 98 percent budget neutrality target amount, as discussed in section VII.D.b of this proposed rule. We interpret this provision as requiring, during the first 3 years of the transition, a budget neutrality adjustment applied to all payments to ESRD facilities (both those paid under the transition and those electing to be paid under the ESRD PPS) to offset the additional payments to those ESRD facilities that elect to be paid a blended payment under the transition rather than to be paid based on 100 percent of the payment amount under the proposed ESRD PPS. Thus, we are proposing to create a transition budget neutrality adjustment factor to be applied to all payments to ESRD facilities during the transition. This transition budget neutrality adjustment factor is intended to make the estimated total payments under the transition equal our estimate of total payments under the ESRD PPS were there no transition.

One alternative we considered was applying the budget neutrality adjustment factor to the 2011 ESRD PPS base rate only. However, we believe this approach would unfairly penalize those facilities that opt to be paid based on 100 percent of the payment amount under the ESRD PPS, as it would lower all of their payments. Those facilities that are paid on a blended payment methodology would only have 25 percent of their payment lowered in CY 2011, as only 25 percent of the blended payment is based on the payment amount under the proposed ESRD PPS. Thus, in effect, this approach would result in those facilities electing to be paid based on 100 percent of the payment rate under the ESRD PPS subsidizing those electing to be paid under the transition. In addition, we believe that the transition budget neutrality adjustment should not change facilities' incentives with respect to whether or not to opt out of the transition. This alternative would change the incentives by lowering payments under the ESRD PPS by a larger percentage than the blended payments under the transition, thereby increasing the incentive to elect to be paid under the transition. For these reasons we rejected this alternative.

Another alternative we considered was applying the adjustment only to the blended payments for facilities that elect to be paid under the transition. However, we believe that this approach would unfairly penalize those ESRD facilities that choose to be paid under the transition, as it would lower their payments but would not lower the payments to those facilities that elect to be paid based on 100 percent of the payment rate under the ESRD PPS. Similar to the alternative in the previous paragraph, this alternative would also affect ESRD facilities' incentives with respect to whether or not to opt out of the transition, and thus we also rejected this alternative.

We therefore propose to apply the transition budget neutrality adjustment factor to all ESRD payments, including the component of the blended rates based on the current basic case-mix adjusted composite payment system. We propose this approach, because we believe that it would not unfairly penalize one group, it would evenly distribute the effect of the transition budget neutrality adjustment, and it would not change ESRD facilities' incentives with respect to whether to opt out of the transition.

In calculating the transition budget neutrality adjustment factor, we propose to first determine the estimated increase in payments under the transition and then determine an offset factor. In order to do this, we must first make assumptions on which facilities would choose to opt out of the transition and be paid based on 100 percent of the payment rate under the ESRD PPS in 2011. In order to estimate which ESRD facilities will and will not elect to opt out of the transition, we are proposing to estimate aggregate payments for each ESRD facility under both the current basic case-mix adjusted composite payment system, including payments for separately billable services, and the proposed ESRD PPS (based on 100 percent of the payment amount under the ESRD PPS). We are assuming that facilities that would receive higher aggregate payments under the proposed ESRD PPS would elect to be paid based on 100 percent of the payment rates under the ESRD PPS. Conversely, ESRD facilities that would receive higher aggregate payments under the current basic case-mix adjusted composite payment system would elect to be paid the blended rate under the transition.

Based on this approach, we estimate that 36 percent of ESRD facilities will choose to be excluded from the transition and that 64 percent of ESRD facilities will choose to be paid the blended rate under the transition. Consequently, we estimate that during the first year of the transition, total payments to all ESRD facilities would exceed the estimated payments under the ESRD PPS in the absence of the transition. Thus, in order to maintain the 98 percent budget neutrality required by section 1881(b)(14)(E)(iii) of the Act during the initial year of the transition period, we are proposing to reduce all payments to ESRD facilities in CY 2011 by a factor that is equal to 1 minus the ratio of the estimated payments under the ESRD PPS were there no transition (that is, 98 percent of total estimated payments that would have been made under the current basic case-mix adjusted payment system) to the total estimated payments under the transition, or 3.0 percent. For 2011, application of this factor would result in a 3.0 percent reduction in all payments to ESRD facilities. We propose to apply this adjustment to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS. We propose to calculate similar factors for CYs 2012 and 2013 that would allow a blended payment system to be budget neutral to a fully implemented 100 percent ESRD PPS.

We invite comments on the calculation and application of the

proposed two part transition budget neutrality adjustment factor.

VIII. Cost Regression Used To Develop Proposed Payment Adjustment Factors

A. Proposed Regression Analysis

1. Dependent Variables

The proposed two-equation regression approach used to develop the proposed ESRD PPS includes a facility–based regression model for composite rate service, and a patient-level regression model for separately billable services. The measures of resource use that were specified as the dependent variables in each of the two equations are explained below.

a. Average Cost per Treatment for Composite Rate Services

We measured resource use for the maintenance dialysis services included in the current bundle of composite rate services using ESRD facility data obtained from the Medicare cost reports for hospital-based ESRD providers and independent ESRD facilities. The average composite rate cost per treatment for each ESRD facility was calculated by dividing the total reported allowable costs for composite rate services for CYs 2004, 2005, and 2006 (Worksheet B, column 11, rows 7–16 on CMS 265–94; Worksheet I–2, column 11, rows 2–11 on CMS 2552–96) by the total number of dialysis treatments and Worksheet C, column 1, rows 1–10 on CMS 265–94; Worksheet I–4, column 1, rows 1–10 on CMS 2552–96). Continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) patient weeks were multiplied by 3 to obtain the number of hemodialysis equivalent treatments. We point out that our computation of the total composite rate costs included in this per treatment calculation includes costs incurred for training expenses, as well as all costs incurred by ESRD facilities for home dialysis patients. The resulting composite rate cost per treatment was adjusted to eliminate the effects of varying wage levels among the areas in which ESRD facilities are located using the CY 2009 ESRD wage index and the estimated labor-related share of costs from the composite rate market basket. The description of that labor-related share was contained in the Secretary's 2008 Report to Congress. That is, 53.711 percent of each ESRD facility's composite rate cost per treatment was divided by the ESRD wage index to control for area wage differences. No floor or ceiling was imposed on the wage index values used to deflate the composite rate costs per treatment. We applied a natural log transformation to the wage-deflated composite rate costs per treatment to better satisfy the statistical assumptions of the regression model, and to be consistent with existing methods of adjusting for case-mix, in which a multiplicative payment adjuster is applied for each case-mix variable. As with other health care cost data, there was skewness in the cost distribution for composite rate services in which a relatively small fraction of observations account for a disproportionate fraction of costs. Cost per treatment values which were determined to be unusually high or low in accordance with predetermined statistical criteria were excluded from further analysis. (For an explanation of the statistical methodology used to identify outlier composite rate costs per treatment, see pp 45–48 of UM–KECC's February 2008 report.)

b. Average Medicare Allowable Payment (MAP) for Separately Billable Services

Resource use for separately billable dialysis related services was measured at the patient level using the payment data on the Medicare claims for CYs 2004–2006. This time period corresponded to the most recent 3 years of Medicare cost report data that were available to measure resource use for composite rate services. Measures of resource use included the following separately billable services: injectable drugs billed by ESRD facilities, including ESAs; oral forms of ESAs and other oral drugs used to treat ESRD payable under Medicare part D; laboratory services provided to ESRD patients, billed by freestanding laboratory suppliers and ordered by physicians who receive monthly capitation payments for treating ESRD patients, or billed by ESRD facilities; other services billed by ESRD facilities, including support services for Method II home patients; medical equipment and supplies for Method II home patients billed by durable medical equipment suppliers.

We obtained Medicare claims data for separately billable services for CYs 2004–2006 for patient months in which outpatient dialysis was provided and Medicare was the primary payer. For oral drugs (formerly) covered under Medicare part D, we used CY 2007 claims data for ESRD beneficiaries with Medicare part D coverage. Measures of resource use were based on MAPs, which were calculated using the payment data on the claims. Currently, the only payment data available for Part D claims are for CYs 2006 and 2007. However, these data were not available in sufficient time to be included in the development of the proposed separately billable case-mix adjusters, given the lead time necessary for the preparation of the proposed rule. We expect that additional Part D claims data will be available for the preparation of the final rule. Therefore, we intend to include appropriate available payment data from Part D claims for CYs 2006 through 2008 in our development of the regression based case-mix adjusters for the overall payment model, and will address their inclusion in the final rule. Payments for Part D drugs were included in the proposed ESRD base rate, which relied on claims for CY 2007. See section VII.A.7.

Medicare payments were inflated by a factor of 1.25 for services that have a 20 percent patient coinsurance (for example, most injectable drugs) to yield the MAP. For laboratory tests that have no patient coinsurance obligation, the Medicare payment is identical to the MAP. As required under section 1881(b)(14)(B) of the Act, as added by section 153(b)(1) of MIPPA, vaccines are excluded from the ESRD PPS and therefore, were excluded from the computation of separately billable drugs. The MAP amounts do not include the annual part B payment deductible, which may apply to separately billable services because we were unable to determine whether the deductible amount was incurred in connection with another part B service. We point out that the part B payment deductible can apply in connection with any part B service, not just outpatient dialysis related services.

For the case-mix analyses, MAP values based on CY 2004 through 2006 claims were adjusted to approximate drug payments for the current year. In CY 2007 the top 11 separately billed Part B drugs accounted for approximately 99.8 percent of drug expenditures for Medicare ESRD beneficiaries. We repriced the MAPs for these drugs in 2004, 2005, and 2006 by using a ratio. That ratio was obtained by dividing the Medicare payment rate in the first quarter of 2008 by the Medicare payment rate in 2004, 2005, and 2006. This repricing was done for the following injectable drugs: epoetin alfa, darbepoetin alfa (ARANESP®), iron dextran, iron sucrose, sodium ferric gluconate, calcitriol, doxercalciferol, paracalcitol, levocarnitine, alteplase recombinant, and vancomycin. (Although iron dextran was among the top 11 drugs in CYs 2004–2006, it was superseded by daptomycin in CY 2007.) The resulting MAP closely reflects the current prices based on Medicare reimbursement rates. The ratios used to

adjust the MAPs for the 11 specified injectable drugs are shown in Table 11.

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Table 11
Payment ratios used to reprice Medicare Allowable Payments (MAP) for 11 separately billable injectable drugs

	Ratios by year/quarter					
Injectable drug	2004	2005	2006, Quarter 1	2006, Quarter 2	2006, Quarter 3	2006, Quarter 4
Epoetin alfa	0.8963	0.9183	0.9366	0.9603	0.9456	0.9489
Darbepoetin alfa	0.6101	**	0.9675	0.9535	0.9557	0.9669
Iron dextran*	0.6488	1.0622	1.0333	1.0242	1.0545	1.0489
Iron sucrose	0.5530	0.9865	1.0224	1.0111	0.9973	1.0055
Sodium ferric gluconate complex	0.5934	0.9794	0.9902	0.9589	1.0208	1.0073
Calcitriol	0.2406	0.3458	0.4709	0.7186	0.6548	0.6324
Doxercalciferol	0.4367	0.9238	0.8946	0.7584	0.7604	0.8355
Paricalcitol	0.7135	0.9508	0.9984	1.0018	0.9982	0.9976
Levocarnitine	0.1677	0.4208	0.5633	0.7135	0.5782	0.5484
Alteplase, recombinant	0.9366	1.0829	1.0944	1.0969	1.0853	1.0717
Vancomycin HCl	0.4909	1.1581	1.1064	1.0655	1.0674	1.0314

*Starting in 2006, the repricing ratio for this drug was determined using the average payment rate for the two forms of iron dextran that could be billed.

**Due to quarterly price changes for darbepoetin alfa during 2005, a different repricing ratio was used for each quarter: 0.8160, 0.8970, 0.9454, and 0.9602 for Quarters 1, 2, 3, and 4 of 2005, respectively.

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The adjusted MAP values were standardized to reflect the number of Medicare outpatient dialysis treatments reported on the claims. This approach is consistent with the unit of payment under the current composite payment system. For patients who received PD during the month, the number of PD days reported on the claims was multiplied by 3/7 to obtain the number of HD-equivalent treatments. For example, 7 PD days were converted to 3 treatments since hemodialysis is typically performed 3 times per week. Monthly treatments reported on the claims were capped at 20 treatments in excess of this number were considered implausible. The average MAP per treatment for EPO was limited to no more than 30,000 units, since higher doses were considered clinically suspect or inappropriate. The ratio of the adjusted MAP values for separately billable services divided by the total number of treatments was used to calculate the average adjusted MAP per treatment. As with the analysis of composite rate services, we applied a natural log transformation to the values of the separately billable MAPs per treatment, with statistical outlier values excluded from further analysis employing the same criteria used to identify aberrant composite rate costs.

2. Independent Variables

Two major types of independent or predictor variables were included in the composite rate and separately billable regression equations—case-mix payment variables and control variables. Case-mix payment variables were included as factors that may be used to adjust payments in either the composite rate or the separately billable equation. Control variables, which generally represent characteristics of ESRD facilities such as size, type of ownership, facility type (whether hospital-based or independent), etc., were specifically included to obtain more accurate estimates of the payment impact of the potential payment variables in each equation. Control variables were excluded from consideration as actual payment adjusters because they represent facility characteristics rather than patient characteristics. In the absence of using control variables in each regression equation, the relationship between the payment variables and measures of resource use may be biased.

a. Control Variables

Seven control variables were included in the regression analysis. They were: (1) Renal dialysis facility type (hospital-

based versus independent facility); (2) facility size (<3,000 for less than three years, 3,000 to 5,000, 5,000–10,000, and >10,000 dialysis treatments); (3) type of ownership (independent, large dialysis organization, regional chain, unknown); (4) whether the ESRD facility received a composite rate payment exception between November 1993 and July 2001; (5) adequacy of dialysis, based on the percentage of patients having a urea reduction ratio (URR) <65 percent; (6) rural versus urban location; and (7) calendar year. Calendar years 2004, 2005, and 2006 were included as a control variable in analyses that pooled three years of data.

b. Proposed Case-Mix Adjustment Variables

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix, but gives the Secretary broad discretion with regard to the selection of patient-specific measures which would comprise the case-mix adjusters. As part of our case-mix analysis, we identified the same patient demographic variables used in connection with the basic case-mix adjusters under the current composite payment system: Age (five groups, excluding patients less than age 18), BSA, and low BMI (values less than 18.5 kg/m^2). BSA was calculated as a function of height (H, in centimeters) and weight (W, in kilograms) using the following formula:

$$BSA = 0.007184 \times H^{(0.725)} \times W^{(0.425)}$$

BMI values below 18.5 kg/m^2 were used to identify patients who were underweight. BSA and low BMI are currently used as part of the basic case-mix adjustment for the composite payment system.

The same set of independent variables was included in both the composite rate and separately billable regression equations. To define the independent variables for each equation, however, it was necessary to link patient and facility-level data. For example, measures for patient characteristics (for example, female gender) were included as potential payment variables in the facility level composite rate equation, while measures for facility characteristics (for example, hospital-based or independent facility) were included as control variables in the patient level separately billable equation. For the composite rate equation, we defined case-mix measures using data for all Medicare dialysis patients treated in each facility. Specifically, we determined the percentage of a facility's patients having each patient characteristic. For example, patient's sex was measured as the percentage of patients that were female. For the equation of the separately billable MAPs, we defined measures for facility characteristics using data for all facilities that treated each Medicare dialysis patient.

These patient and facility control variables were weighted to give greater emphasis to patient and facility observations that accounted for more of the care that was delivered, based on the number of dialysis treatments. For example, in defining facility-level case-mix measures, the characteristics of patients who were treated at the dialysis facility for twelve full months (for example, with 13 treatments each month), were given twelve times as much weight as the characteristics of patients who were treated at the facility for only one month (for example, with 13 treatments). Similarly, to define patient-level measures for the control variables, the characteristics of the facility that treated the patient for nine full months were given three times as much weight as the characteristics of the facility that treated the patient for the remaining three full months. The resulting case-mix variables were examined as potential payment variables in the composite rate equation (for example, percent female and average BSA among patients in each facility). This was the same approach used to define the basic case-mix measures under the composite payment system. The resulting facility variables were included as control variables in the separately billable equation (for example, percent of a patient's treatment furnished in a hospital-based facility). In the sections that follow, we describe how we considered and evaluated independent variables for use as potential case-mix adjusters in the proposed ESRD PPS to determine their relationship to composite rate costs and separately billable payments.

B. Proposed Patient-Level Adjustments

The following are the patient level adjustments we considered for the proposed ESRD PPS. The patient level adjustments that we are proposing are set forth at proposed § 413.235.

1. Patient Age

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's age. Consequently, we analyzed age as part of the regression analysis and found that age is a strong predictor of variation in payments for ESRD patients. In addition, age is an objective measure and data on age are readily available.

As discussed previously in section I.B.3., the basic case-mix adjusted composite payment system currently in effect includes payment adjustments for age. As shown in Table 12 below, there are five age groupings and payment adjustment factors that describe the distribution of the patient population:

Table 12
Age Adjustment in the Current Basic Case-Mix Adjusted Composite Payment System

Variable	Multiplier
Pediatrics <18	1.62
Ages 18-44	1.223
Ages 45-59.	1.055
Ages 60-69	1.000
Ages 70-79	1.094
Ages 80+	1.112

As we found when we developed the current basic case-mix adjusted composite payment system, the regression analysis for the proposed ESRD PPS indicates that MAPs rise as a patient's age increases. We analyzed information on patient age from the REMIS system and compared the costs for each age group to a reference group. Although the reference group for age under the current basic case-mix adjusted composite payment system was ages 60–69, the reference group used for the proposed ESRD PPS was determined to be ages 45–59. We selected the 45–59 age range as the reference group because it was identified as the lowest cost group and results in positive adjustments for all age categories except for the 45–59 age group, and avoids age adjustments that are less than one. In addition, we determined the age groupings based upon stability of the data and the similarity of the adjustments for the ages within the group.

The proposed regression analysis for the proposed ESRD PPS revealed the following: (1) Patients in the 18–44 age grouping were 19.4 percent more costly than the reference group; (2) Patients age 45–59 were the reference group; (3) Patients age 60–69 were 1.2 percent more costly than the reference group; (4) Patients age 70–79 were 5.7 percent more costly than the reference group; and (4) Patients over 80 years of age were 7.6 percent more costly than patients in the reference group.

This U-shaped relationship of age with average composite rate per treatment costs in the proposed ESRD PPS is similar to the pattern we observed in developing the current basic case-mix adjusted composite payment system. That is, elevated costs were observed for the youngest and oldest adult age groups (ages 18–44 and 80+, respectively) compared to the reference age group.

Based on age, the model indicates that one of the largest increments in cost is for pediatric patients. We note, however, that using the current regression-based approach, the precision of the pediatric multiplier is limited by the small fraction of pediatric patients in most ESRD facilities and would distort the results. Due to the relatively small number of pediatric patients, we are proposing to use a separate regression analysis for pediatric patients, as discussed in section IX of this proposed rule.

Under the ESRD PPS, we are proposing payment adjustment factors for five age groups as shown in Table 13 below.

TABLE 13—PATIENT AGE

Variable	Multiplier
Ages 18–44	1.194
Ages 45–59	1.000
Ages 60–69	1.012
Ages 70–79	1.057
Ages 80+	1.076

2. Patient Sex

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a number of variables and may include ''other appropriate factors.'' Consequently, we analyzed patient sex as part of the regression analysis and found that patient sex is a strong predictor of variation in payments for ESRD patients. In addition, patient sex is an objective measure and data on patient sex are readily available. In the regression analysis for the proposed ESRD PPS, we found that female ESRD patients are more costly to treat than male ESRD patients. We discuss below, prior research related to patient adjusters for males/females in prior rulemaking for the current basic case-mix adjusted composite payment system, before addressing our proposal for such a case-mix adjuster.

In the CY 2005 Physician Fee Schedule (PFS) proposed rule (69 FR 47487 through 47730), published August 5, 2004, we included an adjustment for gender as part of our proposal for the current basic case-mix adjusted composite payment system. We analyzed the effect of a combination of gender and age on composite rate costs compared to the lowest cost combination (that is, female ages 65–79). No data on separately billable services was analyzed because those services are excluded from the basic case-mix adjusted composite payment system. We found that male patients were consistently more costly than females. However, we did not include an adjustment for gender because of the availability of certain data.

As we explained in the CY 2005 PFS final rule with comment period (69 FR 66235 through 66915), published on November 15, 2004, gender was proposed as a surrogate measure for body size. We believed that using height and weight to measure body size would be better predictors of facility variation in composite rate costs, however, that information was not available on claims at the time the CY 2005 PFS proposed rule was published, whereas gender was reported on the outpatient bill.

During development of the final basic case-mix adjusted composite payment system, we became aware that the National Uniform Billing Committee would be approving the use of two new value codes for reporting weight and height after publication of the final rule. We determined that mandatory reporting of such data would enable the development of case-mix measures that reflected the superior predictors related to body size, that is BMI and BSA. As a result, we adopted in the final rule BSA and low BMI, and eliminated gender as a patient classification variable for purposes of case-mix adjustment.

In developing the proposed ESRD PPS, we again analyzed the extent to which the regression model explains composite rate and separately billable payments based on a patient's sex and, as a result of that analysis, are proposing an adjustment based on a patient's sex. (We believe using the term sex is a more accurate term than gender. Sex is defined as a classification according to an individual's reproductive function while gender is defined in terms of masculine/feminine characteristics). In analyzing more current data on patient sex from the REMIS system, we found that MAPs (including both composite rate and separately billable services) were higher for female patients even when body size measures are included. In the regression analysis, we found that females were 13.2 percent more costly on a per treatment basis than males primarily due to differences in use of ESAs between male and female patients. Therefore, we are proposing an adjustment of 13.2 percent for female patients. We are soliciting public comments around unintended consequences of providing a payment adjustment for female patients that may lead to admission practices favoring female patients. Decisions for the final rule regarding this adjustment would be made based on analysis of more current data and public comments received on this issue.

3. Body Surface Area and Body Mass Index

Section 1881(b)(14)(D)(i) of the Act requires that the bundled ESRD PPS must include a payment adjustment based on case-mix that may take into account patient weight, BMI, and other appropriate factors. Consequently, we evaluated height and weight because the combination of these two characteristics allows us to analyze two measures of body size; BSA and BMI. For this proposed rule, we analyzed both BSA and low BMI (<18.5kg/m^2) individually as part of the regression analysis and found that both body size measures are strong predictors of variation in payments for ESRD patients. In addition, both BSA and low BMI are objective measures and the necessary data, that is, height and weight, to compute the BSA and low BMI are readily available from patient claims.

a. Body Surface Area

As discussed previously in section I.B.3, the current basic case-mix adjusted composite payment system includes a payment adjustment for BSA. The regression analysis conducted for the current basic case-mix adjusted composite payment system indicated that composite rate costs rise as a patient's BSA increases. The payment adjustment factor for BSA in the current basic case-mix adjusted composite payment system is 1.037. This adjustment factor implies a 3.7 percent elevated cost for every 0.1m^2 increase in BSA. The increased costs suggest that there are longer treatment times and additional resources for larger patients.

As discussed in the CY 2005 PFS final rule with comment period, we chose to include BSA as a payment variable because effective January 1, 2005, we were able to collect height and weight data from patient claims (for purposes of calculating the BSA) and determined that including the BSA variable improved the model's ability to predict the costs of the composite rate service compared to using BMI or weight alone. We adopted the DuBois and DuBois formula for BSA because based on our research, this formula was the most widely known and accepted. This formula is: BSA = $W^{0.425} * H^{0.725} * 0.007184$ (DuBois D. and DuBois, EF. ''A Formula to Estimate the Approximate Surface Area if Height and Weight be Known'': Arch. Int. Med. 1916 17:863–71.), where w and h represent weight in kilograms and height in centimeters, respectively.

In addition, we explored a number of options for setting the reference values for the BSA. We examined the distributions for both the midpoint of the BSA and the count of dialysis patients by age, body surface and low BMI. Based on that analysis, we set the reference point at a BSA of 1.84 (the national patient average). Setting the reference point at the average BSA reflects the relationship of a specific patient's BSA to the average BSA of all patients. Therefore, some adjusters would be greater than 1.0 and some would be less than 1.0. In this way, we were able to minimize the magnitude of the budget neutrality offset to the composite payment rate. (For more information on this discussion, we refer readers to 69 FR 66239.)

The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.84 divided by 0.1. The BSA adjustment factor of 1.037 is then exponentiated based on the calculated BSA factor as $1.037^{(BSA - 1.84)/0.1}$

As we found when we developed the current basic case-mix adjusted composite payment system, the regression analysis conducted for this proposed rule indicates that MAPs rise as a patient's BSA increases. However, we have found that the case-mix adjustment based on a patient's BSA under the proposed ESRD PPS reflects slightly different values from those used in connection with the current basic case-mix methodology under the composite payment system. The BSA case-mix adjustment factor in connection with the current basic case-mix adjustment was 3.7 percent for every 0.1 m^2 change in BSA from the national average of 1.84. The BSA case-mix adjustment factor under the proposed ESRD PPS is 3.4 percent for every 0.1 m^2 change in BSA from a national average of 1.87 based on updated and more complete data.

In the regression analysis we conducted for this proposed rule, we found that BSA continues to be a strong predictor of cost variation among ESRD patients. Accordingly, we are proposing 1.034 as a payment adjustment factor for BSA in the proposed ESRD PPS.

b. BMI

As discussed previously in section I.B.3, the current basic case-mix adjusted composite payment system includes a payment adjustment for low BMI (<18.5 kg/m^2). The regression analysis conducted for the current basic case-mix adjusted composite payment system indicated that those patients who are underweight consume more resources than other patients. The payment adjuster factor for low BMI in the current basic case-mix adjusted composite payment system is 1.112. This adjustment serves as a surrogate for the severity of co-morbid conditions associated with malnourishment in the dialysis population.

As discussed in the CY 2005 PFS final rule with comment period, we elected to include low BMI as a payment variable because effective January 1, 2005, we were going to be able to collect height and weight data from patient claims and including the low BMI variable improved the model's ability to predict the costs of the composite rate services compared to using BMI or weight alone. We chose the measure of low BMI as

less than 18.5 kg/m^2 because it was consistent with the CDC and the NIH's definition for malnourishment. Furthermore, our exploration of alternative BMI thresholds did not improve the model's ability to predict the costs of composite rate services. (For more information on this discussion, we refer readers to 69 FR 66329.)

Based on the regression analysis conducted for this proposed rule, we found that low BMI continues to be a strong predictor of cost variation among ESRD patients. For the proposed ESRD PPS, we are proposing 1.020 as a payment adjustment factor for low BMI. Further discussion of co-morbidities and low BMI as case-mix adjusters can be found below in section VIII.B. of this proposed rule.

4. Onset of Dialysis (New Patient Adjustment)

Section 1881(b)(14)(D)(i) of the Act, as added by MIPPA, requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's length of time on dialysis. Consequently, we analyzed length of time patients have been receiving dialysis. The regression analysis performed for this proposed rule showed that patients who are in their first four months of dialysis have higher costs. This means that individuals who have been newly diagnosed with ESRD have higher costs for the first 4 months of dialysis. We looked at the amount of separately billable payments relative to the number of months the patient has been on dialysis. After reviewing the separately billable payment amounts for patients ranging from one month to twelve months since onset of dialysis, we found that there was a drop in the amount of separately billable payments after four months on dialysis. These higher costs for new patients may be due to stabilization of the patient's condition; administrative and labor costs associated with the patients being new to dialysis either in-center or home setting; or initial costs incurred to train patients and their caregivers to perform home dialysis.

Based on our analysis and for purposes of the ESRD PPS, we propose to define onset of dialysis beginning with the starting date as reported on the ESRD Medical Evidence Report Form through the first 4 months a patient is receiving dialysis.

Accordingly, we are proposing an adjustment of 1.473 for patients in their first 4 months of dialysis. This adjustment factor is based on the results of regression analysis conducted for this proposed rule as described above. We are proposing that this adjustment be applied to both in-facility and home dialysis patients. We acknowledge that there may be patients whose first 4 months of initial dialysis occur when they are not eligible for the Medicare ESRD benefit. In these circumstances, no adjustment would be made. We also acknowledge that eligibility for the ESRD benefit may occur during the first 4 months. In that situation, only the period of time in the first 4 months of dialysis that occurs while the patient is under the ESRD benefit would apply. In other words, the onset of dialysis adjustment is made only in the initial first 4 months of dialysis and for the period of time that the individual is eligible for the ESRD benefit.

5. Co-morbidities

As discussed above, section 1881(b)(14)(D)(i), as added by section 153(b) of MIPPA, requires that the bundled ESRD PPS include a payment adjustment based on case-mix that may take into account patient co-morbidities. Consequently, we analyzed co-morbidities as part of the regression analysis and found that certain co-morbidities are predictors of variation in payments for ESRD patients. The intent of the proposed co-morbidity adjustment is to recognize the increased costs associated with co-morbidities by providing additional payments for certain conditions that occur concurrently with the need for dialysis. In other words, co-morbidities are specific patient conditions that are secondary to the patient's principal diagnosis that necessitates dialysis, yet have a direct affect on dialysis. In addition, co-morbidities are an objective measure and data are readily available.

In the CY 2005 PFS proposed rule (69 FR 47529 through 47533), we proposed case-mix adjustments for a limited number of patient characteristics including a large number of specific co-morbidities. Using linear regression analyses, we assessed the relationship of patient characteristics and co-morbidity measures to per session cost and Medicare payments to ESRD facilities. We noted that we were able to develop case-mix adjustment factors for a limited number of patient characteristics, which were modest predictors of variation in average costs for composite rate services. However, as ESRD facilities did not list individual composite rate items and services on dialysis claims, the available data did not identify use of resources by individual patients. We acknowledged that ESRD facilities could under report or not report co-morbidities as there was no requirement to do so as the current basic case-mix adjusted composite payment system does not provide for co-morbidity payment adjusters. In an attempt to obtain information on co-morbidities, in the CY 2005 PFS final rule with comment, ESRD facilities were encouraged to report co-morbidities. Therefore, we used a combination of data sources (discussed below), to determine co-morbidities for ESRD patients on maintenance dialysis.

A stepwise regression analysis was conducted for the current basic case-mix adjusted composite payment system to identify case-mix factors that explained statistically significant variation in ESRD facility costs. Stepwise regression is used when there are a large number of potential explanatory variables with variables added or removed from the regression model to identify a subset of predictors and the highest R^2. The forward (step-up) method begins with no variables in the model with variables individually included if they are statistically significant (no additional variables have a p-value level <0.05). Backward (step-down) method begins with a model of all variables and eliminates the least significant variables until no nonsignificant variables remain (until all remaining variables have a p-value <0.10). The step-up method was performed to identify payment variables while the step-down method was performed to determine how much co-morbidity categories affected the R^2. As a result of our analysis, four patient characteristic variables (sex, age, AIDS and peripheral vascular disease) were found to be modest predictors of cost variation among ESRD facilities.

In the CY 2005 PFS proposed rule, we explained that a number of co-morbidities were analyzed, including several that did not have statistically significant relationships to facility costs, as well as co-morbidity conditions that were excluded due to lack of data. For example, we explained that a patient's history of cancer was associated with higher costs; however, we found the measure too broad to be clinically meaningful. We indicated that we would continue to evaluate cancer as a potential variable for refinement purposes.

We also discussed in that proposed rule that we explored whether diabetes as a co-morbidity is predictive of high resource use and found that the predictive power of diabetes was dependent on whether peripheral vascular disease (PVD) was part of the model. We explained that PVD was always statistically significant, when accounted for, while most diabetic measures were not strongly associated with facility costs. Therefore, we

proposed a case-mix adjustment for PVD diagnoses. We note that 73 percent of patients with diabetes also included PVD. (For more information on this discussion, we refer readers to 69 FR 47531).

In the CY 2005 PFS final rule with comment period, which implemented the current basic case-mix adjusted composite payment system, we acknowledged that although the regression modeling suggested the inclusion of co-morbidities in the basic case-mix adjusted composite payment system, we were concerned that the available data to determine patient level co-morbidities might not accurately reflect relevant diagnoses. For example, we explained that AIDS would not likely be recorded on claims for outpatient dialysis patients and that requiring its inclusion could create powerful incentives for ESRD facilities to circumvent confidentiality requirements (69 FR 66326). We also explained that we found that the predictive power of diabetes was dependent on whether PVD, which was statistically significant, was part of the model (69 FR 47531). However, most measures of diabetes were not strongly associated with ESRD facility costs. While we proposed a case-mix adjustment for PVD in the CY 2005 PFS proposed rule (69 FR 47531), we received comments indicating that there was apparent disagreement among clinicians as to whether certain diagnoses are reflective of PVD in ESRD patients. Therefore, we eliminated the case-mix adjustment for PVD in the CY 2005 PFS final rule with comment period.

There also were other factors that contributed to our decision not to include patient-level co-morbidities in the basic case-mix adjusted composite payment system. For example, with regard to substance abuse, we acknowledged in the CY 2005 PFS proposed rule, while the presence of alcohol and drug dependence was found to be predictive of higher facility level costs, we did not propose an adjustment as we believed substance abuse was underreported. Accordingly, we concluded that we would not include co-morbidities as a case-mix adjustment. However, we did establish the case-mix adjustments based on age, BMI, and BSA. Our analysis indicated that patients with extremely low or high BMI were costly to treat and included these as we believed this factor could be an important measure of resource consumption related to the composite rate services and could serve as a surrogate for the severity of co-morbidities. We also noted that the average patient BSA was found to be statistically significant and a consistent predictor of average treatment costs, indicating higher costs for larger adult patients. As discussed above, in the CY 2005 PFS final rule with comment period, we indicated that while co-morbidities were not part of the current basic case-mix adjusted composite payment system, we encouraged all facilities to report co-morbid conditions on the claims in order to enable future refinements to the basic case-mix adjustments that would reflect the type of co-morbidities that beneficiaries receiving ESRD services have which would provide a better database from which we can develop future case-mix measures for the ESRD PPS.

As discussed in section VIII.A, we retained UM–KECC to assist us in developing a case-mix adjustment for the proposed ESRD PPS. One of the tasks was the identification of specific diagnoses within co-morbidity categories. For this proposed rule, to capture changes in patient conditions, patient co-morbidities were measured using a combination of the co-morbidities reported on the Medical Evidence Form (CMS–2728) to obtain co-morbidities at the onset of dialysis adjustment, and diagnoses reported on the Medicare claims to identify co-morbidities not obtained from the Medical Evidence Form (CMS–2728).

We began with a long list of patient characteristics based on diagnostic categories developed for the Medicare Advantage Program and categories developed for the co-morbidities on the Medical Evidence Form (CMS 2728). We also used co-diagnoses reported in multiple types of Medicare claims (inpatient dialysis and other outpatient, skilled nursing facility, physician/supplier, hospice, and home health). We are soliciting recommendations on the type of claims that reflect the co-morbidities for beneficiaries receiving renal dialysis services that could be used in future analyses.

We acknowledge the likelihood that some diagnoses reported on laboratory claims may represent a condition being excluded by the test, and therefore, diagnoses reported on laboratory claims were not used. A potential limitation of excluding laboratory claims from the identification process is that we may have underestimated the frequency of certain conditions. Patient characteristics considered for inclusion in the model are based on the magnitude and statistical significance of relationship to composite rate costs and separately billable payments.

To ensure that each potential case-mix adjuster has a relationship to cost which is statistically significant and to ensure that the magnitude of the relationship is economically meaningful, patient co-morbidities having statistically significant, low magnitude association with cost, as well as co-morbidities with ambiguous definitions were excluded. Several patient co-morbidities having statistically significant, low magnitude association with cost in the preliminary models and additional co-morbidities with ambiguous definitions, high prevalence, or both, were excluded.

A refined list of case-mix co-morbidities comprised of 1,022 ICD–9–CM diagnoses codes were evaluated for persistence of effect and cost. The resulting co-morbidity categories were cardiac arrest; pericarditis; substance abuse; positive HIV status and AIDS; gastrointestinal tract bleeding; cancer since 1999 (excludes non-melanoma skin cancer); septicemia/shock; opportunistic infections (pneumonias); aspiration and specified bacterial pneumonias; pneumococcal pneumonia, empyema, lung abscess; monoclonial gammopathy; myelodysplastic syndrome; leukemia; hereditary hemolytic anemias and sickle cell anemia; lymphoma; hepatitis B; and multiple myeloma.

We used the stepwise regression model in analyzing co-morbidity data for case-mix adjustments in the proposed ESRD PPS. The relationship between patient characteristics and cost for composite rate services was estimated using a facility level regression model, as patient level data are not available. In other words, the average patient characteristics are related to the reported facility costs.

A patient level model was used to identify potential payment adjusters for separately billable services. The regression model, weighted by the number of dialysis sessions examined the same refined list of patient characteristics used in the model of composite rate costs. Eleven co-morbidity variables had statistically significant relationships to cost. However, the magnitude of the co-morbidity effects varied substantially. The largest payment multipliers were associated with gastrointestinal (GI) bleeding (31.6 percent), HIV/AIDS (31.6 percent), bacterial and other pneumonias/opportunistic infections (30.7 percent), hereditary hemolytic/sickle cell anemias (22.6 percent) and pericarditis (19.5 percent). As infections, GI bleeding and pericarditis are acute conditions with a diagnosis not exceeding 3 months, these diagnoses would result in a temporary payment adjustment. The chronic conditions

result in a permanent increase on payment which we believe may tend to have a more persistent effect on cost. For example, cancer diagnosis would be eligible for a payment adjustment if the cancer diagnosis has a direct effect on the cost of ESRD treatment. In other words, the fact that an individual has or had cancer would not in itself imply that a co-morbidity payment adjustment is warranted as the adjustment is intended to adjust for higher patient costs. The same applies for any diagnosis in any of the co-morbidity categories.

While the modeling approach used separate equations for the composite rate and separately billable services to select patient characteristics as payment variables, we combined the estimated payment multipliers for composite rate and separately billable services. The payment multipliers were calculated as the weighted average of the composite rate and separately billable multipliers. The weights reflect each component's proportion of the total estimated costs, so that the resulting case-mix adjustment reflects the overall relationship between patient characteristics and estimated costs for the proposed ESRD PPS.

We note that cancer is included in the proposed co-morbidity adjustment diagnoses. As discussed above, we indicated in the CY 2005 PFS proposed rule that although a history of cancer was associated with higher costs, it was found that the measure was too broad to be meaningful. Subsequent to the research we performed in support of the basic case-mix adjusted composite payment system, we investigated the relationship between specific categories of cancer and costs. In an effort to create more clinically homogenous groups, we began with clinical categories that were developed for risk adjustment under the Medicare Advantage program. The source for these cancer diagnoses was the Medicare claims, based on any occurrence since 1999. Starting with all cancers except for non-melanoma skin cancers, we split them into groups of cancers that were used by the Medicare Advantage Program namely, lung; upper digestive tract and other severe cancers; lymphatic system, head, and other major cancers; metastatic cancers; breast, prostate, colorectal, and other cancers and tumors; lymphoma; multiple myeloma; and leukemia. We performed analyses to estimate the relationship between these diagnostic categories and separately billable MAPs. These analyses demonstrated statistically significant associations between each of the cancer categories and SB MAP. In fact, the coefficient estimates were similar across categories. To advance the goal of parsimony in the model, we recombined the categories.

We also note that AIDS is included as a co-morbidity case-mix adjustment although it had been eliminated as an adjustment from the current basic case-mix adjusted composite payment system as reporting of AIDS was limited due to confidentiality requirements (69 FR 66326.) However, we found that inclusion of HIV/AIDS in the proposed ESRD PPS increases the explanatory power of the model and provides higher payments for patients who are substantially more costly to treat. We recognize that these benefits must be balanced against the goal to maintain patient confidentiality in this sensitive clinical area. The model that we are currently proposing is the result of applying a combination of empirical results and our policy decision regarding the appropriateness of adjusting for specific patient characteristics. We recognize that this may result in difficulties for ESRD facilities required by State law to maintain patient confidentiality and therefore are unable to comply with reporting HIV/AIDS diagnoses on claims. We also acknowledge facilities may not be aware of patients' HIV/AIDS status. We are specifically soliciting comments on our proposal to include HIV/AIDS diagnoses in the proposed model.

Based upon our analysis, we are proposing adjustments for the following eleven co-morbidity categories under the proposed ESRD PPS as indicated in table 14 below, and seek comment on each adjustment.

TABLE 14—CO-MORBIDITY CASE-MIX ADJUSTMENT

Case-mix adjustment co-morbidity	Modeled case-mix adjustment [1]
Alcohol/Drug Dependence	1.150
Cardiac Arrest	1.032
Pericarditis (0–3 months ago)	1.195
HIV/AIDS	1.316
Hepatitis B	1.089
Infection (0–3 months ago Septicemia	1.234
Bacterial Pneumonia and Other Pneumonias/Opportunistic Infections	1.307
Gastrointestinal Tract Bleeding (0–3 months ago)	1.316
Hereditary Hemolytic or sickle cell anemias	1.226
Cancer Since 1999 (exclude nonmelanoma skin cancer)	1.128
Myelodysplastic Syndrome	1.084
Monoclonial Gammopathy	1.021

[1] Payment multipliers were calculated as the weighted average of the composite rate and separately billable multipliers. The weights used reflect each component's proportion of the total estimated costs so that the resulting case-mix adjustment reflects the overall relationships between patient characteristics and estimated costs for an expanded bundle of services.

Diagnoses that relate to earlier periods of care and have no bearing on the current RRT are excluded from the proposed co-morbidity case-mix adjustment. Therefore, we are proposing that in order to be eligible for the proposed co-morbidity payment adjustment, the co-morbid condition must exist (or have existed within the past 3 months for the diagnoses, as noted above) and affect treatment. For each claim, we are proposing that an ESRD facility may receive only one co-morbidity case-mix adjustment per co-morbidity category, but it may receive an adjustment for more than one co-morbidity category.

We are proposing that in order to receive a co-morbidity payment adjustment, the appropriate ICD–9–CM code that corresponds to the specific condition/disease that results in increased costs to ESRD facilities is to be placed on the claims and that coding guidelines are to be used in determining the appropriate codes. This includes using V codes for those conditions that reflect that a patient had a disease/condition in the past and that the disease/condition has no effect on the cost of providing RRT. That is to say, we propose that these V codes (that is, history of a disease) for past disease/condition are not subject to any co-morbidity payment adjustment. We note we will issue through sub-regulatory guidance, any changes in codes eligible for a co-morbidity payment adjustment in the event of any changes in coding (for example, ICD–10–CM) in the future.

We performed analyses on FY 2007 dialysis claims to determine the extent that specific diagnoses within the eleven co-morbidity categories are on ESRD claims. We found that less than 50,000 claims out of three million (representing 1.7 percent of 3 million claims) had a diagnostic code corresponding to the co-morbidity categories eligible for a co-morbidity payment adjustment. Of these, 40,609 diagnoses related to septicemia and shock; 2,853 related to cancer; 1,933

related to Hepatitis B, and 973 to HIV/AIDS.

We also analyzed the ICD–9–CM diagnostic codes as identified by UM–KECC. A complete list of the codes identified by UM–KECC is found in Table A of the Addenda.

Table B, which can be found in the Addenda represents the codes associated with diseases/conditions that would be recognized for the purposes of an ESRD co-morbidity payment adjustment.

Please note that we have eliminated specific ICD–9–CM codes associated with specific diseases/conditions that we propose would not be recognized for purposes of a co-morbidity payment adjustment. These ineligible codes are discussed further below.

ICD–9–CM Codes With Their Associated Conditions/Diseases Not Recognized for the Purposes of a Co-morbidity Payment Adjustment

Based on our analyses, we are proposing that conditions/diseases associated with the following ICD–9 codes will not be recognized for the purposes of a co-morbidity case-mix adjustment. We explain the reason for not recognizing these codes in the sections discussed below. We are soliciting comments regarding the conditions/diseases associated with the excluded codes. We are also soliciting suggestions of ICD–9–CM codes for conditions/diseases associated with which we should consider for future refinements.

1. *ICD–9–CM Co-morbidities Not Affecting Costs in Outpatient ESRD Facility and Not Recognized for Co-morbidity Payment Adjustment(s)*

We believe that patients with the following co-morbidity condition(s) in Table 15 below, would not result in higher costs in an ESRD facility. We believe that patients with these acute conditions/diseases, many which are highly communicable, would not receive dialysis in an outpatient setting and therefore, a history of these conditions/diseases would not have an impact on ESRD provider/facility costs. Therefore, we are proposing that these conditions would not be recognized for purposes of the proposed co-morbidity adjustment. We are soliciting comments on these ICD–9–CM codes and their associated diseases/conditions.

TABLE 15—ICD–9–CM CO-MORBIDITIES NOT AFFECTING COSTS IN OUTPATIENT ESRD FACILITY AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)

Drug and/or Alcohol Induced Mental Disorders	
291.0	Delirium tremors.
291.1	Alcohol psychosis, alcoholic amnestic syndrome.
291.2	Alcoholic psychosis, other alcohol dementia.
291.3	Alcoholic psychosis, alcoholic withdrawal hallucinosis.
291.4	Alcoholic psychosis, idiosyncratic alcohol intoxication.
291.5	Alcoholic psychoses, alcohol jealousy.
Hepatitis B	
070.20	Viral hepatitis B with hepatic coma acute or unspecified w/o hepatitis delta.
070.21	Viral hepatitis B w/hepatic coma acute or unspecified w/hepatitis delta.
070.22	Viral hepatitis B w/hepatic coma chronic w/o hepatitis delta.
070.23	Viral hepatitis B w/hepatic coma chronic w/hepatitis delta.
Septicemia and Shock	
020.2	Septicemic plague.
020.3	Primary pneumonic plague.
036.2	Meningococcemia.
038.3	Septicemia due to anaerobes.
040.82	Toxic shock syndrome.
054.5	Herpetic septicemia.
771.81	Newborn septicemia.
Bacterial pneumonias/opportunistic infections/pneumococcal pneumonias	
003.22	Salmonella pneumonia.
006.4	Amebic lung abscess.
007.4	Cryptosporidosis.
020.4	Secondary pneumonic plague.
021.2	Pulmonary tularemia.
022.1	Pulmonary anthrax.
031.2	Disseminated mycobacteria.
039.1	Pulmonary actinomycosis.
078.5	Cytomagalovirus disease.
112.4	Candidiasis lung.
112.5	Candidiasis disseminated.
114.0	Primary coccidioidomycosis pulmonary.
114.4	Chronic pulmonary coccidioidomycosis.
115.05	Histoplasma capsulatum pneumonia.
115.15	Histoplasma duboisii pneumonia.
115.95	Histoplasmosis unspecified pneumonia.
117.3	Aspergillosis.
117.5	Cryptococcosis.
117.7	Zygomycosis (phycomycosis/mucomycosis).
121.2	Paragonimiais.
122.1	Echinoccus granulosis lung.

TABLE 15—ICD–9–CM CO-MORBIDITIES NOT AFFECTING COSTS IN OUTPATIENT ESRD FACILITY AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)—Continued

130.0	Toxoplasmosis meningoencephalitis.
130.4	Toxoplasmosis pneumonitis (strep pneumoniae pneumonia).
130.8	Multisystemic disseminated toxoplasmosis.
136.3	Pneumocytosis.

2. *ICD–9–CM NEC/NOS/Unspecified Codes Not Recognized for Purposes of a Co-Morbidity Payment Adjustment(s) Payment*

The following ICD–9–CM codes/diagnoses in Table 16 are designated as not otherwise specified (NOS); not elsewhere specified (NEC) or are unspecified. As these codes are general and do not provide meaningful identification of a disease, we are proposing that these ICD–9–CM codes/diagnoses will not be recognized for purposes of a co-morbidity case-mix adjustment.

TABLE 16—ICD–9–CM NEC/NOS/UNSPECIFIED CODES NOT RECOGNIZED FOR PURPOSES OF A CO-MORBIDITY PAYMENT ADJUSTMENT(S) PAYMENT

Cancer (Excludes Non-Melanoma Skin Cancer)	
141.9	malignant neoplasm tongue NOS.
142.8	malignant neoplasm major salivary NEC.
142.9	malignant neoplasm salivary NOS.
143.8	malignant neoplasm gum NEC.
143.9	malignant neoplasm gum NOS.
144.9	malignant neoplasm mouth floor NOS.
145.5	malignant neoplasm palate NOS.
145.9	malignant neoplasm mouth NOS.
146.9	malignant neoplasm oropharynx NOS.
147.8	malignant neoplasm nasopharynx NEC.
147.9	malignant neoplasm nasopharynx NOS.
148.9	malignant neoplasm hypopharynx NOS.
149.0	malignant neoplasm pharynx NOS.
150.8	malignant neoplasm esophagus NEC.
150.9	malignant neoplasm esophagus NOS.
151.8	malignant neoplasm stomach NEC.
151.9	malignant neoplasm stomach NOS.
152.9	malignant neoplasm small bowel NOS.
153.8	malignant neoplasm colon NEC.
153.9	malignant neoplasm colon NOS.
154.3	malignant neoplasm anus NOS.
154.8	malignant neoplasm rectum/anus NEC.
155.2	malignant neoplasm liver NOS.
156.9	malignant neoplasm biliary NOS.
157.9	malignant neoplasm pancreas NOS.
158.9	malignant neoplasm peritoneum NOS.
159.0	malignant neoplasm intestine NOS.
159.1	malignant neoplasm spleen NEC.
159.8	malignant neoplasm gastrointestinal/intra-abdominal NEC.
159.9	malignant neoplasm gastrointestinal tract ill-defined.
160.9	malignant neoplasm access sinus NOS.
161.9	malignant neoplasm larynx NOS.
162.8	malignant neoplasm bronchus/lung NEC.
162.9	malignant neoplasm bronchus/lung NOS.
163.8	malignant neoplasm pleura NEC.
163.9	malignant neoplasm pleura NOS.
164.8	malignant neoplasm mediastinum NEC.
164.9	malignant neoplasm mediastinum NOS.
165.0	malignant neoplasm upper respiratory NOS.
165.9	malignant neoplasm respiratory system NOS.
170.9	malignant neoplasm bone NOS.
171.7	malignant neoplasm trunk NOS.
171.8	malignant neoplasm soft tissue NEC.
171.9	malignant neoplasm soft tissue NOS.
172.8	malignant melanoma skin NEC.
172.9	malignant melanoma skin NOS.
172.3	malignant melanoma face NEC/NOS.
174.8	malignant neoplasm breast NEC.
174.9	malignant neoplasm breast NOS.
175.9	malignant neoplasm male breast NEC.
176.9	Kaposi's sarcoma NOS.
179.9	malignant neoplasm uterus NOS.
180.9	malignant neoplasm cervix uteri NOS.

TABLE 16—ICD–9–CM NEC/NOS/UNSPECIFIED CODES NOT RECOGNIZED FOR PURPOSES OF A CO-MORBIDITY PAYMENT ADJUSTMENT(S) PAYMENT—Continued

183.8	malignant neoplasm adnexa NEC.
183.9	malignant neoplasm adnexa NOS.
184.4	malignant neoplasm vulva NOS.
184.8	malignant neoplasm female genitals NEC.
184.9	malignant neoplasm female genitals NOS.
187.4	malignant neoplasm penis NOS.
187.9	malignant neoplasm male genital NOS.
187.8	malignant neoplasm male genital NEC.
188.8	malignant neoplasm bladder NEC.
188.9	malignant neoplasm bladder NOS.
189.8	malignant neoplasm urinary NEC.
189.9	malignant neoplasm urinary NOS.
190.9	malignant neoplasm eye NOS.
191.6	mal neoplasm cerebellum NOS.
191.8	malignant neoplasm brain NEC.
191.9	malignant neoplasm brain NOS.
192.8	malignant neoplasm nervous system NEC.
192.9	malignant neoplasm nervous system NOS.
194.8	malignant neoplasm endocrine NEC.
194.9	malignant neoplasm endocrine NOS.
195.8	malignant neoplasm site NEC.
196.9	malignant neoplasm lymph node NOS.
197.3	secondary malignant neoplasm respiratory NEC.
197.8	secondary malignant neoplasm gastrointestinal NEC.
198.82	secondary malignant neoplasm genital.
198.89	secondary malignant neoplasm NEC.
199.1	malignant neoplasm NOS.
200.80	other variant unspecified extranodal.
208.20	subacute leukemia unspecified cell without remission.
208.21	subacute leukemia unspecified cell with remission.
208.80	other leukemia unspecified cell type without remission.
208.81	other leukemia unspecified cell type with remission.
208.90	leukemia NOS without remission.
208.91	leukemia NOS with remission.
209.00	malignant carcinoid tumor small intestine unspecified portion.
209.10	malignant carcinoid tumor large intestine unspecified portion.
209.20	malignant carcinoid tumor of unknown primary site.
209.25	malignant carcinoid tumor of foregut, NOS.
209.26	malignant carcinoid tumor of midgut, NOS.
209.27	malignant carcinoid tumor of hindgut, NOS.
209.29	malignant carcinoid tumor of other sites.
209.30	malignant poorly differentiated neuroendocrine cancer, any site.
237.70	neurofibromatosis NOS.
237.9	uncharacteristic behavior neurologic nervous system NEC.
239.6	brain neoplasm NOS.
259.2	other endocrine disorders, carcinoid syndrome.
Drug and/or alcohol induced mental disorders	
291.81	alcohol psychosis other specified alcohol psychosis/alcohol withdrawal.
291.89	alcohol psychosis, other specified alcohol psychosis, other.
291.9	alcoholic psychoses/unspecified alcohol psycho.
292.0	drug withdrawal.
292.11	paranoid/hallucinatory drugs induced, drug-induced organic delusion syndrome.
292.12	drug psychiatric disorder with hallucinations.
292.2	pathologic drug intoxication.
292.81	other specified drug-induced mental disorders, drug-induced delirium.
292.82	other specified drug-induced mental disorders, drug-induced dementia.
292.84	other specified drug-induced mental disorders, drug-induced organic affective syndrome.
292.89	other specified drug-induced mental disorders, other.
292.9	unspecified drug-induced mental disorders.
303.00	acute alcohol intoxication-unspecified.
303.01	alcohol dependent syndrome, acute alcohol intoxication, continuous.
303.90	alcohol dependence syndrome, other & unspecified alcohol dependence unspecified.
304.00	drug dependence, opioid, unspecified.
304.10	drug dependence barbiturate/similarly acting sedative/hypnotic dependence unspecified.
304.20	drug dependence, cocaine unspecified.
304.30	drug dependence, cannabis unspecified.
304.40	drug dependence amphetamine/other psychostimulator unspecified.
304.50	drug dependence hallucinogen unspecified.
304.60	other specified drug dependence unspecified.
304.70	drug dependence opioid type w/other drug unspecified.
304.80	drug depend comb w/o opioid type unspecified.

TABLE 16—ICD–9–CM NEC/NOS/UNSPECIFIED CODES NOT RECOGNIZED FOR PURPOSES OF A CO-MORBIDITY PAYMENT ADJUSTMENT(S) PAYMENT—Continued

304.90	drug dependence unspecified depend unspecified.
305.00	nondependence drug abuse alcohol unspecified.
571.3	alcoholic liver damage unspecified.
V11.3	personal mental disorder history alcoholism.
Pericarditis	
420.0	acute pericarditis in diseases classified elsewhere.
420.99	other/unspecified pericarditis other.
HIV/AIDS	
079.53	HIV–2 infection other disease.
Septicemia and shock	
038.10	septicemia, staphylococcal unspecified.
038.19	septicemia, staphylococcal other.
038.9	septicemia other unspecified.
785.59	other shock: endotoxic, gram negative hypovolemia.
Bacterial Pneumonias/Opportunistic Infections/Pneumococcal Pneumonias	
482.30	streptococcus pneumonia unspecified.
482.39	streptococcus other strep pneumonia.
482.40	pneumonia due to staphlococcus unspecified.
482.49	pneumonia due to other staphlococcus pneumonia.
482.83	pneumonia due to other gram negative bacteria.
482.89	pneumonia due to other specified bacteria.
484.7	other systemic mycoses pneumonia.
Gastrointestinal tract bleeding	
531.40	chronic/unspecified gastric ulcer w/hemorrhage w/o obstruction.
531.41	chronic/unspecified gastric ulcer w/hemorrhage w/obstruction.
531.60	chronic/unspecified gastric ulcer w/hemorrhage/perforation w/o obstruction.
531.61	chronic/unspecified gastric ulcer w/hemorrhage/perforation w/obstruction.
532.40	chronic/unspecified duodenal ulcer w/hemorrhage w/o obstruction.
532.41	chronic/unspecified duodenal ulcer w/hemorrhage w/obstruction.
532.60	chronic/unspecified duodenal ulcer w/hemorrhage/perforation w/o obstruction.
532.61	chronic/unspecified duodenal ulcer w/hemorrhage/perforation w/obstruction.
533.40	chronic/unspecified peptic ulcer w/hemorrhage w/o obstruction.
533.41	chronic/unspecified peptic ulcer w/hemorrhage w/obstruction.
533.60	chronic/unspecified peptic ulcer w/hemorrhage/perforation w/o obstruction.
533.61	chronic/unspecified peptic ulcer w/hemorrhage/perforation w/obstruction.
534.40	chronic/unspecified gastrojejunal ulcer w/hemorrhage w/o obstruction.
534.41	chronic/unspecified gastrojejunal ulcer w/hemorrhage w/obstruction.
534.60	chronic/unspecified gastrojejunal ulcer w/hemorrhage/perforation w/o obstruction.
534.61	chronic/unspecified gastrojejunal ulcer w/hemorrhage/perforation w/obstruction.
Hereditary hemolytic anemias/sickle cell anemias	
282.69	sickle-cell disease other sickle-cell disease w/crisis.
282.9	hereditary hemolytic anemia unspecified.

3. *ICD–9–CM Benign Tumor Codes Not Recognized for Co-Morbidity Payment Adjustment(s)*

As noted previously, the intent of the case-mix adjustment is to provide additional payment for conditions which are predictors of variation of average costs. Although the regression analysis identified cancer as a co-morbidity category because it resulted in higher costs, we believe that this would exclude benign tumors. Therefore, we are proposing that the following benign tumor codes/diagnoses in Table 17 will not be recognized for the proposed cancer co-morbidity payment adjustment.

TABLE 17—ICD–9–CM BENIGN TUMOR CODES NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)

209.40	Benign carcinoid tumor small intestine, unspecified portion.
209.41	Benign carcinoid tumor of the duodenum.
209.42	Benign carcinoid tumor of the jejunum.
209.43	Benign carcinoid tumor of the ileum.
209.50	Benign carcinoid tumor large intestine, unspecified portion.
209.51	Benign carcinoid tumor of the appendix.
209.52	Benign carcinoid tumor of the cecum.

TABLE 17—ICD–9–CM BENIGN TUMOR CODES NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)—Continued

209.53	Benign carcinoid tumor ascend colon.
209.54	Benign carcinoid tumor of the transverse colon.
209.55	Benign carcinoid tumor descend colon.
209.56	Benign carcinoid tumor of the sigmoid colon.
209.57	Benign carcinoid tumor of the rectum.
209.60	Benign carcinoid tumor unknown primary site.
209.61	Benign carcinoid tumor bronchus/lung.
209.62	Benign carcinoid tumor thymus.
209.63	Benign carcinoid tumor of the stomach.
209.64	Benign carcinoid tumor of the kidney.
22.5	Benign neoplasm brain/other nervous system parts.
225.0	Benign neoplasm brain.
225.1	Benign neoplasm cranial nerves.
225.2	Benign neoplasm cerebral meninges.
225.3	Benign neoplasm spinal cord.
225.4	Benign neoplasm spinal meninges.
225.8	Benign neoplasm nervous system NEC.
225.9	Benign neoplasm nervous system NOS.
226	Benign neoplasm thyroid.
227.3	Benign neoplasm pituitary.
227.4	Benign neoplasm pineal gland.

4. *ICD–9 Codes as Category Headings and Not Recognized for Co-Morbidity Payment Adjustment(s)*

We are proposing that the following ICD–9–CM codes/diagnoses in Table 18 will not be recognized for purposes of a co-morbidity case-mix adjustment because these codes are ICD–9–CM category headings not be used to identify diagnoses.

TABLE 18—ICD–9 CODES AS CATEGORY HEADINGS AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)

Cancer (excludes non-melanoma skin cancer)	
141	malignant neoplasm tongue.
142	malignant neoplasm major salivary/parotid.
143	malignant neoplasm gum.
144	malignant neoplasm floor of mouth.
145	malignant neo other/unspecified mouth parts.
146	malignant neoplasm oropharynx.
147	malignant neoplasm nasopharynx.
148	malignant neoplasm hypopharynx.
149	mal neoplasm other/ill-defined lip/oral cavity/pharynx.
150	malignant neoplasm esophagus.
151	malignant neoplasm stomach.
152	malignant neoplasm intestine/duodenum.
153	malignant neoplasm colon.
154	malignant neo rectum/rectosigmoid junction/anus.
155	malignant neoplasm liver/intrahepatic bile ducts.
156	malignant neoplasm gall bladder/extrahepatic bile ducts.
157	malignant neoplasm pancreas.
158	malignant neoplasm retroperitoneum/peritoneum.
159	malignant neoplasm other/ill-defined digest org/peritoneum.
160	malignant neoplasm nasal cavities/middle ear/access sinuses.
161	malignant neoplasm larynx.
162	malignant neoplasm trachea/bronchus/lung.
163	malignant neoplasm pleura.
164	malignant neoplasm thymus/heart/mediastinum.
Cancer (excludes non-melanoma skin cancer)	
165	malignant neoplasm other/ill-defined respiratory system/intrathoracic.
170	malignant neoplasm bone/articular cartilage.
171	malignant neoplasm connective/other soft tissue.
172	malignant melanoma skin.
174	malignant neoplasm female breast.
175	malignant neoplasm male breast.
176	Kaposi's sarcoma.
180	malignant neoplasm cervix uteri.
182	malignant neoplasm uterine body.
183	malignant neoplasm ovary/other uterine adnexa.
184	malignant neoplasm other/unspecified female genitals.
186	malignant neoplasm testis.

TABLE 18—ICD–9 CODES AS CATEGORY HEADINGS AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)—Continued

187	malignant neoplasm penis/other male genitals.
188	malignant neoplasm bladder.
189	malignant neoplasm kidney/other/unspecified urinary organs.
190	malignant neoplasm eye.
191	malignant neoplasm brain.
192	malignant neoplasm other/unspecified nervous system.
194	malignant neoplasm other endocrine/related structures.
195	malignant neoplasm other/ill-defined sites.
196	secondary/unspecified malignant neoplasm lymph nodes.
197	secondary malignant neoplasm respiratory/digestive systems.
198	secondary malignant neoplasm other specified sites.
199	malignant neoplasm without site specification.
200	lymphosarcoma & reticulosarcoma.
200.1	lymphosarcoma/reticulosarcoma/lymphosarcoma.
200.2	lymphosarc/reticulosarcoma, Berkett tumor/lymphoma.
Cancer (excludes non-melanoma skin cancer)	
200.8	lymphosarcoma/reticulsarcoma other variants.
201	Hodgkin's disease.
201.0	Hodgkin's disease Hodgkin's paragranuloma.
201.1	Hodgkin's disease Hodgkin's granuloma.
201.2	Hodgkin's disease Hodgkin's sarcoma.
201.4	Hodgkin's disease lymphocystic-histiocytic.
201.5	Hodgkin's disease nodular sclerosis.
201.6	Hodgkin's disease mixed cellularity.
201.7	Hodgkin's disease lymphocytic depletion.
201.9	Hodgkin's disease unspecified.
202	other malignant neoplasm lymphoid/histiocytic tissue.
202.0	nodular lymphoma.
202.1	other malignant neoplasm lymphoid/histiocytic tissue; mycosis fungoides.
202.2	other malignant neoplasm lymphoid/histiocytic tissue; Sezary's disease.
202.3	other malignant neoplasm lymphoid/histiocytic tissue; malignant histiocytosis.
202.4	other malignant neoplasm lymphoid/histiocytic tissue, leukemic reticuloendotheliosis.
202.5	other malignant neoplasm lymphoid/histiocytic tissue, Letterer-Siwe disease.
202.6	other malignant neoplasm lymphoid/histiocytic tissue, malignant mast cell tumors.
202.8	other lymphomas.
202.9	other malignant neoplasm lymphoid/histiocytic tissue, other/unspecified.
203	multiple myeloma/immunoproliferative neoplasms.
203.0	multiple myeloma.
203.1	plasma cell leukemia.
203.8	other immunoproliferative neoplasms.
204	lymphoid leukemia.
204.0	acute lymphoid leukemia.
204.1	chronic lymphoid leukemia.
Cancer (excludes non-melanoma skin cancer)	
204.2	subacute lymphoid leukemia.
204.8	lymphoid leukemia other.
204.9	lymphoid leukemia unspecified.
205	myeloid leukemia.
205.0	acute myeloid leukemia.
205.1	chronic myeloid leukemia.
205.2	subacute myeloid leukemia.
205.3	myeloid leukemia, myeloid sarcoma.
205.8	myeloid leukemia other.
205.9	myeloid leukemia unspecified.
206	monocytic leukemia.
206.0	acute monocytic leukemia.
206.1	chronic monocytic leukemia.
206.2	subacute monocytic leukemia.
206.8	monocytic leukemia other.
206.9	monocytic leukemia unspecified.
207	other specified leukemia.
207.0	other specified leukemia, acute erythremia/erythroleukemia.
207.1	other specified leukemia, chronic erythremia.
207.2	other specified leukemia megakaryocytic leukemia.
207.8	other specified leukemia other.
208	leukemia unspecified cell type.
208.0	acute leukemia unspecified cell type.
208.1	chronic leukemia unspecified cell type.
208.2	subacute leukemia unspecified cell type.

TABLE 18—ICD–9 CODES AS CATEGORY HEADINGS AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)—Continued

208.8 leukemia unspecified cell type other.
208.9 leukemia unspecified cell type unspecified.
22.5 benign neoplasm brain/other nervous system parts.
237.7 neurofibromatosis.
Drug and/or Alcohol Induced Mental Disorders
291 Alcoholic psychosis.
291.8 Alcohol psychoses, other specified alcohol psychosis.
292 Drug psychoses.
292.1 Paranoid/hallucinatory induced by drugs.
292.8 other specified drug-induced mental disorders.
303 alcohol dependence syndrome.
303.0 alcohol dependence syndrome, acute alcohol intoxication.
303.9 alcohol dependence syndrome, other & unspecified alcohol dependence.
304 drug dependence.
304.0 drug dependence, opioid.
304.1 drug dependence barbiturate/similarly acting sedative/hypnotic dependence.
304.2 drug dependence, cocaine.
304.3 drug dependence, cannabis.
304.4 drug dependence, amphetamine/other psychostimulant.
304.5 drug dependence hallucinogen.
304.6 other specified drug dependence.
304.7 drug dependence opioid type with other drug.
304.8 drug dependence combination without opioid.
304.9 drug dependence unspecified dependence.
305.0 nondependence drug abuse alcohol.
Pericarditis
420 acute pericarditis.
420.9 other/unspecified pericarditis.
Hepatitis B
070.2 viral hepatitis B w/hepatic coma.
070.3 viral hepatitis B w/o hepatic coma.
Septicemia and Shock
031 diseases due to other mycobacteria.
038 septicemia.
038.1 septicemia, staphylococcal.
038.4 septicemia due to other gram negative organisms.
Bacterial pneumonias/opportunistic infections/pneumococcal pneumonias
482 other bacterial pneumonias.
482.3 streptococcus pneumonia.
482.4 pneumonia due to staphylococcus.
482.8 pneumonia due to other specified bacteria.
507 pneumonitis due to solids & liquids.
510 empyema.
513 lung/mediastinum abscess.
Gastrointestinal Tract Bleeding
531.0 acute gastric ulcer w/hemorrhage.
531.2 acute gastric ulcer w/hemorrhage/perforation.
531.4 chronic/unspecified gastric ulcer w/hemorrhage.
531.6 chronic/unspecified gastric ulcer w/hemorrhage/perforation.
532.0 acute duodenal ulcer w/hemorrhage.
532.2 acute duodenal ulcer w/hemorrhage/perforation.
532.4 chronic/unspecified duodenal ulcer with hemorrhage.
532.6 chronic/unspecified duodenal ulcer without hemorrhage/perforation.
533.0 acute peptic ulcer w/hemorrhage.
533.2 acute peptic ulcer w/hemorrhage/perforation.
533.4 chronic/unspecified peptic ulcer w/hemorrhage.
533.6 chronic/unspecified peptic ulcer w/hemorrhage/perforation.
534.0 acute gastrojejunal ulcer w/hemorrhage.
534.2 acute gastrojejunal ulcer w/hemorrhage/perforation.
534.4 chronic/unspecified gastrojejunal ulcer w/hemorrhage.
534.6 chronic/unspecified gastrojejunal ulcer w/hemorrhage/perforation.

TABLE 18—ICD–9 CODES AS CATEGORY HEADINGS AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)—Continued

Hereditary hemollytic anemias/sickle cell anemias
282 hereditary hemolytic anemias.
282.4 Thalassemias.
282.6 sickle-cell disease.
Myelodysplastic Syndrome
238.7 neoplasm other lymphatic/hematopoietic tissues includes myelodysplastic syndrome.

6. Race/Ethnicity

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's race and ethnicity. Consequently, we analyzed race and ethnicity as part of the regression analysis for the proposed ESRD PPS to inform our proposal for this rule.

Prior to the enactment of MIPPA, we considered race and ethnicity as potential patient level payment adjusters. First, race was one of the 35 patient characteristics that were examined in developing the basic case-mix adjustments to the ESRD composite rate required under section 1881(b)(12) of the Act. Ultimately, however, the final basic case-mix adjusted composite payment system published in the CY 2005 PFS final rule with comment period did not include adjustments for race and ethnicity. (For more information, we refer readers to 69 FR 66330.)

We again considered race and ethnicity as potential patient level payment adjusters as part of our research for the Secretary's 2008 Report to Congress. In the Report, we concluded that although race and ethnicity perhaps had a statistically significant relationship with costs and payments, such indicators were judged not to be suitable for making payment distinctions in a bundled ESRD PPS given that race/ethnicity is not objectively measured.

Specifically, because there is no quantifiable mechanism by which to measure one's race or ethnicity, the classification is commonly based on self-reported information. We believed that more measurable indicators of cost and payment would be the patient's underlying clinical conditions. We further noted in the Report a demonstrated significance that race has on provider costs and drug utilization, indicating that this adjustment may warrant further consideration in the development and implementation of a new ESRD PPS. We note that any relationship between race/ethnicity and costs and payments revealed in the analyses conducted for purposes of this ESRD PPS proposed rule is discussed further in the sections that follow.

The regression analysis conducted for purposes of this proposed rule relied on two separate data sources for race and ethnicity status to assess the extent to which race and ethnicity would account for cost factors that are otherwise unexplained in the model. The first analysis was based on race and ethnicity data retrieved from the Renal Management Information System (REMIS) and the second analysis was based on data retrieved from the Medicare Enrollment Database (EDB). In Table 19 below, the table captures the key differences in racial and ethnic categorizations between the REMIS and EDB databases.

TABLE 19—RACE/ETHNICITY OF MEDICARE DIALYSIS PATIENTS [1, 2]

REMIS/CMS Form 2728	Percent	Medicare Enrollment Database (EDB)	Percent
Race:		Race:	
American Indian/Alaskan Native	1.6	North American Native	1.4
Asian/Pacific Islander	3.6	Asian	2.7
Black	38.5	Black	37.7
White	55.2	White	48.7
Other	1.1	Hispanic	5.2
Unknown	<0.1	Other	2.1
		Unknown	2.2
Ethnicity:			
Hispanic	12.2		
Not Hispanic	83.8		
Unknown	4.0		

[1] n = 890,776 patient years.
[2] Hispanic ethnicity is reported separately from race on CMS Form 2728 (the Medical Evidence Form), while Hispanic is a race category in the Medicare Enrollment Database.

Most notably, REMIS data includes both beneficiary race and ethnicity designations whereas EDB data includes ethnicity as a racial category. For example, an individual self-identifying as being of Hispanic ethnicity and White race would be reflected as both Hispanic and White in the REMIS database but this same individual would be categorized as either Hispanic or White in EDB. A summary of each analysis is set forth below.

a. REMIS Data Analysis

REMIS, a tracking system for the ESRD patient population for both Medicare and non-Medicare patients, is populated by the ESRD Networks with race and ethnicity data that are collected on the ESRD Medical Evidence Report (Form CMS–2728). The form is completed, signed and certified by the patient's physician at the onset of ESRD treatment.

As noted previously, the proposed ESRD PPS model set forth is based on 2004–2006 data. During this 3-year timeframe, two versions of the Medical Evidence Report Form were used, each with differing categorizations for race and ethnicity.

The earlier version (dated 6/1997), included three ethnicity categories from which to choose—(1) Hispanic: Mexican, (2) Hispanic: Other, and (3) Non-Hispanic. The form did not specify whether to check one or more ethnicity categories. In addition, the form included nine race categories from which to choose—(1) White, (2) Black, (3) American Indian/Alaskan Native, (4) Asian, (5) Pacific Islander, (6) Mid-East/Arabian, (7) Indian sub-Continent, (8) Other, specify, and (9) Unknown. The form instructed individuals to check the *one* race category that applied.

The later version (dated 6/2004), includes two ethnicity categories from which to choose—(1) Not Hispanic or Latino and (2) Hispanic or Latino (including country/area of origin or ancestry). While the form does not include instructions for selecting ethnicity, it is assumed that the individual would choose one of the two categories. In addition, the form includes five race categories from which to choose—(1) White, (2) Black or African American, (3) American Indian/Alaskan Native, (4) Asian, and (5) Native Hawaiian or Other Pacific Islander. This form instructs individuals to check all race categories that apply.

Reporting using the later version (dated 6/2004) became mandatory on June 1, 2005. Therefore, for purposes of our analysis using REMIS race and ethnicity data, beneficiaries for whom the Medical Evidence Report Form 2728 was completed prior to June 2005 comprise the race and ethnicity categories of the earlier version of the form whereas beneficiaries for whom the Medical Evidence Report Form was completed between June through December of 2005 and 2006 comprise the race and ethnicity categories of the later version of the form. We note that for comparison purposes between the two versions of the Medical Evidence Form, it was necessary to designate the following beneficiaries into the category of ''Other'': (1) beneficiaries for whom more than one racial category was marked on the 2004 version of the form and (2) beneficiaries for whom the Mid-East/Arabian or the Indian sub-Continent categories were marked on the 1997 version of the form.

Relying on REMIS as the basis of race and ethnicity data, it was possible to evaluate the potential for race and ethnicity to predict differences in composite rate costs among ESRD facilities as well as differences in MAP for separately billable services at the patient level.

In our analysis using REMIS data in examining race, we found that combined composite rate and separately billable payments are lowest in the category ''Asian/Pacific Islander.'' As a result, this category was used as the reference group. Compared to the reference group, ''Native American/Alaskan Natives'' are 12.6 percent costlier; ''Whites'' are 14.2 percent costlier; ''Blacks'' are 20.7 percent costlier; and individuals in the category ''Other'' are 64.6 percent costlier. As noted previously, for purposes of our analysis, it was necessary to default beneficiaries into the ''Other'' category to reconcile differences between the two versions of the Medical Evidence Report Form and in instances where multiple race categories were selected on the form. As a result of defaulting individuals into the ''Other'' category, we believe that this designation may fail to reflect an individual's true racial status.

In our analysis using REMIS data in examining ethnic background, we found that non-Hispanic patients are 6.5 percent more costly than Hispanic patients.

b. EDB Data Analysis

The EDB is the source of enrollment and entitlement information for all people who are or were ever entitled to Medicare. The EDB is populated with race and ethnicity data that come from the Social Security Administration (SSA). The SSA's race and ethnicity data are collected on the SS–5 form. Unlike CMS' Medical Evidence Report Form that captures both race and ethnicity, the SSA's SS–5 form combines these two elements, instructing the individual to voluntarily select one of the following 5 categories: (1) Asian, Asian-American or Pacific Islander; (2) Hispanic; (3) Black (Not Hispanic); (4) North American Indian or Alaskan Native; or (5) White (Not Hispanic). The SS–5 form is completed when an individual does the following: (1) applies for a social security number; (2) requests a replacement of the social security card; or (3) requests changes to personal information on their record, such as a name change (Social Security Administration Web site instructions *http://www.ssa.gov/online/ss-5.pdf*). Prior to 1980, the SS–5 form included 3 categories for race: White, Black or Other.

The EDB is also populated with data collected by the Railroad Retirement Board (RRB). However, the data are not inclusive of race and ethnicity as these elements are not collected or maintained within the RRB's system. In 1964, the RRB began requiring new railroad industry employees to obtain social security numbers from the SSA, despite ineligibility for Social Security benefits. As a result, race or ethnicity data voluntarily specified by these individuals are reflected in EDB. However, the EDB does not include race or ethnicity on behalf of railroad industry beneficiaries lacking social security numbers; that is, those individuals entering the RRB system prior to 1964. As a result, the race and ethnicity of these individuals is defaulted to ''Unknown'' within EDB.

Each January, CMS creates a finder file consisting of those beneficiaries who were added to CMS' EDB during the previous calendar year as well as all living beneficiaries whose race is identified as ''Other'' or ''Unknown.'' This finder file is sent to the SSA to be processed against their Numerical Identification file, referred to as ''NUMIDENT'', which contains the expanded race categories captured on the SS–5 form. When the results are returned to us, the EDB is updated with the latest information. During subsequent iterations of this annual process, we do not include those beneficiaries that were processed in previous years into the subsequent finder file unless the race was either ''Unknown'' or ''Other.''

In addition to the NUMIDENT file provided by the SSA, several other efforts have been undertaken in an attempt to improve the validity of EDB data including (1) a one-time, voluntary survey of beneficiaries, conducted by CMS in 1997, whose race was identified as ''Unknown'' or ''Other,'' and (2) coordination with the Indian Health Service (IHS) since 2000 on a quarterly basis to record beneficiaries race as American Indian or Alaskan native. Despite these efforts, researchers have identified concerns with CMS' continued reliance on SSA race and ethnicity data collected through the SS–5 form, pointing to deficiencies in data among the smaller minority groups of Asians, Hispanics, and American Indians/Alaskan Natives. A study of 2002 data revealed that only 52 percent of Asian, 33 percent of Hispanic, and 33 percent of American Indian/Alaskan Native Medicare beneficiaries can be correctly identified in the Medicare data (McBean, M, ''Medicare Race and Ethnicity Data Report.'' December 2004.). However, EDB codes are generally reliable for White and Black affiliations (Waldo, D, ''Accuracy and Bias of Race/Ethnicity Codes in the

Medicare Enrollment Database.'' HCFA Review Vol. 26 No. 2 (Winter 2004–2005): 61–72).

Linking race and ethnicity data from the EDB to ESRD patients, we evaluated the potential for race and ethnicity to predict differences in composite rate costs among ESRD facilities, as well as differences in MAP for separately billable services at the patient level.

In our analysis using EDB data in examining race and ethnicity, we found that combined composite rate and separately billable payments are lowest among those individuals categorized as ''Other'' and ''Hispanic.'' In using the category ''Asian'' as the reference group, individuals categorized as ''Other'' and ''Hispanic'' have approximately 6 percent and 4 percent lower costs, respectively than the reference group. Individuals categorized as ''North American Native'' have 7.4 percent higher costs; individuals categorized as ''White'' have 11.9 percent higher costs; and individuals categorized as ''Black'' have 17.8 percent higher costs. Please see Table 20 below.

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Table 20

Modeled case-mix adjustment for an expanded ESRD prospective payment system

Comparison of payment models with vs. without patient race/ethnicity

Variable	Modeled case-mix adjustment[1]		
	Payment model without race/ethnicity	Payment model with race and ethnicity from REMIS/CMS Form 2728	Payment model with race from the Medicare Enrollment Database (EDB)
	$Multiplier_{EB}$	$Multiplier_{EB}$	$Multiplier_{EB}$
Adjustments for dialysis patient characteristics			
Age			
18-44	1.194	1.154	1.158
45-59	1.000	1.000	1.000
60-69	1.012	1.001	1.001
70-79	1.057	1.038	1.011
80+	1.076	1.037	1.008
Female	1.132	1.080	1.058
Race/ethnicity			
American Indian / Alaskan Native (Form 2728) or North American Native (EDB)	--	1.126	1.074
Asian / Pacific Islander (Form 2728) or Asian (EDB)	--	1.000	1.000
Black	--	1.207	1.178
White	--	1.142	1.119
Other	--	1.645	0.939
Hispanic[2]	--	1.000	0.956
Non-Hispanic[2]	--	1.065	--
Body surface area (per 0.1 m^2)	1.034	1.014	1.006
Underweight (BMI <18.5)	1.020	1.012	1.013
Duration of RRT: <4 months	1.473	1.493	1.439
Alcohol/drug dependence (claims since 2000 or 2728)	1.150	1.085	1.074
Cardiac arrest (claims since 2000 or 2728)	1.032	1.035	1.034
Pericarditis from same month to three months ago	1.195	1.195	1.195
HIV/AIDS (claims since 2000 or 2728)	1.316	1.197	1.237
Hepatitis B (claims since 2000)	1.089	1.083	1.081
Specified infection from same month to three months ago			
Septicemia	1.234	1.230	1.231
Bacterial pneumonia and other pneumonias/opportunistic infections	1.307	1.414	1.407
Gastro-intestinal tract bleeding from same month to three months ago	1.316	1.307	1.307
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.226	1.188	1.187
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.128	1.080	1.087
Myelodysplastic syndrome (claims since 2000)	1.084	1.093	1.093
Monoclonal gammopathy (claims since 2000)	1.021	1.017	1.017
Low volume facility adjustment			
Facility size < 3,000 treatments during each year from 2004-06	1.202	1.209	1.202

[1]The combined payment multipliers for patient characteristics were calculated as PmtMultEB = WeightCR×PmtMultCR +

WeightSB×PmtMultSB, where PmtMultCR is the estimated multiplier from a facility level model of composite rate costs and PmtMultSB is the estimated multiplier from a patient level model of separately billable costs. Based on total estimated costs of $169.67 per session for composite rate services, $82.45 per session for separately billable services, and $252.12 per session for an expanded bundle ($169.67+$82.45), the relative weights are WeightCR=0.673 for composite rate services ($169.67/$252.12) and WeightSB=0.327 for separately billable services ($82.45/$252.12).

[2]Hispanic ethnicity is reported separately from race on CMS Form 2728 (the Medical Evidence Form), while Hispanic is a race category in the Medicare Enrollment Database.

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c. Concerns With Available Race/Ethnicity Data

There are several specific concerns with the quality of the REMIS and the EDB data. The race and ethnicity data in REMIS have been collected with different versions of the Medical Evidence Report Form, making it difficult to accurately assess the effect of race and ethnicity on composite rate costs and separately billable payments. That is, a significant portion of the payment is reflected in the default category ''Other''. In addition, while not relevant for purposes of modeling the ESRD PPS, we are concerned about relying on the race and ethnicity data collected from the Medical Evidence Report Form for purposes of future refinements to the ESRD PPS. This form is routinely completed and signed by the physician at the ESRD facility. To mitigate the potential for provider manipulation of Medical Evidence Report Form in the interest of racial or ethnic payment adjustment, we would expect that ESRD facilities would accurately document race or ethnicity within the patient's medical record along with any care planning activities that may be based on the individual's race or ethnicity. There are also concerns related to relying on EDB data for modeling race and ethnicity data within the proposed ESRD PPS. Specifically, race and ethnicity classification on behalf of some segments of the population is either unavailable or defaulted into the ''Unknown'' category within EDB, for example, RRB beneficiaries that entered the RRB system prior to 1964. In addition, we have concerns regarding the race and ethnicity data for individuals entering the SSA system via the enumeration at birth (EAB) process that has been in place since 1989. The EAB process allows the parent, at the time of the child's birth, to indicate on the child's birth certificate that they are interested in obtaining a social security number (SSN) for their child. Therefore, the parent is not required to file a separate application for an SSN for the child. The State vital statistics office receives the request with the birth registration data from the hospital and then forwards this information to SSA. Absent the SS–5 form that includes race and ethnicity fields, we are not aware of any current mechanism by which these data elements are captured by the SSA on behalf of individuals entering the SSA system via the EAB process.

We note that relying on EDB data for purposes of ESRD PPS modeling is that they are not updated in real time. To the extent a beneficiary completes a new SS–5 form for any of the reasons discussed above and there are changes in race information, those changes are not currently reflected in CMS' EDB data in real time. Rather, they occur only after the annual NUMIDENT update.

In addition to the REMIS and EDB data concerns, racial and ethnic categories are not well defined as evidenced by the ongoing changes to the instruments used in collecting these data. Lastly, it is not possible to quantify an individual's race absent a genetic test to determine racial status. This presents the greatest challenge when considering individuals who identify with more than one race. Collection tools such as the SSA's SS–5 form and the Census Bureau's survey instrument depend on the individual to self select the one racial category with which they associate. While the current Medical Evidence Report Form allows for selection of more than one racial category, absent a mechanism for establishing a primary race, it is difficult to conduct comparisons without first defaulting those with multiple race selections into the ''Other'' category.

In summary, the analyses of REMIS and EDB race and ethnicity data demonstrate associations between these patient characteristics and facility level composite rate costs and patient level separately billable payments. As such, including these factors may improve the predictive value of the proposed ESRD PPS. However, we have concerns about whether the data are of sufficient quality upon which to base payment adjustments. The race or ethnicity status designations within the current CMS data systems may fall short in assigning individuals to the most correct racial and ethnic categories and reflecting the unique and measurable traits of individuals. As a result, ESRD facilities may be overpaid for certain patients and underpaid for others. However, to the extent that including race and ethnicity in the model explains additional variation in treatment costs not otherwise reflected, such adjustments may be warranted. We specifically invite public comment on the data issues presented in this section, other data sources for race and ethnicity we should consider, and specifically, the need for adjustments for race and ethnicity in the final ESRD PPS. It is important to note that any adjustments for race would result in additional reductions to the base rate through the standardization process described in section VII.C.

d. CMS Initiatives to Evaluate Health Disparities Based on Race and Ethnicity

In accordance with MIPPA, we plan to explore opportunities for improving Medicare program data on race and ethnicity. Specifically, section 185 of MIPPA amends the Act to add new section 1809 entitled ''Addressing Health Care Disparities.'' This section charges the Secretary with several key

tasks and goals including (1) evaluating approaches for Medicare data collection that will allow for collection and evaluation of data on disparities in health care services and performance based on race, ethnicity and gender; (2) submitting several Reports to Congress that describe the evaluation of Medicare data and make recommendations for improving the identification of health care disparities for Medicare beneficiaries; and (3) implementing the identified approaches for the ongoing, accurate, and timely collection and evaluation of data on health care disparities on the basis of race, ethnicity and gender.

In addition to the tasks associated with MIPPA section 185 that will focus on addressing health care disparities, health care disparities across several settings of care are currently being monitored by the Quality Improvement Organization (QIO) Program. In three cases, active intervention projects are underway to reduce health care disparities. As part of this department-wide effort, we will continue to explore additional approaches to improve the accuracy of this data. Some of these approaches will involve cooperation with entities outside of the Department of Health and Human Services (for example, the SSA), as described above. The first Report to Congress summarizing the possible approaches is due January 1, 2010.

In summary, we believe that the analyses that we will conduct for purposes of developing the Reports to Congress will serve as the basis for improving the accuracy of Medicare race and ethnicity data.

7. Modality

Section 1881(b)(14)(D)(iv) of the Act, as added by section 153(b) of MIPPA, gives the Secretary the discretionary authority to establish an ESRD PPS, which may include payment adjustments as the Secretary determines appropriate. PD, which is the primary mode for home dialysis, is a substantially less costly mode of dialysis compared to in-center HD. Therefore, the Act gives the Secretary the authority to develop an ESRD PPS, which would establish payment rates based on dialysis modality.

Table K.5 from the 2008 Annual Data Report of the U.S. Renal Data System indicates that the average annual cost for all HD patients in 2006 was $71,889, whereas the corresponding figure for PD patients was $53,327 (Table K.7). Data from the Medicare cost reports and Medicare claims for CYs 2004–2006 show a similar difference in resource utilization, with PD patients incurring significantly lower composite rate and separately billable expenses.

COMPARISON OF COMPOSITE RATE COSTS BY MODALITY, CY 2004–06 [1]

Facility type	Hemodialysis		Peritoneal dialysis	
	Facility years (n)	Average composite rate cost per treatment	Facility years (n)	Average composite rate cost per treatment
Freestanding	11,058	$159.60	3,839	$150.39
Hospital based	878	248.92	349	155.99
Total	11,936	168.99	4,188	151.15

[1] Based on the Medicare Independent Renal Dialysis Facility and Hospital Cost Reports. ESRD facilities that opened or closed or reported less than one full dialysis patient year for the modality (156 hemodialysis-equivalent treatments) during the calendar year were excluded. Excludes potential outliers using a standard outer fence methodology that was applied on the log scale. Average CR costs were weighted by the total hemodialysis-equivalent treatments in the facility.

COMPARISON OF SEPARATELY BILLABLE MEDICARE ALLOWABLE PAYMENTS BY MODALITY, CY 2004–06 [1]

Hemodialysis		Peritoneal dialysis	
Patient facility months (n)	Average separately billable MAP per treatment	Patient facility months (n)	Average separately billable MAP per treatment
2,817,067	$87.20	186,296	$35.15

[1] Based on the Medicare claims. MAP for the top 11 injectable drugs were repriced to reflect the payment rates used in the first quarter of 2008. MAP for EPO were capped at 30,000 units per treatment. Average SB MAPs were weighted by the Medicare hemodialysis-equivalent treatments in each patient facility month.

Despite this distinction, we are proposing not to develop an ESRD PPS which uses type of dialysis modality as a payment variable, despite the increased predictive power a modality variable would yield in the resulting regression equations. Because composite rate costs and separately billable payments are lower for PD, the use of a modality payment variable would result in substantially lower payments for PD patients. The payment rates for HD patients would be slightly higher, because of the greater volume of HD patients, and the exclusion of PD patients from the average payment amount that would apply to HD patients. We believe that the substantially lower payments for PD patients that would result if modality were used as a payment adjuster in the ESRD PPS would discourage the increased use of PD for patients able to use that modality. Because we want to encourage home dialysis, in which PD is currently the prevailing mode of treatment, we are proposing an ESRD PPS which does not rely on separate payment rates based on modality. By establishing prospective payment rates that are higher for PD patients than they otherwise would be if separate payments were established based on modality, we believe home dialysis will be encouraged for patients able to use PD. We invite comment on this approach.

However, we note that the case-mix adjustments we are proposing for pediatric patients, described in section IX. of the proposed rule, distinguish between HD and PD as a payment variable. The small number of pediatric

dialysis patients, the limited ability of the two-equation regression model to accurately predict the separately billable MAP for pediatric patients, and the far greater prevalence of PD among pediatric patients, led us to examine alternative approaches in devising case-mix adjustments for those patients. The pediatric payment adjustments described in section IX., use modality, in part, to determine the case-mix adjusters for pediatric dialysis patients. Except for pediatric patients, modality is not otherwise used in developing the proposed case-mix adjustments under the ESRD PPS.

C. Proposed Facility-Level Adjustments

1. Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act, as added by section 153(b) of MIPPA, specifies that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment by a geographic index, such as the index referred to under the existing basic case-mix adjusted composite payment system, as the Secretary determines to be appropriate.

In the current basic case-mix adjusted composite payment system, we use an index based on hospital wage and employment data from Medicare cost reports. In the CY 2006 PFS final rule with comment period (70 FR 70167), we announced our adoption of the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to develop revised urban/rural definitions and corresponding wage index values for purposes of calculating ESRD composite rates under the basic case-mix adjusted composite payment system. OMB's CBSA-based geographic area designations are described in OMB Bulletin 03–04, originally issued June 6, 2003, and is available online at: *http://www.whitehouse.gov/omb/bulletins/b03–04.html*. In addition, OMB has published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. We stated that this and all subsequent ESRD rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage index (73 FR 69758). The OMB bulletins may be accessed online at: *http://www.whitehouse.gov/omb/bulletins/index.html*.

We also stated that we intended to update the ESRD wage index values annually (70 FR 70167). The ESRD wage index values used in the basic case-mix adjusted composite payment system are calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix (71 FR 69685; 73 FR 69758). We apply the current ESRD wage index to a 53.711 labor share of the composite rate. As we indicated, this labor share was developed from the labor-related components of the ESRD composite rate market basket (70 FR 70168). The ESRD wage index in the current basic case-mix adjusted composite payment system applies a wage index budget neutrality factor to ensure that the ESRD wage index is made in a budget neutral manner (70 FR 70170). As we previously noted, in our current basic case-mix adjusted composite payment system, we incorporate the wage index budget neutrality factor into the wage index. We compute a wage index factor and adjust it so that wage index budget neutrality can be achieved by the labor share component only.

For purposes of the current basic case-mix adjusted composite payment system, section 1881(b)(12)(D) of the Act required the Secretary to adjust payment rates, as the Secretary determined appropriate, and if the Secretary applied a geographic adjustment that differed from the current index applied under the old (composite rate) system, the Secretary would be required to phase in such an index over a multi-year period. Under this authority, CMS elected a 4-year transition from the wage index based on MSAs to an updated wage index based on CBSAs. This 4-year transition began in CY 2006 and ended in CY 2009, when ESRD facilities receive a wage adjusted composite rate that is computed using 100 percent CBSAs in CY 2009 (70 FR 70167).

For the proposed ESRD PPS, we are proposing to use the same method and source of wage index values as we have been using for the basic case-mix adjusted composite payment system. Specifically, we propose that the ESRD wage index values used in the proposed ESRD PPS be calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act, and utilize pre-floor hospital data that are unadjusted for occupational mix. We also propose to use the OMB's CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values. OMB's CBSA-based geographic area designations are described in OMB Bulletin 03–04, originally issued June 6, 2003, and is available online at: *http://www.whitehouse.gov/omb/bulletins/b03–04.html.*

In addition, as we indicated above, OMB has published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. We propose that this and all subsequent ESRD PPS rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage index. The OMB bulletins may be accessed online at: *http://www.whitehouse.gov/omb/bulletins/index.html.* Consistent with those definitions, we are proposing to define urban and rural areas in proposed § 413.231(b) of this proposed rule as follows: The term ''urban area'' would mean a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB. The term ''rural area'' would mean any area outside an urban area.

Under the current basic case-mix adjusted composite payment system, we apply a floor as a substitute wage index for areas with very low wage index values. However, we have gradually reduced the ESRD wage index floor from 0.90 in CY 2005, to 0.85 in CY 2006, 0.80 in CY 2007, 0.75 in CY 2008, and 0.70 in CY 2009 (73 FR 69758). We also stated that a gradual reduction was needed to ensure that patient access in areas that have low wage index values, and that we would continue to reassess the need for a wage index floor in future years.

For the ESRD PPS proposed rule, we are proposing not to adopt a wage index floor, as we believe we have provided a gradual reduction to the ESRD wage index floor through the existing basic case-mix adjusted composite payment system and that the impact on ESRD facilities will be minimal. We note that ESRD facilities affected by the floor may opt to go through the transition to the ESRD PPS, where the portion of their payment that is based on the ESRD PPS will be gradually increased from 25 percent of their payments in 2011 to 100 percent of their payments in 2014. We intend to continue to gradually reduce the ESRD wage index floor for the portion of the payment that is based on the current basic case-mix adjusted composite payment system. Applying a gradual reduction only to the floor that applies to the existing basic case-mix adjusted composite payment system ESRD wage index will accelerate the decline in the floor so that ESRD facilities are less dependent on the floor and at the end of the transition we would apply their actual wage index values.

In CY 2006, while adopting the CBSA designations, we identified a small number of ESRD facilities in both urban and rural areas where there are no hospital data from which to calculate ESRD wage index values. Since there are ESRD facilities in these areas, we developed policies for each of these areas, and we provide the details of these policies below (72 FR 66283). The areas with ESRD facilities that have no hospital data are rural Massachusetts, rural Puerto Rico, and Hinesville, GA (CBSA 25980). In the CY 2008 PFS final rule with comment (72 FR 66283), we stated that we would continue to evaluate exiting hospital wage data and possibly wage data from other sources such as the Bureau of Labor Statistics, to determine if other methodologies might be appropriate for imputing wage index values for areas without hospital wage data for CY 2009 and subsequent years. To date, no data from other sources, superior to that currently used in connection with the inpatient hospital PPS wage index, have emerged. Therefore, for purposes of the proposed ESRD PPS, we are proposing to continue with our current policies for rural Massachusetts and Hinesville, Georgia:

- For rural Massachusetts, we propose to adopt the methodology originally adopted for CY 2008 for establishing a wage index value for rural Massachusetts. Because we had used the same wage index value for 2 years with no update, we believed it was appropriate to establish a methodology which employed reasonable proxy data for rural areas (including rural Massachusetts) and also permitted annual updates to the wage index based on that proxy data. We used the average wage index values from all contiguous CBSAs as a reasonable proxy for rural Massachusetts. In determining an imputed rural wage index, we interpret the term ''contiguous'' to mean sharing a border. In the case of Massachusetts, the entire rural area consists of Dukes and Nantucket Counties. We determined that the borders of Dukes and Nantucket counties are contiguous with CBSA 12700, Barnstable Town, MA and CBSA 39300, Providence-New Bedford-Fall River, RI-MA. We propose to continue to use this methodology that averages the wage index values for the contiguous CBSAs, Barnstable Town, MA (CBSA 12700) and Providence-New Bedford-Fall River, RI-MA (CBSA 39300) for an imputed wage index value for rural Massachusetts for CY 2011.
- For Hinesville, GA (CBSA 25980), which is an urban area without specific hospital wage data, we propose to continue to use the methodology that was adopted in the CY 2007 PFS final rule (71 FR 231), which was to impute a wage index value for Hinesville, GA, using the average proposed ESRD wage index value for all urban areas within the State of Georgia.

With regard to rural Puerto Rico, we are proposing a different policy under the proposed ESRD PPS. In particular, we have previously applied the ESRD wage index floor for rural Puerto Rico because all areas in Puerto Rico that have a wage index were eligible for the ESRD wage index floor. However, as we stated earlier in this section, for the proposed ESRD PPS, we are proposing to eliminate the use of a wage index floor under the proposed ESRD PPS wage index. Therefore, for rural Puerto Rico, we propose to use the value for rural Puerto Rico (0.4047) that has been used by other payment systems that do not use a wage index floor. This wage index value is the latest available wage index value for rural Puerto Rico and is currently used for rural Puerto Rico by other payments systems that do not have a wage index floor. We note that there are currently no ESRD facilities located in rural Puerto Rico.

We are also proposing to use the labor share as measured by the proposed ESRD bundled market basket, which is 38.160 percent (as described in section XII. of this proposed rule). We note that the labor-related share from the proposed ESRD bundled market basket (38.160 percent) is lower than the labor-related share from the existing ESRD composite rate index (53.711 percent) because there are no labor costs associated with the separately billable portion of the proposed ESRD bundled market basket. Our proposed adjustment for wages is set forth in proposed § 413.231. For this proposed rule, we used the most current final wage index that was available at the time analysis was completed. This was the final CY 2009 wage index data. As stated earlier in this section, the ESRD wage index values used in the basic case-mix adjusted composite payment system are calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix (71 FR 69685; 73 FR 69758). We are proposing to use the same wage index for the ESRD PPS.

As we previously noted, in our current basic case-mix adjusted composite payment system, we incorporate the wage index budget neutrality factor into the wage index values. Since the CY 2009 ESRD wage index has the same values as the FY 2009 SNF PPS wage index, we recommend that entities wishing to replicate our analysis refer to the FY 2009 final rule where the FY 2009 Skilled Nursing Facility (SNF) PPS wage index was published. The FY 2009 SNF PPS final rule (73 FR 46415) includes tables with these wage index values. Table 8 shows the wage index values for urban areas (73 FR 46441 through 46462) and table 9 shows the wage index values for rural areas (73 FR 46462).

Since the ESRD PPS will be implemented in CY 2011, we believe it is appropriate to use CY 2011 wage index values. However, the wage data will not yet be available when the ESRD PPS final rule is published. Therefore, we propose to include the proposed CY 2011 ESRD PPS wage index data for purposes of the ESRD PPS (that would not include any wage index budget neutrality adjustment) along with the CY 2011 proposed update to the existing basic case-mix adjusted composite payment system. We anticipate that this would be published in the CY 2011 Physician Fee Schedule proposed rule, which we expect to be published in the summer of 2010. We also propose to publish the final CY 2011 ESRD PPS wage index along with the CY 2011 final rule update to the existing basic case-mix adjusted composite payment system. We anticipate that this would be published in the CY 2011 Physician Fee Schedule final rule, which we expect to be published in November of 2010.

2. Low-Volume Adjustment

a. Statutory Authority

Section 1881(b)(14)(D)(iii) of the Act requires a payment adjustment that ''reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent.''

b. Defining a Low-Volume Facility

As indicated above, section 1881(b)(14)(D)(iii) of the Act authorizes the Secretary to define ''low-volume facilities'' for purposes of a payment adjustment in the proposed ESRD PPS. We believe the low-volume adjustment should encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic. UM–KECC has performed analyses using data from CMS Medicare cost reports, SIMS, and OSCAR for years 2004–2006 to assist us in determining

what the ESRD facility-level characteristics are that best demonstrate what is a low-volume facility.

To begin our process of developing the methodology for defining a low-volume facility, we set parameters for ESRD facility size. In this explanation and throughout this section, the term 'year' is established by the ESRD facility's final-settled cost report, where the final-settled cost report reports costs for 12-consecutive months. Under the initial categorization, an ESRD facility with less than 5,000 treatments per year was considered small, a ESRD facility with 5,000 to 10,000 treatments per year was considered medium, and an ESRD facility with 10,000 treatments per year or more was considered large. The average ESRD facility size is relatively close to 10,000 treatments and this threshold has been used by others, for example, MedPAC.

With the data compiled and analyzed by UM–KECC, we were interested to see the distribution of ESRD facility size across the different ESRD facility ownership types. For purposes of defining a low-volume facility, we chose to categorize all ESRD facilities into four ESRD facility ownership types; (1) Independent, (2) regional chains, (3) Large Dialysis Organizations (LDOs), and (4) unknown ownership type. Of the hospital-based ESRD facilities, we found that 75.5 percent are independent, 10.7 percent are members of a regional chain/other category, 0.7 percent are members of an LDO, and 13.2 percent have unknown chain status. UM–KECC's comparison between ESRD facility size and ownership type, (Table 21: ESRD facility size and ownership type, 2004–2006), indicated that ownership varies with ESRD facility size and smaller ESRD facilities, especially those with less than 3,000 treatments, are relatively more likely to be independent than larger ESRD facilities. For example, 31 percent of ESRD facilities with less than 3,000 treatments are independent while only 18 percent of ESRD facilities with more than 10,000 treatments are independent.

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Table 21

ESRD facility size and ownership type, 2004-06

Preliminary

December 4, 2008

Total dialysis sessions at ESRD facility based on Cost Reports	ESRD facility ownership type										
	Independent		Regional chain		Large dialysis organization (LDO)*		Unknown		All		
	Facility years (n)	% of row	Facility years (n)	% of row	Facility years (n)	% of row	Facility years (n)	% of row	Facility years (n)	% of row	% of column
<5,000	588	23.7%	298	12.0%	1,521	61.4%	70	2.8%	2,477	100.0%	20.3%
<2,000	131	37.3%	47	13.4%	147	41.9%	26	7.4%	351	100.0%	2.9%
2 to 3,000	140	27.0%	63	12.1%	301	58.0%	15	2.9%	519	100.0%	4.2%
3 to 4,000	156	20.7%	86	11.4%	493	65.4%	19	2.5%	754	100.0%	6.2%
4 to 5,000	161	18.9%	102	12.0%	580	68.0%	10	1.2%	853	100.0%	7.0%
5 to 10,000	628	15.3%	361	8.8%	3,079	75.2%	29	0.7%	4,097	100.0%	33.5%
Total	2,277	18.6%	1,233	10.1%	8,500	69.6%	203	1.7%	12,213	100.0%	100.0%

* LDO status includes Fresenius, Davita, and Dialysis Clinic Inc. along with the following recent acquisitions:

Renal Care (acquired by Fresenius), Gambro (acquired by Davita), and National Nephrology Associates (acquired

by Renal Care in 2004 before Renal Care was acquired by Fresenius).

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UM–KECC's comparison also indicated that while smaller ESRD facilities are less likely to be members of an LDO than larger ESRD facilities, a relatively large fraction of smaller ESRD facilities are members of an LDO. For an example, 61.4 percent of ESRD facilities with less than 5,000 treatments and 41.9 percent of ESRD facilities with less than 2,000 treatments are members of an LDO. As a result of the comparison between ESRD facility size and ESRD facility ownership type, we chose to use ESRD facility ownership type as a variable in a two-equation regression analysis to test whether cost varies by ESRD facility ownership type within a ESRD facility size category.

With the data analyzed by UM–KECC, we were also interested to see the distribution of ESRD facility size across ESRD facilities that have an urban or rural status. UM–KECC's comparison of ESRD facility size and urban/rural status, (Table 22: ESRD facility size and rural status, 2004–2006 (n=11,814)), indicated that nearly half of the small ESRD facilities are rural and larger ESRD facilities are less likely to be rural.

TABLE 22—ESRD FACILITY SIZE AND RURAL STATUS, 2004–2006 (N=11,814)*

[Preliminary]

Total dialysis sessions at ESRD facility based on Cost Reports	ESRD facility rural status								
	Rural			Urban			All		
	Facility years (n)	% of row	% of column	Facility years (n)	% of row	% of column	Facility years (n)	% of row	% of column
<1,000	11	19.6	0.4	45	80.4	0.5	56	100	0.5
1 to 2,000	78	47.3	2.9	87	52.7	1.0	165	100	1.4
2 to 3,000	210	49.3	7.7	216	50.7	2.4	426	100	3.6
3 to 4,000	312	44.4	11.5	390	55.6	4.3	702	100	5.9
4 to 5,000	334	41.1	12.3	481	59.0	5.3	815	100	6.9
5 to 10,000	1164	28.8	42.8	2877	71.2	31.6	4041	100	34.2
10,000+	611	10.9	22.5	4998	89.1	55.0	5609	100	47.5
Total	2720	23	100.0	9094	77	100.0	11814	100	100.0

* Excludes facilities that opened or closed during the year. Based on data reported in SIMS.

UM–KECC's comparison also indicated that because most ESRD facilities are urban, even with the lower percentage of small ESRD facilities in urban areas, more urban ESRD facilities than rural ESRD facilities would benefit from a low-volume payment adjustment. As a result of the comparison between ESRD facility size and urban/rural status, we chose to use urban/rural status as a variable in a two-equation regression analysis to test whether cost varies by urban/rural status within a ESRD facility size category.

UM–KECC was able to develop a two-equation regression analysis using the variables discussed above (Table 23: Analysis for ESRD facility size, rural/urban status, and ownership type, 2004–2006 Model 2 and Table 24: Analysis for ESRD facility size, rural/urban status, and ownership type, 2004–2006 Model 4).

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Table 23
Analysis for facility size, rural/urban status, and ownership type, 2004-2006^, Model 2
Preliminary
December 17, 2008

	***Facility level log-linear model of average cost per session (n=11,814)** R-sq: 46.08% Average $169.67/session		****Patient level log-linear model of MAP per session (n=890,776)** R-sq: 8.73% Average $82.45/session		
Variable	CR Multiplier	p-value	SB Multiplier	p-value	Combined
Facility: < 1,000 treatments, Rural	1.410	0.1396	0.713	<.0001	1.182
Facility: < 1,000 treatments, Urban	1.792	<.0001	0.899	0.0151	1.500
Facility: 1,000 - 1,999 treatments, Rural	1.414	<.0001	0.953	0.012	1.263
Facility: 1,000 - 1,999 treatments, Urban	1.558	<.0001	1.110	<.0001	1.411
Facility: 2,000 - 2,999 treatments, Rural	1.413	<.0001	0.930	<.0001	1.255
Facility: 2,000 - 2,999 treatments, Urban	1.427	<.0001	0.947	<.0001	1.270
Facility: 3,000 - 3,999 treatments, Rural	1.297	<.0001	0.978	0.0027	1.193
Facility: 3,000 - 3,999 treatments, Urban	1.329	<.0001	1.010	0.1501	1.225
Facility: 4,000 - 4,999 treatments, Rural	1.208	<.0001	0.960	<.0001	1.127
Facility: 4,000 - 4,999 treatments, Urban	1.255	<.0001	1.018	0.002	1.177
Facility: 5,000 - 9,999 treatments, Rural	1.121	<.0001	0.984	<.0001	1.076
Facility: 5,000 - 9,999 treatments, Urban	1.122	<.0001	1.017	<.0001	1.087
Facility: 10,000+ treatments, Rural	1.001	0.9319	0.997	0.3507	0.999
Facility: 10,000+ treatments, Urban	1.000	ref	1.000	ref	1.000
Large dialysis organization (chain1-chain6)	1.017	0.0002	1.157	<.0001	1.063
Regional chain	1.024	<.0001	1.059	<.0001	1.036
Unknown chain status	1.049	<.0001	1.002	0.7254	1.034
Independent facility	1.000	ref	1.000	ref	1.000
Hospital-based facility***	1.442	<.0001	1.022	<.0001	1.304

^Excludes facilities that opened or closed during the year and patients treated in those facilities during that year. Based on data reported in SIMS.

*Other variables included in the CR model are age, female, body surface area, duration of RRT:< 4 month, alcohol/drug dependence, hepatitis B, bacterial pneumonia and other pneumonias/opportunistic infections, hereditary hemolytic or sickle cell anemias, cancer, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

**Other variables included in the SB model are age, female, body surface area, low BMI, duration of RRT:< 4 month, alcohol/drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, septicemia, bacterial pneumonia and other pneumonias/opportunistic infections, gastro- intestinal tract bleeding, hereditary hemolytic or sickle cell anemias, cancer, myelodysplastic syndrome, monoclonal gammopathy, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

***Of hospital-based facilities, 75.5% are independent, 10.7% are members of a regional chain/other organization, 0.7% are members of an LDO, and 13.2% have unknown chain status.

Table 24
Analysis for facility size, rural/urban status, and ownership type, 2004-2006, Model 4
Preliminary
December 17, 2008

	*Facility level log-linear model of average cost per session (n=11,814) R-sq: 46.26% Average $169.67/session		**Patient level log-linear model of MAP per session (n=890,776) R-sq: 8.71% Average $82.45/session		
Variable	CR Multiplier	p-value	SB Multiplier	p-value	Combined
Fac: <3,000 treatments, rural, LDO	1.480	<.0001	0.917	<.0001	1.296
Fac: <3,000 treatments, rural, not LDO	1.327	<.0001	0.950	0.0002	1.204
Fac: <3,000 treatments, urban, LDO	1.604	<.0001	0.957	0.0012	1.392
Fac: <3,000 treatments, urban, not LDO	1.321	<.0001	1.004	0.7802	1.217
Fac: 3,000-5,000 treatments, rural, LDO	1.288	<.0001	0.983	0.0056	1.188
Fac: 3,000-5,000 treatments, rural, not LDO	1.163	<.0001	0.939	<.0001	1.090
Fac: 3,000-5,000 treatments, urban, LDO	1.318	<.0001	1.010	0.059	1.217
Fac: 3,000-5,000 treatments, urban, not LDO	1.206	<.0001	1.027	0.0011	1.147
Facility: 5,000 - 9,999 treatments	1.122	<.0001	1.007	<.0001	1.084
Facility: 10,000+ treatments	1.000	ref	1.000	ref	1.000
Large dialysis organization (chain1-chain6)	1.010	0.0377	1.157	<.0001	1.058
Regional chain	1.024	<.0001	1.060	<.0001	1.036
Unknown chain status	1.047	<.0001	1.001	0.8261	1.032
Independent facility	1.000	ref	1.000	ref	1.000
Hospital-based facility***	1.438	<.0001	1.021	<.0001	1.302

^Excludes facilities that opened or closed during the year and patients treated in those facilities during that year. Based on data reported in SIMS.

*Other variables included in the CR model are age, female, body surface area, duration of RRT:< 4 month, alcohol/drug dependence, HIV/AIDS, hepatitis B, bacterial pneumonia and other pneumonias/opportunistic infections, hereditary hemolytic or sickle cell anemias, cancer, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

**Other variables included in the SB model are age, female, body surface area, low BMI, duration of RRT:< 4 month, alcohol/drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, septicemia, bacterial pneumonia and other pneumonias/opportunistic infections, gastro-intestinal tract bleeding, hereditary hemolytic or sickle cell anemias, cancer, myelodysplastic syndrome, monoclonal gammopathy, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

***Of hospital-based facilities, 75.5% are independent, 10.7% are members of a regional chain/other organization, 0.7% are members of an LDO, and 13.2% have unknown chain status.

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In Table 23, UM–KECC split the ESRD facility size variable into 7 categories including rural/urban status with increments of 1,000 treatments (<1,000, 1,000–1,999, 2,000–2,999, 3,000–3,999, 4,000–4,999, 5,000–10,000, and 10,000+). They then estimated ESRD facility-level models for composite rate costs and patient-level models for separately billable MAP per treatment. UM–KECC attempted to exclude ESRD facilities whose small number of treatments might be a temporary phenomenon (for example, ESRD facilities that opened, changed ownership, or closed). This was done using the initial certification date reported in OSCAR and the date of ESRD facility closure reported in SIMS. Changes of ownership where the new owner of the existing ESRD facility continues under the existing ESRD facility's provider number were included in the analysis. UM–KECC's analysis indicated that composite rate costs per treatment decline substantially as ESRD facility size increases and separately billable MAPs per treatment do not change substantially by ESRD facility size. UM–KECC's analysis also indicated that by controlling for ESRD facility size, being a member of an LDO does not lower costs and rural ESRD facilities do not report higher costs than urban ESRD facilities.

UM–KECC's two-equation regression analysis gave us the ability to see what other factors can be targeted to ensure that we have the right population of ESRD facilities that are low-volume. From UM–KECC's comparisons discussed above, we were able to determine that small rural ESRD facilities did not have higher composite rate costs in any of the small ESRD facility categories when compared to small urban ESRD facilities. In Table 24 we were able to see interactions between LDO status/small ESRD facility size/rural vs. urban status. We found that small ESRD facilities owned by LDOs were shown to have higher costs than small ESRD facilities that are non-LDOs.

We further evaluated how many dialysis treatments per year would best describe low-volume. As mentioned above, we began with our definition of a small ESRD facility, that is, less than 5,000 treatments. UM–KECC was able to provide us with another two-equation regression analysis that controlled for ESRD facility size and divided the small ESRD facility size variable into 3 categories; less than 2,000 treatments, less than 3,000 treatments, and less than 4,000 treatments. (Table 25: Analysis for low-volume ESRD facility size, 2004–2006).

TABLE 25—ANALYSIS FOR LOW-VOLUME ESRD FACILITY SIZE, 2004–2006—INCLUDE ADDITIONAL CONTROLS FOR ESRD FACILITY SIZE: MODEL 1

[Preliminary January 29, 2009]

Variable	*Facility level log-linear model of average cost per session (n=11,814) R-sq: 45.8%, Average $169.67/session			**Patient level log-linear model of MAP per session (n=890,776) R-sq: 8.7%, Average $82.45/session			Combined payment multiplier^
	Modeled CR multiplier	p-value	CR payment multiplier^	Modeled CR multiplier	p-value	CR payment multiplier^	
Facility size < 2,000 treatments during each year from 2004–06	1.497	<.0001	1.439	0.878	0.0929	0.876	1.254
Facility size < 2,000 treatments during current year but not during all 3 years	1.520	<.0001	1.000	1.055	0.0002	1.000	1.000
Facility size 2,000–4,999 treatments	1.290	<.0001	1.000	0.992	0.0101	1.000	1.000
Facility size 5,000–9,999 treatments	1.122	<.0001	1.000	1.011	<.0001	1.000	1.000
Facility size 10,000+ treatments	1.000	ref	1.000	1.000	ref	1.000	1.000
Rural	0.997	0.4674		0.981	<.0001		

TABLE 26—MODEL 2

Variable	*Facility level log-linear model of average cost per session (n=11,814) R-sq: 46.0%, Average $169.67/session			**Patient level log-linear model of MAP per session (n=890,776) R-sq: 8.7%, Average $82.45/session			Combined payment multiplier^
	Modeled CR multiplier	p-value	CR payment multiplier^	Modeled CR multiplier	p-value	CR payment multiplier^	
Facility size < 3,000 treatments during each year from 2004–06	1.383	<.0001	1.330	0.940	<.0001	0.938	1.202
Facility size < 3,000 treatments during current year, but not during all 3 years	1.478	<.0001	1.000	0.976	0.0036	1.000	1.000
Facility size 3,000–4,999 treatments	1.268	<.0001	1.000	1.000	0.9622	1.000	1.000
Facility size 5,000–9,999 treatments	1.122	<.0001	1.000	1.011	<.0001	1.000	1.000
Facility size 10,000+ treatments	1.000	ref	1.000	1.000	ref	1.000	1.000
Rural	0.997	0.4419		0.981	<.0001		

TABLE 27—MODEL 3

Variable	*Facility level log-linear model of average cost per session (n=11,814) R-sq: 45.9%, Average $169.67/session			**Patient level log-linear model of MAP per session (n=890,776) R-sq: 8.7%, Average $82.45/session			Combined payment multiplier^
	Modeled CR multiplier	p-value	CR payment multiplier^	Modeled CR multiplier	p-value	CR payment multiplier^	
Facility size < 4.000 treatments during each year from 2004–06	1.348	<.0001	1.300	0.978	0.0002	0.976	1.194
Facility size < 4,000 treatments during current year, but not during all 3 years	1.373	<.0001	1.000	0.997	0.5825	1.000	1.000
Facility size 4,000–4,999 treatments	1.237	<.0001	1.000	0.999	0.766	1.000	1.000
Facility size 5,000–9,999 treatments	1.122	<.0001	1.000	1.011	<.0001	1.000	1.000
Facility size 10,000+ treatments	1.000	ref	1.000	1.000	ref	1.000	1.000
Rural	0.997	0.427		0.981	<.0001		

^ The potential low-volume payment adjustment was calculated relative to all other facilities combined (i.e., using a weighted average of the other ESRD facility size coefficients).

* Other variables included in the CR model are age, female, body surface area, duration of RRT: <4 month, alcohol/drug dependence, HIV/AIDS, hepatitis B, bacterial pneumonia and other pneumonias/opportunistic infections, hereditary hemolytic or sickle cell anemias, cancer, calendar year, ESRD facility ownership type, composite rate payment exception, and % of patients in the ESRD facility with URR <65%.

** Other variables included in the SB model are age, female, body surface area, low BMI, duration of RRT: <4 month, alcohol/drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, septicemia, bacterial pneumonia and other pneumonias/opportunistic infections, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemias, cancer, myelodysplastic syndrome, monoclonal gammopathy, calendar year, ESRD facility ownership type, composite rate payment exception, and % of patients in the ESRD facility with URR <65%.

We found that the cost multipliers for small ESRD facilities are greater than 1.1 for any of the definitions for small ESRD facility size with respect to number of treatments per year and that they decline for successively higher cutoffs for defining small ESRD facilities. We also found that if a payment multiplier fully reflects the cost multiplier, there will be a strong disincentive for ESRD facilities to increase volume above cutoff. However, to the extent that a payment multiplier is smaller than the cost multiplier, this disincentive is somewhat diminished.

Since UM–KECC's analyses included data that spanned a 3-year period (2004–2006), we further evaluated the three ESRD facility size categories that we applied in the previous paragraph's regression analysis, that is, less than 2,000 treatments, less than 3,000 treatments, and less than 4,000

treatments per year. We were interested to see the number of small ESRD facilities that were able to maintain their ESRD facility size status each year of the 3-year period.

In this evaluation, we excluded ESRD facilities that opened, changed ownership, or closed during any one of the 3 years used for data. Status as a ''closed'' ESRD facility was based on information in the SIMS that the ESRD facility closed. Status as an ''opening'' ESRD facility was based on the initial Medicare certification date reported in OSCAR. Changes of ownership where the new owner of an existing ESRD facility continues under the existing ESRD facility's provider number were included in the analysis. We found there were 25 dialysis ESRD facilities that provided less than 2,000 treatments annually across the 3-year period (2004–2006), 89 ESRD facilities provided less than 3,000 treatments annually across the 3-year period, and 241 ESRD facilities provided less than 4,000 treatments annually across the 3-year period. These data indicate that ESRD facilities that provide less than 2,000 treatments per year across the 3-year period would result in low-volume adjustments being applied to very few ESRD facilities. These data also indicate that ESRD facilities that provide less than 4,000 treatments across the 3-year period would apply to almost 10 times more the number of ESRD facilities that provided less than 2,000 treatments and almost 3 times more the number of ESRD facilities that provided less than 3,000 treatments.

Accordingly, we propose to use a threshold of ESRD facilities that provide less than 3,000 treatments per year across the 3-year period. The threshold at 3,000 treatments strikes a balance between establishing an increment in payment that reflects the substantially higher treatment costs incurred by low-volume facilities (an increment that decreases relatively quickly as the low-volume threshold is raised) but still applies to a sufficiently large number of ESRD facilities to have an impact.

As mentioned above, the statute gives the Secretary the authority to define ''low-volume facilities''. Based on the above results, we propose in § 413.232, that a ''low-volume facility'' is an ESRD facility that meets the following criteria: (1) Furnished less than 3,000 treatments in each of the 3 years preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year. In the event an ESRD facility provides 3,000 or more treatments during their payment year, that is, no longer eligible for the low-volume adjustment; the ESRD facility would stop receiving the adjustment at the time they reach their 3,000th treatment. Where a change of ownership occurs and the new owner receives a new provider number during the 3-year period, the ESRD facility would not be eligible for the adjustment until it demonstrates that it meets the low-volume criteria under its new provider number. We are aware that there are Medicare-certified ESRD facilities that solely furnish support services and training for home peritoneal dialysis and home hemodialysis ESRD beneficiaries. Therefore, we are concerned that it may not be appropriate to extend low-volume eligibility to these types of facilities. We also are concerned that a treatment threshold may create an incentive for ESRD facilities to turn away patients rather than lose their low-volume status. We are requesting comment on the change of ownership element of our proposed definition, the appropriateness of applying the low-volume adjustment to training ESRD facilities, and the possible unintended effects of having a treatment threshold.

We believe that this approach would identify appropriate ESRD facilities for an adjustment and provide access to care for a vulnerable patient population. Under this proposal, new ESRD facilities would not be able to benefit from a low-volume adjustment until the 4th year in operation. For example, an ESRD facility opening in 2008 would need to meet the low-volume criteria for 2009, 2010, and 2011 to be eligible for the low-volume adjustment in 2012.

We are very concerned about potential misuse of the proposed 20.2 percent low-volume adjustment (the proposed figure is discussed below). Specifically, our concern is that the low-volume adjustment could incentivize dialysis companies to establish small ESRD facilities in close geographic proximity to other ESRD facilities, thereby leading to unnecessary inefficiencies, in order to obtain the low-volume adjustment. To address our concern, we are proposing additional criteria described below in connection with the proposed definition discussed above.

We propose, for purposes of determining the number of treatments under the proposed definition of a low-volume facility, that the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments actually furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both: (i) Under common ownership with and; (ii) 25 road miles or less from the ESRD facility in question. Under our proposal, ''common ownership'' means the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more of each ESRD facility. Our intention is to create a disincentive for commonly-owned ESRD facilities to purposively establish new ESRD facilities in close geographic proximity to other ESRD facilities, which could lead to unnecessary inefficiencies. The 25 road mile threshold is a standard that is used for low-volume adjustments in Medicare. For example, this criterion is used in the prospective payment system for inpatient hospital services. We are soliciting comment on our proposed definition of a ''low volume facility'' and our proposed geographic requirement with regard to determining the number of treatments furnished. We are also requesting comment concerning other potential vulnerabilities of the proposed low-volume definition and ways to address them.

Although we propose to limit the application of the low-volume adjustment to ESRD facilities with common ownership in a certain geographic location for purposes of determining the number of treatments under the proposed definition, we propose to grandfather those commonly owned ESRD facilities that have been in existence and certified for Medicare participation on or before December 31, 2010. Specifically, ESRD facilities that are in existence and certified for Medicare participation prior to January 1, 2011, will be exempt from treatment determination requirement and the geographic proximity restriction discussed above. We intend to monitor this grandfathering provision for abuse on a going forward basis and invite comment on the vulnerability it may present and ways to address them.

We also intend to work with our Regional Offices to monitor changes in the ESRD industry's behaviors and emerging trends in the ESRD industry nationwide. In this way, we would be able to monitor survey and certification activities and impose additional safeguards that maybe necessary in the interest of program integrity.

In order to identify which existing ESRD facilities meet the low-volume criteria, we propose that ESRD facilities could attest to the FI/MAC that they qualify as a low-volume facility. In this approach the FI/MAC would verify the ESRD facility's attestation of their low-volume status using the ESRD facility's final-settled cost reports. We invite comments on this approach and welcome other suggestions to identify

existing low-volume facilities. Instruction as to how the FIs/MACs would implement the proposed ESRD PPS will be provided in future guidance.

c. Defining the Percent of Increase

As discussed above, section 1881(14)(D)(iii) of the Act also requires the ESRD PPS to include a ''payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) * * * and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment not be less than 10 percent.'' Based on the definition described above and on the analysis discussed above in Table 26, Model 2, limiting the low-volume category to ESRD facilities that had not open, closed, or received a new provider number due to a change in ownership and remained small, that is, less than 3,000 treatments during all 3 years from 2004–2006 and including additional controls for ESRD facility size, the resulting low-volume payment adjustment was determined to be 20.2 percent. This chart takes into consideration paying the low-volume facilities based on the model's multiplier relative to the weighted average of the multipliers of the other ESRD facility size classes, therefore the extra payment would be calculated relative to an ESRD facility of typical size, not a ESRD facility in the largest size category.

Using our proposed low-volume criteria, we measured the payments received by these ESRD facilities and determined that 76.4 percent of ESRD facilities meeting the proposed low-volume criteria would get an adjustment of 10 percent or more increase in payment relative to what they received under the current system (see Table 28: Measured costs, current payments and proposed payment per dialysis session for an expanded bundle, 2006).

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Table 28
Measured costs, current payments and proposed payments per dialysis session for an expanded bundle, 2006*
Low-volume facility definition: did not open or close and reported <3,000 total sessions for each year from 2004-06
Preliminary
February 12, 2009

	Dialysis facilities	Mean	Median	Percent of facilities with a given change in payment per session					
				Loss in payment of 10% or more	-10% to -5%	-5% to 0%	0% to 5%	5% to 10%	Gain in payment of 10% or more
Total									
Measured costs for an expanded bundle (CR+SB)	4,286	$256.64	$248.54	--	--	--	--	--	--
Current Medicare Allowable Payments (MAP)									
Composite rate services	4,399	$153.49	$152.67	--	--	--	--	--	--
Separately billable services	4,399	$79.33	$78.66	--	--	--	--	--	--
Total	4,399	$232.82	$232.82	--	--	--	--	--	--
Proposed MAP for an expanded bundle									
No low-volume adjustment	4,399	$232.82	$230.16	10.7%	18.3%	25.1%	21.0%	12.1%	12.8%
Low-volume facility multiplier: 1.100	4,399	$232.82	$230.20	10.5%	18.1%	25.1%	20.8%	12.2%	13.3%
Low-volume facility multiplier: 1.150	4,399	$232.82	$230.25	10.5%	18.2%	25.0%	20.7%	12.1%	13.6%
Low-volume facility multiplier: 1.202	4,399	$232.82	$230.20	10.6%	18.2%	24.9%	20.5%	12.1%	13.7%
Low-volume facilities (as defined above)									
Measured costs for an expanded bundle (CR+SB)	88	$299.31	$289.55	--	--	--	--	--	--
Current Medicare Allowable Payments (MAP)									
Composite rate services	89	$150.25	$148.84	--	--	--	--	--	--
Separately billable services	89	$73.66	$73.46	--	--	--	--	--	--
Total	89	$223.91	$221.93	--	--	--	--	--	--
Low-volume facilities (as defined above)									
Proposed MAP for an expanded bundle									
No low-volume adjustment	89	$224.27	$216.68	15.7%	14.6%	19.1%	19.1%	12.4%	19.1%
Low-volume facility multiplier: 1.100	89	$246.31	$237.73	4.5%	3.4%	9.0%	16.9%	15.7%	50.6%
Low-volume facility multiplier: 1.150	89	$257.32	$248.30	1.1%	3.4%	4.5%	12.4%	13.5%	65.2%
Low-volume facility multiplier: 1.202	89	$268.77	$259.47	1.1%	1.1%	3.4%	4.5%	13.5%	76.4%
Other facilities									
Measured costs for an expanded bundle (CR+SB)	4,198	$256.48	$248.39	--	--	--	--	--	--
Current Medicare Allowable Payments (MAP)									
Composite rate services	4,310	$153.51	$152.71	--	--	--	--	--	--
Separately billable services	4,310	$79.35	$78.69	--	--	--	--	--	--
Total	4,310	$232.86	$232.88	--	--	--	--	--	--
Proposed MAP for an expanded bundle									
No low-volume adjustment	4,310	$232.86	$230.24	10.6%	18.4%	25.3%	21.0%	12.1%	12.7%
Low-volume facility multiplier: 1.100	4,310	$232.76	$230.14	10.6%	18.5%	25.4%	20.9%	12.1%	12.5%
Low-volume facility multiplier: 1.150	4,310	$232.71	$230.10	10.7%	18.5%	25.4%	20.8%	12.1%	12.5%
Low-volume facility multiplier: 1.202	4,310	$232.66	$230.05	10.8%	18.6%	25.3%	20.8%	12.1%	12.4%

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Based on the analysis provided by UM–KECC, we are proposing a 20.2 percent increase to the base rate to account for the costs incurred by low-volume facilities for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014.

The proposed low-volume adjustment policy is set forth in proposed § 413.232. We invite comments on the low-volume facility proposed adjustment.

For purposes of determining the appropriate adjustment for the low-volume facilities defined above, we are considering other options in addition to the 20.2 percent adjustment we described. As mentioned previously, section 1881(14)(D)(iii) of the Act requires the payment adjustment for low-volume facilities be not less than 10 percent during the transition. We

believe that adopting the statutory adjustment of 10 percent would provide relief to low-volume facilities of the costs they incur to provide services. In addition, providing a lower payment adjustment results in less of a decrease in the ESRD PPS base rate which would apply to treatments furnished by all ESRD facilities.

Another option for the low-volume adjustment would be the midpoint between the statutory adjustment of 10 percent and the results of our data analysis which is 20.2 percent. We believe that a 15 percent increase could establish an appropriate adjustment amount that would provide low-volume facilities the incentive to utilize resources more efficiently and control their costs.

We invite comments on these alternative options for determining the percent low-volume adjustment.

3. Alaska/Hawaii Facilities

Section 1881(b)(14)(D)(iv) of the Act permits the Secretary to include other payment adjustments as the Secretary determines appropriate. The basic case-mix adjusted composite payment system currently does not provide a separate adjustment for ESRD facilities located in Hawaii and Alaska. However, some prospective payment systems, such as the hospital inpatient PPS and the inpatient psychiatric facility PPS, provide a cost of living adjustment (COLA) for facilities located in Alaska and Hawaii. These COLA adjustments are applied to the non-labor portion of the payment and are based on the rationale that the wage index adjustment to the labor portion of the payment is not sufficient to provide for the higher costs incurred by facilities in Alaska and Hawaii. For example, the same supplies used by an ESRD facility located in Hawaii cost more because there are additional (higher) transportation costs incurred to receive the same supplies compared to an ESRD facility located in the mainland United States. Analysis completed for the 2008 Report to Congress indicated there was no need for a COLA for these areas. After all adjustments (including wage and other adjustments), our analysis of ESRD facilities located in Alaska and Hawaii did not demonstrate any adverse impact from the proposed ESRD PPS.

Our analysis continues to support that the proposed ESRD PPS would adequately reimburse ESRD facilities located in Alaska and Hawaii. Therefore, we are not proposing to adopt COLA adjustments for ESRD facilities in Alaska and Hawaii under the proposed ESRD PPS. We invite public comments on this proposal.

4. Rural

Section 1881(b)(14)(D)(iv)(III) of the Act provides that the ESRD PPS may include payment adjustments as the Secretary determines appropriate such as a payment adjustment for facilities located in rural areas. Accordingly, we analyzed rural status as part of the regression analysis for the proposed ESRD PPS to inform our proposal for this rule.

As discussed previously in section VIII. C. 1. of the proposed rule, we are proposing to define rural facilities in proposed § 413.231(b)(2) as facilities that are outside a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB. To decrease distortion among independent variables, rural facilities were considered control variables rather than payment variables.

We do not believe that the proposed ESRD PPS would result in decreased access to care for beneficiaries residing in rural areas based on the results of the impact analysis. Specifically, as illustrated in the impact table in Table 48, the proposed ESRD PPS reveals an overall decrease in payment of 2.5 percent for rural facilities under the proposed ESRD PPS in 2011 as compared to the current basic case-mix adjusted composite payment system. However, 2 percent of this amount is associated with the statutory requirement that payments under the ESRD PPS equal 98 percent of what ESRD facilities would have received had this ESRD PPS not been implemented (98 percent of payments to ESRD facilities under the current payment system). In summary, this analysis reveals that rural ESRD facilities would be adequately reimbursed under the proposed ESRD PPS.

We also included facility treatment volume as a control variable in the payment model. Based on the analysis conducted by UM–KECC, 66 of the 166 ESRD facilities that met the low volume criteria discussed further in section VIII.C.2 of this proposed rule are located in rural areas. Thus, some of the effects of rural status on cost and payment are captured via the low volume payment adjustments. Therefore, we are not proposing a facility level adjustment that is based on rural location. We invite public comments on this proposal.

5. Site Neutral ESRD PPS Rate

For dialysis services furnished prior to January 1, 2009, the basic case-mix composite rate differentiated between hospital-based and independent ESRD facilities. That is to say, the composite rate for hospital-based facilities was on average $4.00 more per treatment more than the composite rate for independent dialysis facilities.

Section 1881(b)(12)(A) of the Act, as amended by section 153(a)(2), requires a site neutral composite rate so that the payment rate for services furnished on or after January 1, 2009, by hospital-based facilities is the same as the payment rate paid to independent renal dialysis facilities under the current system. In addition, section 1881(b)(12)(A) of the Act, as amended by section 153(a)(2) of MIPPA, requires that in applying the geographic index to hospital-based facilities, the labor share shall be based on the labor share otherwise applied to the renal dialysis facilities. In the CY 2009 final rule (72 FR 69881 and 69935), we revised § 413.174, which described the methodology for prospective rates for ESRD facilities, to conform to the statutory requirement.

Section 1881(b)(14)(A)(i) of the Act, as amended by section 153(b) of MIPPA, provides that for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this title to ESRD facilities for renal dialysis services, in lieu of any other payment. Therefore, the site neutral payment provisions discussed above will automatically be incorporated under the ESRD PPS and used to establish a single base rate that will apply to ESRD facilities.

D. Determination of ESRD PPS Payment Adjusters

We have described the selection of patient characteristics as potential case-mix adjusters using a modeling approach that has relied on separate regression equations for CR and SB services. The predictive power of the separate estimating equation for CR services in terms of the proportion of variance explained (R^2) was 46.0 percent. The comparable figure for the SB regression equation was 8.7 percent. The overall estimated R^2 for the ESRD PPS payment model is 39.0 percent. While the case-mix adjustments were based on separate estimating equations, the equations can be combined into a single payment formula for the ESRD PPS.

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Table 29				
Payment multipliers for an expanded bundle of services, ages 18 and older, 2004-06				
	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment[3,4]	
	Composite rate services[1]	Separately billable services[2]		
Variable	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$	
Adjustments for dialysis patient characteristics				
Age				
18-44	1.280	1.018	1.194	
45-59	1.000	1.000	1.000	
60-69	1.014	1.006	1.012	
70-79	1.105	0.960	1.057	
80+	1.150	0.923	1.076	
Female	1.124	1.149	1.132	
Body surface area (BSA, per 0.1 m^2; mean BSA=1.87)	1.035	1.033	1.034	
Underweight (BMI <18.5)	1.000^	1.060	1.020	
Time since onset of renal dialysis: <4 months	1.508	1.401	1.473	
Alcohol/drug dependence (claims since 2000 or 2728)	1.155	1.139	1.150	
Cardiac arrest (claims since 2000 or 2728)	1.000^	1.098	1.032	
Pericarditis from same month to three months ago	1.000^	1.595	1.195	
HIV/AIDS (claims since 2000 or 2728)	1.363	1.220	1.316	
Hepatitis B (claims since 2000)	1.115	1.035	1.089	
Specified infection from same month to 3 months ago				
Septicemia	1.000^	1.715	1.234	
Bacterial pneumonia and other	1.256	1.412	1.307	
pneumonias/opportunistic infections				
Gastro-intestinal tract bleeding from same month to 3 months ago	1.000^	1.965	1.316	
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.248	1.179	1.226	
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.143	1.097	1.128	
Myelodysplastic syndrome (claims since 2000)	1.000^	1.257	1.084	
Monoclonal gammopathy (claims since 2000)	1.000^	1.063	1.021	

Low volume facility adjustment Facility size < 3,000 treatments during each year from 2004-06	1.383	0.940	1.202	
^A multiplier 1.000 was used for factors that lacked statistical significance in models of resource use or lacked stability over time in the estimated multipliers.				
[1]The CR payment multipliers ($PmtMult_{CR}$) are based on a facility level log-linear regression model of the average composite rate cost/session for 2004-06 (n=11,814 facility years). This model also included facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%) and the percent of pediatric patients as additional covariates (R-sq=46.0%).				
[2]Based on a patient level log-linear regression model of separately billable Medicare Allowable Payments/session for 2004-06 (n=890,776 patient years) that included included facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%) as additional covariates (R-sq=8.7%).				
[3]The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB}$ = $Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility level model of composite rate costs and $PmtMult_{SB}$ is the estimated multiplier from a patient level model of separately billable costs. Based on total estimated costs of $169.67 per session for composite rate services, $82.45 per session for separately billable services, and $252.12 per session for an expanded bundle ($169.67+$82.45), the relative weights are $Weight_{CR}$=0.673 for composite rate services ($169.67/$252.12) and $Weight_{SB}$=0.327 for separately billable services ($82.45/$252.12).				
[4]To determine the incremental payment for low volume facilities, the low volume facility payment multiplier was calculated relative to all other facilities combined. The estimated low volume coefficients from the regression models (which correspond to the CR and SB multipliers of 1.383 and 0.940, respectively, in the table above) were first divided by the weighted average of the other facility size coefficients in the models. A similar weighting procedure to that described above for the other payment multipliers was then used in calculating the resulting low volume adjustment of 1.202. The same payment adjustment is being used for both adult and pediatric patients in a low volume facility.				

Table 29 shows how the payment adjusters from the separate CR and SB regressions were combined. The first two columns in Table 29 represent the CR and SB model results for each of the regression equations, carried to three significant figures. The third column of Table 29 presents a single payment multiplier for each patient characteristic based on its relationship to resource use for both CR and SB services. The payment adjusters in the third column ($PmtMult_{EB}$) were calculated as the weighted average of the CR and SB multipliers. The weights correspond to each component's proportion of the sum of the average CR costs and SB payments per treatment for CYs 2004–2006, as shown in Table 30.

Table 30
Estimated costs for composite rate and separately billable services, CY 2004-06[1]

	2004		2005		2006		Pooled, 2004-2006	
Measure of resource use	n	Average $ per treatment	n	Average $ per treatment	n	Average $ per treatment	n	Average $ per treatment
Facility composite rate costs[2]	3,794	$161.33	3,948	$168.09	4,072	$179.24	11,814	$169.67
Patient separately billable Medicare Allowable Payments (repriced)[3]								
Ages <18	719	$44.76	866	$52.42	790	$49.60	2,375	$49.11
Ages 18 and older	289,587	$82.97	297,718	$84.39	303,471	$80.07	890,776	$82.45

[1]Weighted by the number of hemodialysis-equivalent dialysis treatments.
[2]Source: Medicare cost reports for freestanding and hospital-based dialysis facilities.
[3]Source: Medicare dialysis patient claims. MAP amounts were repriced to reflect 2008Q1 payment rates for the top injectable drugs.

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The weights were calculated using the 3 years of pooled data. Based on this analysis, the average cost for CR services per treatment as computed from the Medicare cost reports was $169.67. The average MAP per treatment for SB services based on Medicare claims for the same period was $82.45. Based on total estimated costs of $252.12 per treatment ($169.67 + $82.45), the relative weights are $weight_{CR}$ = 0.673 for composite rate services ($169.67/$252.12) and $weight_{SB}$ = 0.327 for separately billable services ($82.45/$252.12). The payment multipliers presented in the third column of Table 29 were calculated as $PmtMult_{EB} = 0.673 \times PmtMult_{CR} + 0.327\ PmtMult_{SB}$. In this manner, the separate case-mix adjusters for composite rate and separately billable services were combined to obtain a single set of multipliers (shown in the third column of Table 29) to compute the payment rates under the proposed ESRD PPS.

Six co-morbidities were identified as payment adjusters for separately billable services only, as they did not have a statistically significant association with composite rate costs based on the regression results. These patient characteristic variables have a composite rate multiplier in Table 29 of 1.000. For these co-morbidities, there is no payment adjuster for composite rate services. Therefore, the payment multiplier is equal to $0.673 \times 1.000 + 0.327 \times PmtMult_{SB}$. The payment multipliers in the third column of Table 29 reflect the combined results from the two-equation model previously described in this proposed rule, and represent the case-mix adjustment factors that we propose to apply to the base rate to compute the payment amount per treatment under the proposed ESRD PPS.

IX. Pediatric Patients

Section 1881(b)(14)(D)(iv)(I) of the Act, as added by section 153(b) of MIPPA, gives the Secretary the discretionary authority to develop pediatric payment adjustments in connection with the ESRD PPS. Below we discuss the current system with regard to ESRD facilities that furnish renal dialysis services to pediatric patients, as well as our proposed methodology for developing a pediatric payment adjustment under the proposed ESRD PPS.

A. Current System

The current basic case-mix adjusted composite payment system uses a set of case-mix adjusters or multipliers based on three variables—age, BSA, and low BMI. Employing the same 2000 to 2002 data and regression methodology used to derive the basic case-mix adjusters, we attempted, when implementing the current payment system, to develop case-mix adjusters for outpatient ESRD patients under age 18. However, we found that for the approximately 600 Medicare pediatric patients for whom claims were available from 2000 through 2002, the results were highly variable and statistically unstable, and therefore, inappropriate for the development of case-mix adjusters in accordance with the same methodology otherwise applicable to adult Medicare ESRD patients (see 69 FR 66326–27 published November 15, 2004). Section 623(b)(1)(D) of the MMA amended section 422(a)(2) of BIPA to provide that beginning October 1, 2002, ESRD facilities in which at least 50 percent of patients are under age 18, are considered ESRD pediatric facilities, and are eligible for a pediatric exception to the composite payment rate. However, due to the relative costliness of pediatric ESRD patients, we believed that it was appropriate to develop a temporary methodology applicable to ESRD facilities, which furnish outpatient dialysis to pediatric patients, regardless of whether the facility met the definition of a pediatric facility. Our intent was to rely on a temporary methodology pending the completion of research, which could yield empirically based case-mix adjusters under a bundled ESRD PPS.

In the CY 2005 PFS final rule with comment period, published on November 15, 2004 (69 FR 66327), implementing the basic case-mix adjustment to the composite payment system we described the methodology used to develop a 62 percent pediatric increase (that is, an adjustment factor of

1.62) automatically applied to the composite payment rate per treatment for any facility furnishing outpatient dialysis services to pediatric patients. That factor was based on the average amount of the atypical services exceptions granted for 20 ESRD facilities, each of which sought and received an exception for the atypical costs incurred for the treatment of outpatient pediatric patients, compared to the average unadjusted composite payment rate (that is, the payment without regard to exception amounts) for these same 20 facilities. We explained that application of the pediatric adjustment factor of 1.62 in lieu of an explicit pediatric case-mix adjustment was temporary, and would be eliminated once an appropriate methodology, preferably one applicable to both pediatric and adult Medicare patients, could be developed.

The Secretary's 2008 Report presented a design for a case-mix adjusted ESRD PPS, which included not only composite rate services but also separately billable dialysis services, weighted in accordance with the two-equation model described in section VIII. of this notice of proposed rulemaking.

In applying the case-mix adjustment factors resulting from the two-equation regression model described in the Secretary's 2008 Report to pediatric patients, we noted the following:

> [P]ediatric dialysis patients are comparatively rare among Medicare dialysis patients, comprising about 0.2 percent of the population. The impact of the BSA adjustment in the above example is a payment reduction of over 37 percent, compared to the age related increase of 9.1 percent. UM–KECC has performed analyses which demonstrate that the predicted separately billable MAP falls substantially short of the actual separately billable MAP for pediatric patients (that is, those less than age 18). This occurs because the BSA multiplier of 1.035 does not accurately reflect the relationship between BSA and separately billable services for pediatric patients because of their small size and relative rarity in the Medicare dialysis population. Given the small number of pediatric patients, there is a lack of statistical robustness in the payment model with respect to those patients. The data limitations do not permit a ready solution to this problem. We are currently examining approaches to determine if modifications to the regression based payment methodology for pediatric patients is feasible.
>
> See Secretary's February 2008 Report to Congress, pp. 47–48.

Based on UM–KECC research subsequent to the issuance of the Secretary's 2008 Report, we believe that a separate regression based case-mix model is feasible for pediatric patients using a limited number of variables. In the following sections, we describe the payment model used to develop the payment adjusters which we are proposing to apply for Medicare pediatric ESRD patients.

B. Selection of a Pediatric Composite Rate Payment Adjustment

One approach to developing a payment adjustment is to use the results of an updated composite rate cost model. Such a model could employ one or several age categories for pediatric patients. Table 31 presents a model of composite rate costs for the purpose of demonstrating a method for arriving at a pediatric composite rate multiplier, with a single pediatric age category. This model was estimated using Medicare cost report, claims, and other data for CYs 2004–2006. The model uses ESRD facility data on composite rate costs and average patient characteristics. Because pediatric patients comprise such a low percentage of the total patient load of most facilities, the measures of many patient characteristics at the facility level (that is, the average patient characteristics at the facility) are dominated by the characteristics of adult patients. Therefore, while average patient characteristics are shown in Table 31 in the model, they are only used as control variables. That is, while statistically significant payment adjusters may be shown in Table 31 for patient characteristic variables, there is no actual associated payment adjustment that would apply to composite rate services for pediatric patients. For example, the pediatric composite rate cost model assumes no payment adjustment for body size (BSA or low BMI), gender, duration of renal replacement therapy, or co-morbidities. The key coefficient is the one for the age less than 18 variable. The estimated regression-based multiplier of 1.199 reflects an increase in the composite rate portion of the base payment rate of 19.9 percent for patients less than 18, relative to patients age 45–59. The model shown in Table 31 with a single pediatric age category is the model we are proposing to use to adjust the composite rate portion of the proposed ESRD for pediatric patients.

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Table 31
Payment multipliers from a facility level model of composite rate costs

Variable*	Composite rate services (n=11,814 facility years; R-sq=46.0%)	
	$Mult_{CR}$	p-value
Adjustments for dialysis patient characteristics		
Age		
<18	1.199	<0.001
18-44	1.280	<0.001
45-59	1.000	ref
60-69	1.014	0.665
70-79	1.105	<0.001
80+	1.150	<0.001
Female	1.124	<0.001
Body surface area (BSA, per 0.1 m^2; mean BSA=1.87)	1.035	<0.001
Underweight (BMI <18.5)	1.000^	--
Time since onset of renal dialysis: <4 months	1.508	<0.001
Alcohol/drug dependence (claims since 2000 or 2728)	1.155	<0.001
Cardiac Arrest (claims since 2000 or 2728)	1.000^	--
Pericarditis from same month to three months ago	1.000^	--
HIV/AIDS (claims since 2000 or 2728)	1.363	<0.001
Hepatitis B (claims since 2000)	1.115	<0.001
Specified infection from same month to three months ago		
Septicemia	1.000^	--
Bacterial pneumonia and other pneumonias/opportunistic infections	1.256	0.021
Gastro-intestinal tract bleeding from same month to three months ago	1.000^	--
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.248	<0.001
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.143	<0.001
Myelodysplastic Syndrome (claims since 2000)	1.000^	--
Monoclonal Gammopathy between (claims since 2000)	1.000^	--
Low volume facility adjustment		
Facility size < 3,000 treatments during each year from 2004-06	1.383	<0.001

*Both the composite rate and separately billable models included the following facility control variables: facility size categories other than the low volume category, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%.

^A multiplier of 1.000 was used for factors that lacked statistical significance in models of resource use or lacked stability over time in the estimated multipliers.

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The type of cost model shown in Table 31 could also employ multiple pediatric age categories. However, because of the small number of patients in each pediatric age category, the payment adjusters, based on the coefficients of the age variables, are unstable. Therefore, with respect to a payment adjustment applicable to composite rate services for pediatric patients, we believe that a single age

category is most appropriate. Although the proposed payment adjuster of 1.199 for the composite rate portion of the ESRD PPS for pediatric patients is substantially less than the current adjustment of 1.62, we point out that this is an empirically developed measure derived from data for all Medicare outpatient ESRD pediatric patients treated by ESRD facilities. The 1.62 value was developed from only those facilities that sought and obtained an exception to their otherwise applicable composite payment rates.

C. Selection of a Pediatric Separately Billable Payment Adjustment

Although the number of pediatric patients is small, we believe that it is feasible to estimate a payment model for separately billable services furnished to pediatric patients. However, the small sample size limits statistical power and results in a more limited set of potential payment adjusters. Unlike the adult separately billable payment model, which includes multipliers for particular patient co-morbidities, age, body size, and other variables, we evaluated pediatric separately billable payment models based on categories defined by patient characteristics including age, the presence of co-morbidities, and dialysis modality. This model structure is feasible because of the relatively small number of characteristics generating adjustments.

We considered several factors in developing the payment model for separately billable services: The number and definition of the age categories; the number and set of co-morbidities; the reflection of modality as a payment variable; and the potential inclusion of other patient characteristics, such as gender, onset of renal dialysis, and history of transplantation. We developed several exploratory models for separately billable services furnished to pediatric patients in order to develop the model proposed in this notice.

All of the analyses were performed using log-linear regression models of the average separately billable MAP per treatment during the year as the dependent variable. The data were pooled over the 3-year period CY 2004–2006, resulting in up to three yearly observations for each pediatric patient. The potential payment multipliers that were estimated by the model often required a statistical ''smearing'' adjustment to limit retransformation bias.

Under statistical ''smearing'', a correction factor is applied to the predictions from a model that is estimated on the logarithmic scale (for example, the log of the average MAP per treatment). In the context of examining healthcare cost data that are not normally distributed, retransformation bias may occur when converting predicted values that are made on the log scale (that is, log dollars) back to the original scale (that is, dollars), yielding biased estimates of the mean cost in dollars. In order to make valid inferences about the relationships between patient characteristics and the MAPs (that is, in dollars), it is essential that retransformation bias be limited as much as possible. Because the difference between the measured MAP and predicted MAP for each observation (that is, the residuals) did not vary in the desired random pattern, indicating correlation between the variance of the residuals and some of the patient characteristics in each model (statistically known as ''heteroscedasticity''), separate smearing factors were applied by patient subgroup. The smearing adjustments were based on the average retransformed residual for each patient category. For further information on the use of statistical smearing, retransformation, and heteroscedasticity, see Duan, N., *Smearing estimate: a nonparametric retransformation method,* Journal of the American Statistical Association, 78, 1983, pp. 605–610, and Manning, W. G., *The logged dependent variable, heteroscedasticity, and the retransformation problem,* Journal of Health Economics, 17, 1998, pp. 283–295.

We examined numerous separately billable payment models to determine the most appropriate age categories (defined by two age groups), and the selection of co-morbidity categories, defined as two groups (no co-morbidities, and the presence of one or more of the co-morbidities listed in the footnotes to Table 32). Individual co-morbidities that were considered for inclusion in the co-morbidity categories were each identified as statistically significant predictors of separately billable MAP per treatment based on a stepwise regression model. Some of the more important factors which we considered before arriving at the pediatric payment model we are proposing in this notice of proposed rulemaking are discussed below. Because our consideration of each of these factors resulted in the pediatric payment adjustments we are proposing in this rule, we invite comment on their use.

(1) Use of two age categories <13, and 13–17

Because of the small number of pediatric patients, we limited the number of age groups to two. Because the data revealed a natural break relating to increased body size and greater utilization of resources corresponding with the onset of adolescence, we defined the pediatric age categories as less than 13, and age 13–17.

(2) Omission of hyperparathyroidism as a co-morbidity

Hyperparathyroidism had a relatively low reported incidence in the claims data. However, hyperparathyroidism clinically is a frequently encountered condition in pediatric dialysis patients. This co-morbidity has a relatively high potential for overreporting compared to other co-morbidities. Because hyperparathyroidism was associated with a relatively small payment increase, omitting this diagnosis from the list of co-morbidities generating a payment adjustment increases the potential payment multipliers for other co-morbidities. However, given the widespread occurrence of hyperparathyroidism in the pediatric dialysis patient population, we believe its omission results in minimal distortion in the adjusters for most payment categories. We invite comment on our proposal to omit hyperparathyroidism as a co-morbidity in our proposed pediatric payment model.

(3) Capping Separately Billable MAP per Treatment at $289.00 per Treatment for All Pediatric Patients

The cap of $289.00 was based on a standard outer fence method for identifying statistically aberrant values. (For a further explanation on the application of this method, see p. 46 of UM–KECC's February 2008 report, ''End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle'' and footnote 35 of the Secretary's February 2008 Report to Congress, both cited previously in this proposed rule. The outer fence was defined as the 75th percentile of the separately billable MAP per treatment, plus three times the interquartile range, which is the 75th percentile minus the 25th percentile.) Capping the separately billable MAP does not lead to substantially different payment multipliers. The standard deviation of the prediction error falls substantially for some of the payment groups, especially those that were quite large. Some of this reduction may be

due to the elimination of erroneous data through the capping mechanism. In any case, the fact that the case-mix payment adjusters did not materially change regardless of the application of the standard outer fence method for eliminating aberrant values suggests that the predicted payments are not biased through the inclusion of valid or invalid values.

(4) Adjustment for Dialysis Modality

Our analysis revealed that the main problem with a separately billable payment model that does not recognize modality is that it results in an underpayment for HD and an overpayment for PD. For models that did not pay differentially by modality, the average prediction errors were all positive for PD and negative for HD. The errors in both directions were large relative to the predicted means. By contrast, the prediction errors in models that distinguish payment by modality were much smaller and did not consistently favor PD over HD. Hence, payment by modality reduces the difference between actual and predicted payments. In doing so, it reduces the incentive to steer patients to a particular modality based purely on the payment implications. It also substantially improves the predictive power of the payment models.

However, payment by modality introduces an inconsistency with how modality is treated currently under the basic case-mix adjusted composite payment system, and with how we are proposing to treat it for adults under the proposed ESRD PPS. There are a small number of payment groups with relatively large differences between actual and predicted payments even when the models adjust for modality. Paying by modality for pediatric patients is also inconsistent with the payment goal of encouraging home dialysis. However, we note that partly because of the popularity of PD among pediatric patients, it may not be necessary to encourage home therapies for this population. In addition, paying by modality doubles the number of payment categories from four to eight, increasing administrative complexity. We are specifically soliciting comments on our proposal to use modality as a payment variable in our pediatric payment model.

(5) Exclusion of Other Patient Characteristic Variables

Among the other patient characteristics that were considered as potential payment adjusters for separately billable pediatric services, gender, and onset of dialysis (that is, the start of dialysis within 4 months of the current treatment), were not identified as statistically significant predictors of MAP using CY 2004–2006 data. Based on models that included adjustments for age, dialysis modality, and number of co-morbidities, history of transplantation was associated with a higher separately billable MAP per treatment. However, the inclusion of an additional adjustment for history of transplantation did not substantially improve the explanatory power of the model, or substantially reduce the prediction errors for most patient subgroups. In addition, its inclusion would double the number of payment categories in the model from 8 to 16, six of which had very small numbers of patients (less than 50 patients).

Given the results of the analyses described, we are proposing a pediatric payment adjustment for separately billable services that uses two age categories (<age 13, age 13–17), two co-morbidity categories (none, and one or more co-morbidities from among the following diagnoses: HIV/AIDS, septicemia, cardiac arrest, and diabetes), and dialysis modality (HD or PD), as the bases for classifying pediatric patients into one of eight groups. The specified co-morbidities were the only statistically significant predictors of SB MAP resulting from the application of the stepwise regression. Using data available for CY 2004–2006, we present the results in Table 32. Similar to the adult ESRD PPS payment model, the proposed pediatric separately billable payment model reflects the repricing of the top 11 Part B separately billable drugs to the payment rates used in the first quarter of 2008. The ratios used to adjust the MAPs for the 11 specified injectable drugs are identical to those used to reprice the drugs for the adult separately billable MAPs shown in Table 11.

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Table 32
Measured and predicted separately billable Medicare Allowable Payments (MAP) for pediatric patients, 2004-2006

Preliminary **Predicted MAP based on age, modality, and comorbidity groups**

	Patient characteristics					Modeled separately billable (SB) multiplier[3]	Separately billable MAP per session			
									Prediction error	
Cell	Age	Modality	Comorbidities[1]	Patients[2]	Patient-facility months		Actual mean	Predicted mean[4]	Mean	SD
1	<13	PD	None	333	3,376	1.000	$12.28	$12.06	-$0.22	$21.39
2	<13	PD	1 or more	68	310	1.485	$10.14	$17.90	$7.76	$17.35
3	<13	Hemo	None	267	1,757	3.861	$51.82	$46.55	-$5.27	$52.81
4	<13	Hemo	1 or more	120	751	5.647	$83.35	$68.08	-$15.27	$67.89
5	13-17	PD	None	296	2,598	1.508	$19.70	$18.18	-$1.52	$37.12
6	13-17	PD	1 or more	66	456	2.244	$33.49	$27.06	-$6.43	$54.88
7	13-17	Hemo	None	656	5,765	5.831	$70.95	$70.30	-$0.65	$62.28
8	13-17	Hemo	1 or more	255	2,002	8.534	$87.61	$102.89	$15.28	$64.08

[1]The comorbidity adjustment is based on the presence of HIV/AIDS (2728 or claims since 2000), septicemia within 3 months, diabetes (2728 or claims since 2000), and cardiac arrest (2728 or claims since 2000).

[2]Note that individual patients can appear in more than one cell during 2004-06.

[3]Based on a pediatric patient level regression model of SB MAP/session for 2004-06 (n=2,375 pediatric patient years) that included age (<13 vs. 13-17), modality (PD vs. HD), and comorbidity (none vs. 1 or more) as covariates (R-sq=32.8%). Subgroup-specific smearing adjustments were applied to the model estimates.

[4]Predicted SB MAP per session are based on a log-linear regression model that included the patient characteristics in this table, subgroup-specific smearing adjustments, and a budget neutrality adjustment.

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For purposes of the payment adjustments, the relevant column is labeled ''Modeled separately billable (SB) multiplier''. These values reflect the relative costliness of separately billable services for each of the eight pediatric patient groups, with the reference category (under 13, PD, no co-morbidities) having a multiplier set to 1.00. We invite comment on our proposed use of these variables to construct the proposed pediatric ESRD payment model.

D. A Combined Composite Rate and Separately Billable Payment Model for Pediatric Patients

Similar to the payment model for adult patients described in section X of this proposed rule, a payment model for pediatric patients can be constructed from cost/payment models of composite rate and separately billable services. A composite rate cost model can be estimated to generate a payment adjuster or multiplier for patients in a pediatric age group or groups. Because this kind of composite rate cost model is based on ESRD facility data, and there are very few pediatric patients, estimating additional pediatric co-morbidity multipliers is not feasible. However, a separately billable cost model can be estimated that would generate payment adjustments for particular patient characteristics. While the results from the composite rate and separately billable cost models can be combined into a single payment model following the same approach used in connection with the two equation adult payment methodology, the payment model for adult patients cannot be applied to pediatric patients without modification.

The results presented in Tables 31 and 32 can be used to develop a payment model for ESRD pediatric patients (age < 18). The method which we propose combines results from a facility-level model for CR services (Table 31) and a pediatric patient-level model for SB services (Table 32). The outcome is a single set of payment multipliers that can be used to determine the case-mix adjusted payment rate for individual pediatric patients.

The process of combining the CR and SB adjustments required decisions about the following issues:

1. How to apply the modeled SB multipliers, which are based on a separate payment model for pediatric patients, to the SB portion of the overall base rate, which applies to both adult and pediatric patients as described in section VII.

2. The relative weighting of CR and SB services for pediatric patients.

For each of the 8 pediatric classification categories in Table 32, the modeled SB multipliers are expressed relative to a reference category of pediatric patients (age < 13, PD, no co-morbidities). To obtain payment multipliers that can be applied to an overall base rate, the modeled SB multipliers need to be expressed relative to the estimated SB portion of the overall base rate for all patients. This can be accomplished by adjusting the modeled SB payment multipliers by the ratio of the actual SB MAP for the pediatric reference category ($12.28 per treatment for patients < age 13, PD, no co-morbidities) to the actual SB MAP among patients of all ages ($82.38 per treatment). These SB MAP values were computed from claims for CYs 2004 through 2006, the latest available in time for the preparation of this proposed rule. This results in an SB adjustment factor of $12.28/$82.38 or 0.1491. This adjustment was applied to each of the modeled SB multipliers in Table 33, and results in SB payment multipliers which range from 0.149 to 1.272 across the 8 pediatric classification groups. These payment multipliers can be applied to the SB portion of the overall base rate described in section VII. under the ESRD PPS.

The pediatric SB MAP for CYs 2004 through 2006 is $49.11. This SB MAP

reveals that most pediatric patients use substantially fewer SB services than adult patients, for which the comparable SB MAP is $82.45. Consequently, SB services account for a relatively smaller portion of total ESRD facility costs for pediatric patients. To develop overall payment adjustments that reflect the different mix of resources required to treat pediatric patients, the CR and SB multipliers were weighted according to the relative utilization of resources among pediatric patients. Based on the average SB MAP of $49.11 per treatment for pediatric patients and an overall average ESRD facility CR cost for CYs 2004 through 2006 of $169.67 per treatment, the resulting SB and CR weights were calculated as follows:

SB_{weight} = $49.11/ ($49.11 + $169.67) = 0.2245

CR_{weight} = $169.67/ ($49.11 + $169.67) = 0.7755

The multipliers from the CR and SB models can be used to calculate combined payment multipliers using the following formula:

$Mult_{PPS} = (Mult_{CR} * CR_{weight}) + (Mult_{SB} * SB_{AdjFactor} * SB_{weight})$

Using the SB adjustment factor of 0.1491, and the CR and SB weights of 0.7755 and 0.2245, respectively, that were calculated above, the formula becomes:

$Mult_{PPS} = (Mult_{CR} * 0.7755) + (Mult_{SB} * 0.1491 * 0.2245)$

By applying this formula to each of the 8 pediatric classification groups, we obtained the payment multipliers shown in the last column of Table 33.

TABLE 33—CALCULATING COMBINED PAYMENT MULTIPLIERS FOR PEDIATRIC PATIENTS BASED ON ADJUSTMENTS FOR AGE, MODALITY, AND CO-MORBIDITY

Cell	Patient characteristics			Modeled separately billable (SB) multiplier	Payment multipliers		
	Age	Modality	Comorbidities [1]		SB payment multiplier ($PmtMult^{SB}$)	CR payment multiplier ($PmtMult^{CR}$)	Expanded bundle payment multiplier ($PmtMult^{EB}$)
1	<13	PD	None	1.000	0.149	1.199	0.963
2	<13	PD	1 or more	1.485	0.221	1.199	0.980
3	<13	Hemo	None	3.861	0.576	1.199	1.059
4	<13	Hemo	1 or more	5.647	0.842	1.199	1.119
5	13–17	PD	None	1.508	0.225	1.199	0.980
6	13–17	PD	1 or more	2.244	0.335	1.199	1.005
7	13–17	Hemo	None	5.831	0.869	1.199	1.125
8	13–17	Hemo	1 or more	8.534	1.272	1.199	1.215

[1] The comorbidity adjustment is based on the presence of HIV/AIDS (2728 or claims since 2000), septicemia within 3 months, diabetes (2728 or claims since 2000), and cardiac arrest (2728 or claims since 2000).

These combined multipliers range from 0.963 to 1.215. These are the proposed pediatric patient-specific case-mix adjustment factors that would be applied to the base rate under the ESRD PPS. For comprehensive examples of how the proposed pediatric payment adjusters would be applied, see examples 6 and 7 in section XI. of this proposed rule.

Using CY 2007 claims data, we calculated combined payment multipliers for pediatric patients. The average pediatric patient-specific payment adjustment multiplier was 1.067, without any adjustment for budget neutrality. This compares with an average payment multiplier of 1.287 for adult patients based on CY 2007 claims. These average payment multipliers reflect both the case-mix and low volume adjustments.

The multipliers in Table 33 do not include the proposed adjustment for low-volume ESRD facilities described in section VIII.C.2. of this proposed rule. In CY 2007, approximately 24 percent of pediatric outpatient Medicare dialysis treatments were provided in facilities with less than 3,000 total treatments. This figure compares to 2.3 percent of Medicare dialysis treatments among adult patients. In addition, approximately 12.6 percent of Medicare treatments for pediatric patients were furnished in facilities with less than 3,000 treatments during each year from CY 2004 through 2006, and which neither opened nor closed during CY 2006. The comparable figure for adult patients was 0.6 percent. Therefore, pediatric patients would be much more likely to be eligible for the low-volume facility adjustment of 20.2 percent, which we have proposed, as described in section VIII.C.2. of this proposed rule.

X. Other Proposed Adjustments

A. Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management. The outlier payment policy would be designed to protect an ESRD facility from significant financial losses due to unusually high costs. Any outlier payment due would be added to the per-treatment, patient and facility-level adjusted ESRD PPS payment amount.

Generally, outlier payment mechanisms in Medicare prospective payment systems are based on a provider's cost for care compared to projected payments under the PPS. When a provider's cost exceeds a threshold amount (the projected payment plus a fixed dollar loss amount), Medicare pays a percentage of the difference (the loss sharing percentage) as an outlier payment. We propose that the ESRD outlier policy parallel the outlier policies adopted under other Medicare PPSs.

Specifically, as discussed in more detail below, we would compare an ESRD facility's predicted Medicare Allowable Payment (MAP) amount per treatment for outlier services to the facility's imputed MAP amount per treatment for outlier services to determine whether the ESRD facility would be eligible for additional payment under the proposed outlier policy. We propose to limit the outlier services to those items and services that currently are separately billable under Part B and renal dialysis service drugs proposed for inclusion under the ESRD PPS that currently are separately billable under Part D.

An ESRD facility would be eligible for an outlier payment when its imputed MAP amount per treatment for the outlier services exceeds the outlier

threshold, or the facility's predicted MAP amount per treatment for the outlier services plus the fixed dollar loss amount. We propose that the outlier payment would be equal to 80 percent of the amount by which the facility's imputed costs exceeds the outlier threshold.

The current basic case-mix adjusted composite payment system does not provide for outlier payments. However, in the 2008 Report to Congress entitled ''A Design for a Bundled End Stage Renal Disease Prospective Payment System'', we discussed outlier payments as a way of mitigating risk incurred by ESRD facilities in providing treatment to patients with characteristics associated with higher costs. The 2008 report described a hypothetical outlier policy that would target higher payments to facilities for patients who encountered higher than average monthly Medicare Allowable Payments (MAPs) for items and services that currently are separately billable under Part B. Specifically, the report proposed setting the hypothetical outlier payment amount at 80 percent of the difference between the separately billable MAP and a threshold amount. The report proposed that the threshold amount be based on the average separately billable MAP amount per treatment plus 2 or more standard deviations. ESRD facilities meeting this criterion were assumed to receive an outlier payment equal to a percentage of the difference between the separately billable MAP amount and the threshold amount.

To maintain budget neutrality, the 2008 report proposed that the portion of the base rate attributable to items and services that currently are separately billable under Part B be reduced by 2.5 percent to fund projected outlier payments. This percentage would have qualified approximately 5 percent of total patient months as outliers. A copy of the 2008 report is available at: *http://www.cms.hhs.gov/ESRDGeneralInformation/Downloads/ESRDReportToCongress.pdf*.

1. Eligibility for Outlier Payment

We are proposing that an ESRD facility would be eligible for an additional payment under the ESRD PPS where the facility's imputed, average per treatment costs for ESRD outlier services furnished to a beneficiary exceed the predicted per treatment MAP amount for outlier services plus the fixed dollar loss amount, as indicated in proposed § 413.237(b). We propose to base eligibility for outlier payments on ESRD outlier services, that is, only those items and services that are separately billable under Medicare Part B with regard to the current basic case-mix adjusted composite payment system and renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Medicare Part D, rather than all items and services comprising the bundled payment under the proposed ESRD PPS.

The comprehensive listing of our outlier policy definitions are set forth in § 413.237 of this proposed rule.

a. ESRD Outlier Services

Section 1881(b)(14)(D)(ii) of the Act provides that the ESRD PPS shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management.

We believe that any unusual variation in the cost of the renal dialysis services comprising the base rate under the proposed ESRD PPS is likely to be due to variation in the items and services that currently are separately billable under Part B and those renal dialysis service drugs currently covered under Part D. Therefore, including these items and services that are either currently separately billable under Part B or covered under Part D under the proposed ESRD PPS creates new financial risk for ESRD facilities. In addition, significant variations in these services may impair access to appropriate care, as an ESRD facility may have a disincentive to provide adequate treatment to those ESRD patients likely to have significantly higher than average costs. We believe these concerns could be addressed by an outlier policy.

As set forth in proposed § 413.237(a), we are proposing to base eligibility for outlier payments under the ESRD PPS on a comparison of the predicted MAP amounts and imputed MAP amounts for (1) items and services that currently are separately billable under Medicare Part B, including ESRD-related drugs, ESRD-related laboratory tests, and ESRD-related services; and (2) renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Medicare Part D. From this point forward, we refer to these services as the ''ESRD outlier services.''

As described further in section XIV, of this proposed rule, we are considering the extent to which the 50 percent rule that pertains to the Automated Multi-Channel Chemistry (AMCC) separately billable laboratory tests under the basic case mix adjusted composite payment system should continue to apply in the context of the proposed ESRD PPS.

Section 1881(b)(14) prohibits the unbundling of services, including laboratory services. Thus, under the proposed ESRD PPS, Medicare would not make separate payment for laboratory tests, rendering the 50 percent rule irrelevant for payment purposes. The 50 percent rule's relevance would be limited to its use in determining eligibility for outlier payment.

As described above, we are proposing to define outlier services as items and services that currently are separately billable under Medicare Part B, including ESRD-related drugs, ESRD-related laboratory tests, and ESRD-related services; and (2) renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Medicare Part D. Under this proposal, to ensure that the AMCC tests qualify as separately billable under the basic case mix adjusted composite payment system, and thus, qualify as outlier services, it would be necessary for ESRD facilities to continue applying the 50 percent rule under the proposed ESRD PPS. Conversely, excluding AAMC tests to which the 50 percent rule apply from the definition of outlier services would negate the need to apply the 50 percent rule under the proposed ESRD PPS.

We believe that the overall impact of excluding the AMCC tests to which the 50 percent rule applies from the definition of outlier services would be small. As shown in table 8, laboratory tests comprise 3.45 percent of the total MAP amount which is the basis of the ESRD PPS base rate. The subset of laboratory tests associated with the AMCC tests to which the 50 percent rule applies under the basic case mix adjusted composite payment system comprises an even smaller proportion of the overall base rate. As a result, we are considering excluding AAMC tests to which the 50 percent rule apply from the definition of outlier services, thus negating the need to apply the 50 percent rule under the proposed ESRD PPS. We request public comments on whether or not to include the the AMCC tests to which the 50 percent rule applies within the definition of outlier services and retain the 50 percent rule under the proposed ESRD PPS. We also invite comment on our proposal to limit the ESRD outlier services to items and services currently separately billable under Part B and those renal dialysis service drugs currently covered under Part D.

We note that if we also were to base eligibility for outlier payments on

variation in the cost of all items and services included in the ESRD PPS bundle, including those services included in the bundle under the current ESRD basic case-mix adjusted composite payment amount (hereinafter the ''composite rate items and services''), this may require an expansion in the data that we currently collect from ESRD facilities, which would increase ESRD facilities' reporting burden. Specifically, if we were to base eligibility for outlier payments on variation in the cost of all items and services included in the ESRD PPS bundle, we would need to compare a more comprehensive predicted MAP amount for a treatment to the ESRD facility's more comprehensive imputed MAP amount for the treatment. However, composite rate items and services, and the ESRD facilities' costs associated with providing these items and services, are not listed individually on the claims. As a result, it would not be possible to compare an imputed MAP amount for the more comprehensive definition of outlier services, that is, all items and services included in the ESRD PPS bundle, to the predicted MAP amount for these items and services.

To correct this deficiency, we could collect patient-level data reflecting the cost of the composite rate items and services. Under this approach, we believe that it would be necessary to revise the ESRD facility claim form. For example, ESRD facilities would need to report by line item all composite rate services and the associated charges of each of those services. However, we are not proposing revisions to the ESRD facility claim.

We believe that under a bundled payment system, in the future we may be able to simulate ESRD facility costs for outlier services using charges on the claims and applying the cost-to-charge ratios calculated using the cost reports. However, this data would only become available after the 2011 cost reports had been settled.

b. Predicted ESRD Outlier Services MAP Amounts

Predicted outlier services MAP amounts for a patient would be determined by multiplying the adjusted average outlier services MAP amount, described further below, by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers used in the regression analysis to compute the payment adjustments.

As described previously in section VIII. of this proposed rule, the predicted separately billable MAP amounts are based on the patient-level regression model for separately billable services. Thus, it is possible to predict patient-specific separately billable MAP amounts for these services by multiplying the average separately billable MAP amounts by the separately billable case-mix adjusters. However, although in this proposed rule we have included the cost of the Part D drugs in the base rate, the Part D drugs have not been incorporated into the separately billable services regression model that generates case-mix payment adjusters. Therefore, we are unable to predict payment for renal dialysis service drugs proposed for inclusion in the ESRD PPS that are currently covered under Medicare Part D. As a result, the predicted MAP amounts are understated. Nonetheless, within this proposed rule, our references to predicted outlier services MAP amounts assume the inclusion of these additional drugs to demonstrate the way in which the outlier policy would apply when these additional drugs are incorporated into the regression model for purposes of the final rule. For the final rule we intend to incorporate these drugs into the regression analysis to derive a comprehensive predicted MAP amount for all proposed ESRD outlier services, including (1) the items and services that currently are separately billable under Medicare Part B and (2) renal dialysis service drugs proposed for inclusion in the ESRD PPS that currently are covered under Medicare Part D.

Specifically, for the final rule, the separately billable case-mix adjusters could either be updated to reflect Part D drugs, assigning appropriate weights to the separately billable and Part D portions of the outlier services case-mix adjusters, or distinct payment multipliers for the Part D drugs could be developed.

Please refer to Table 34 below for the list of case-mix adjustment multipliers for outlier services for adult patients.

TABLE 34—PAYMENT MULTIPLIERS FOR AN EXPANDED BUNDLE OF SERVICES, AGES 18 AND OLDER, 2004–06

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment [3,4]
	Composite rate services [1]	Outlier services [2]	
	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for dialysis patient characteristics:			
Age:			
18–44	1.280	1.018	1.194
45–59	1.000	1.000	1.000
60–69	1.014	1.006	1.012
70–79	1.105	0.960	1.057
80+	1.150	0.923	1.076
Female	1.124	1.149	1.132
Body surface area (BSA, per 0.1 m^2; mean BSA = 1.87)	1.035	1.033	1.034
Underweight (BMI <18.5)	∧1.000	1.060	1.020
Time since onset of renal dialysis: < 4 months	1.508	1.401	1.473
Alcohol/drug dependence (claims since 2000 or 2728)	1.155	1.139	1.150
Cardiac arrest (claims since 2000 or 2728)	∧1.000	1.098	1.032
Pericarditis from same month to three months ago	∧1.000	1.595	1.195
HIV/AIDS (claims since 2000 or 2728)	1.363	1.220	1.316
Hepatitis B (claims since 2000)	1.115	1.035	1.089
Specified infection from same month to 3 months ago			
Septicemia	∧1.000	1.715	1.234
Bacterial pneumonia and other pneumonias/opportunistic infections	1.256	1.412	1.307
Gastro-intestinal tract bleeding from same month to 3 months ago	∧1.000	1.965	1.316
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.248	1.179	1.226

TABLE 34—PAYMENT MULTIPLIERS FOR AN EXPANDED BUNDLE OF SERVICES, AGES 18 AND OLDER, 2004–06—Continued

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment [3,4]
	Composite rate services [1]	Outlier services [2]	
	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.143	1.097	1.128
Myelodysplastic syndrome (claims since 2000)	∧1.000	1.257	1.084
Monoclonal gammopathy (claims since 2000)	∧1.000	1.063	1.021
Low volume facility adjustment			
Facility size < 3,000 treatments during each year from 2004–06	1.383	0.940	1.202

∧ A multiplier 1.000 was used for factors that lacked statistical significance in models of resource use or lacked stability over time in the estimated multipliers.

[1] The CR payment multipliers ($PmtMult_{CR}$) are based on a facility level log-linear regression model of the average composite rate cost/session for 2004–06 (n = 11,814 facility years). This model also included facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR < 65%) and the percent of pediatric patients as additional covariates (R-sq = 46.0%).

[2] Although we refer to outlier services, these multipliers are limited to the inclusion of items and services that currently are separately billable under Medicare Part B and do not reflect renal dialysis service drugs proposed for inclusion in the ESRD PPS that are currently covered under Medicare Part D. Based on a patient level log-linear regression model of separately billable Medicare Allowable Payments/session for 2004–06 (n = 890,776 patient years) that included included facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%) as additional covariates (R-sq = 8.7%).

[3] The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility level model of composite rate costs and $PmtMult_{SB}$ is the estimated multiplier from a patient level model of separately billable costs. Based on total estimated costs of $169.67 per session for composite rate services, $82.45 per session for separately billable services, and $252.12 per session for an expanded bundle ($169.67 + $82.45), the relative weights are $Weight_{CR}$ = 0.673 for composite rate services ($169.67/$252.12) and $Weight_{SB}$ = 0.327 for separately billable services ($82.45/$252.12).

[4] To determine the incremental payment for low volume facilities, the low volume facility payment multiplier was calculated relative to all other facilities combined. The estimated low volume coefficients from the regression models (which correspond to the CR and SB multipliers of 1.383 and 0.940, respectively, in the table above) were first divided by the weighted average of the other facility size coefficients in the models. A similar weighting procedure to that described above for the other payment multipliers was then used in calculating the resulting low volume adjustment of 1.202. The same payment adjustment is being used for both adult and pediatric patients in a low volume facility.

Please refer to Table 35 below for the list of case-mix adjustment multipliers for outlier services for pediatric patients.

TABLE 35—CALCULATING COMBINED PAYMENT MULTIPLIERS FOR PEDIATRIC PATIENTS BASED ON ADJUSTMENTS FOR AGE, MODALITY, AND COMORBIDITY

Cell	Patient characteristics			Modeled outlier services[2] multiplier	Payment multipliers		
	Age	Modality	Comorbidities[1]		Outlier Services[2] payment multiplier ($PmtMult_{SB}$)	CR payment multiplier ($PmtMult_{CR}$)	Expanded bundle payment multiplier ($PmtMult_{EB}$)
1	<13	PD	None	1.000	0.149	1.199	0.963
2	<13	PD	1 or more	1.485	0.221	1.199	0.980
3	<13	Hemo	None	3.861	0.576	1.199	1.059
4	<13	Hemo	1 or more	5.647	0.842	1.199	1.119
5	13–17	PD	None	1.508	0.225	1.199	0.980
6	13–17	PD	1 or more	2.244	0.335	1.199	1.005
7	13–17	Hemo	None	5.831	0.869	1.199	1.125
8	13–17	Hemo	1 or more	8.534	1.272	1.199	1.215

[1] The comorbidity adjustment is based on the presence of HIV/AIDS (2728 or claims since 2000), septicemia within 3 months, diabetes (2728 or claims since 2000), and cardiac arrest (2728 or claims since 2000).

[2] Although we refer to outlier services, these multipliers are limited to the inclusion of items and services that currently are separately billable under Medicare Part B and do not reflect renal dialysis service drugs proposed for inclusion in the ESRD PPS that are currently covered under Medicare Part D.

To generate the adjusted average outlier services MAP amount that is multiplied by the product of the patient-specific outlier services case-mix adjusters, we begin with the average outlier services MAP amount per treatment. The average outlier services MAP amount per treatment is based on payment amounts reported on 2007 claims and adjusted to reflect projected prices for 2011. As discussed above, payments for Part D drugs are not included. The average MAP amount per treatment for outlier services is then adjusted by the case-mix and wage adjustment standardization factor, a MIPPA reduction of .98, and the outlier policy of .99 resulting in the adjusted average outlier services MAP amount by which the product of the patient-

specific outlier services case-mix adjusters are multiplied.

The proposed adjusted average outlier services MAP amount is $64.54. As illustrated in the hypothetical examples in section X.A.3, the adjusted average outlier services MAP amount would be multiplied by the product of the patient-specific outlier services payment multipliers to yield the predicted outlier services MAP amount.

As described further in section X.A.1.d., the fixed dollar loss amount would be added to this amount.

TABLE 36—ADJUSTED AVERAGE OUTLIER SERVICES MAP AMOUNT

Average outlier services MAP amount per treatment [1]		$84.99
Adjustments		
Standardization for case mix and wage adjustments [2]		0.7827
MIPPA reduction		0.98
Outlier policy		0.99
Adjusted average outlier services MAP amount [3]		$64.54
	Patient age	
	<18	18 and older
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold [4]	$174.31	$134.96

[1] Excludes patients for whom not all case mix measures were available to calculate projected payments under an expanded bundle.
[2] Applied to the average outlier MAP per treatment.
[3] Because Part D drugs are not yet reflected in the outlier services payment multipliers, this number is understated. This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP for each patient.
[4] The fixed dollar loss amounts were calculated using 2007 data to yield total outlier payments that represent 1% of total projected payments for an expanded ESRD PPS. These amounts correspond to 1.963 times the standard deviation of the prediction error for ages <18 and 1.952 times the standard deviation of the prediction error for ages 18 and older.

c. Estimating the Imputed ESRD Outlier Services MAP Amounts

As discussed above, we propose to base eligibility for outlier payments on a comparison of an ESRD facility's predicted Medicare Allowable Payment (MAP) amount per treatment for the ESRD outlier services to the facility's imputed MAP amount per treatment for the ESRD outlier services. We discuss above our proposed methodology for determining the predicted outlier services MAP amounts for a patient. In estimating a provider's imputed costs, under some Medicare PPSs, such as the Hospital Inpatient Prospective Payment System, we estimate a provider's costs by applying a provider-specific cost-to-charge ratio to the covered charges for the treatment. The cost-to-charge ratio is based in part on the provider's cost report. Under other Medicare PPSs, we estimate a provider's costs using available data. For example, under the Prospective Payment System for Home Health Agencies we impute the cost for each episode by multiplying the national per-visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines (42 CFR § 484.240(d)). For the reasons discussed below, we are proposing to estimate an ESRD facility's imputed costs for the ESRD outlier services based on available data rather than a provider-specific cost-to-charge ratio.

Although ESRD facilities currently identify costs associated with certain ESRD outlier services such as EPO and vaccines, our analysis revealed that other ESRD-related drugs and biologicals appear to be under-reported or not reported. For this reason, we do not believe that a cost-to-charge ratio that would be based on such reported information would accurately reflect an ESRD facility's cost for drugs. We therefore are proposing to estimate a provider's costs based on available data, rather than applying a cost-to-charge ratio to facility charges to impute their cost.

As described in greater detail below, the imputed separately billable MAP amounts would be based on pricing mechanisms currently in place for these services. Whereas, in the case of Part D drugs proposed for inclusion in the ESRD PPS, we have not proposed a preferred pricing mechanism for the imputed MAP amounts but rather, solicit comments on several approaches for imputing these drug prices.

i. Data Used to Estimate Imputed ESRD Outlier Services MAP Amounts

With respect to estimating the imputed MAP amounts of ESRD outlier services that are separately billable under Part B, we propose to use Average Sales Prices (ASP) data for the Part B ESRD-related drugs (which is updated quarterly) and annual laboratory fee schedules for the previously separately billable laboratory tests. We propose to use various pricing mechanisms for the other separately billable ESRD-related services. Specifically, for medical/surgical supplies used to administer separately billable drugs, we propose to estimate MAP amounts based on the predetermined fees that apply to these items under the current base case-mix adjusted composite payment system. For example, we pay $0.50 for each syringe identified on an ESRD facility's claims form. For other medical/surgical supplies such as IV sets and gloves, the claims processing manual currently allows Medicare contractors to elect among various options to price these supplies, such as the Drug Topics Red Book, Med-Span, or First Data Bank (CMS Pub 100–04, Chapter 8, Section 60.2.1). We propose that the FI/MAC would continue to use the pricing mechanisms that are currently in place for items and services that currently are separately billable under Part B to estimate costs for these other medical/surgical supplies.

Finally, payment for blood, supplies used to administer blood, and blood processing fees furnished by hospital-based ESRD facilities under the current basic case-mix adjusted composite payment system is based on a reasonable cost basis. Payment for blood, supplies used to administer the blood, and blood processing fees, on behalf of patients in independent ESRD facilities currently is made at the lower of the actual charge on the bill or a reasonable charge that the MAC/FI determines. We are proposing to estimate hospital-based and independent ESRD facilities' costs for blood, supplies used to administer blood, and blood processing fees using the pricing mechanisms that are currently in place for items and services that currently are separately billable

under Part B. We are not in this proposed rule, specifying the mechanism by which we propose to estimate the imputed MAP amounts for drugs formerly covered under Medicare Part D but that would become renal dialysis service drugs when the ESRD PPS would be implemented in 2011. Rather, we request public comment on the following potential approaches for estimating the imputed MAP amounts of these drugs and on alternative approaches.

Approach 1:

First, although we believe ASP pricing data for renal dialysis service drugs currently covered under Part D would facilitate the computation of the estimated costs of these drugs, we do not collect ASP pricing information under section 1927 of the Act for these drugs. We request public comment on whether manufacturers would be willing to submit ASP pricing data for renal dialysis service drugs currently covered under Part D on a voluntary basis.

Approach 2:

An alternate approach for estimating the imputed MAP amounts of renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D would be to use data retrieved from the online Medicare Prescription Drug Plan Finder. (This online tool, available at medicare.gov provides the prices that are charged by each Part D plan's network pharmacy.) For example, the Part D drug prices for each drug designated as a Part B renal dialysis service could be estimated based on a national average price charged by all Part D plans and their network pharmacies. We believe that establishing a single national average price for each drug designated as a Part B renal dialysis service would be consistent with the approach for Part B drugs in which we use national ASP pricing.

These national average prices could be updated on an ongoing basis using data on the Medicare Prescription Drug Plan Finder. Similar to the way in which we update Part B ASP pricing, national average Medicare Prescription Drug Plan Finder prices could be updated on a quarterly basis. The prices reflected in the Medicare Prescription Drug Plan Finder are reflective of the prices that are negotiated by larger buying groups. As a result, our primary concern with this pricing approach is that such prices may fail to reflect the drug prices that smaller facilities may pay in acquiring these drugs and could therefore disadvantage these facilities.

Approach 3:

An alternative approach for estimating the imputed MAP amounts of renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D would be to use Wholesale Acquisition Cost (WAC). Because WAC is the manufacturer's list price to wholesalers, we believe that it is more reflective of the price paid by the end user than the Average Wholesale Price. In addition, as set forth in CMS Pub 100–04, Chapter 17, Section 20.1.3, payment allowance limits for drugs and biological that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. As a result, we believe that this pricing mechanism would be consistent with pricing that currently occurs for drugs that are separately billable under Part B.

Approach 4:

Another alternative option for estimating the imputed MAP amounts of the renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle but currently covered under Part D would be to use the national average prescription drug event (PDE) data that is submitted for each Part D claim. To correct for the lag time for receipt of complete PDE data by CMS, we would update the most recent PDE data by the CPI update for drugs.

Approach 5:

A final approach for estimating the imputed MAP amounts for renal dialysis service drugs currently covered under Part D would be to require ESRD facilities to list on their claims forms their costs for the renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D. The facility cost that would be reported on the claim would need to be the amount after accounting for manufacturer rebates, discounts, and other price concessions. Under this approach, payment would be based on an ESRD facility's cost as identified on the claim. As indicated previously, while it may be possible to use cost-to-charge ratios on the cost report to simulate cost in the future, that information would not be available when the ESRD PPS would begin in 2011.

We believe that most, if not all, of the renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D have clinical treatment indications beyond ESRD, such as for the treatment of bone disease in advanced chronic kidney disease patients. These drugs therefore will continue to be covered under Part D for these other indications. Consequently, Part D pricing information would continue to be available for these drugs and could be used in the computation of outlier eligibility and payment under the approaches #2, and #4 discussed above.

We request public comment on the potential approaches set forth above for estimating the imputed MAP amounts of renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Part D. We are also interested in any other potential data sources for estimating the imputed MAP amount of those ESRD-related drugs currently paid under Part D.

ii. Determining Imputed Per Treatment ESRD Outlier Services MAP Amount

ESRD facilities currently submit claims on a monthly basis that identify line item dates of service. For purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the patient. Specifically, we are proposing that the ESRD facility would identify by line item on the monthly claim, all ESRD outlier services furnished to the patient. We would then estimate the imputed MAP amount for these services applying one of the proposed methodologies discussed above in section X.A.1.

c. i. The imputed outlier services MAP amounts for each of these services would be aggregated and then divided by the corresponding number of treatments identified on the claim to yield the imputed outlier services MAP amount per treatment. An ESRD facility would be eligible for an outlier payment if the imputed average outlier services MAP amount per treatment exceeds the sum of the predicted, outlier services MAP amount per treatment and the fixed dollar loss amount, as described below.

d. Outlier Percentage and Fixed Dollar Loss Amounts

As discussed in section VII.D.a, we are proposing that payments under section 1881(b)(14)(D)(ii) of the Act for outlier cases be applied in a budget

neutral manner. Therefore, to ensure that the proposed outlier policy under the ESRD PPS is budget neutral, we propose to reduce the base rate by the proposed outlier percentage, or the percentage of total ESRD PPS payments that are intended for payment of outlier cases, as defined in proposed § 413.220(b)(4).

Using an outlier loss sharing percentage of 80 percent (which is discussed in the following section), we considered various percentages from 1 percent to 3 percent of aggregate payments and the fixed dollar loss amount that is computed from these two factors. (As discussed below, we are proposing separate fixed dollar loss amounts for the pediatric and adult populations.) The appropriate outlier amount was determined by comparing the predicted outlier services MAP amount (which, for the reasons explained previously was limited to items and services that were separately billable under Medicare Part B), for the treatment plus the fixed dollar loss amount to the imputed per treatment ESRD outlier services MAP amount. For example, using an outlier percentage of 1 percent, if the total outlier payment amount for all providers was determined to be higher or lower than 1 percent of the total payments under the proposed ESRD PPS, then the fixed dollar loss amount was adjusted accordingly. This was done in an iterative fashion until the fixed dollar amount produced total outlier payment amounts for all ESRD facilities equal to 1 percent of total payments. We applied a similar process to identify the fixed dollar loss amount associated with other outlier percentages.

We analyzed outlier percentages from 1 to 3 percent of total ESRD PPS payments and the corresponding fixed dollar loss amounts and percentage of patient months qualifying for outlier payments, which are presented in Table 37.

TABLE 37—IMPACT OF OUTLIER PERCENTAGE ON PATIENT MONTHS QUALIFYING FOR OUTLIER PAYMENT

	1%	1.5%	2%	2.5%	3%
Age 18 and Older: Patient months qualifying for outlier payment	5.3%	7.3%	9.3%	11.5%	13.8%
Age < 18: Patient months qualifying for outlier payment	2.6%	3.8%	5.7%	7.6%	10.7%
Age 18 and Older: fixed dollar loss amount	$134.96	$109.24	$89.88	$74.32	$61.67
Age < 18: Fixed dollar loss amount	$174.31	$124.32	$90.04	$65.62	$47.70

Based on consideration of the various outlier percentages, we are proposing that the outlier percentage would be 1 percent of total ESRD PPS payments. We believe an outlier percentage of 1 percent strikes an appropriate balance between our objectives of paying an adequate amount for the most costly patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. In addition, this outlier percentage is consistent with other Medicare PPSs, such as the 1 percent policy paid under the Outpatient PPS.

The fixed dollar loss amounts that would be added to the predicted, outlier services MAP amounts would differ for adult and pediatric patients due to differences in the usage of separately billable services among adult and pediatric patients, especially drugs. As a result, we are proposing separate fixed dollar loss amounts, defined in proposed § 413.237(a)(4–5) of $134.96 for adult patients and $174.31 for pediatric patients.

2. Outlier Payments

The loss sharing percentage is the percentage of costs exceeding the fixed dollar loss amount that is paid by Medicare. We considered various loss sharing percentages for the proposed ESRD PPS outlier policy. We are proposing an 80 percent loss sharing percentage because this percentage is consistent with certain other Medicare payment systems, including the Inpatient Rehabilitation Facility and Home Health PPSs, and, more importantly, is consistent with the amount Medicare pays, in general, for Part B services.

In addition, while for the reasons stated above we believe it is important to ensure that we pay ESRD facilities an outlier payment that is an adequate amount for treatments involving high costs, at the same time we want to preserve the efficiency incentives inherent under a prospective payment system. We believe an 80 percent loss sharing percentage strikes a reasonable balance between these policy objectives. In particular, we note that to the extent the cost to ESRD facilities of the inputs required to deliver additional services beyond the outlier threshold (the sum of the predicted outlier services MAP amount plus the fixed dollar loss amount) is greater than the 80 percent loss sharing ratio, there would be less incentive to increase utilization of outlier services inappropriately to receive outlier payments.

We propose to implement an annual monitoring process that would identify patterns of increased utilization of outlier services and any associated outlier payments across ESRD facilities. For example, we would be most interested in identifying ESRD facilities that receive significant outlier payments. We believe that this monitoring effort would prevent potential abuse and provide us with an outlet for addressing abuse.

For treatments eligible for outlier payments, we are proposing that the per treatment outlier payment equal 80 percent (the loss sharing percentage) of the imputed average ESRD outlier service MAP amounts in excess of the sum of the predicted, outlier services MAP amount per treatment and the fixed dollar loss amount, as specified in proposed § 413.237(c). For treatments eligible for the outlier payment, the outlier payment would be added to each ESRD PPS per treatment payment amount.

3. Hypothetical Outlier Payment Examples

Please refer to the hypothetical outlier examples for both adult and pediatric patients set forth below for an illustration of (1) the way in which predicted and imputed ESRD outlier services MAP amounts are calculated and compared in determining eligibility for outlier payment, and (2) the way in which outlier payments would be calculated.

Hypothetical Example—Adult Patient:

Martha, a 66 year old female who is 167.64 cm. tall, weighs 105 kg. and has three co-morbid conditions; HIV/AIDS, septicemia and hereditary hemolytic or sickle cell anemia. As described in hypothetical example number 4 within section XI. of this proposed rule, a patient of this weight and height is not below the threshold for underweight status and thus would not qualify for a low BMI adjustment.

The formula for calculation of a patient's BSA is:

$$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$$

Martha's BSA is calculated as:

BSA_{Martha} = 0.00718 * $167.64^{.725}$ * $105^{.425}$
= 0.007184 * 40.9896 * 7.2278
= 2.1284

As identified in table 29, the separately billable multiplier for BSA would be 1.033. Martha's case-mix adjustment based on her BSA of 2.1284 would be:

= $1.033^{(2.1284-1.87/0.1)}$ = 1.088
= $1.033^{2.584}$
= 1.088

Step 1: Determine the predicted, ESRD outlier services MAP amount.

The product of the patient-level outlier services case-mix adjusters as identified in table 34:= 66 year old: 1.006, female: 1.149, BSA: 1.088, HIV/AIDS: 1.220, septicemia: 1.715, and hereditary hemolytic or sickle cell anemias: 1.179

= 1.006 * 1.149 * 1.088 * 1.220 * 1.715 * 1.179
= 3.10231

The adjusted, average, ESRD outlier services MAP amount

= $64.54

The adjusted, average ESRD outlier services MAP amount * product of the outlier services case-mix adjusters:

=$64.54 * 3.10231
= $200.22

Step 2: Determine the imputed average, per treatment, ESRD outlier services MAP amount.

The imputed monthly ESRD outlier services amount = $4000
The corresponding total number of treatments = 10
The imputed, average, per treatment, outlier services MAP amount =
= $4000/10
= $400

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount.

The fixed dollar loss amount = $134.96
The predicted, ESRD outlier services MAP amount = $200.22
= $200.22 + $134.96
= $335.18

Step 4: Calculate outlier payment.

Outlier payment = imputed average, per treatment, outlier services MAP amount—(predicted, ESRD outlier services MAP amount plus the fixed dollar loss amount) * loss sharing percentage:

= ($400 − $335.18) * .80
= $64.82 * .80
= $51.22

Hypothetical Example—Pediatric Patient:

John, a 13 year old hemodialysis pediatric patient with 1 or more co-morbidities.

Step 1: Determine the predicted, ESRD outlier services MAP amount.

As identified in table 35, the patient-level ESRD outlier services case-mix adjuster:

=13 year old hemodialysis patient with 1 or more co-morbidities
= 1.272
The adjusted, average, ESRD outlier services MAP amount = $64.54

The adjusted, average, ESRD outlier services MAP amount * the product of the outlier services case-mix adjusters:

= $64.54 * 1.272
= $80.09

Step 2: Determine the imputed, average, per treatment, ESRD outlier services MAP amount.

The imputed monthly ESRD outlier services amount = $4000
The corresponding total number of treatments = 10
The imputed, average, per treatment, outlier services MAP amount =
= $4000/10
= $400

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount.

The fixed dollar loss amount = $174.31
The predicted, ESRD outlier services MAP amount = $80.09
= $80.09 + $174.31
= $254.40

Step 4: Calculate outlier payment.

Outlier payment = imputed, average, per treatment, outlier services MAP amount − (predicted, ESRD outlier services MAP amount plus the fixed dollar loss amount) * loss sharing percentage:

= ($400 − $254.40) * .80
= $145.60 * .80
= $116.48

The outlier payment amount would be added to the ESRD PPS payment amount, per treatment. For a detailed description of calculating the ESRD PPS payment amount per treatment, please refer to the hypothetical examples in section XI. of this proposed rule.

4. Application of Outlier Policy During the Transition and in Relation to the ESA Monitoring Policy

As discussed in section XIII. A. of this proposed rule, section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide a four-year transition from the current basic case-mix adjusted composite payment system to the ESRD PPS for renal dialysis services furnished beginning January 1, 2011. Under the transition, ESRD facilities would receive a blended rate based in part on the payment rates under the current basic case-mix adjusted composite rate payment system and in part on the payment rates under the ESRD PPS. Section 1881(b)(14)(E)(ii) of the Act permits ESRD facilities to make a one-time election to be excluded from the transition from the current case-mix adjusted composite payment system to the ESRD PPS. Those ESRD providers and facilities that elect to be excluded from the transition would receive payments for renal dialysis services provided on or after January 1, 2011 based on 100 percent of the payment rate under the ESRD PPS, rather than a blended rate.

As indicated above, the current ESRD basic case-mix adjusted composite payment system does not provide for outlier payments. Rather, the proposed outlier payment policy would be limited to the proposed ESRD PPS. We therefore propose that for those ESRD facilities that do not elect to be excluded from the 4-year transition, outlier payments would be limited to the portion of the blended rate based on the payment rates under the proposed ESRD PPS.

Nothing within this proposed outlier payment policy would replace the claims monitoring implications related to the utilization of separately billable erythropoiesis-stimulating agents (ESAs) including currently available epoetin alfa (EPOGEN®, or EPO), darbepoetin alfa (ARANESP®) or any ESAs that may be developed in the future and used by beneficiaries receiving renal dialysis services. As we discuss in section XIV.B of this proposed rule, we are evaluating the extent to which we could continue to apply the ESA Monitoring Policy under the proposed ESRD PPS. We are also considering ways in which outlier payments would be computed under the proposed ESRD PPS. We believe that any dosing reductions associated with the application of the ESA Monitoring Policy would be factored in prior to determining eligibility for outlier payment.

We expect that ESRD facilities would exercise prudent clinical judgment in prescribing ESAs for patients who are resistant to these drugs, so as not to over-prescribe with the intent of capitalizing on outlier payments. However, we request public comments that would outline additional safeguards to protect against overuse of ESAs among the ESA-resistant patient population.

XI. Comprehensive Payment Model Examples

In section VIII., we demonstrated how the case-mix adjustments based on separate estimating equations for CR and SB services (that is, the two equation model), were combined to obtain a single payment formula under

the proposed ESRD PPS. Table 29 in that section contained the proposed case-mix adjustments applicable to adult patients. In section IX, we presented our proposed pediatric payment model under the ESRD PPS. Table 33 in that section contained the pediatric classification categories and corresponding case-mix adjusters which we propose to apply to pediatric ESRD patients. In this section, we explain how the area wage index and the case-mix adjustments would be applied to the proposed base rate described in section VII. reflecting combined CR and SB services, resulting in a patient-specific per treatment payment amount under the proposed ESRD PPS, as set forth in proposed § 413.215. We demonstrate how the proposed case-mix adjustments presented in Tables 29 and 33 would be applied for 7 hypothetical ESRD patients to obtain the per treatment payment amounts under the ESRD PPS. The product of the applicable case-mix adjustment factors is the patient multiplier or PM. The ESRD PPS case-mix adjusters are shown in Table 29 for adult patients and Table 33 for pediatric patients. Each example uses the base rate of $198.64, covering Part B renal dialysis services and self-care home dialysis services as set forth under section 1881(b)(4) of the Act. Each example also assumes an ESRD wage index value of 1.1000. Therefore, our starting point in each example prior to determining the patient-specific PM is a wage index adjusted base rate of $206.22. This amount was computed as follows:

Base rate $198.64

Labor-related share of base rate

($198.64 * .38160 = $75.80) 75.80

Wage index adjusted labor-related share

($75.80 * 1.1000) = $83.38 83.38

Non labor-related share of base rate

($198.64 * (1 − 0.38160) = $122.84 122.84

Wage index adjusted base rate

($83.38 + $122.84) = $206.22 $206.22

(The labor-related and non labor-related shares of the base rate (that is, 38.160 percent and 1–0.38160 or 61.840 percent, respectively, represent the labor-related and non labor-related components of the bundled ESRD PPS market basket, described in section XII. of this proposed rule.)

Example 1—Relatively Healthy ESRD Patient With no Co-morbidities; no Outlier Payments Apply

John, a 45 year old male Medicare beneficiary, is 187.96 cm. (1.8796 m.) in height and weighs 95 kg. John was diagnosed with ESRD in early 2009 and has been on HD since August 2009. He has chronic glomerulonephritis and hypertension, and has an AV fistula. The patient also has secondary hyperparathyroidism.

Table 29 reveals that none of John's co-morbidities is among those for which a case-mix adjustment applies. The only pertinent factors to adjust the base rate amount are age, height, and weight. Using the formula for BMI, we see that John is not underweight, having a BMI of 26.89 kg/m^2, which is greater than the threshold value of 18.5, the cut-off for underweight status:

$BMI = weight_{kg}/height\ (m^2)$
$= 95/1.8796^2$
$= 95/3.5329$
$= 26.89$

Therefore, there is no case-mix adjustment for low BMI. The formula for calculation of a patient's BSA is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$

John's BSA is calculated as:

$BSA_{John} = 0.007184 * 187.96^{.725} * 95^{.425}$
$= 0.007184 * 44.5346 * 6.9268$
$= 2.2161$

Using the Table 29 multiplier of 1.034, John's case-mix adjustment based on his BSA of 2.2161 is computed as follows:

$PmtMult_{BSA} = 1.034^{(2.2161-187)/0.1}$
$= 1.034^{3.461}$
$= 1.1227$

John's PM would reflect the applicable case-mix adjustments from Table 29 for both age and BSA and may be expressed as:

$PM = PmtMult_{age} * PmtMult_{BSA}$
$= 1.000 * 1.1227$
$= 1.1227$

The ESRD PPS payment rate per treatment would be:

$206.22 * 1.1227 = $231.52

Example 2—Same as Example 1, Except Dialysis Began November 15, 2010

John's PM would have to include the adjustment for the onset of dialysis because the treatments for which we are calculating the payment amount occur within 4 months of November 15, 2010. This particular adjustment would continue to apply for treatments furnished between January 1, 2011 and March 15, 2011. The applicable case-mix adjustments would be for a patient new to dialysis, age, and BSA, and may be expressed as:

$PM = PmtMult_{DialOnset} * PmtMult_{age} * PmtMult_{BSA}$
$= 1.473 * 1.000 * 1.1227$
$= 1.6537$

The ESRD PPS payment rate per treatment would be:

$206.22 * 1.6537 = $341.03

Example 3—Same as Example 1, with outlier payments. (For a description of the outlier payment methodology, see section X.)

John normally receives HD 3 times weekly. However, in January 2011 he suffered a compound ankle fracture and was hospitalized for 5 days. During the hospitalization John did not undergo any dialysis treatments. After John was discharged and he resumed receiving outpatient dialysis, it was noted that John's dialysis clinical indicators were depressed, requiring additional laboratory testing and above average doses of several injectable drugs, particularly EPO®, to bring them to normal levels. During January, John, who received HD at his usual facility, received only 9 treatments. The facility submitted a bill for allowable total SB drugs and biologicals, laboratory tests, and supplies for January totaling $3000.00.

John's dialysis facility would receive $231.52 for each of the 9 treatments it furnished. The SB MAP per treatment averaged $3000.00/9 or $333.33 per session. We first determine if John's dialysis facility would be entitled to outlier payments:

Using Table 29 we compute the predicted SB MAP per treatment based on SB case-mix adjustments for BSA and age.

BSA $PmtMult_{SB} = 1.033^{(2.2161–1.87)/0.1}$
$= 1.033^{3.461}$
$= 1.1189$
Age $PmtMult_{SB} = 1.000$
$PM_{SB} = 1.1189 * 1.000 = 1.1189$
SB MAP per treatment (see section X.A.1.b) $64.54

The case-mix adjusted predicted SB MAP is:

$64.54 * 1.1189 = $72.21

The fixed dollar loss amount for the predicted SB MAP, reflecting the case-mix adjustments for BSA and age, becomes:

$72.21 + $134.96 = $207.17

Because John's average SB MAP for services furnished was $333.33, which exceeds the case-mix adjusted fixed dollar loss amount of $207.17, John's ESRD facility is eligible for outlier payments beyond the otherwise applicable $231.52 ESRD PPS amount. The outlier payments are computed as follows:

Amount in excess of fixed dollar loss amount

($333.33—$207.17) = $126.16

Loss sharing ratio 80%

Outlier payments per treatment

($126.16 * .80) = $100.93 $100.93

Outlier payments
($100.93 * 9 treatments) = $908.37

The total ESRD payments to this facility on behalf of John for January would be:

Regular ESRD payments
$231.52 * 9 = $2083.68
Outlier payments 908.37
Total payments $2992.05

Example 4—ESRD Patient With Multiple Co-morbidities

Mary, a 66 year old female, is 167.64 cm. in height and weighs 105 kg. She has diabetes mellitus, a history of chronic Hepatitis B, parathyroidism, and liver cirrhosis. She was diagnosed with ESRD in 2005, esophageal varices in 2006, and had a diagnosis of upper gastrointestinal (GI) bleeding in January 2011. Mary receives HD at an ESRD facility which qualifies for the low volume adjustment. We will not repeat the calculation for BMI in this example. Suffice it to say that this patient does not have a BMI less than 18.5 kg/m^2, the required threshold for underweight status. Table 29 reveals that the PM in this example must be calculated to reflect the case-mix adjustments for gender, BSA, Hepatitis B, and upper GI bleeding, as well as a facility low volume adjustment. The formula for calculation of a patient's BSA is:

$$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$$

Mary's BSA is calculated as:

$$BSA_{Mary} = 0.00718 * 167.64^{.725} * 105^{.425}$$
$$= 0.007184 * 40.9896 * 7.2278$$
$$= 2.1284$$

Based on the Table 29 multiplier of 1.034, Mary's case-mix adjustment based on her BSA of 2.1284 would be:

$$PmtMult_{BSA} = 1.034^{(2.1284-1.87)/0.1}$$
$$= 1.034^{2.584}$$
$$= 1.0902$$

Mary's PM, including application of the low volume payment adjuster, may be expressed as:

$$PM = PmtMult_{gender} * PmtMult_{BSA} * PmtMult_{HepB} * PmtMult_{GIBleed} * PmtMult_{LV}$$
$$= 1.132 * 1.0902 * 1.089 * 1.316 * 1.202$$
$$= 2.1259$$

The ESRD PPS payment rate per treatment applicable to Mary would be:

$206.22 * 2.1259 = $438.40

Example 5—Aged ESRD Patient With Low BMI (< 18.5kg/m^2) and History of Hospitalization

Agnes, an 82 year old female, is 160.02 cm. (1.6002 m.) in height and weighs 45.36 kg. She has longstanding type II diabetes mellitus and was diagnosed with ESRD in 2004. The patient has coronary artery disease and peripheral vascular disease. In January 2008 Agnes began dialyzing with an upper arm AV fistula, which had been created in 2006. In March 2009, after an unsuccessful attempt to declot the AV fistula during hospitalization, Agnes experienced additional bleeding complications, and has been dialyzed using a catheter ever since. In December 2010, the patient was admitted to the hospital after suffering an observed cardiac arrest during outpatient dialysis. She was diagnosed with myocardial infarction, and underwent coronary artery angioplasty and coronary artery stent placement during that hospitalization. Agnes was again admitted to the hospital on January 3, 2011 for congestive heart failure, and discharged January 11. She resumed outpatient dialysis on January 13, 2011.

We must first use Agnes' height and weight to determine if a case-mix adjustment for low BMI applies, and the magnitude of the case-mix adjustment for BSA. The patient's BMI is computed as follows:

$$BMI = weight_{kg}/height(m^2)$$
$$= 45.36/1.6002^2$$
$$= 45.36/2.5606$$
$$= 17.71$$

Agnes' BMI is less than 18.5. Therefore, her PM will include a 2.0 percent case-mix adjustment for underweight status.

The formula for calculation of a patient's BSA is:

$$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$$

Agnes' BSA is computed as:

$$BSA_{Agnes} = 0.007184 * 160.02^{.725} * 45.36^{.425}$$
$$= 0.007184 * 39.6302 * 5.0592$$
$$= 1.4404$$

Using the Table 29 multiplier of 1.034, Agnes' case-mix adjustment based on her BSA of 1.4404 is calculated as follows:

$$PmtMult_{BSA} = 1.034^{(1.4404-1.87)/0.1}$$
$$=1.034^{(-4.296)}$$
$$= .8662$$

Agnes's PM would reflect the applicable case-mix adjustments from Table 29 for age, gender, BSA, low BMI, and cardiac arrest. It may be expressed as:

$$M = PmtMult_{age} * PmtMult_{gender} * PmtMult_{BSA} * PmtMult_{BMI} * PmtMult_{CardArrest}$$
$$= 1.076 * 1.132 * .8662 * 1.020 * 1.032$$
$$= 1.1106$$

The ESRD PPS payment rate per treatment for Agnes would be:

$206.22 * 1.1106 = $229.03

Example 6—Pediatric ESRD Patient With 2 Co-morbidities; no Outlier Payments Apply

Jonathan, a 24-month old male, began dialysis 8 months ago due to autosomal recessive polycystic kidney disease. Jonathan inherited HIV/AIDS from his mother, who has a history of drug abuse. Jonathan also has diabetes. The patient undergoes PD, with the assistance of a cycler.

Table 33 reveals that Jonathan has two qualifying co-morbidities, diabetes and HIV/AIDS. Because Jonathan is less than 13 years old, and undergoes PD, his pediatric classification group is category 2, for which the PM is 0.980. Jonathan's ESRD PPS payment rate per treatment would be:

$206.22 * 0.980 = $202.10

For as long as Jonathan is on PD, his treating dialysis facility would receive 3 times $202.10 or $606.30 weekly.

Example 7—Pediatric ESRD Patient With 1 Co-morbidity; Outlier Payments Apply. (For a Description of the Outlier Payment Methodology, See Section X.)

Timmy is a 16 year old male with ESRD due to renal hypoplasia. The patient was on PD until 2005, when he received a deceased donor kidney transplant. Timmy's transplant failed in August 2007, and he has been on HD since that time. The patient receives dialysis through an AV fistula. Timmy has a history of post-transplant lymphoma, which is in remission. He also has diabetes mellitus, which developed after the kidney transplantation. Timmy weighs 66.2 kg. and is 161.6 cm in height. He was hospitalized one month ago with Klebsiella bacteremia. As part of his HD, Timmy receives Aranesp® 60 mcg. IV q 2 weeks, paracalcitol 4 mcg. IV 3 times a week, and iron dextran 100 mg. IV every 2 weeks. The patient also takes 2 tablets (667 mg. each) of calcium acetate 3 times per day. Timmy had 12 HD treatments in January 2011. The facility submitted a bill for allowable SB drugs and biologicals, laboratory tests, and supplies totaling $3250.00.

Table 33 reveals that Timmy has 1 qualifying co-morbidity, diabetes. Because Timmy is 16 and undergoes HD, his pediatric classification group is category 8, for which the PM is 1.215. Timmy's payment rate per treatment, without regard to outlier payments, would be:

$206.22 * 1.215 = $250.56

Timmy's dialysis facility would receive $250.56 for each of the 12 treatments it furnished in January. Based on the total allowable billed SB services of $3250, the SB MAP per

treatment averaged $3250/12 or $270.83 per session. We must determine if Timmy's dialysis facility would be eligible for outlier payments.

Using Table 33, we must calculate the case-mix adjusted predicted SB MAP. (See section X.A.1.b)

SB MAP * PmtMult = $64.54 * 1.272 = $82.09

The fixed dollar loss amount for the predicted SB MAP is:
$82.09 + $174.31 = $256.40

Because Timmy's average SB MAP for services furnished was $270.83, which exceeds the case-mix adjusted fixed dollar loss amount of $256.40, Timmy's ESRD facility is eligible for outlier payments beyond the otherwise applicable $250.56 ESRD PPS amount. The outlier payments are computed as follows:

Amount in excess of fixed dollar loss amount

($270.83—$256.40) = $14.43
Loss sharing ratio 80%

Outlier payments per treatment

($14.43 * .80) = $11.54 $11.54

Outlier payments

($11.54 * 12) = $138.48 $138.48

The total ESRD payments to this facility on behalf of Timmy for January would be:

Regular ESRD payments

($250.56 * 12) = $3006.72 $3006.72

Outlier payments 138.48
Total payments $3145.20

XII. ESRD Bundled Market Basket

Under section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA, beginning in 2012, the ESRD bundled payment amounts are required to be annually increased by an ESRD market basket increase factor minus 1.0 percentage point. The statute further provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services. As noted in section VII.B of this proposed rule, under section 1881(b)(14)(F)(ii) of the Act, the ESRD bundled rate market basket will also be used to update the composite rate portion of ESRD payments during the PPS phase-in period from 2011 through 2013.

As required under section 1881(b)(14) of the Act, effective for CY 2012, CMS has developed an all inclusive ESRD bundled rate (ESRDB) input price index. Although ''market basket'' technically describes the mix of goods and services used to produce ESRD care, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from that market basket. Accordingly, the term ''ESRDB market basket'' as used in this document refers to the ESRDB input price index.

A market basket has historically been used under the Medicare program to account for the price increases of the requisite inputs associated with the services furnished by providers. The percentage change in the ESRDB market basket reflects the average change in the price of goods and services purchased by ESRD facilities in providing renal dialysis services. Since we are proposing a single payment rate for both operating and capital-related costs, the proposed ESRDB market basket for ESRD facilities includes both operating and capital-related costs.

The following discussion includes an explanation of the methodology and results of the proposed ESRDB market basket. First, we describe the methodology behind the development of the proposed cost category weights. Next, we explain the basis for the selection of each price measure used to proxy the rate of price change for each expenditure or cost category. Next, we present the results of the proposed ESRDB market basket, and finally we propose our definition of the ESRDB labor-related share.

The ESRDB market basket is constructed in three steps. First, a base period is selected and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories. Then, the proportion of total costs that each category represents is determined. These proportions are called cost or expenditure weights. Each expenditure weight category is then matched to an appropriate price or wage variable, referred to as a price proxy. These price proxies are price index levels derived from publicly available statistical series that are published on a consistent schedule, preferably at least on a quarterly basis. Finally, the expenditure weight for each category is multiplied by the index level of the respective price proxy to arrive at a weighted index level for each cost category. The sum of the products (that is, the expenditure weights multiplied by the price levels) for all cost categories yields the aggregate index level of the market basket in a given year. Repeating this step for different time periods produces a series of market basket index levels over time. Dividing an index level in one period by an index level in an earlier period produces a rate of growth in the input price index over that time period.

We are proposing to use CY 2007 as the base year for the development of the ESRDB market basket cost weights. The cost weights for this proposed ESRDB market basket are based on the cost report data for independent ESRD facilities.

We refer to the market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2007 = 100. Source data included CY 2007 Medicare cost reports (Form CMS–265–94), supplemented with 2002 data from the U.S. Department of Commerce, Bureau of the Census' Business Expenditure Survey (BES). The BES data were aged to 2007 using appropriate price proxies to estimate price growth. The price proxies used for the aging of the BES data come from publicly available price indexes such as various producer price indexes (PPI), consumer price indexes (CPI), or employment cost indexes (ECI). All of these price proxies are published by the U.S. Department of Labor, Bureau of Labor Statistics (BLS). We are proposing to use CY 2007 because it is the most recent year that both relatively complete Medicare cost report data and supplemental BES data is available. Analysis of Medicare cost reports for CY 2002 through CY 2006 showed little difference in cost weights compared to CY 2007. Medicare cost reports from hospital-based ESRD providers were not used to construct the proposed ESRDB market basket because data from independent ESRD facilities tend to better reflect the actual cost structure faced by the ESRD facility itself, and are not influenced by the allocation of overhead over the entire institution, as can be the case with hospital-based providers. This approach is consistent with our standard methodology used in the development of other market baskets, particularly those used for updating the skilled nursing facility PPS and home health PPS.

Cost Category Weights

Using Worksheets A, A2, and B from the CY 2007 Medicare cost reports, we first computed cost shares for nine major expenditure categories: Wages and Salaries, Employee Benefits for direct patient care, Pharmaceuticals, Supplies, Laboratory Services, Blood Products, Administrative and General and Other (A&O), Housekeeping and Operations, and Capital-Related costs. Edits were applied to include only cost reports that had total costs greater than zero. In order to reduce potential distortions from outliers in the calculation of the cost weights for the major expenditure categories, cost values for each category less than the 5th percentile or greater than the 95th percentile were excluded from the

computations. The resulting data set included information from approximately 3,572 independent ESRD facilities' cost reports from an available pool of 3,970 cost reports. Expenditures for the nine cost categories as a proportion of total expenditures are shown in Table 38.

Table 38
Initial 2007-Based End-Stage Renal Disease Bundled Rate Major Cost Categories and Weights Determined from the Medicare Cost Reports

Expense Category	CY 2007-Based Weights
Wages and Salaries	25.106%
Benefits for Direct Patient Care	5.076%
Pharmaceuticals	28.775%
Blood products	0.043%
Supplies	9.409%
Laboratory Services	0.330%
Housekeeping and Operations	3.353%
Administrative and General, and Other	17.847%
Capital-Related Costs	10.061%
Total	100.000%

Note: Totals may not sum to 100 due to rounding

Some costs that are required to be included in the ESRD bundled payment are not reported on the Medicare cost report. As a result, we supplemented Medicare cost report data with expenditure estimates for various ESRD-related drugs currently covered by Medicare Part D, as well as with additional lab expenses. The estimates for both of the aforementioned expenditures were provided by KECC. There are also costs that are reported on the Medicare cost report, but are not included in the ESRD bundled payment. As a result, we removed the expenses related to vaccine costs from total expenditures since these are excluded from the ESRD bundled payment, but reported on the Medicare cost report.

We are proposing to expand the expenditure categories developed from the Medicare cost reports to allow for a more detailed expenditure decomposition. To expand these cost categories, BES data were used as the Medicare cost reports do not collect detailed information on the items in question. Those categories include: benefits for all employees, professional fees, telephone, utilities, and all other services. We chose to separately break out these categories to more accurately reflect changes in ESRD facility costs. We describe below how the initially computed categories and weights were modified to yield the final ESRDB market basket expenditure categories and weights presented in this proposed rule.

Wages and Salaries

The weight for wages and salaries for direct patient care that was initially computed was derived from Worksheet B of the Medicare cost report. However, because Worksheet B only includes direct patient care salaries, it was necessary to derive a methodology to include all salaries, not just direct patient care salaries, in order to calculate the appropriate market basket cost weight. This was accomplished in the following steps.

(1) From the trial balance of the cost report (Worksheet A), we computed the ratio of salaries to total costs in each cost center. The cost centers for which we calculated this ratio were drugs, housekeeping and operations, A&O, supplies, blood and blood products, laboratories, capital-related machinery, and EPO.

(2) We then multiplied the ratios computed in step 1 by the total costs for each corresponding cost center from Worksheet B. This provided us with an estimate of non-direct patient care salaries for each cost center.

(3) The estimated non-direct patient care salaries for each of the cost centers on Worksheet B estimated in step 2 were subsequently summed and added to the direct patient care salary figure (resulting in a new total salaries figure).

(4) The estimated non-direct patient care salaries (see step 2) were then subtracted from their respective cost categories to avoid double-counting their values in the total costs.

As a result of this process, we moved from an estimated Wages and Salaries cost weight of 20.965 percent (as estimated using only direct patient care salaries as a percent of total costs found on the Medicare cost report) to a weight of 25.106 percent (capturing both direct and non-direct patient care salaries and, again, dividing that by total costs found on the Medicare cost report), as seen in Table 38.

When we add the expenditures related to lab expenses that were previously paid for under the Medicare fee schedule and not included in the Medicare cost report and the ESRD-related drug expenditures currently covered under Part D that were not included in the Medicare cost report, and remove the estimated vaccine costs that are to be paid outside of the bundle, then the cost weight for the Wages and Salaries category falls to 22.798 percent.

The final adjustment made to this category is to include contract labor costs. These costs appear on the Medicare cost report, however, they are embedded in the Administrative and General and Other category and cannot be disentangled using the Medicare cost reports alone. To move the appropriate expenses from the A&O category to Wages and Salaries, we used data from the BES. We first summed total contract labor costs in the survey. We then took 80 percent of that figure and added it to Wages and Salaries. At the same time, we subtracted that same amount from A&O. The 80 percent figure that was used was determined by taking salaries as a percentage of total compensation (excluding contract labor). The resulting cost weight for Wages and Salaries increases to 24.516 percent.

Benefits

The Benefits weight was derived from the 2002 BES data aged forward to 2007 as a benefit share for all employees is not available from the ESRD Medicare cost report. The cost report only reflects benefits for direct patient care. In order to include the benefits related to non-

direct patient care, we estimated this marginal increase from the BES Benefits weight. This resulted in a Benefits weight that was 0.672 percentage point larger (5.748 vs. 5.076) than the Benefits weight for direct patient care calculated directly from the cost reports. To avoid double-counting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 0.672 percentage point for Benefits from Pharmaceuticals, Biological Products, Administrative and General and Other, Supplies, Laboratory Services, Housekeeping and Operations, and the Capital-related Machinery components. This calculation reapportions the benefits expense for each of these categories using a method similar to the method used for distributing non-direct patient care salaries as described above.

The final adjustment made to this category is to include contract labor costs. Once again, these costs appear on the Medicare cost report, however, they are embedded in the Administrative and General and Other category and cannot be disentangled using the Medicare cost report alone. To move the appropriate expenses from the A&O category to Benefits, we followed the same methodology used to apportion contract labor wages and salaries noted immediately above. For Benefits, we applied the remaining 20 percent of total contract labor costs, as estimated using the BES, and included that in the Benefits cost weight. At the same time, we subtracted that same amount from A&O. The 20 percent figure that was used was determined by summing direct patient care benefits (as estimated using the Medicare cost report) and non-direct patient care benefits (as estimated using the BES) and taking that sum as a percentage of total compensation (excluding contract labor). The resulting cost weight for Benefits increases to 6.177 percent.

Utilities

We developed a weight for Utility expenses using the 2002 BES data, as utilities are not separately identified on the Medicare cost report. We aged the 2002 utility expenditures to 2007. We then disaggregated the Utilities category to reflect three subcategories: Electricity, Fuel (natural gas), and Water and Sewerage. We computed the ratio of each BES category to the total BES operating expenses. We then applied each ratio to the total operating expense percentage share as calculated from the cost reports, including the additions of ESRD-related drugs currently covered under Part D and additional lab expenses, to estimate the ESRD facility weight for each utility expenditure category. These amounts were then deducted from the share of the combined Operation & Maintenance of Plant and Housekeeping cost category, where the expenses are included on the Medicare cost report (but cannot be separately identified). The resulting Electricity, Fuel (Natural Gas), and Water and Sewerage ESRDB market basket weights are 0.586, 0.111, and 0.483 percent, respectively, yielding a combined Utilities cost weight of 1.180 percent.

Pharmaceuticals

The proposed ESRDB market basket includes expenditures for all drugs, including separately billable drugs and ESRD-related drugs currently covered under Medicare Part D. We were able to calculate an expenditure weight for pharmaceuticals directly from the Drugs cost center on Worksheet B plus the expenditures of EPO which are reported on worksheet A2 of the Medicare cost reports. Vaccine expenditures, which are mandated as separately reimbursable, were excluded when calculating this cost weight. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines described in subparagraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the drug. Since these drugs are excluded from other prospective payment systems, we exclude them from the proposed ESRDB market basket, as well. We estimate that expenditures for these three vaccines are approximately 1 percent of the total Medicare-allowable payments for separately billable drugs. 2007 expenditures for ESRD-related drugs currently covered under Part D were added to cost report totals.

Finally, to avoid double-counting, the weight for the Pharmaceuticals category was reduced to exclude the estimated share of non-direct patient care salaries and benefits associated with the Drugs and Epoetin cost centers. This resulted in a proposed ESRDB market basket weight for Pharmaceuticals of 30.743 percent. EPO expenditures accounted for 19.351 percentage points of the Pharmaceuticals weight, ESRD-related drugs currently covered under Part D accounted for 4.681 percentage points of the Pharmaceuticals weight, and all other drugs accounted for the remaining 6.710 percentage points of the Pharmaceuticals weight.

Blood Products

We calculated the weight for Blood Products in the ESRDB market basket using the separately billable expenditure amounts for the Whole Blood and Packed Red Blood Cells cost center on Worksheet A of the Medicare cost report. We then added the expenditures for A&O for Whole Blood and Packed Red Blood Cells from Worksheet B to the net expenses from worksheet A to arrive at a total expenditure amount for Blood Products. This total was divided by total expenses to derive a weight for the Blood Products component in the bundled rate market basket. Similar to other expenditure category adjustments, we reduced the computed weight to exclude non-direct patient care salaries and benefits associated with the Blood cost centers. The proposed adjusted Blood Products market basket weight is 0.035 percent.

Supplies

We calculated the weight for Supplies included in the bundled rate using the reimbursable and separately billable expenditure amounts for the Supplies cost center on Worksheet B of the Medicare cost report. Supplies that are separately billable are reported as a separate line item on the cost reports and were also included. This total was divided by total expenses to derive a weight for the Supplies component in the ESRDB market basket. The computed weight for this category was reduced by the non-direct patient care salaries and benefits associated with the Supplies cost center. The resulting proposed market basket weight for Supplies is 8.543 percent.

Laboratory Services

We calculated the weight for Laboratory Services included in the bundled rate using the reimbursable and separately billable expenditure amounts for the Laboratory cost center on Worksheet B of the Medicare cost report. The cost report expenditures do not include laboratory services paid for under the Medicare fee schedule, only facility-furnished laboratory tests. Since a large majority of laboratory tests are paid via the fee schedule, we adjusted the laboratory fees upward. The inflation factor was computed from the ratio of ESRD facility Medicare laboratory payment data to the other facility Medicare laboratory payment data. This provides a measure of the extent to which laboratory services fall under the Medicare fee schedule. For 2007, we increased the laboratory expenditures by a factor of 16.298, as estimated by KECC. The weight for this category was similarly reduced by the non-direct patient care salaries and benefits associated with the Laboratory cost center. The resulting proposed

market basket weight for Laboratory Services is 4.875 percent.

Housekeeping and Operations

We developed a market basket weight for this category using data from Worksheet A of the Medicare cost reports. Worksheet B combines the capital-related costs for buildings and fixtures with the Operation and Maintenance of Plant (Operations) and Housekeeping cost centers, so we were unable to calculate a weight directly from Worksheet B. We separated these expenses from capital-related costs because we believe housekeeping and operations expenditures, such as janitorial and building services costs, are largely service-related and would be more appropriately proxied by a service-related price index. To avoid double-counting, we subtracted from the Housekeeping and Operations weight the utilities proportion described above, as well as the non-direct patient care salaries and benefits share associated with the Operations and Housekeeping cost center. The resulting proposed market basket weight for Housekeeping and Operations is 1.766 percent.

Administrative and General and Other (A&O)

We computed the proportion of total A&O expenditures using the A&O cost center data from Worksheet B of the Medicare cost reports minus the A&O expenditures related to the Blood Products category. As described above, we exclude contract labor from this cost category and apportion these costs to the salary and benefits cost weights. Similar to other expenditure category adjustments, we then reduced the computed weight to exclude salaries and benefits associated with the A&O cost center. The resulting A&O cost weight is 13.617 percent. This A&O cost weight is then fully apportioned to derive detailed cost weights for Professional Fees, Telephone, All Other Labor-related Services, and All Other Nonlabor-related Services.

Professional Fees

A separate weight for Professional Fees was developed using the 2002 BES data aged to 2007. Professional fees include fees associated with the following: Advertising, accounting, bookkeeping, legal, management, consulting, administrative, and other professional services fees. To estimate professional fees, we first calculated the ratio of BES professional fees to a total of administrative and other expenses from BES. We applied this ratio to the A&O total cost weight to estimate the proportion of ESRD facility professional fees. The resulting weight is 1.692 percent. This proposed cost weight is then separated into Labor-related Professional Fees (1.478 percent) and Nonlabor-related Professional Fees (0.214 percent), which is described in more detail below.

Telephone

Because telephone service expenses are not separately identified on the Medicare cost report, we developed a Telephone Services weight using the 2002 BES expenses aged to 2007. We estimated a ratio of telephone services expenses to total administrative and other expenses from BES. We applied this ratio to the total A&O cost weight to estimate the proportion of ESRD facility telephone expenses. The resulting proposed market basket cost weight for Telephone Services is 0.590 percent.

All Other Labor-related Services

A separate weight for All Other Labor-related Services was developed using the 2002 BES data aged to 2007. All other labor-related services include repair and maintenance fees. We estimated a ratio of all other labor-related services expenses to total administrative and other expenses from BES. We applied this ratio to the total A&O cost weight to estimate the cost weight for ESRD facility All Other Labor-related Services. The resulting proposed market basket cost weight is 1.163 percent.

All Other Nonlabor-related Services

A separate weight for All Other Nonlabor-related Services was developed using the 2002 BES data aged to 2007. Non labor-related services include insurance, transportation, shipping, warehousing, printing, data processing services, and all other operating expenses not otherwise classified. We estimated a ratio of all other nonlabor-related services expenses to total administrative and other expenses from BES. We applied this ratio to the total A&O cost weight to estimate the cost weight for ESRD facility All Other Nonlabor-related Services. The resulting proposed market basket cost weight is 10.172 percent.

Capital

We developed a market basket weight for the Capital category using data from Worksheet B of the Medicare cost reports. Capital-related costs include depreciation and lease expense for buildings, fixtures, movable equipment, property taxes, insurance, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. Because housekeeping and operations costs are included in the Worksheet B cost center for Buildings and Fixtures capital-related expense, we excluded these costs and developed a separate expenditure category as noted above. Similar to the methodology used for other market basket cost categories with a salaries component, we computed a share for non-direct patient care salaries and benefits associated with the Capital-related Machinery cost center. We used Worksheet B to develop two capital-related cost categories, one for Buildings and Fixtures, and one for Machinery. We reasoned this was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with Buildings and Fixtures could move differently than those associated with Machinery, we felt that separate price proxies would be more appropriate to track price changes for the different capital-related categories over time. The resulting proposed market basket weights for Capital-related Buildings and Equipment and Capital-related Machinery are 6.653 and 1.894 percent, respectively.

Table 39 lists all of the expenditure categories in the ESRDB market basket and their corresponding CY 2007 cost weights and proxies, as developed in accordance with the methodology described above.

TABLE 39—ESRDB MARKET BASKET COST CATEGORIES, PRICE PROXIES, AND COST WEIGHTS

Cost	Price/wage	ESRDB market basket
Category	Variable	CY 2007 weights
		(Percent)
Total Compensation		30.693
Wages and Salaries	ECI—Health Care and Social Assistance (Civilian)	24.516
Employee Benefits	ECI—Benefits Health Care and Social Assistance (Civilian)	6.177
Utilities		1.180
Electricity	PPI—Commercial Electric Power	0.586
Natural Gas	PPI—Commercial Natural Gas	0.111
Water and Sewerage	CPI—Water & Sewerage	0.483
All Other Materials		44.196
Pharmaceuticals	PPI—Prescription Drugs	30.743
Blood Products	PPI—Blood and Organ Banks	0.035
Supplies	PPI- Medical, surgical, and personal aid devices	8.543
Laboratories	PPI—Medical Laboratories	4.875
All Other Services		15.383
Telephone	CPI—Telephone Services	0.590
Housekeeping and Operations	PPI—Building, cleaning, and maintenance	1.766
Labor-Related		2.641
Professional fees Labor-Related	ECI—Compensation Professional and Related (Priv.)	1.478
All Other Labor-Related Services	ECI—Compensation Service Occupations (Priv.)	1.163
Nonlabor-Related		10.386
Professional fees Nonlabor-Related	ECI—Compensation Professional and Related (Priv.)	0.214
All Other Nonlabor-Related Services	CPI—All items less food and energy	10.172
Capital Costs		8.547
Capital Related-Building and Equipment	CPI—Residential Rent	6.653
Capital Related-Machinery	PPI–Electrical Machinery and Equipment	1.894

Price Proxies

Once we determined the proposed CY 2007 ESRDB market basket expenditure categories and weights, appropriate wage and price series or proxies were selected to measure the rate of price change for each category. All of the proxies are based on BLS data, and are grouped into one of the following three BLS categories:

PPIs—PPIs measure changes in the prices producers receive for their outputs. PPIs are the preferable price proxies for goods and services that ESRD facilities purchase as inputs in producing dialysis services, since these facilities generally make purchases in the wholesale market. The PPIs that we use measure price change at the final stage of production.

CPIs—CPIs measure changes in the prices of final goods and services purchased by the typical consumer. Because these indexes may not reflect the prices faced by a producer, we used CPIs only if an appropriate PPI was not available, or if the expenditure more closely resembled a retail rather than wholesale purchase. For example, we used the CPI for telephone services as a proxy for the Telephone cost category because there is no corresponding PPI, and we reasoned that commercial and residential rates change similarly.

ECIs—ECIs measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. They are fixed-weight indexes that strictly measure changes in wages and benefits per hour, and are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs we propose to use meet these criteria.

Wages and Salaries

We propose to use the ECI (Wages and Salaries) for Health Care and Social Assistance Workers (Civilian) as the measure of price growth for Wages and Salaries in the ESRDB market basket. We feel that this price proxy most closely reflects both the types of occupations employed by ESRD facilities, and the competitive nature of the dialysis and health services labor markets.

Benefits

We propose to use the ECI for Employee Benefits for Health Care and Social Assistance Workers (Civilian) as the measure of price growth for Benefits in the ESRDB market basket. We selected this price proxy because it most accurately represents the labor conditions associated with ESRD facilities' employee benefit costs, similar to our finding for wages and salaries.

Professional Fees

We propose to use the ECI (Compensation) for Professional and Related Occupations (Private) as the proxy for professional fees. We selected this price proxy because it includes occupations such as lawyers, accountants, and bookkeepers that are represented in this cost category.

Utilities

We propose to use the PPI for Commercial Electric Power and the PPI for Commercial Natural Gas as the proxies for the Electricity and Natural Gas cost categories, respectively. We propose to use the CPI for Water and sewerage as the price proxy for the water and sewerage cost category.

Capital-Related—Building and Equipment

We propose to use the CPI for Residential Rent as the price proxy for the Capital-related Building and Equipment cost category. As described earlier, this cost category includes building and fixtures, leased buildings, fixed equipment, and moveable equipment. Because machine equipment, particularly dialysis machines, is reflected in a separate cost category, the bulk of the expenditures captured here are for building and fixed equipment. Thus, we would prefer to have a proxy that captures the price change associated with this type of capital expense. While there can sometimes be differences in the price levels for residential and commercial rent, we believe the CPI for Residential Rent approximates the change in the underlying costs associated with ESRD facilities' capital costs such as depreciation, interest, taxes, and other capital costs. Given the lack of an ESRD-specific proxy for capital costs, we believe that the CPI for Residential Rent represents an adequate proxy for the changes in capital costs facing ESRD facilities.

Capital-Related—Machinery

We propose to use the PPI for Electrical Machinery and Equipment as the price proxy for the Capital-related Machinery cost category. This PPI includes dialysis machines, which are a significant component of machine equipment costs reported by ESRD facilities. Therefore, we believe that this price proxy is the best measure of the price growth of this cost category.

Pharmaceuticals

ESRD facilities use a variety of drugs during dialysis treatment including EPO which is currently a separately billable drug and accounts for the majority of ESRD facility drug expenses. We pay for erythropoietic agents to treat chronic anemia in ESRD patients. At present, Epogen© and Aranesp© (both manufactured by a single supplier) are two of the prevailing erythropoietic drugs available to treat anemia in ESRD patients. Medicare is the dominant purchaser of EPO since it is mainly used to treat kidney dialysis patients.

For the proposed ESRDB market basket, we propose to use the PPI for Prescription Drugs as the price proxy for the Pharmaceuticals category. We propose the use of this proxy for a variety of reasons. First, all of the market baskets that we produce include price proxies that are intended to reflect the efficient average price increase associated with the purchase of the particular input category. Accordingly, we have chosen to proxy the Pharmaceuticals cost category in the proposed ESRD market basket, which includes the mix of all prescription drugs purchased by dialysis facilities, by the PPI for Prescription Drugs because it reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. Second, we anticipate the price changes associated with the assortment of drugs administered in ESRD facilities should, over time, be similar to the average prescription drug price changes observed across the entire economy. Finally, this price series was chosen as it is both publicly available and regularly published.

Blood Products

We propose to use the industry PPI for Blood and Organ Banks as the price proxy for this cost category. This is the price proxy that we recently proposed to use in the 2006-based inpatient hospital market basket (74 FR 24157).

Supplies

We propose to use the commodity-based PPI for Medical, Surgical, and Personal Aid Devices as a proxy for changes in ESRD supply prices. Many of the supplies used in dialysis are included in this PPI, such as dialyzers, catheters, I.V. equipment, syringes, and other general medical supplies used in dialysis treatment.

Laboratory Services

We propose to use the PPI for Medical Laboratories as the price proxy for the ESRD Laboratory Services cost category. Most of the laboratory tests used in dialysis are blood chemistry tests (a covered component of the medical labs PPI). Additionally, some ESRD facilities are using diagnostic imaging services to monitor patient site access, and the points where waste exchange takes place (also a covered component of the medical labs PPI).

Telephone

We propose to use the CPI for Telephone Services as the price proxy for the Telephone cost category. This index is used as the price proxy for Telephone Services in other market baskets produced by CMS.

Housekeeping and Operations

We propose to use the PPI for Building Cleaning and Maintenance Services as the price proxy for the Housekeeping and Operations cost category. This PPI includes housekeeping, janitorial, and maintenance (excluding repairs) services, and is representative of the types of costs included in this cost category.

All Other Labor-Related Services

We propose to use the ECI (compensation) for Service Occupations (Private) as the price proxy for the All Other Labor-related Services cost category. This category includes expenses related to repair services. We feel that the service occupations most accurately reflect the costs for these types of repair and maintenance services purchased by ESRD facilities.

All Other Nonlabor-Related Services

We propose to use the CPI for All Items Less Food and Energy as the price proxy for the All Other Nonlabor-related Services cost category. This category includes costs such as data processing, purchasing, taxes, home office costs, and malpractice costs. The costs represented in this category are diverse and are primarily associated with the purchase of services. These costs are best represented by a general measure of inflation such as the CPI for All Items Less Food and Energy. Food and energy are excluded from the index to remove the volatility associated with those items. Additionally, energy prices are already captured in the utility price proxies.

ESRDB Market Basket Increases

The proposed ESRDB market basket reflects the combination of weights and proxies discussed above. Table 40 contains the forecasted rate of growth for CY 2009 through CY 2019 for the ESRDB market basket. Over this time period, the ESRDB market basket average increase is projected to be 2.7 percent.

TABLE 40—FORECAST OF THE 2007-BASED ESRD BUNDLED RATE MARKET BASKET PERCENT CHANGE, 2009 THROUGH 2019

Cy beginning January 1st	ESRDB
CY2009	3.4
CY2010	2.3
CY2011	2.5
CY2012	2.6
CY2013	2.6
CY2014	2.7
CY2015	2.7
CY2016	2.7
CY2017	2.7
CY2018	2.7
CY2019	2.7

Note: These percent changes do not reflect the −1 percentage point update in the market basket as mandated by MIPPA.

Source: 2009 2nd Quarter Forecast from IHS Global Insight.

ESRD Labor-Related Share

The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share is typically the sum of Wages and Salaries, Benefits, Professional Fees, Labor-related Services, and a portion of the Capital share from a given market basket.

We used the 2007-based ESRDB market basket costs to determine the proposed labor-related share for ESRD facilities under a bundled system. Under the proposed ESRDB market basket, the labor-related share for ESRD facilities is 38.160 percent; as shown in Table 41 below. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping and Operations, All Other Labor-related Services, 87 percent of the weight for Professional Fees (details discussed below), and 46 percent of the weight for Capital-related Building and Equipment expenses (details discussed below).

TABLE 41—ESRDB MARKET BASKETS LABOR-RELATED

Share cost category	2007-based ESRDB labor-related share (percent)
Wages	24.516
Benefits	6.177
Housekeeping and operations	1.766
All other labor-related services	1.163
Professional fees labor-related	1.478
Capital labor-related	3.060
Total	38.160

The labor-related share for Professional Fees (87 percent) reflects the proportion of ESRD facilities' professional fees expenses that we believe varies with local labor market. We recently conducted a survey of ESRD facilities to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD's local labor market. Thus, we are proposing to include 87 percent of the cost weight for Professional Fees in the labor-related share.

The labor-related share for capital-related expenses (46 percent of ESRD facilities' adjusted Capital-related Building and Equipment expenses) reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages. Capital-related expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

XIII. Proposed Implementation for the ESRD PPS

A. Transition Period

Section 1881(b)(14) of the Act replaces the current basic case-mix adjusted composite payment system with a case-mix adjusted bundled prospective payment system, or the ESRD PPS, for Medicare outpatient ESRD facilities beginning January 1, 2011. Section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide ''a four-year phase-in'' of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011. Although the statute uses the term ''phase-in'', other Medicare payment systems use the term ''transition'' to describe the timeframe during which payments are based on a blend of the payment rates under the prior payment system and the new payment system. For purposes of this ESRD PPS proposed rule, we will use the term ''transition'' to describe this timeframe. Section 1881(b)(14)(E)(i) of the Act further requires that the transition occur ''in equal increments,'' with payments under the ESRD PPS ''fully implemented for renal dialysis services furnished on or after January 1, 2014.'' In addition, section 1881(b)(14)(E)(ii) of the Act permits an ESRD facility to make a one-time election to be excluded from the transition from the current basic case-mix adjusted composite payment system, with its payment amount for renal dialysis services based entirely on the payment amount under the ESRD PPS. This election must be made prior to January 1, 2011. In addition, section 1881(b)(14)(E)(iii) of the Act requires that we make an adjustment during the transition so that payments during the transition equal the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. The transition budget-neutrality adjustment is discussed further in section VII.E.

In accordance with section 1881(b)(14)(E) of the Act, we propose to implement the transition from the current basic case-mix adjusted composite payment system in equal increments, with renal dialysis services and home dialysis furnished on or after January 1, 2014, paid entirely based on the payment amount under the ESRD PPS. Specifically, we propose that for renal dialysis services and home dialysis services provided during the transition period beginning January 1, 2011 and ending December 31, 2013, ESRD facilities receive a blended payment for each dialysis treatment consisting of the payment amount under the basic-case mix adjusted composite system and the payment amount under the ESRD PPS. Therefore, because ESRD facilities would receive an all-inclusive payment during the transition for all renal dialysis services and home dialysis items and services, other entities, such as Method II DME suppliers, laboratories, and Part D plans would no longer bill Medicare beginning January 1, 2011. To the extent these entities furnish items or services to ESRD patients, the entities would need to seek payments from the patient's ESRD facility. Further discussion on Method II DME suppliers, laboratories, and Part D plans can be found below.

For CY 2011, we are proposing to make payments based on 75 percent of the payment rate under the basic case-mix adjusted composite payment system and 25 percent of the payment rate under the ESRD PPS. For CY 2012 we are proposing to make payment based on 50 percent of the payment rate under the basic case-mix adjusted composite payment system and 50 percent of the payment rate under the ESRD PPS. For CY 2013 we are proposing to make payment based on 25 percent of the payment rate under the basic case-mix adjusted composite payment system and 75 percent of the payment rate under the ESRD PPS. For renal dialysis services furnished on or after January 1, 2014, we propose that payment to ESRD facilities be based on 100 percent of the payment amount under the ESRD PPS.

In particular, we propose that the portion of the blended rate based on the

payment amount with regard to the basic case-mix adjusted composite payment system would be comprised of the composite payment rate (which is adjusted by the basic case-mix and a wage index), the drug add-on amount, and payment amounts for items and services furnished to dialysis patients that are currently separately paid under Part B by Medicare to entities other than the ESRD facility. In addition to the above components of the basic case-mix adjusted payment system, as part of the transitional budget neutrality adjustment (describe in section VII.E.), we are also proposing to include a 14 dollar adjustment to the portion of the blended rate related to the basic case-mix adjusted payment system during the transition. The 14 dollar adjustment to the portion of the blended payment amount related to the basic case-mix adjusted payment system accounts for the ESRD related drugs and biological that are currently separately paid under Part D and are being proposed to be included in the ESRD PPS base rate.

For the years during which the phase-in (transition) is applicable, section 1881(b)(14)(F)(ii) of the Act requires the Secretary to annually increase the portion of the proposed ESRD PPS that is based on the composite rate that would otherwise apply if the ESRD PPS had not been enacted. In particular, section 1881(b)(14)(F)(ii)(II) of the Act requires the composite rate portion of the blended payment to be updated annually by the ESRDB market basket minus 1.0 percentage point. Our interpretation of section 1881(b)(14)(F)(ii) of the Act is that the ESRDB market basket minus 1.0 percentage point would be applied only to the composite payment rate portion of the blended payment amount for each year of the transition (which includes CY 2011). A full description of the ESRDB market basket is presented in section XII.

Therefore, for each year of the transition, we are proposing that the composite payment rate portion of the blended amount would be updated by a case-mix adjustment, the drug add-on adjustment, the current wage index, the ESRDB market basket minus 1.0 percentage point, and an adjustment to account for former ESRD-related Part D drugs to maintain transitional budget neutrality. Payments for items and services furnished to dialysis patients that are paid separately under Part B with regard to the current composite payment rate methodology, that is, ESRD-related laboratory tests, ESRD-related drugs, and ESRD-related supplies, blood, and blood products would no longer be paid separately. Instead, those items and services would be priced to reflect how they are currently paid, for example, using a fee schedule or ASP amount.

We note that there are ESRD facilities that have existing exception amounts that are used for payment in lieu of the composite rate, drug add-on payment, and basic case-mix adjustments (further discussion of exceptions under the basic case-mix adjustment composite payment system can be found in section I.B.3). Any existing exception amount would not be updated by the ESRDB market basket throughout the transition.

The portion of the blended rate based on the payment amount under the ESRD PPS includes the base rate and all applicable patient-level and facility-level adjustments, as would be determined under proposed § 413.231 and § 413.235. As set forth in proposed § 413.237, we propose that the ESRD PPS portion of the blended rate would also include outlier payments.

As specified in proposed § 413.178, bad debt is paid separately from the ESRD PPS and any payment for bad debt would occur at the time a FI/MAC reviews an ESRD facility's cost report and makes a final determination on if there are any overpayments/underpayments due to the ESRD facility/Medicare. For more information regarding bad debt payments see section XIV.D.

As previously noted, section 1881(b)(14)(E)(ii) of the Act gives an ESRD facility the option to make a one-time election to be excluded from the four-year transition from the current basic case-mix adjusted composite payment system in the form and manner specified by the Secretary. Once made, this election may not be rescinded. ESRD facilities may choose to be paid the blended rate under the transition period in order to give them time to determine the impact of the ESRD PPS on their operations and to adjust their operations accordingly. We believe ESRD facilities will choose to be excluded from the transition if they conclude that they would benefit financially from the payment amount under the ESRD PPS.

Section 1881(b)(14)(E)(ii) of the Act requires that ESRD facilities wishing to be excluded from the transition make their election prior to January 1, 2011, in the form and manner specified by the Secretary. We are proposing that ESRD facilities notify CMS of their election choice in a manner established by their respective FI/MAC no later than November 1, 2010 regardless of any postmarks or anticipated delivery dates. A timeframe of 60 days before implementation is consistent with the timeframe that a FI/MAC is given to incorporate any updates to rates. We are also proposing that those ESRD facilities that become certified for Medicare participation and begin to provide renal dialysis services between November 1, 2010 and December 31, 2010 would notify their FI/MAC of their election choice at the time of enrollment. Once an ESRD facility notifies their respective FI/MAC of their election choice, on or before November 1, 2010 (or at the time of enrollment for newly certified ESRD facilities that begin to provide renal dialysis services between November 1, 2010 and December 31, 2010), the ESRD facility's election cannot be rescinded. We note that section 1881(b)(14)(E)(ii) of the Act provides that all ESRD facilities wishing to be excluded from the transition must make an election to be excluded from the transition. We therefore are further proposing that those ESRD facilities that fail to affirmatively make an election by November 1, 2010, would be paid based on the blended amount under the transition. Elections submitted by ESRD facilities that wish to be excluded from the transition that are received, postmarked, or delivered by other means after November 1, 2010 would not be accepted. All ESRD facilities wishing to be excluded from the transition should submit their election choice by the proposed deadline if they wish to be excluded from the transition and paid entirely based on the payment amount under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011. Instruction as to how the FIs/MACs would implement the proposed ESRD PPS would be provided in future guidance. If the FIs/MACs express concern about the November 1, 2010 date, we would revisit the deadline in the ESRD PPS final rule. The proposed transition period policy is set forth in proposed § 413.239.

We are requesting public comment regarding our proposed blended payment rates and our proposed process for making the election to be excluded from the transition period.

1. New ESRD Facilities

Although the first sentence of section 1881(b)(14)(E)(i) of the Act permits ''a provider of services or renal dialysis facility'' to make a one-time election to be excluded from the transition, the second sentence provides that this election must be made prior to January 1, 2011. Reading these two sentences together, we believe that only ESRD facilities providing renal dialysis services to Medicare beneficiaries before January 1, 2011, should have the option to choose whether to be paid under the

transition or under the ESRD PPS. We further note that the transition period provided for under section 1881(b)(14)(E)(i) of the Act is intended to provide existing ESRD facilities time to adjust from payments based on the current basic case-mix adjusted composite payment methodology to bundled payments under the ESRD PPS. New ESRD facilities that begin providing renal dialysis services and home dialysis to Medicare beneficiaries on or after January 1, 2011, would not have received payment under the current basic case-mix adjusted composite payment system; therefore, we do not believe new ESRD facilities require a transition period in order to make adjustments to their operating procedures. Accordingly, we propose that ESRD facilities that are certified for Medicare participation and begin providing renal dialysis services and home dialysis on or after January 1, 2011, not have the option to choose whether to be paid a blended rate under the transition or the payment amount under the ESRD PPS. Rather, we propose that new ESRD facilities be paid based on 100 percent of the payment amount under the ESRD PPS.

As set forth in § 413.171 of this proposed rule, we are proposing to define a new ESRD facility as an ESRD facility that is certified for Medicare participation on or after January 1, 2011.

2. Limitation on Beneficiary Charges Under the Proposed ESRD PPS and Beneficiary Deductible and Coinsurance Obligations

Section 1833 of the Act governs payments of benefits for Part B services and the cost sharing amounts for services that are considered medical and other health services. In general, many Part B services are subject to a payment structure that requires beneficiaries to be responsible for a 20 percent coinsurance after the deductible (and Medicare pays 80 percent). With respect to dialysis services furnished by ESRD facilities to individuals with ESRD, under section 1881(b)(2)(a) of the Act, payment amounts are 80 percent (and 20 percent by the individual).

In this rule, we have proposed the items and services that would be considered renal dialysis services included in the ESRD PPS payment such as the composite rate related services, certain separately billable drugs, former Part D drugs used in the treatment of ESRD, laboratory testing, etc. We understand that certain items and services such as laboratory tests and Part D drugs have different beneficiary coinsurance structures. However, these items and services would be considered renal dialysis services after the ESRD PPS is implemented when furnished by an ESRD dialysis facility to an ESRD beneficiary. Therefore, a 20 percent beneficiary coinsurance would be applicable to the ESRD PPS payment for these services including any adjustments to the ESRD PPS payment such as adjustments for case-mix, geographic wage index, outlier, etc.

Thus, we are proposing that an ESRD facility receiving an ESRD PPS payment may charge the Medicare beneficiary or other person only for the applicable deductible and coinsurance amounts as specified in § 413.176. The beneficiary coinsurance amount for the ESRD PPS base rate is 20 percent of the total ESRD PPS payment (including payments made under the transition). We note that the amount of coinsurance is based on the proposed ESRD PPS payment for renal dialysis services and home dialysis in 42 CFR part 413. In general, facilities are paid monthly by Medicare for the ESRD services they furnished to a beneficiary even though payment is on a per treatment basis. We are proposing to continue this practice to pay ESRD facilities monthly for services furnished to a beneficiary beginning January 1, 2011. During the transition period before January 1, 2014, ESRD facilities that do not elect to go 100 percent into the ESRD PPS in 2011 would receive a blended payment amount of the prospective payment system in effect prior to January 1, 2011, and the ESRD PPS payment amount for services furnished to a beneficiary. ESRD Facilities would receive a monthly payment that is a blended payment amount for services furnished to a beneficiary. The services included in this blended monthly payment amount would be subject to a 20 percent beneficiary coinsurance.

Additionally, in accordance with section 1881(b)(1) of the Act and consistent with other established prospective payment systems policies, we are proposing in § 413.172(b) that an ESRD facility may not charge a beneficiary for any service for which payment is made by Medicare. This policy would apply, even if the ESRD facility's costs of furnishing services to that beneficiary are greater than the amount the ESRD facility would be paid under the proposed ESRD PPS.

B. Claims Processing

As indicated above, section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made for renal dialysis services and other items and services related to home dialysis. For example, those services would include supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, and support services.

Implementation of the proposed ESRD PPS will require a significant amount of changes to the way we process claims. Some of the changes could entail consolidated billing rules and edits and the data elements reported on claims, as discussed below.

1. Consolidated Billing

Since the ESRD PPS payment model represents an all-inclusive payment for renal dialysis services and home dialysis items and services, the ESRD facility itself is responsible for virtually all of the services mentioned above that its patients receive. It is important that billing and payment for these services, which could be provided by other entities, such as laboratories, is made only to the ESRD facility so that duplicate payment is not made by Medicare. Therefore, as stated previously in section XIII.B, suppliers, laboratories, and Part D plans would not be permitted to bill Medicare for renal dialysis services and home dialysis items and services that they furnish to ESRD beneficiaries. The consolidated billing approach essentially confers to the ESRD facility itself the Medicare billing responsibility for all of the renal dialysis services that its patients receive.

a. Laboratory Tests

ESRD patients generally have many co-morbid conditions and are treated by other specialists for those conditions. As such, many of the same laboratory tests ordered by a physician to monitor a patient's ESRD, could also be ordered by other physician specialists treating the ESRD patient for other medical conditions. Therefore, it is difficult to differentiate between an ESRD related laboratory test and a test ordered for another condition. While the ideal scenario would be to require that payment for all potential ESRD related laboratory tests be made only to the ESRD facility, ESRD facilities may not be able to control the ordering of tests by physicians not treating the patient's renal disease. A consolidated billing approach could identify the source of a given laboratory test to allow separate payment when the test was not ordered in connection with the patient's ESRD condition. In order to ensure proper payment in all settings, we are exploring the use of modifiers to identify those services furnished to ESRD beneficiaries, which are excluded from the proposed ESRD PPS.

b. Drugs and Biologicals

Certain drugs and biologicals routinely furnished to ESRD beneficiaries that are paid under the Medicare ESRD benefit are included in the current basic case-mix adjusted composite rate. Other ESRD-related injectable drugs are separately paid under Medicare Part B. However, as mentioned above, section 1881(b)(14)(B) of the Act requires the inclusion of all drugs and biologicals used for the treatment of ESRD, including drugs and biologicals that were formerly covered under Medicare Part D. Therefore, we would include these drugs as part of the consolidated billing mechanism discussed above. As a result of including these former Part D ESRD drugs and biologicals in the proposed ESRD PPS, we are proposing that ESRD facilities would be required to furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement. Such arrangements would prevent potential Medicare overpayments made under both Parts B and D. Further discussion regarding payment for former Part D drugs and biologicals can be found in section III.C.

c. Home Dialysis

Section 1881(b)(14)(A)(i) of the Act requires the costs of home dialysis supplies and services furnished under Method I and Method II, regardless of home treatment modality, be included in the proposed ESRD PPS. Thus, we are proposing that the Method II home dialysis approach in its present form would no longer exist under the proposed ESRD PPS effective January 1, 2011. This proposal does not eliminate Method I in its present form. Therefore, a supplier could only furnish, under arrangement with the ESRD facility, home dialysis equipment and supplies to a Medicare home dialysis beneficiary, and the supplier would have to look to the ESRD facility for payment. We believe that this approach is simpler and would reduce the administrative burden of maintaining two payment methods for home dialysis patients, as we believe that section 1881(b)(14)(A)(i) of the Act requires that all Medicare home dialysis supplies and services be paid under the proposed ESRD PPS and such payment be made to the ESRD facility. Further discussion of this proposal and information on home dialysis can be found in section III.E.

2. Expansion of the Data Elements Reported on Claims

Under the current basic case-mix composite adjusted payment system, ESRD facilities are paid a composite rate for each dialysis treatment performed. Currently the composite rate includes a number of items and services beyond the dialysis treatment itself. The services that are billed on the claim do not provide any detail of the composite rate items and services that are furnished to the patient beyond the treatment itself. Examples of additional types of items and services that are included in the composite rate but are not captured on the claims and that we believe would be helpful in our ability to predict composite rate costs are: time on machine, nutritional services, social work services, and nursing services. We are not proposing additional reporting requirements at this time, but we believe that collecting additional data at patient-level is necessary for refinements to the proposed case-mix adjustments of the proposed ESRD PPS payment model.

In the future, we may implement new reporting requirements where data elements, such as time on machine, nutritional services, social work services, and nursing services, would be relevant for case-mix refinements. We are requesting public comment regarding these data elements and other claim-based information that would identify patients who are high cost. Identifying other factors that explain costs could assist us in developing future patient-level adjusters that would further refine the model that we used to develop the proposed ESRD PPS. Detailed instruction as to how claims would be processed under the proposed ESRD PPS will be provided in future guidance.

C. Operational Issues Surrounding Payment for Self Administered ESRD–Related Drugs and Biologicals

As we discussed in section III. of this proposed rule, section 1881(b)(14)(B)of the Act defines renal dialysis services to include, among other things, certain drugs and biologicals, including drugs and biologicals that were separately payable under Parts B and D. Under the current ESRD basic case-mix adjusted composite payment system, ESRD facilities generally do not furnish oral drugs and biologicals to their ESRD patients. ESRD patients currently acquire these drugs and biologicals either through Medicare Part D, private insurance, or independently.

As described in section III. of this proposed rule, we are proposing to include renal dialysis service drugs formerly covered under Part D under the proposed ESRD PPS. As a result, we are further proposing that ESRD facilities would be required to furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement. Regardless of the mechanism by which these drugs would be furnished (directly or under arrangement), as ESRD facilities assume responsibility for the provision of these drugs that were formerly furnished by the Part D plans, we believe that some of the Part D provisions set forth in the 42 CFR Part 423, would become relevant for ESRD facilities. We are particularly interested in assuring beneficiary access to these drugs. As such, we request public comment on the extent to which Part D access requirements including, but not limited to, pharmacy networks and formularies may be relevant in the context of ESRD facilities' provision of renal dialysis service drugs.

In addition, consistent with the patients' rights processes set forth in § 494.70(a) and the condition: governance processes set forth in § 494.180(e) of the conditions for coverage for ESRD facilities, we would expect that the ESRD facilities would update their grievance processes to account for all self-administered ESRD-related drugs. Patients would continue to have access to both internal and external grievance processes including the ESRD Network and the State survey agency.

In the case of any ESRD facility that would seek to furnish drugs directly by dispensing on-site, we would expect that such facility comply with state pharmacy licensure requirements. As an alternative, we believe that many ESRD facilities would forego the process of becoming licensed as a pharmacy and instead, furnish renal dialysis service drugs formerly covered under Part D under arrangement with a licensed pharmacy. Under this scenario, the patient's MCP physician would prescribe the drugs or biologicals. The patient would obtain these drugs from a retail or mail order pharmacy with which the ESRD facility has contracted. We would expect that the ESRD facility would provide their patients with a listing of pharmacies with which it would have arrangements with to dispense the renal dialysis service drugs.

As indicated in proposed § 413.241 of this proposed rule, we would further expect that the ESRD facilities would establish arrangements with pharmacies in a manner that would facilitate beneficiary access to renal dialysis service drugs. That is to say, at a minimum, we would expect that the arrangement would take into account variables like the terrain, whether the patient's home is located in an urban or

rural area, the availability of transportation, the usual distances traveled by patients in the area to obtain health care services, and the pharmacy's capability to provide all classes of renal dialysis service drugs to patients in a timely manner.

In addition, we would expect that ESRD facilities would coordinate the provision of renal dialysis service drugs on behalf of traveling patients to facilitate ongoing compliance with the plan of care during periods of travel.

To prevent duplicate payment under both Part D and Part B for bundled drugs and biologicals formerly covered under Part D, we are considering the incorporation of an ESRD indicator on the Part D eligibility information that would prevent Part D drug payments for bundled ESRD drugs and biologicals at the pharmacy. For example, similar to the Part D requirements in § 423.120(c), ESRD facilities could issue a card or other type of technology that its enrollees may use to access renal dialysis service drugs through pharmacies with which they have established arrangements.

The pharmacy would bill the ESRD facility for all renal dialysis service drugs and biologicals included in the proposed ESRD PPS that were dispensed, but would not be permitted to bill the patient for the usual Part B coinsurance amount, nor treat these drugs in accordance with the Part D rules. As discussed in section XIII.A.2. of this proposed rule, the ESRD facility would collect applicable beneficiary coinsurance that is based on the proposed ESRD PPS per treatment payment amount.

As discussed in section VII. of this proposed rule, the cost of the drugs and biologicals currently separately payable under Part D that we propose to be designated as Part B renal dialysis services for purposes of the proposed ESRD PPS, would be reflected in the ESRD PPS portion of the blended payment. In addition, the mechanism by which we propose to address payment for these drugs during the transition as an adjustment to the blended payment related to basic case-mix adjusted composite payment system is discussed in section VII.D.b. of this proposed rule.

XIV. Evaluation of Existing ESRD Policies and Other Issues

We reviewed existing ESRD policies to determine their applicability to the proposed ESRD PPS. We propose to eliminate the exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities that exist under the case-mix adjusted composite payment system. We would maintain the current erythropoeisis stimulating agent monitoring policy, bad debt policy, reporting requirements for circumstances whereby Medicare is the secondary payer (MSP), and the 50-cent deduction to fund the ESRD Networks. We also propose to set forth in § 413.195 the limitation on review with regard to the ESRD PPS. In addition, we are considering the extent to which the laboratory services 50 percent rule would continue to apply under the proposed ESRD PPS.

A. Exceptions Under the Case-Mix Adjusted Composite Payment System

Section 1881(b)(7) of the Act and § 413.182 generally address exceptions to the composite payment rates. Section 422(a)(2) of BIPA prohibited the granting of new exceptions to the composite payment rates after December 31, 2000, but did allow the continuation of the existing exceptions as long as the exception rate exceeded the applicable composite payment rate. Section 623(b) of the MMA amended section 422(a)(2) of BIPA to restore composite rate exceptions for pediatric facilities that did not have an exception rate in effect as of October 1, 2002. Section 422(a)(2)(D) of BIPA defined a pediatric facility as a renal dialysis facility at least 50 percent of whose patients are under 18 years of age.

In the calendar year (CY) 2005 Physician Fee Schedule (PFS) proposed rule (69 FR 47535), we explained that section 422(a)(2)(C) of BIPA provided that any ESRD composite rate exception in effect on December 31, 2000, would continue as long as the exception rate exceeds the applicable composite payment rate. We further explained that when computing an exception amount, the facility's patient population and the higher costs relating to case-mix are taken into consideration. We indicated that we were proposing to allow each dialysis facility the option of continuing to be paid at its exception rate or at the basic case-mix adjusted composite rate. On April 1, 2004, we opened the exception window for pediatric facilities and noted that the window would close in September 27, 2004. In the CY 2005 PFS final rule with comment period (69 FR 66332), we stated that the exception process was opened each time there is a legislative change in the composite payment rate or when we open the exception window. We indicated our intent to open the pediatric exception windows on an annual basis. We also noted that we would provide for the continuation of the home training exception to allow for facilities with home training exceptions to retain their current training exception rates as well as take advantage of the case-mix adjusted rates for non-training dialysis.

While section 153 of the MIPPA does not directly address exceptions, we believe that the ESRD PPS under section 1881(b)(14) of the Act, creates an ESRD bundled prospective payment in lieu of payment under previous ESRD payment systems and given that the ESRD PPS no longer directly addresses changes in the ESRD composite rate, we believe that the exceptions currently in place would no longer apply. We also believe that we have addressed the higher costs relating to case-mix through the patient characteristic adjustments and outlier payments that are discussed in detail in sections VIII.B and X.A. Therefore, we are proposing the elimination of the isolated essential facility, self dialysis training costs, atypical service intensity (patient mix) and pediatric facility exceptions effective for ESRD renal dialysis services furnished on or after January 1, 2014 (at the conclusion of the phase-in). In other words, any existing exceptions would terminate effective for ESRD treatment on or after January 1, 2014. Additionally, no further exception windows would be open effective for ESRD treatment furnished on or after January 1, 2011, the effective date of the ESRD PPS. In the event that an ESRD facility elects to receive full payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, any existing exceptions would no longer be recognized. In the event that an ESRD facility elects to receive payment under the transition period, any existing exceptions would be recognized for purpose of the basic case-mix adjusted composite payment system portion of the blended payment through the transition. We propose to include the periods of exceptions and the elimination of the exceptions to the composite payment rates in § 413.180 of the regulations. With respect to appeals under § 413.194(b) we point out that such appeals apply only to exceptions to the composite rate granted before January 1, 2011.

B. Erythropoiesis Stimulating Agent (ESA) Monitoring Policy

In 2003, we solicited input from the ESRD community, in order to develop an erythropoiesis stimulating agent (ESA) Monitoring Policy. After input from the community, we implemented, through administrative issuance, the first iteration of the monitoring policy effective for services provided on or after April 1, 2006. On July 20, 2007, we issued through administrative issuance, a revised policy effective for services

furnished on or after January 1, 2008. We are currently evaluating the extent to which we could continue the ESA Monitoring Policy for renal dialysis services furnished on or after January 1, 2011. Specifically, at the current time it is not known how the reduction in payment that is currently applied to the separately billed ESAs would be applied under the proposed ESRD PPS. As discussed in section X.A, we are also continuing to evaluate how to establish eligibility for outlier payments in instances where the ESA Monitoring Policy is implicated. We request public comments on this issue to inform our evaluation.

C. ESRD Facility Network Deduction

Pursuant to section 1881(b)(7) of the Act, to fund the ESRD Networks, 50 cents is deducted from the amount of each payment for each treatment (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis). The reduction amount applies to all treatment modalities. The methodology for calculating the reduction is described in the Medicare Claims Processing Manual, Pub. 100–04, Ch. 8, section 110. We would continue this deduction with the ESRD PPS effective for services provided on or after January 1, 2011, with a 50 cent reduction per treatment from the payment made to ESRD facilities under the ESRD PPS for facilities that elect to receive payment under the ESRD PPS (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis). For facilities that elect to receive ESRD payment during the transition, we would apply the reduction methodology as described above to the blended payment amount during the transition.

D. Bad Debt

Section 413.89 of the regulations and Chapter 3 of the Provider Reimbursement Manual, Part 1 (PRM) (CMS Pub. 15–1) set forth the general requirements and policies for payment of bad debts attributable to unpaid Medicare deductibles and coinsurance amounts. Additional requirements for ESRD facilities are set forth at § 413.178.

Under the basic case-mix adjusted payment system, Medicare pays ESRD facilities 80 percent of a prospectively set composite rate for outpatient dialysis services. The Medicare beneficiary is responsible for the remaining 20 percent as coinsurance, as well as any applicable deductible amounts as set forth in § 413.176 of the regulations. If the ESRD facility makes reasonable collection efforts, as described in the Section 310 of the PRM, but is unable to collect the deductible or coinsurance amounts for items or services associated with the composite rate, we consider the uncollected amount to be a ''bad debt'' if the facility meets the requirements at § 413.178 and § 413.89 of the regulations and Chapter 3 of this proposed rule.

At the end of the ESRD facility cost reporting period, Medicare recognizes a facility's Medicare bad debts. However, § 413.178(a) requires CMS to reimburse ESRD facilities for its allowable bad debt up to the facility's costs as determined under Medicare principles.

In developing the proposed changes to the ESRD payment system described in this proposed rule, section 153(a)(4) of MIPPA states, as a Rule of Construction, that, ''nothing in this subsection or the amendments made by this subsection shall be construed as authorizing or requiring the Secretary of Health and Human Services to make payments under the payment system implemented under paragraph (14)(A)(i) of section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)), as added by paragraph (1), for any unrecovered amount for any bad debt attributable to deductible and coinsurance on items and services not included in the basic case-mix adjusted composite rate under paragraph (12) of such section as in effect before the date of the enactment of this Act.''

Therefore, under the proposed ESRD PPS, bad debt payments will continue to be made for the unpaid Medicare deductibles and coinsurance amounts for only those items and services associated with the basic case-mix adjusted composite rate. However, since the proposed single ESRD payment rate is for items and services included in the composite rate and for drugs and laboratory tests, we are proposing to use only the composite rate portion of the proposed single ESRD payment rate to determine bad debt payments. We are proposing that bad debt payments for ESRD facilities would continue to be capped as required under § 413.178(a). The Medicare cost report and instructions in the PRM, Part 2 (CMS Pub. 15–2) may be revised to report the case mix adjusted composite rate payment and associated cost data necessary to compute the ESRD facility bad debt payments.

In addition, we are proposing to make a conforming change to regulation text at § 413.178(d) regarding ESRD bad debt payment made under the proposed ESRD payment system described in this proposed rule. We are also including a cross-reference to § 413.178 in § 413.89(h) and (i).

E. Limitation on Review

In addition to requiring the establishment of the ESRD PPS, section 153(b) of MIPPA amends section 1881(b) of the Act to provide for a limitation on review. Specifically, section 1881(b)(14)(G) of the Act provides the following: ''There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act or otherwise of the determination of payment amounts under [section 1881(b)(14)(A)], the establishment of an appropriate unit of payment under [section 1881(b)(14)(C)], the identification of of renal dialysis services included in the bundled payment, the adjustments under [section 1881(B)(14)(D)], the application of the phase-in under [section 1881(b)(14)(E)], and the establishment of the market basket percentage increase factors under [section 1881(b)(14)(F)].'' We propose to codify this limitation on review in § 413.195 of the regulations.

F. 50 Percent Rule Utilized in Laboratory Payments

As specified in CMS Pub 100–04, Chapter 16, Sect. 40.6, for a particular date of service to a beneficiary, if 50 percent or more of the covered laboratory tests within an Automated Multi-Channel Chemistry (AMCC) test are included under the composite rate payment, then all submitted tests are included within the composite payment and no separate payment in addition to the composite rate is made for any of the separately billable tests. If less than 50 percent of the covered laboratory tests within the AMCC are composite rate tests, then all AMCC tests submitted are separately payable. When ordering ESRD-related AMCC tests, ESRD facilities identify, for a particular date of service, each test that is included in the composite rate and each test that is not included. A ''non-composite rate test'' is defined as ''any test separately payable outside the composite rate or beyond the normal frequency covered under the composite rate that is reasonable and necessary.''

During the transition period, the 50 percent rule would continue to apply to the basic case mix adjusted composite payment system portion of the blended payment. Under the proposed consolidated billing provisions discussed further in section XIII B. of this proposed rule, the ESRD facility itself would assume the Medicare billing responsibility for all of the renal dialysis services that its patients receive, including laboratory tests. As a result, the ESRD facilities would apply the 50 percent rule billing procedures

including application of the relevant modifiers.

As described in section X of this proposed rule, under the proposed ESRD PPS, Medicare would not make separate payment for laboratory tests, rendering the 50 percent rule irrelevant for payment purposes. The 50 percent rule's relevance would be limited to its use in determining eligibility for outlier payment.

In addition, preliminary analyses reveal a small impact upon removing from eligibility for outlier services the AMCC tests to which the 50 percent rule applies. As a result, we are considering excluding AAMC tests to which the 50 percent rule applies from the definition of outlier services, thus negating the need to apply the 50 percent rule under the proposed ESRD PPS. We plan to continue to evaluate the impact of this approach and include further discussion in the final rule. We request public comments on whether or not to include the AMCC tests to which the 50 percent rule applies within the definition of outlier services and retain the 50 percent rule under the proposed ESRD PPS.

G. Medicare as a Secondary Payer

Medicare may be a secondary payer (MSP) when the primary payer is a group health plan for ESRD items and services furnished to Medicare beneficiaries during the 30-month Medicare coordination of benefit period. At this time, we are unable to identify the systems operations and billing procedures impact of this relationship under the current basic case-mix adjusted composite payment system, and we are exploring how it will be utilized and managed under the proposed ESRD prospective payment system. We believe that while there may need to be system changes in order to process MSP claims under the Proposed ESRD prospective payment system, there should be no impact on ESRD providers and on primary payers. We will issue through administrative issuance, any changes in the manner of reporting information, should that be required. We are soliciting public comment on the operational issues of MSP under the proposed ESRD payment system.

XV. Quality Incentives in the End-Stage Renal Disease (ESRD) Program

A. Introduction

Section 1881(h) of the Social Security Act (the Act), as added by section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), requires the Secretary to develop a quality incentive program (QIP) that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established with respect to certain specified measures. As provided under section 1881(h) of the Act, the payment reductions, which will be up to 2.0 percent of the payments otherwise made to providers and facilities under section 1881(b)(14), will apply to renal dialysis services furnished on or after January 1, 2012, and the total performance score that providers and facilities must meet or exceed in order to receive their full payment will be based on a specific performance period prior to this date. The payment reductions will apply with respect to the year involved and will not be taken into account when computing future payment rates.

The CMS is committed to developing and implementing an ESRD QIP, and we intend to issue a subsequent proposed rule that makes detailed proposals regarding how we plan to implement section 1881(h) of the Act. However, in the interim, with one exception described below, we believe it is important to describe the QIP conceptual model that CMS is considering proposing for purposes of the payment reduction that will apply with respect to renal dialysis services furnished on or after January 1, 2012. Therefore, we will present the model below so that the public has an opportunity to comment on it, and we will use the comments to inform our evaluative, analytic, and guidance efforts during the development of the QIP.

The one exception mentioned above is the measure set that will apply for purposes of the CY 2012 payment reduction. We are making specific proposals with respect to that measure set in this proposed rule so that the public will be informed as early as possible regarding the measures on which the performance standards will be based.

B. Background

Quality monitoring and provider accountability is important in the ESRD payment system and has been done for over 30 years. We will describe the evolution of our ESRD quality monitoring initiatives by category below:

1. ESRD Network Organization Program

In the End-Stage Renal Disease Amendments of 1978 (Pub. L. 95–292), Congress required the formation of ESRD Network Organizations to further support the ESRD program. CMS currently contracts with 18 ESRD Networks throughout the United States to perform oversight activities and to ensure that dialysis patients are provided appropriate care. The Networks' responsibilities include monitoring the quality and improvement of care received, providing technical assistance to patients who have ESRD and providers/facilities that treat ESRD patients, and addressing patient grievances. In 1994, CMS and the Networks, with input from the renal community, established the ESRD Core Indicators Project (CIP). The ESRD CIP was CMS's first nationwide population-based study designed to assess and identify opportunities to improve the care of patients with ESRD. This project established the first consistent clinical ESRD database. Information included in the database included clinical measures thought to be indicative of key components of care surrounding dialysis.

2. Clinical Performance Measures (CPMs)

Section 4558(b) of the Balanced Budget Act of 1997 required CMS to develop and implement, by January 1, 2000, a method to measure and report the quality of renal dialysis services furnished under the Medicare program. To implement this legislation, CMS developed the ESRD Clinical Performance Measures (CPM) Project, based on the National Kidney Foundation's Dialysis Outcome Quality Initiative (NKF–DOQI) Clinical Practice Guidelines. The purpose of the ESRD CPM Project is to provide comparative data to ESRD facilities to assist them in assessing and improving the care furnished to ESRD patients. Sixteen CPMs were developed in 1998 to measure and report the quality of dialysis services furnished under Medicare in the areas of hemodialysis and peritoneal dialysis adequacy, anemia management, and vascular access management. The first data collection effort for the ESRD CPMs began in 1999. These CPMs are calculated using information contained in patients' records. CPMs are collected on a national random sample of adult in-center hemodialysis patients, all in-center hemodialysis patients less than 18 years of age, and a national random sample of peritoneal dialysis patients. Data are collected annually and submitted to CMS via a predominantly paper-based process. The CPMs are calculated and released in the Department of Health and Human Services' Annual Report on the ESRD CPM Project.

3. Dialysis Facility Compare (DFC)

Also in response to the Balanced Budget Act of 1997, we created Dialysis Facility Compare (DFC) as a new feature on *http://www.medicare.gov* that was modeled after Nursing Home Compare. We worked with a contractor and a consumer workgroup to identify dialysis facility-specific measures that could be provided to the public for consumer choice and information purposes. This tool was launched in January 2001 on the *http://www.medicare.gov* Web site to provide information to the public for comparing the quality of dialysis facilities and providers across the country, including specific information about services and the quality of care furnished by a specific dialysis facility/provider. DFC captures administrative and quality related data submitted by dialysis facilities and providers.

The key quality measures captured in this tool include facility-level measures of anemia control, adequacy of hemodialysis treatment and patient survival. Medicare claims data are used to calculate the anemia management and dialysis adequacy rates and administrative data (non-clinically based data such as demographic data, and data acquired from the Social Security Administration and obtained from the CMS forms 2728 and 2746) used to determine the patient survival rates. The anemia measure shows the raw number or the percentage of patients at a given facility/provider whose anemia (low red blood cell count) was not controlled. More specifically, the anemia measure is the percentage of patients whose hematocrit levels are at 33 percent (33 percent out of 100 percent) or more (or hemoglobin levels of 11 g/dL or more). The dialysis adequacy measure shows the raw number or the percentage of in-center hemodialysis patients at a facility that get effective treatments during dialysis. More specifically, the measure is the percentage of patients with urea reduction ratio (URR) levels of 65 percent or more. The patient survival measure shows whether patients treated at a certain facility generally live longer, as long, or not as long as expected. These measures are updated annually on the DFC Web site, usually at the end of the year, using data from the previous year for the dialysis adequacy and anemia measures and data from the past four years for the patient survival measure.

In November 2008, the anemia management measure was updated using facility and claims data from 2007. Recent evidence about increased risk of certain adverse events associated with the use of erythropoiesis-stimulating agents (ESAs), which are used to treat anemia, raised concerns about patients who have hemoglobin levels too high, as well as patients whose hemoglobin levels are too low. The Food and Drug Administration (FDA) responded by requiring manufacturers to develop a Medication Guide (*http://www.fda.gov/cder/drug/advisory/RHE200711.htm*) and to ensure that this information is provided to patients. The labeling guideline states ''The dosing recommendations for anemic patients with chronic renal failure have been revised to recommend maintaining hemoglobin levels within 10 g/dL to 12 g/dL'' (*http://www.fda.gov/cder/drug/advisory/RHE200711.htm*). As a result of this guideline, DFC was revised to include two anemia measures: one measure shows the percentage of patients whose hemoglobin levels are considered too low (that is, below 10 g/dL), and a second measure shows the percentage of patients whose hemoglobin levels are too high (that is, above 12 g/dL). In addition, CMS has updated the way it reports patient survival rates on DFC to reflect whether patients treated at a provider/facility generally live longer than, as long, or not as long as expected.

4. ESRD Quality Initiative

In 2004, the ESRD Quality Initiative was launched. The objective was to stimulate and support significant improvements in the quality of dialysis care. The initiative aimed to refine and standardize dialysis care measures, ESRD data definitions, and data transmission to support the needs of the ESRD program; empower patients and consumers by providing access to facility service and quality information; provide quality improvement support to dialysis providers; assure compliance with conditions of coverage; and build strategic partnerships with patients, providers, professionals, and other stakeholders. Components of this Quality Initiative included the DFC, the CPM Project, and the Fistula First Breakthrough Initiative.

5. ESRD Conditions for Coverage

The ESRD Conditions for Coverage final rule published on April 15, 2008, and contains revised requirements that dialysis providers and facilities must meet in order to be certified under the Medicare program. As part of the revised requirements, dialysis providers and facilities are required to implement a quality assessment and performance improvement program. In addition, providers and facilities are required to submit the CPMs electronically on all their patients on an annual basis. The CPMs were updated and expanded in April 2008 through a National Quality Forum (NQF) endorsement process. The current CPMs include 26 measures in the areas of anemia management; hemodialysis adequacy; peritoneal dialysis adequacy; mineral metabolism; vascular access; patient education/perception of care/quality of life; and patient survival. The anemia management measures for patients receiving erythropoiesis-stimulating agents (ESAs) and the urea reduction ratio (URR) measure (in-center hemodialysis) are not NQF endorsed.

6. CROWNWeb

CMS has developed a new Web-based system, Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) for the purposes of collecting CPM data electronically from dialysis facilities. Use of the CROWNWeb system will increase the efficiency of data collection for both CMS and providers/facilities, improve data quality, and provide a more stable and accessible platform for continual improvements in functionality. In February 2009, CMS began implementing the CROWNWeb system with a number of providers/facilities and plans to expand reporting to additional providers/facilities as soon as practicable.

C. The ESRD Quality Incentive Program as Authorized by Section 1881(h) of the Act

Recognizing the need for additional quality monitoring in an ESRD payment system, Congress required in section 153 of MIPPA that the Secretary implement an ESRD quality incentive program (QIP). We believe that the QIP is the next step in the evolution of the ESRD quality program because it measures provider/facility performance versus being focused on reporting outcome data.

Specifically, section 1881(h) of the Act, as added by section 153(c) of MIPPA, requires the Secretary to develop a QIP that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established with respect to certain specified measures. As provided under this section, the payment reductions, which will be up to 2.0 percent of payments otherwise made to providers and facilities under section 1881(b)(14), will apply to renal dialysis services furnished on or after January 1, 2012, and the total performance score that providers and facilities must meet

or exceed in order to receive their full payment will be based on a specific performance period prior to this date. Under section 1881(h)(1)(C), the payment reduction will only apply with respect to the year involved and will not be taken into account when computing future payment rates.

For the ESRD quality incentive program, section 1881(h) of the Act generally requires the Secretary to: (1) Select measures; (2) establish the performance standards that apply to the individual measures; (3) specify a performance period with respect to a year; (4) develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures for a performance period; and (5) apply an appropriate payment reduction to providers and facilities that do not meet or exceed the established total performance score.

We view the ESRD QIP required by section 1881(h) of the Act as the next step in the evolution of the ESRD quality program that began more than 30 years ago. Our vision is to develop a robust, comprehensive ESRD QIP that builds on the foundation that has already been established. As we move towards this larger goal, we understand the importance of giving providers and facilities time to prepare for the implementation of this new quality incentive program and to assess how the new program will affect them.

Therefore, we are outlining below a conceptual model that describes various components of an ESRD QIP that we are considering proposing in a future proposed rule. We want to make clear that this is only a model, with one exception. The exception, more fully described below, is that we are proposing to initially adopt for the QIP three measures, two of which assess anemia management and one which assesses hemodialysis adequacy, which can be calculated using Medicare claims data.

Our goal is to propose to implement other components of the QIP in future rulemaking. Our purpose in describing a model in this proposed rule is to notify the public regarding what we believe at this time to be essential components of the QIP in the hope of receiving detailed comments on those components. We also note that the model described below represents our thinking on what we are considering implementing only for payment consequence year 2012 because we anticipate that the program will evolve as we conduct additional analyses, gather experience, and respond to industry feedback.

1. Proposed Anemia Management and Dialysis Adequacy Measures

Section 1881(h)(2)(A)(i) of the Act requires that the measures specified for the QIP include measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management, and measures on dialysis adequacy. To implement this section, we are proposing that for the first QIP performance period, we will adopt the two anemia management measures and one hemodialysis adequacy measure that are currently used for DFC. Data needed to calculate these measures can be collected from Medicare claims submitted by ESRD providers and facilities on a patient-specific basis.

The anemia management measures used for DFC assess the percentage of patients at a facility whose anemia was not controlled at both the high and low ends of the FDA recommended hemoglobin levels. Specifically, these measures are: (1) The percentage of patients at a provider/facility whose hemoglobin levels were less than 10 g/dL, and (2) the percentage of patients at a provider/facility whose hemoglobin levels were greater than 12 g/dL.

Section 1881(h)(2)(A)(i) of the Act provides that the anemia management measures must reflect the labeling approved by the FDA for such management. The current FDA labeling guideline released November 8, 2007 for the administration of erythropoesis-stimulating agents (ESAs) to patients with chronic kidney disease, including ESRD patients, states ''The dosing recommendations for anemic patients with chronic renal failure have been revised to recommend maintaining hemoglobin levels within 10 g/dL to 12 g/dL.''

We believe that the proposed anemia management measures reflect the approved FDA labeling for anemia management because they assess the number of patients whose hemoglobin levels are at the low and high end of the FDA label recommendation. In addition, we believe that it is more appropriate to adopt two measures which together assess the high and low ends of the FDA recommended hemoglobin level range, rather than a single measure that reflects the percentage of patients who have hemoglobin levels within the 10 through 12 g/dL range, because two measures will provide a richer picture of provider/facility performance. These data will also allow us to calculate the percentage of patients who have hemoglobin levels within the 10 through 12 range g/dL. Therefore, we propose to adopt these two anemia management measures for the QIP.

Anemia data has been reported on Dialysis Facility Compare (DFC) since January 2001. As we noted above, we updated the reporting of anemia data for DFC in November of 2008 to be consistent with the new FDA labeling guideline released in November 2007; however, the methodology for calculating the provider/facility, state, and national averages for anemia measures has not changed since the initial release of DFC. We are proposing to use the same methodology we use to calculate the anemia management measures for purposes of DFC to calculate them for purposes of the QIP because the methodology is consistent with how we have calculated that data since 2001. Under this methodology, we will calculate the measures using hemoglobin data for Medicare patients who have been diagnosed with ESRD for at least 90 days and whose Medicare claims submitted by providers/facilities indicated the use of an ESA during that 90-day period. Data from patients whose first ESRD maintenance dialysis starts before day 90 or who have hemoglobin values of less than 5 or greater than 20 will be excluded from the measure calculation. In addition, there must be for the same patient at least 4 claims meeting this criteria for that data to be included in the data for a specific provider or facility. Technical details on the methodology we are proposing to use to calculate the anemia measures are available on the University of Michigan Kidney Epidemiology and Cost Center Web site at *http://www.sph.umich.edu/kecc/assets/documents/facguide.pdf.*

The hemodialysis adequacy measure (urea reduction ratio [URR]) that we are proposing to adopt is also used for DFC and assesses the percentage of patients at a provider or facility that get their blood cleaned adequately (blood urea is removed during their in-center hemodialysis). Specifically, this measure assesses the percentage of hemodialysis patients at a provider or facility whose urea reduction ratio (URR) is 65 percent or greater, a standard based on the National Kidney Foundation's Kidney Disease Quality Initiative Clinical Practice Guidelines (NKF–KDOQI). These guidelines are widely used and generally accepted throughout the ESRD community. More information on the calculation of the URR is available on the DFC Web site at *http://www.medicare.gov.* This measure has been endorsed by the National Quality Forum (NQF), an organization that endorses quality measures through a public consensus process, although we note that NQF

endorsement of dialysis adequacy measures is not a requirement under section 1881(h)(2)(A)(i).

The methodology for calculating the provider/facility, state, and national averages for the in-center hemodialysis measure has been used since January 2001 with the initial release of DFC, and we are proposing to use the same methodology to calculate the measure for purposes of the QIP to be consistent with how that data has been calculated since 2001. Under this methodology, we will calculate URR data only for Medicare patients who have been diagnosed with ESRD and received maintenance dialysis for at least 183 days from the date that they received their first maintenance dialysis treatment, and whose Medicare claims submitted by providers/facilities included a value for the URR. In addition, there must be for the same patient at least 4 claims meeting the criteria above for that data to be included in the data for a specific provider or facility. Technical details about the methodology we are proposing to use to calculate the hemodialysis adequacy measure are available on the University of Michigan Kidney Epidemiology and Cost Center Website at *http://www.sph.umich.edu/kecc/assets/documents/facguide.pdf.*

We note that the data we need to calculate the proposed anemia management and hemodialysis adequacy measures described above can be collected through ESRD claims, which is the only complete provider and facility level data set available to CMS at this time. For this reason, we are proposing to adopt only the two anemia management measures and one dialysis adequacy measure described above. Although we recognize that section 1881(h)(2)(A)(i) states that the measures shall include ''measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management and measures on dialysis adequacy,'' only one dialysis adequacy measure is collected nationally and available to determine provider and facility-specific values. For this reason, we are proposing at this time to adopt only one dialysis adequacy measure. We also note that section 1881(h)(2)(A)(iii) states that the measures shall include, to the extent feasible, other measures as the Secretary specifies including measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula). CMS is not proposing to adopt any measures in these categories at this time since we are not currently collecting data that would allow determination of provider and facility-specific performance with respect to these categories of measures. We are working to identify appropriate sources from which we can adequately capture data to support the future adoption of additional measures. Finally, it is not feasible to propose a patient satisfaction measure at this time because there is no validated data collection tool available to collect relevant and industry accepted patient satisfaction measure data. Therefore, it is not feasible to propose more than the aforementioned measures at this time because of the lack of complete and accurate data. Subsequent rulemaking will address other measures.

2. Performance Standards for the ESRD QIP Measures

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the QIP for a performance period with respect to a year. Section 1881(h)(4)(B) provides that the performance standards shall include levels of achievement and improvement, as determined appropriate by the Secretary. However, in our model, for the first performance period, we would establish a performance standard for the proposed anemia management and hemodialysis adequacy measures based on the special rule in Section 1881(h)(4)(E). This provision requires the Secretary to ''initially'' use as a performance standard for the anemia management and dialysis adequacy measures the lesser of a facility-specific performance rate in the year selected by the Secretary under the second sentence of section 1881(b)(14)(A)(ii), or a standard based on the national performance rate for such measures in a period determined by the Secretary. We would not include in this performance standard levels of achievement or improvement because we do not believe that section 1881(h)(4)(E) requires that we include such levels. In addition, we would interpret the term ''initially'' to apply only to the performance period applicable for payment consequence year 2012. For subsequent performance periods, we plan to propose performance standards under section 1881(h)(4)(A). Such standards will include levels of achievement and improvement, as required under section 1881(h)(4)(B).

As stated above, to implement the special rule for the proposed anemia management and hemodialysis adequacy measures, we would need to compare the performance of a provider or facility on these measures during the year selected by the Secretary for purposes of calculating the ESRD bundle with the performance of the provider or facility using a performance standard based on the national performance rates for these measures in a period determined by the Secretary. For purposes of making this comparison in our model, the provider/facility-level performance year referenced in section 1881(h)(4)(E)(i) would be 2007, 2008, or 2009, depending on which of those years is selected by the Secretary for purposes of calculating the ESRD bundle. We would refer to this year as the ''base utilization year.'' The provider/facility-specific rates for 2007 are currently posted on the DFC Web site.

In terms of establishing a performance standard based on national performance rates as required under section 1881(h)(4)(E)(ii), we are considering adopting a standard that is equal to the average performance of all dialysis providers and facilities based on 2008 data. These data for the anemia management and hemodialysis adequacy measures will be posted on DFC in November 2009.

Although the 2008 data are not yet available on DFC, the national averages currently posted on the DFC website for 2007 are

- For the proposed anemia management measure (Anemia Management Measure less than 10)—the percentage of Medicare patients who have an average hemoglobin value less than 10.0 g/dL in a provider/facility: *2 Percent*
- For the proposed anemia management measure (Anemia Management Measure more than 12)—the percentage of Medicare patients who have an average hemoglobin value greater than 12.0 g/dL in a provider/facility: *44 Percent*
- For the proposed hemodialysis adequacy measure (Hemodialysis Adequacy One)—the percentage of Medicare patients in a provider/facility with URR levels above 65 percent: *95 Percent.*

We expect that these averages will change for 2008.

This means that, for purposes of implementing the special rule in our model for the proposed anemia management and hemodialysis adequacy measures, the performance standard for the initial performance period would be the lesser of (1) the provider/facility-specific rate for the base utilization year, or (2) the national average results from 2008 claims data. If a provider or facility performed below the national average, then we would

look at the provider/facility-specific rate for the base utilization year to determine whether the provider/facility's performance during the initial performance period meets or exceeds the performance standard.

We note that the proposed hemodialysis adequacy measure would assess hemoglobin values only in hemodialysis patients who receive treatment at a provider or facility (and not in hemodialysis or peritoneal dialysis patients treated at home). In addition, the proposed hemodialysis adequacy measure would not assess hemoglobin values in pediatric dialysis patients. Therefore, we are seeking public input about this issue and ideas about whether and how we could assess dialysis adequacy for home dialysis (home hemodialysis and peritoneal dialysis) and pediatric dialysis.

3. Performance Period for the ESRD QIP Measures

Section 1881(h)(4)(D) of the Act requires the Secretary to establish a performance period with respect to a year, and for that performance period to occur prior to the beginning of such year. Because we are required under section 1881(h)(1)(A) to implement the payment reduction beginning with renal dialysis services furnished on or after January 1, 2012, the first performance period would need to occur prior to that date.

In selecting a performance period, we need to allow sufficient time to calculate the provider/facility-specific scores, determine whether providers and facilities meet the performance standards and prepare the pricing files needed to implement applicable payment reductions beginning on January 1, 2012. Among potential performance periods in our model would be all or portions of 2010. However, we are also considering other performance periods. We seek public comments about performance periods and will propose a specific performance period in future rulemaking.

4. Methodology for Calculating the Total Performance Score for the ESRD QIP Measures

Section 1881(h)(3)(A)(i) of the Act requires the Secretary to develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures selected for a performance period. Section 1881(h)(3)(A)(iii) states that the methodology must also include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement, such as weighting scores to ensure that providers/facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary. In addition, section 1881(h)(3)(B) requires the Secretary to calculate separate performance scores for each measure.

Finally, under section 1881(h)(3)(A)(ii), for those providers and facilities that do not meet (or exceed) the total performance score, the Secretary is directed to ensure that the application of the scoring methodology results in an appropriate distribution of reductions in payments to providers and facilities, with providers and facilities achieving the lowest total performance scores receiving the largest reductions.

As discussed earlier, we are proposing to adopt for the initial performance period two anemia management measures and one hemodialysis adequacy measure that are currently used for DFC. In our model, for purposes of calculating the total performance of each provider and facility during the initial performance period, we are considering assigning 10 points to each of these measures. That is, if a provider or facility meets the performance standard for one measure, then it would receive 10 points for that measure, and if the provider or facility meets the performance standards for all three measures, it would receive a total performance score of 30 points.

In our model, we are considering, for scoring purposes, that a provider or facility that does not meet the performance standard set for a measure would receive fewer than 10 points, with the exact number of points corresponding to how far from the set standard the provider/facility's performance falls. Specifically, we are considering implementing a scoring methodology that subtracts 2 points for each 2 percentage point increment range the provider or facility's performance falls from the set performance standard. For example, if we used as the performance standard during the initial performance period the national average of 44 percent (based on 2007 DFC data) for one of the proposed anemia management measures (percentage of patients whose hemoglobin levels are greater than 12 g/dL), and a particular provider/facility had 46 percent of patients with hemoglobin levels greater than 12 g/dL during that period, the provider/facility would receive 8 points for its performance on the measure because 46 percent is within the first 2 percentage point increment range from 44 percent (see Table 42 below). However, applying the special rule for the initial performance period, as required by section 1881(h)(4)(E), the provider/facility's performance of 46 percent would become the performance standard for scoring purposes, and the provider/facility would receive 10 points for this measure (see Table 43 below).

Under our model, providers and facilities that exceed the performance standards based on the national average for the period that the Secretary has determined and if their performance rate improved from the ''base utilization year'' then the provider or facility would receive additional points. Using the 2007 DFC data again to illustrate, if a provider/facility had 43 percent of patients with hemoglobin levels greater than 12 g/dL during the initial performance period, the provider/facility's performance would be better than the 2007 national average of 44 percent. In addition, if the provider/facility had a performance rate of 46 percent in the base utilization year then the provider/facility's performance of 43 percent for the initial performance period would also be better. Therefore, the provider/facility would receive 12 points, which is an additional 2 points or a ''bonus'' (maximum bonus in this conceptual model) above the 10 points that could be received for meeting the performance standard of a measure. We believe providers and facilities should only receive additional points if they achieve higher levels of performance, that is, their actual performance exceeds the performance standard for the national average for the period that the Secretary has determined and improves above the base utilization year.

As we noted above, the right side of Table 42 that represents the percentage of patients whose hemoglobin levels are greater than 12 g/dL, illustrates how this scoring methodology could work for a provider/facility for which, after applying the special rule, the performance standard for the proposed anemia management measures is the national performance rates for 2007. Likewise, Table 43 shows an example using a provider/facility-specific rate as the performance standard (after applying the special rule) for the proposed anemia management measures. In addition, Table 44 illustrates how the scoring methodology would work using the national performance rate for 2007 as the performance standard (after applying the special rule) for the proposed hemodialysis adequacy measure, and Table 45 shows an example of the scoring for the proposed hemodialysis adequacy measure using a facility-

specific rate as the performance standard (after applying the special rule).

Note that the bolded rows show the performance standard for the applicable measure.

TABLE 42—MODEL SCORING METHODOLOGY FOR PROPOSED ANEMIA MANAGEMENT MEASURES USING NATIONAL PERFORMANCE RATES IN 2007 AS THE PERFORMANCE STANDARDS

Points	Proposed anemia management measures			
	Percentage of patients whose hemoglobin levels are less than 10 g/dL		Percentage of patients whose hemoglobin levels are greater than 12 g/dL	
	Percentage	Distribution of facilities	Percentage	Distribution of facilities
12 points**	Below 2 percent	2,523	Below 44 percent	2,283
10 points	**2 percent**	**657**	**44 percent**	**73**
8 points	3 to 4 percent	884	45 to 46 percent	155
6 points	5 to 6 percent	358	47 to 48 percent	143
4 points	7 to 8 percent	149	49 to 50 percent	228
2 points	9 to 10 percent	54	51 to 52 percent	76
0 point	Over 11percent	119	Over 53 percent	1,786

* Provider/Facility must be above both performance standards to receive the bonus points for the anemia management measures.

TABLE 43—MODEL SCORING METHODOLOGY FOR PROPOSED ANEMIA MANAGEMENT MEASURES USING FACILITY-SPECIFIC RATES AS THE PERFORMANCE STANDARDS

Points	Proposed anemia management measures	
	Percentage of patients whose hemoglobin levels are less than 10 g/dL	Percentage of patients whose hemoglobin levels are less than 12 g/dL
	Percentage	Percentage
12 points*	Below 3 percent	Below 46 percent.
10 points	**3 percent**	**46 percent**
	(Example of a facility-specific score)	**(Example of a facility-specific score).**
8 points	4 to 5 percent	47 to 48 percent.
6 points	6 to 7 percent	49 to 50 percent.
4 points	8 to 9 percent	51 to 52 percent.
2 points	10 to 11 percent	53 to 54 percent.
0 point	Over 12 percent	Over 55 percent.

* Provider/Facility must be above both performance standards to receive the bonus points for the anemia management measures.

TABLE 44—MODEL SCORING METHODOLOGY FOR PROPOSED HEMODIALYSIS ADEQUACY MEASURE USING NATIONAL PERFORMANCE RATES IN 2007 AS THE PERFORMANCE STANDARD

Points	Proposed hemodialysis adequacy measure	
	Percentage of patients whose URR levels are greater than 65 percent	Distribution of facilities
12 points**	Over 95 percent	3,142
10 points	**95 percent**	**296**
8 points	93 to 94 percent	417
6 points	91 to 92 percent	245
4 points	89 to 90 percent	181
2 points	87 to 88 percent	102
0 point	Below 86 percent	296

** Provider/Facility must be above both performance standards to receive the bonus points for the hemodialysis adequacy measure.

TABLE 45—MODEL SCORING METHODOLOGY FOR PROPOSED HEMODIALYSIS ADEQUACY MEASURE USING THE FACILITY-SPECIFIC RATES AS THE PERFORMANCE STANDARD

Points	Proposed hemodialysis adequacy measure
	Percentage of patients whose URR levels are greater than 65 percent
12 points**	Above 92 percent.
10 points	92 percent (Example of a facility-specific score).
8 points	90 to 91 percent.
6 points	88 to 89 percent.
4 points	86 to 87 percent.
2 points	84 to 85 percent.
0 point	Below 83 percent.

Provider/Facility must be above both performance standards to receive the bonus points for the hemodialysis adequacy measure.

Another example of how the scoring methodology might work follows below. The example assumes that Facility A achieves the following results during the initial performance period:

1. Anemia Management (less than 10 g/dL): Percentage of patients whose hemoglobin levels are less than 10 g/dL is *4 percent*.

2. Anemia Management (more than 12 g/dL): Percentage of patients whose hemoglobin levels are greater than 12 g/dL is *43 percent*.

3. Hemodialysis Adequacy: Percentage of patients whose URR levels are greater than 65 percent is 93 percent.

The total performance score for Facility A would be 30 points. Facility A would receive bonus points for the anemia management (more than 12 g/dL) because the facility was above the national performance standard for the period determined by the Secretary, which in this example is 2007, and improved above the base utilization year, which is also 2007 in this example. However, the facility would not receive bonus points for the hemodialysis adequacy measure even though it improved from its base utilization year because it did not receive a percentage higher than the national average so the facility would receive a score of 10 points. Table 46 shows how the total performance score would be calculated for Facility A.

TABLE 46—EXAMPLE OF TOTAL PERFORMANCE SCORE METHODOLOGY USING FACILITY A

Measure	Facility performance rate	Performance standard using special rule	Score
Anemia Management: Percentage of patients whose hemoglobin levels are less than 10 g/dL.	4 percent	3 Percent ..... (Use Table 43).	8 points.
Anemia Management: Percentage of patients whose hemoglobin levels are greater than 12 g/dL.	43 percent	44 Percent and 46 Percent ..... (Use Tables 42 and 43).	12 points.
Hemodialysis Adequacy: Percentage of patients whose URR levels are greater than 65 percent.	93 percent	92 Percent ..... (Use Table 45).	10 points.
Total			30 points.

We believe this total performance score methodology is appropriate for the initial performance period in the new ESRD QIP because it is basic and straightforward, allowing providers and facilities to familiarize themselves with the new pay-for-performance quality system. We plan to propose a total performance scoring methodology using the applicable set of measures in future rulemaking. However, we are seeking input on this model of a total performance score methodology to be applied for payment consequence year 2012.

In our model, the initial scoring method weights each of the three proposed measures equally. As we stated above, we also plan to implement performance standards that include levels of achievement and improvement after the initial performance period. From a clinical perspective, we believe that providers and facilities may be concerned about whether they have as much opportunity to improve their performance on one of the proposed anemia management measures (hemoglobin levels less than 10 g/dL) as they might with the other two proposed measures. We are specifically soliciting comments on whether this is truly a concern among providers and facilities and, if so, whether we should consider assigning less weight to the measure based on that concern. We are also soliciting comments on how reassigning weights to measures in general (that is, less to some, more to others) might affect providers and facilities in terms of the payment consequence.

5. Application of Payment Reductions Using the Total Performance Score

With respect to the providers/facilities that do not meet (or exceed) the total performance score, section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of reductions in payments among providers and facilities achieving different levels of total performance scores, with providers and facilities achieving the lowest total performance scores receiving the largest reductions.

Under our model, for payment consequence year 2012, we are thinking about implementing a sliding scale of payment reductions, where the payment reduction for the lowest total performance score would be 2.0 percent.

Under our model, the minimum total performance score that providers and facilities would need to achieve in order to avoid a payment reduction would be 28 points. The range for the payment reductions is shown in Table 6:

TABLE 47—MODEL RANGE OF PAYMENT REDUCTIONS

Total performance score	Percent of payment reduction
28 to 30 Points	0 Percent.
24 to 26 Points	.25 Percent.
20 to 22 Points	.50 Percent.
16 to 18 Points	.75 Percent.
12 to 14 Points	1.0 Percent.
8 to 10 Points	1.25 Percent.
4 to 6 Points	1.50 Percent.
2 Points	1.75 Percent.

TABLE 47—MODEL RANGE OF PAYMENT REDUCTIONS—Continued

Total performance score	Percent of payment reduction
0 Points	2.0 Percent.

Based on our example involving Facility A above, this facility would not receive a payment reduction in 2012 because it achieved a total performance score of 30 points.

We recognize that under our model, a provider or facility that scores poorly on one measure could nonetheless receive no reduction in payment because the provider or facility also exceeded the performance standard for one or both of the other two measures. We are concerned about this possibility and are considering proposing that, for any measure for which a provider or facility receives 4 points or less, the provider/facility receive a 0.25 percent payment reduction even if it receives a total performance score of 28 points. We are seeking comments on our modeled methodology for applying payment reductions in 2012.

6. Public Reporting of Measures

Section 1881(h)(6) requires the Secretary to establish procedures for making information regarding performance under the QIP available to the public, including information on the total performance score and performance scores for individual measures achieved by each provider and facility. Providers and facilities are required to have an opportunity to review this information prior to it being made public. The Secretary is also directed in section 1881(h)(6)(D) to post a list of providers and facilities on the CMS Web site that indicates the total performance score and the performance scores for individual measures achieved by each provider and facility. In addition, under section 1881(h)(6)(C), the Secretary is required to provide certificates to providers and facilities that indicate the total performance score achieved by the provider or facility, and the provider or facility must prominently display the certificate in patient areas.

We plan to establish procedures for making information available to the public in a future rulemaking, but welcome comments on how to best implement these statutory requirements.

XVI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding a Low-Volume Adjustment (§ 413.232(f))

As discussed in section VIII.A.2.b. of this proposed rule, to receive the low-volume adjustment, we propose that an ESRD facility must provide an attestation to the Medicare administrative contractor or fiscal intermediary that it has met the criteria to qualify as a low-volume facility. The Medicare administrative contractor or fiscal intermediary would verify the ESRD facility's attestation of their low-volume status using the ESRD facility's final-settled cost reports.

The burden associated with the requirement is the time and effort necessary for an ESRD facility attesting as a low-volume facility to develop an attestation and submit it to the Medicare administrative contractor or fiscal intermediary. In the 2006 data analysis conducted by our contractor, UM–KECC, 489 ESRD facilities were identified as below the low-volume threshold of 3,000 treatments per year. Of these 488 facilities, 166 met the additional low-volume criteria as specified in § 413.232 of this proposed rule. We estimate that it would require an administrative staff member from each low-volume facility 5 minutes to develop the attestation and a negligible amount of time to submit it to the Medicare administrative contractor or fiscal intermediary. We further estimate several dozen additional ESRD facilities may meet the criteria of a low-volume facility prior to implementation of the ESRD PPS and therefore, we round the total number of estimated low-volume facilities to 200. Therefore, we estimate that the total initial ESRD facility burden would be 16.6 hours.

B. ICRs Regarding Transition Period (§ 413.239)

As discussed in section XIII.A. of this proposed rule, prior to January 1, 2011, an ESRD facility may make a one-time election to be excluded from the four-year transition to the ESRD PPS. That is, a facility may elect to be paid entirely based on the proposed ESRD PPS beginning January 1, 2011. Proposed § 413.239(b) states that an ESRD facility may make a one-time election to be paid for items and services provided during transition based on 100 percent of the payment amount determined under § 413.215 of this part, rather than based on the payment amount determined under paragraph (a) of this section. The section specifies that such election must be submitted to the facility's Medicare administrative contractor or fiscal intermediary no later than November 1, 2010.

We estimate that it would require an accountant or financial management staff member from each of the 4,921 ESRD facilities 1 hour to simulate average aggregate payments under the proposed ESRD PPS and compare them to average aggregate payments under the current basic case-mix adjusted composite payment system, for a total of 4,921 hours. In addition, for those facilities electing to be excluded from the four-year transition, the burden associated with the requirement in proposed § 413.239(b) is the time and effort necessary to develop an election and submit it to the Medicare administrative contractor or fiscal intermediary. We estimate that it would require an administrative staff member from each facility 15 minutes to develop the notice and a negligible amount of time to submit it. We estimate that 36 percent of the estimated 4,921 ESRD facilities, or 1,794 ESRD facilities, would make the election no later than November 1, 2010. Therefore, we estimate that the total one-time ESRD facility burden would be 448.5 hours.

Regulation section(s)	OMB control number	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
413.232	None	488	200	.083	16.6
413.239(b)	None	4,921	1,794	.25	448.5

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS 1418–P. Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.gov.*

XVII. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule is an economically significant rule because we estimate that the requirement under section 1881(b)(14)(A)(ii) of the Act—that the estimated total payments for renal dialysis services in CY 2011 equal 98 percent of the estimated total payments that would have been made if the ESRD PPS were not implemented—equates to an approximate $200 million decrease in payments to ESRD facilities in CY 2011. In addition, given this estimated impact, this proposed rule also is a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the proposed rule. We request comments on the economic analysis provided in this proposed rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, approximately 21 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's size standards, which considers small businesses those dialysis facilities having total Medicare revenues of $34.5 million or less in any 1 year, and 19 percent of dialysis facilities are nonprofit organizations. For more information on SBA's size standards, see the Small Business Administration's Web site at *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf* (Kidney Dialysis Centers are listed as 621492 with a size standard of $34.5 million). For purposes of the RFA, we estimate that approximately 21 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in the impact Table 48. Using the definitions in this ownership category, we consider the 550 facilities that are independent and the 471 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by large dialysis organizations (LDOs) and regional chains would have total revenues more than $34.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain). Overall, a hospital based ESRD facility (as defined by ownership type) is estimated to receive a 2.4 percent increase in payments under the new ESRD PPS for 2011. An independent facility (as defined by ownership type) is estimated to receive a 0.0 percent increase in payments under the proposed ESRD PPS for 2011. Therefore, the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

The claims data we use to estimate payments to ESRD facilities in this RFA and RIA does not identify which dialysis facilities are part of an LDO, regional chain, or other type of ownership. As each individual dialysis facility has its own provider number and bills Medicare using this number. Therefore, in previous RFAs and RIAs presented in proposed and final rules that updated to the basic case-mix adjusted composite payment system, we considered each ESRD to be a small entity for purposes of the RFA. However, we conducted a special analysis for this proposed rule that enabled us to identify the ESRD facilities that are part of an LDO or regional chain. The results of this analysis are presented in the type of ownership category of impact Table 48.

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations 50,000 or less and therefore, they are not enumerated or included in this initial RFA. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule has a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 188 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 189 rural hospital-based dialysis facilities will experience an estimated 1.7 percent increase in payments. As a result, this rule will not have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess

anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2009, that threshold is approximately $133 million. While dialysis facilities will be paid approximately $200 million less, we do not believe that this proposed rule includes any mandates that would impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of $133 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not believe this proposed rule will have a substantial direct effect on State or local governments, preempt State law, or otherwise have Federalism implications.

Payment for ESRD Bad Debt

The proposed changes to the ESRD bad debt payment in this proposed rule are not changes to the existing ESRD bad debt payment methodology and, therefore, there is no impact on ESRD payments from implementing the Rule of Construction described in Section 153(a)(4) of MIPPA and described elsewhere in this proposed rule.

B. Anticipated Effects

1. Effects on ESRD facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2011 under the current basic case-mix adjusted composite payment system (current payments) to estimated payments in CY 2011 under the proposed ESRD PPS, including payments to ESRD facilities paid a blended rate under the transition (new payments). To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of current payments and new payments contain similar inputs. Therefore, we simulated payments only for those ESRD facilities that we are able to calculate both current payments and new payments.

ESRD providers were grouped into the categories based on characteristics provided in the Online Survey and Certification and Reporting (OSCAR) file and the most recent cost report data from the Healthcare Cost Report Information System (HCRIS). We also used the June 2008 update of CY 2007 National Claims History file as a basis for Medicare dialysis treatments and separately billable drugs and biologicals.

Table 48 shows the impact of the proposed ESRD PPS compared to current payments to ESRD facilities under the basic case-mix composite payment system, including all separately billable items. Column A of impact Table 48 indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions).

TABLE 48—IMPACT OF PROPOSED CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2011 ESRD PPS

[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

Facility type	Number of facilities	Number of treatments (in millions)	2011 Impact assuming blended and 100% PPS payments [1]	2011 Impact assuming all facilities paid under 100% PPS payments
	A	B	C	D
All Facilities	4,921	36.5	−2.0%	−2.0%
Type:				
Freestanding	4,330	32.7	−2.5%	−2.6%
Hospital based	591	3.8	2.1%	3.7%
Ownership Type:				
Large dialysis organization	2,987	23.3	−3.1%	−3.7%
Regional chain	753	5.9	−1.3%	−0.3%
Independent	550	4.0	0.0%	1.3%
Unknown	160	0.3	−1.2%	0.0%
Hospital based [2]	471	3.0	2.4%	4.0%
Geographic Location:				
Urban	3,794	30.3	−1.9%	−1.7%
Rural	1,127	6.3	−2.5%	−3.4%
Census Region:				
East North Central	778	5.8	−2.4%	−2.4%
East South Central	384	2.8	−3.0%	−4.4%
Middle Atlantic	577	4.6	0.1%	1.2%
Mountain	267	1.6	−0.6%	0.8%
New England	156	1.2	−1.3%	0.1%
Pacific	556	4.5	−1.9%	−1.0%
South Atlantic	1,116	8.3	−2.5%	−3.3%
West North Central	374	2.0	−1.2%	−0.2%
West South Central	679	5.2	−3.1%	−3.8%
Puerto Rico and Virgin Islands	34	0.4	−2.9%	−6.6%
State:				
Alaska	4	0.0	−2.4%	0.3%
Hawaii	20	0.2	−2.3%	−0.2%
Other	4,897	36.3	−2.0%	−2.0%
Facility Size:				
Less than 3,000 treatments [3]	489	0.9	5.1%	6.0%
3,000 to 9,999 treatments	2,170	10.7	−2.5%	−3.1%
10,000 or more treatments	2,206	24.8	−2.0%	−1.8%

TABLE 48—IMPACT OF PROPOSED CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2011 ESRD PPS—Continued

[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

Facility type	Number of facilities	Number of treatments (in millions)	2011 Impact assuming blended and 100% PPS payments [1]	2011 Impact assuming all facilities paid under 100% PPS payments
	A	B	C	D
Unknown	56	0.1	−1.4%	−1.4%
Percentage of Pediatric Patients:				
Less than 2%	4,808	36.1	−2.0%	−2.0%
Between 2% and 19%	56	0.4	1.0%	2.3%
Between 20% and 49%	12	0.0	−1.9%	−4.9%
More than 50%	45	0.1	−3.6%	−11.7%
Prior Composite Rate Exception (IEF, Atypical):				
Yes[4]	37	0.1	5.2%	4.6%
No	4,884	36.4	−2.0%	−2.0%

[1] Assumed that 1794 out of 4921 Facilities choose to be excluded from the transition based on comparison of payments under current system to payments under proposed ESRD PPS.

If payments under a 100% fully implemented ESRD PPS are higher than payments under current system, we assumed that the facility would elect to be excluded from the transition.

[2] Includes hospital based facilities not reported to have large dialysis organization or regional chain ownership.

[3] Of the 489 Facilities with less than 3,000 treatments, only 166 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress.

The impact to these Low volume Facilites is a 16.6% increase in payments.

[4] These facilities that choose to retain their exception rate (either IEF or atypical) rather than be paid under the current basic case-mix adjusted composite payment system.

Section 1881(b)(14)(E)(ii) of the Act provides all ESRD facilities with the option to make a one-time election to be excluded from the transition from the current payment system to the ESRD PPS (see section VII.E of this proposed rule for details of this statutory provision). Electing to be excluded from the 4-year transition means that the ESRD facility receives payments for renal dialysis services provided on or after January 1, 2011, based on 100 percent of the payment rate under the proposed ESRD PPS, rather than a blended rate based in part on the payment rate under the current payment system and in part on the payment rate under the proposed ESRD PPS. In order to estimate which ESRD facilities would and would not elect to opt out of the transition and receive payment based on 100 percent of the payment amount under the ESRD PPS, we are proposing to estimate both the aggregate payments for each ESRD facility under the proposed ESRD PPS (based on 100 percent of the payment amount under ESRD PPS) and payments in the first year of the transition (based on a blend of 25 percent of payments under the proposed ESRD PPS and 75 percent of payments under the current basic case-mix adjusted composite payment system). We then assume that facilities that would receive higher aggregate payments under the proposed ESRD PPS would elect to be paid based on 100 percent of the payment amount under the proposed ESRD PPS, and facilities that would receive higher aggregate payments under the first year of the transition (based on a blend of 25 percent of payments under the proposed ESRD PPS and 75 percent of payments under the current basic case-mix adjusted composite payment system) will elect to be paid under the transition. Based on these assumptions, we are estimating that 36 percent of ESRD facilities would choose to be excluded from the transition and we estimate that 64 percent of ESRD facilities would choose to be paid the blended rate under the transition.

Additionally, in accordance with section 1881(b)(14)(E)(iii) of the Act and as described in section VII.E of this proposed rule, we are proposing to apply a transition budget-neutrality adjustment factor to all payments. The purpose of this factor is to make the estimated total payments under the ESRD PPS equal the estimated total payments that would have been made if there had been no transition. We estimate this factor to be 0.970. Since the same factor would be applied to all payments, including the blended payment rates under the transition, the effect of the transition budget neutrality adjustment factor is the same for all impact categories.

The overall effect of the proposed ESRD PPS, in the first year of the transition, is shown in column C. This effect is determined by comparing total estimated payments under the proposed ESRD PPS, which includes blended payments and payments that are computed using our assumption that 36 percent of ESRD facilities would elect to be paid 100 percent ESRD PPS and 64 percent of ESRD facilities would elect to go through the transition. These payments have also been adjusted to reflect the proposed transition budget-neutrality adjustment factor. Total payments are then compared to payments that would have been made to facilities for renal dialysis services provided during CY 2011 under the basic case-mix adjusted composite payment system plus items and services separately billable under Title XVIII, including ESRD-related Part D drugs. In column C, the aggregate impact on all facilities is a 2.0 percent reduction in payments, which reflects the statutory 98 percent budget neutrality provision. Hospital-based ESRD providers of services show a 2.1 percent increase because as a group they receive higher payments under the proposed ESRD PPS than they would receive under the current system. We believe that the model used to create the proposed ESRD PPS adjustment factors more accurately predicts costs for this provider category. Facilities with less than 3,000 treatments show a 5.1 percent increase in payments under the proposed ESRD PPS because many of these facilities are eligible to receive the low-volume adjustment, which is a 20.2 percent adjustment per treatment. As with hospital-based ESRD providers of services, we believe that the model more

accurately predicts costs for this category. Facilities that chose to retain a composite rate exception in the current system show a 5.2 percent increase in payments under the proposed ESRD PPS. This may be explained by the fact that the current basic case-mix adjusted composite payment system does not completely account for their higher costs and that the proposed ESRD PPS more accurately accounts for the higher costs of these facilities as a group. The largest decrease in payments under the proposed ESRD PPS is for facilities with more than 50 percent pediatric patients which will experience a 3.6 percent decrease. We believe this decrease may be a result of the current system overpaying for pediatric patients, rather than the proposed ESRD PPS underpaying this group of facilities. As described in more detail in section IX of this proposed rule, the current system provides a 1.62 increase factor for pediatric patients. This factor was developed using cost per treatment for pediatric facilities that had applied for and received an exception under the current system. The current 1.62 adjustment factor was intended as a temporary adjustment and we stated our intention to refine this adjustment (69 FR 66327). We believe that the proposed pediatric patient adjustments under the proposed ESRD PPS provide a more accurate estimate of costs for these pediatric patients and therefore this provider category because they are now empirically driven and tied to the proposed ESRD PPS base rate. While this provider category will experience a decrease in payments under the proposed ESRD PPS as compared to the current system, we believe the transition to the ESRD PPS will provide a more gradual decrease.

Column D shows the effect if all ESRD facilities were paid 100 percent of the proposed ESRD PPS. In this column, we are showing a hypothetical effect, as the statute provides for a 4-year transition to a fully implemented ESRD PPS. We show this column as a comparison to column C, in order to show how each impact category would have been effected if the ESRD PPS had been fully implemented in 2011. In column D, the overall effect for all facilities in aggregate is a 2.0 percent reduction, which reflects the statutory 98 percent budget neutrality provision. As with column C, we see the same categories of ESRD facilities most impacted by the proposed ESRD PPS. However, in column D the changes are generally more pronounced as those providers do not have the mitigating effect of the transition. Since column D shows the hypothetical effect if all ESRD facilities were to be paid 100 percent of the ESRD PPS in the first year of the transition, we do not need to apply the transition budget neutrality factor to column D. We believe that the comparison of columns C and D shows that the statutory option to transition does provide a more gradual affect for provider categories that receive lower payments under the proposed ESRD PPS, as well as the effect of the transition budget neutrality factor. Generally, providers that do well under the proposed ESRD PPS show larger increases in column D compared to column C because column D does not reflect the transition budget neutrality adjustment. However, many provider categories include a combination of providers that are estimated to receive higher payments under the proposed ESRD PPS and providers that are estimated to receive lower payments under the proposed ESRD PPS. We believe the comparison of columns C and D also shows that our proposal to apply the transition budget neutrality factor to all payments does not penalize any one group, but rather it evenly distributes the effect of this transition budget neutrality factor among all provider types.

2. Effects on Other Providers

Under the proposed expanded bundle in the proposed ESRD PPS, other provider types such as laboratories, DME suppliers, and pharmacies would have to seek payment from ESRD facilities rather than Medicare. This is because under the proposed ESRD PPS, Medicare is paying ESRD facilities one combined payment for services that may have been separately paid by Medicare in the past. As discussed in more detail in section X.B of this proposed rule, the other provider types noted above may continue to provide certain ESRD-related services, however, beginning January 1, 2011, they may no longer bill Medicare directly and instead must seek payment from ESRD facilities.

3. Effects on the Medicare and Medicaid Programs

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities over the next five years would be as follows:

TABLE 49—ESTIMATED PAYMENTS

Calendar year	Estimated payments ($ in billions)
2011	7.9
2012	8.2
2013	8.5
2014	8.9
2015	9.2

These estimates are based on current estimates of annual increases in the ESRDB market basket (discussed in detail in section XII of this proposed rule) of 2.6 percent for CY 2012 and CY 2013, and 2.7 for CY 2014 and CY 2015. In addition, we estimate that there will be an increase in fee-for-service Medicare beneficiary enrollment of 1.8 percent in CY 2011, 2.4 percent in CY 2012, 2.5 percent in CY 2013, 2.4 percent in CY 2014 and 2.3 percent in CY 2015.

Consistent with the requirement for 98 percent budget neutrality in the initial year of implementation, we intend for estimated aggregate payments under the proposed ESRD PPS to equal 98 percent of the estimated aggregate payments that would have been made if the proposed ESRD PPS were not implemented. Our methodology for estimating payment for purposes of the budget neutrality calculation uses the best available data.

4. Effects on Medicare Beneficiaries

Medicare beneficiaries are responsible for 20 percent coinsurance on Part B renal dialysis services. The overall effect for all ESRD facilities in aggregate is a 2 percent reduction in payments, which reflects the statutory 98 percent budget neutrality provision. Since Medicare beneficiaries are responsible for 20 percent coinsurance on Part B renal dialysis services, this overall 2 percent reduction translates to a 2 percent reduction to beneficiary coinsurance.

C. Alternatives Considered

In developing this proposed rule, we considered a number of alternatives. We considered other adjustments, including race, modality, and site of service. We considered alternative adjustments to explain variation in cost and resource usage among patients and ESRD facilities. For example, we considered alternatives in the outlier policy, such as outlier percentages of 1.5, 2, 2.5, to 3 percent, rather than the proposed 1 percentage policy. We also considered a monthly payment, but instead proposed a per treatment payment.

We have discretion on some of the adjustments we are proposing, however this has no impact on the aggregate amount of spending in the first year of

the ESRD PPS (CY 2011). The statute requires a low-volume adjustment of at least 10 percent and an outlier policy. However, the statute did provide the Secretary with discretion in defining low-volume facilities and establishing an outlier policy. These issues are discussed in sections VIII.C and X.A, respectively. The sections referenced also discuss our rationale for the policy decisions we made.

D. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement showing the classification of the expenditures associated with the provisions of this proposed rule.

Table 50, below provides our best estimate of the decrease in CY 2011 Medicare payments under the ESRD PPS as a result of the changes presented in this proposed rule based on the best available data. The expenditures are classified as a transfer to the Federal Government of $160 million dollars (or as a savings to the Medicare Program) and as a transfer to beneficiaries of $40 million.

TABLE 50

Category	Primary estimate
Transfers:	
Annualized monetized transfers: "on budget".	−$200 million.
From whom to whom?	Federal Government & Beneficiaries to ESRD Facilities.

Note: The −$200 million from the Federal Government and Beneficiaries to ESRD Providers is distributed as −$160 million from the Federal Government to the ESRD Provider, and −$40 million from the Beneficiaries to the ESRD Provider.

E. Conclusion

The impact analysis shows an overall decrease in payments to all ESRD facilities for renal dialysis services of 2.0 percent. This is because of the statutory requirement that payments under the ESRD PPS in 2011 equal 98 percent of what ESRD facilities would have received were the ESRD PPS not implemented (or 98 percent of payments to ESRD facilities under the current payment system).

The analysis above, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis. The analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Center for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

1. The authority citation for part 410 is revised to read as follows:

Authority: Secs 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

2. Section 410.50 is amended by revising paragraph (a) to read as follows:

§ 410.50 Institutional dialysis services and supplies: Scope and conditions.

* * * * *

(a) All services, items, supplies, and equipment necessary to perform dialysis and drugs medically necessary and the treatment of the patient for ESRD and, as of January 1, 2011, renal dialysis services as defined in § 413.171 of this chapter.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

3. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395(g), 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–113 (133 stat. 1501A–332).

Subpart F—Specific Categories of Costs

4. Section 413.89 is amended by adding a new paragraph (h)(3) to read as follows:

§ 413.89 Bad debts, charity, and courtesy allowances.

* * * * *

(h) * * *

(3) *ESRD facilities—*

(i) *Limitation on bad debt.* The amount of ESRD facility bad debts otherwise treated as allowable costs described in § 413.178.

(ii) *Exception.* Bad debts arising from covered services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program. Additional exceptions for ESRD bad debt payments are described in § 413.178(d).

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services and Organ Procurement Costs

5. Section 413.170 is amended by revising the introductory text, paragraph (a) and paragraph (b) to read as follows:

§ 413.170 Scope.

This subpart implements sections 1881(b)(2), (b)(4), (b)(7), and (b)(12) through (b)(14) of the Act by—

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis services in or under the supervision of an ESRD facility that meets the conditions of coverage in part 494 of this chapter and as defined in § 413.171(c).

(b) Providing procedures and criteria under which a pediatric ESRD facility (an ESRD facility with at least a 50 percent pediatric patient mix as specified in § 413.184 of this subpart) may receive an exception to its prospective payment rate prior to January 1, 2011; and

* * * * *

6. Section 413.171 is added to read as follows:

§ 413.171 Definitions.

For purposes of this subpart, the following definitions apply:

Base rate. The average payment amount per-treatment, standardized to remove the effects of case-mix and area wage levels and further reduced for budget neutrality and the outlier percentage. The base rate is the amount to which the patient-specific case-mix

adjustments and any ESRD facility adjustments described in § 413.230, if applicable, are applied.

Composite Rate Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite rate established under section 1881(b)(7) and section 1881(b)(12) of the Act, the basic case-mix adjusted composite payment system.

ESRD facility. An ESRD facility is an independent facility or a hospital-based provider of services (as described in § 413.174(b) and (c) of this chapter) including facilities that have a self-care dialysis unit that furnishes only self-dialysis services as defined in § 494.10 of this chapter and meets the supervision requirements described in part 494 of this chapter, and that furnishes institutional dialysis services and supplies under § 410.50 of this chapter.

New ESRD facility. A new ESRD facility is an ESRD facility (as defined above), that is certified for Medicare participation on or after January 1, 2011.

Renal dialysis services. Effective January 1, 2011, the following items and services are considered ''renal dialysis services,'' and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:

(1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;

(3) Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form), and any oral equivalent form of such drug and biological;

(4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.

Separately Billable Items and Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act.

7. Section 413.172 is amended by revising paragraph (a), paragraph (b) introductory text, and paragraph (b)(1) to read as follows:

§ 413.172 Principles of prospective payment.

(a) Payment for renal dialysis services as defined in § 413.171 and home dialysis services as defined in § 413.217 of this chapter are based on payment rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered renal dialysis services as defined in § 413.171 or home dialysis services. Approved ESRD facility means—

(1) Any independent ESRD facility or hospital-based provider of services (as defined in § 413.174(b) and § 413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

* * * * *

8. Section 413.174 is amended as follows:

a. By revising paragraph (a).

b. By revising paragraphs (f) introductory text, (f)(3), and (f)(4).

c. By adding a new paragraph (f)(5).

The revisions and additions read as follows:

§ 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based providers of services and independent ESRD facilities for items and services furnished prior to January 1, 2009, under section 1881(b)(7) and section 1881(b)(12) of the Act;

(2) Does not differentiate between hospital-based providers of services and independent ESRD facilities for items and services furnished on or after January 1, 2009; and

(3) Requires the labor share be based on the labor share otherwise applied to independent ESRD facilities when applying the geographic index to hospital-based ESRD providers of services, on or after January 1, 2009.

* * * * *

(f) *Additional payment for separately billable drugs and biologicals.* Prior to January 1, 2011, CMS makes additional payment directly to an ESRD facility for certain ESRD-related drugs and biologicals furnished to ESRD patients. Effective January 1, 2011, as specified in section 1881(b)(14) of the Act, payment to an ESRD facility for certain ESRD-related drugs and biologicals furnished to ESRD patients on or after January 1, 2011 is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

* * * * *

(3) For drugs furnished prior to January 1, 2006, payment is made to hospital-based ESRD providers of services on a reasonable cost basis. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs furnished by a hospital-based ESRD provider of service is based on the methodology specified in § 414.904 of this chapter.

(4) For drugs furnished prior to January 1, 2006, payment is made to independent ESRD facilities based on the methodology specified in § 405.517 of this chapter. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs and biologicals furnished by independent ESRD facilities is based on the methodology specified in § 414.904 of this chapter.

(5) Effective January 1, 2011, payment for drugs and biologicals furnished by ESRD facilities as defined in § 413.171(c) is included in the ESRD prospective payment system rate established in § 413.230.

9. Section 413.176 is revised to read as follows:

§ 413.176 Amount of payments.

For items and services, for which payment is made under section 1881(b)(7), section 1881(b)(12), and section 1881(b)(14)of the Act:

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, Medicare pays the ESRD facility 80 percent of its prospective rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, CMS subtracts the amount applicable to the deductible from the ESRD facility's prospective rate and pays the facility 80 percent of the remainder, if any.

10. Section 413.178 is amended by revising paragraph (d) to read as follows:

§ 413.178 Bad debts.

* * * * *

(d) *Exceptions.* (1) Bad debts arising from covered ESRD services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program.

(2) For services furnished on or after January 1, 2011, bad debts arising from covered ESRD items or services that, prior to January 1, 2011 were paid under a reasonable charge-based methodology

or a fee schedule, including but not limited to drugs, laboratory tests, and supplies are not reimbursable under the program.

11. Section 413.180 is amended by adding a new paragraph (l) to read as follows.

§ 413.180 Procedures for requesting exceptions to payment rates.

* * * * *

(l) *Periods of exceptions.* (1) Prior to December 31, 2000, an ESRD facility may receive an exception to its prospective payment rate for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities.

(2) Effective December 31, 2000, an ESRD facility not subject to paragraph (l)(3), is no longer granted any new exceptions to the prospective payment rate as defined in § 413.180(l).

(3) Effective April 1, 2004 through September 27, 2004, and on an annual basis, an ESRD facility with at least 50 percent pediatric patient mix as specified in § 413.184 of this part, that did not have an exception rate in effect as of October 1, 2002, may apply for an exception to its prospective payment rate.

(4) For ESRD facilities that are paid a blended rate for renal dialysis services provided during the transition described in § 413.235(a) of this part, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities is used as the payment amount in place of the composite rate, for exceptions in effect prior to January 1, 2011 and will be terminated for ESRD services furnished on or after January 1, 2014.

(5) For ESRD facilities that, in accordance with § 413.235(b) of this part, elect to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under § 413.220 any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are terminated for ESRD services furnished on or after January 1, 2011.

12. Section 413.195 is added to read as follows:

§ 413.195 Limitation on review.

Administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise is prohibited of the determination of payment amounts under section 1881(b)(14)(A) of the Act, the establishment of an appropriate unit of payment under section 1881(b)(14)(C) of the Act, the identification of renal dialysis services included in the bundled payment, the adjustments under section 1881(b)(14)(D) of the Act, the application of the phase-in under section 1881(b)(14)(E) of the Act, and the establishment of the market basket percentage increase factors under section 1881(b)(14)(F) of the Act.

13. Section 413.196 is amended by adding new paragraphs (c) and (d) to read as follows:

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

* * * * *

(c) Effective for items and services furnished on or after January 1, 2011, CMS adjusts the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor minus 1.0 percentage point.

(d) Effective for items and services furnished on or after January 1, 2012, CMS updates on an annual basis the following:

(1) The per-treatment base rate and the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor minus 1.0 percentage point.

(2) The wage index using the most current hospital wage data.

(3) The fixed dollar loss amount as defined in § 413.237 of this part to ensure that outlier payments continue to be 1.0 percent of total payments to ESRD facilities.

14. Section 413.210 is added to read as follows:

§ 413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.

Items and services furnished on or after January 1, 2011, under section 1881(b)(14)(A) of the Act and as identified in § 413.217 of this part, are paid under the ESRD prospective payment system described in § 413.215 through § 413.235 of this part.

(a) *Qualifications for payment.* To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter.

(b) *Payment for items and services.* CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and services defined in § 413.217 of this part either directly or under arrangements.

15. Section 413.215 is added to subpart H to read as follows:

§ 413.215 Basis of payment.

(a) Except as otherwise provided under § 413.235 of this part, effective January 1, 2011, ESRD facilities receive a predetermined per treatment payment amount for items and services, specified under section 1881(b)(14) of the Act and as defined in § 413.217 of this part, furnished to Medicare Part B fee-for-service beneficiaries.

(b) The per-treatment payment amount is the product of the per treatment base rate described in § 413.220 plus the applicable adjustments described in § 413.231 through § 413.237 of this part.

(c) In addition to the per-treatment payment amount, as described in § 413.215(a) of this part, the ESRD facility may receive payment for bad debts of Medicare beneficiaries as specified in § 413.178 of this part.

16. Section 413.217 is added to subpart H to read as follows:

§ 413.217 Items and services included in the ESRD prospective payment system.

The following items and services are included in the ESRD prospective payment system effective January 1, 2011:

(a) Renal dialysis services as defined in § 413.171; and

(b) Home dialysis services, support, and equipment as identified in § 410.52 of this chapter.

17. Section 413.220 is added to subpart H to read as follows:

§ 413.220 Methodology for calculating the per-treatment base rate under the ESRD prospective payment system effective January 1, 2011.

(a) *Data sources.* The methodology for determining the per treatment base rate under the ESRD prospective payment system utilized:

(1) Medicare data available to estimate the average cost and payments for items and services.

(2) ESRD facility cost report data capturing the average cost per treatment.

(3) The lowest per patient utilization calendar year as identified from Medicare claims for calendar years 2007, 2008, or 2009.

(4) Wage index values used to adjust for geographic wage levels described in § 413.231 of this part.

(5) An adjustment factor to account for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by ESRD facilities.

(b) *Determining the per treatment base rate for calendar year 2011.* The ESRD prospective payment system combines payments for the composite rate items and services as defined in

§ 413.171 of this part and the items and services that, prior to January 1, 2011, were separately billable items and services, as defined in § 413.171 of this part, into a single per treatment base rate developed from 2007 claims data. The steps to calculating the per-treatment base rate for 2011 are as follows:

(1) *Average payments in CY 2007, 2008 or 2009.* CMS computes the average Medicare allowable payment for composite rate items and services and separately billable items and services furnished in CY 2007, 2008 or 2009 to yield a per treatment base rate for 2007, 2008 or 2009 and selects the year with the lowest per patient utilization.

(2) *Update of per treatment base rate to 2011.* CMS updates the per-treatment base rate under the ESRD prospective payment system in order to reflect estimated per treatment costs in 2011.

(3) *Standardization.* CMS applies a reduction factor to the per treatment base rate to reflect estimated increases resulting from the facility-level and patient-level adjustments applicable to the case as described in § 413.231 through § 413.237 of this part.

(4) *Outlier percentage.* CMS reduces the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD Prospective Payment System that are outlier payments as described in § 413.237 of this part.

(5) *Budget neutrality.* CMS adjusts the per treatment base rate so that the aggregate payments in 2011 are estimated to be 98 percent of the amount that would have been made under title XVIII of the Social Security Act if the ESRD prospective payment system described in § 413.210 through § 413.239 of this part were not implemented.

(6) *First Four Years of the ESRD Prospective Payment* System. During the first four years of ESRD prospective payment system (January 1, 2011 to December 31, 2014), CMS adjusts the per-treatment base rate in accordance with § 413.239(d).

18. Section 413.230 is added to subpart H to read as follows:

§ 413.230 Determining the per treatment payment amount.

The per-treatment payment amount is the product of the per treatment base rate established in § 413.220, the facility-level and patient-level adjustments described in § 413.231, § 413.232 and § 413.235 of this part, and any outlier payment under § 413.237.

19. Section 413.231 is added to subpart H to read as follows:

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located.

(b) The application of the wage index is made on the basis of the location of the ESRD facility in an urban or rural area as defined in this paragraph (b).

(1) *Urban area* means a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB.

(2) *Rural area* means any area outside an urban area.

20. Section 413.232 is added to subpart H to read as follows:

§ 413.232 Low-volume adjustment.

(a) CMS adjusts the base rate for low-volume ESRD facilities, as defined in paragraph (b) of this section.

(b) Definition of low-volume facility. A low-volume facility is an ESRD facility that:

(1) Furnished less than 3,000 treatments in each of the 3 years preceding the payment year; and

(2) Has not opened, closed, or had a change in ownership in the 3 years preceding the payment year.

(c) For the purpose of determining the number of treatments under paragraph (b)(1) of this section, the number of treatments considered furnished by the ESRD facility shall be equal to the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both:

(1) Under common ownership with, and

(2) 25 miles or less from the ESRD facility in question.

(d) The determination under paragraph (c) of this section does not apply to an ESRD facility that was in existence and certified for Medicare participation prior January 1, 2011.

(e) Common ownership means the same individual, individuals, entity, or entities, directly, or indirectly, own 5 percent or more of each ESRD facility.

(f) To receive the low-volume adjustment, an ESRD facility must provide an attestation statement to the fiscal intermediary/MAC that the facility has met all the criteria as established in paragraphs (a), (b), (c), and (d) of this section.

21. Section 413.235 is added to subpart H to read as follows:

§ 413.235 Patient-level adjustments.

Adjustments to the per-treatment base rate may be made to account for variation in case-mix. These adjustments reflect patient characteristics that result in higher costs for ESRD facilities.

(a) CMS adjusts the per treatment base rate for adults to account for patient age, patient sex (female), body surface area, low body mass index, onset of dialysis (new patient), and co-morbidities, as specified by CMS.

(b) CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age, treatment modality, and the presence of co-morbidities.

22. Section 413.237 is added to subpart H to read as follows:

§ 413.237 Outliers.

(a) The following definitions apply to this section.

(1) *ESRD outlier services* are separately billable items and services as defined in § 413.171 of this part and renal dialysis service drugs proposed for inclusion in the ESRD prospective payment system that currently are covered under Medicare Part D.

(2) *Adult predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to an adult beneficiary by an ESRD facility as defined in § 413.171.

(3) *Pediatric predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to a pediatric beneficiary by an ESRD facility as defined in § 413.171.

(4) *Adult fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to an adult beneficiary must exceed the *adult predicted ESRD outlier services MAP amount* to be eligible for an outlier payment.

(5) *Pediatric fixed dollar loss amount:* The amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to a pediatric beneficiary must exceed the *pediatric predicted* ESRD outlier services *MAP amount* to be eligible for an outlier payment.

(6) *Outlier Percentage:* This term has the meaning set forth in § 413.220(c)(4).

(b) Eligibility for outlier payments:

(1) *Adult beneficiaries.* An ESRD facility will receive an outlier payment for a treatment furnished to an adult beneficiary if the ESRD facility's per-

treatment imputed MAP amount for ESRD outlier services exceeds the adult predicted ESRD outlier services MAP amount plus the adult fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for an adult beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the adult beneficiary by the number of dialysis treatments furnished to the adult beneficiary in the relevant month. A beneficiary is considered an adult beneficiary if the beneficiary is 18 years old or older.

(2) *Pediatric beneficiaries.* An ESRD facility will receive an outlier payment for a treatment furnished to a pediatric beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the pediatric predicted ESRD outlier services MAP amount plus the pediatric fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for a pediatric beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the pediatric beneficiary by the number of dialysis treatments furnished to the pediatric beneficiary in the relevant month. A beneficiary is considered a pediatric beneficiary if the beneficiary is under 18 years old.

(c) *Outlier payment amount:* CMS pays 80 percent of the difference between:

(1) The ESRD facility's per-treatment imputed MAP amount for the ESRD outlier services, and

(2) The adult or pediatric predicted ESRD outlier services MAP amount plus the adult or pediatric fixed-dollar loss amount, as applicable.

23. Section 413.239 is added to subpart H to read as follows:

§ 413.239 Transition period.

(a) *Duration of transition period and composition of the blended transition payment.* ESRD facilities not electing under paragraph (b) of this section to be paid based on the payment amount determined under § 413.230 of this part will be paid a per-treatment payment amount for renal dialysis services (as defined in § 413.171 of this part) and home dialysis, provided during the transition as follows—

(1) For services provided on and after January 1, 2011 through December 31, 2011, a blended rate equal to the sum of:

(i) 75 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 25 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(2) For services provided on and after January 1, 2012 through December 31, 2012, a blended rate equal to the sum of:

(i) 50 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 50 percent of the payment rate determined in accordance with section 1881(b)(14) of the Act;

(3) For services provided on and after January 1, 2013 through December 31, 2013, a blended rate equal to the sum of:

(i) 25 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 75 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(4) For services provided on and after January 1, 2014, 100 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act.

(b) *One-time election.* Except as provided in paragraph (b)(2) of this section, ESRD facilities may make a one-time election to be paid for items and services provided during the transition based on 100 percent of the payment amount determined under § 413.215 of this part, rather than based on the payment amount determined under paragraph (a) of this section.

(1) Except as provided in paragraph (b)(3) of this section, the election must be received by each ESRD facility's Medicare administrative contractor (MAC) by November 1, 2010, regardless of any postmarks or anticipated delivery dates. Requests received, postmarked, or delivered by other means after November 1, 2010 will not be accepted. Once the election is made, it may not be rescinded.

(2) If the ESRD facility fails to submit an election, or the ESRD facility's election is not received by CMS by November 1, 2010, payments to the ESRD facility for items and services provided during the transition will be based on the payment amounts determined under paragraph (a) of this section.

(3) ESRD facilities that become certified for Medicare participation and begin to provide renal dialysis services, as defined in § 413.171 of this part, between November 1, 2010 and December 31, 2010, must notify their designated contractor (MAC) of their election choice at the time of enrollment.

(c) *Treatment of new ESRD facilities.* For renal dialysis services as defined in § 413.171, provided during the transition, new ESRD facilities as defined in § 413.171, are paid based on the per-treatment payment amount determined under § 413.215 of this part.

(d) *Transition budget-neutrality adjustment.* During the first 3 years of the transition (January 1, 2011 through December 31, 2013), CMS adjusts all payments, including payments under this section, under the ESRD prospective payment system so that the estimated total amount of payment equals the estimated total amount of payments that would otherwise occur without such a transition.

24. Section 413.241 is added to subpart H to read as follows:

§ 413.241 Pharmacy arrangements.

Effective January 1, 2011, the ESRD facility that enters into an arrangement with a pharmacy to furnish renal dialysis service drugs must ensure that the pharmacy is located such that it has the capability to provide all classes of renal dialysis service drugs to patients in a timely manner.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

25. The authority citation for part 414 continues to read as follows:

Authority: Secs 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

Subpart E—Determination of Reasonable Charges Under the ESRD Program

26. Section 414.330 is amended by—

A. Removing ''§ 413.170'' and adding in its place ''§ 413.210'' in paragraph (a)(1) and paragraph (b)(1).

B. Revising the heading of paragraph (a)(2).

C. Revising the heading of paragraph (b)(2).

D. Removing the paragraph heading and adding in its place new introductory text in paragraph (c).

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) * * *

(2) *Exception for equipment and supplies furnished prior to January 1, 2011.* * * *

* * * * *

(b) * * *

(2) *Exception for home support services furnished prior to January 1, 2011.* * * *

* * * * *

(c) Payment limits for support services, equipment and supplies, and notification of changes to the payment limits apply prior to January 1, 2011 as follows:

* * * * *

27. Section 414.335 is amended by revising paragraph (a) to read as follows:

§ 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Prior to January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies. Effective January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to a Medicare approved ESRD facility.

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(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 28, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 23, 2009.

Kathleen Sebelius,

Secretary.

Note: The following Appendices will not appear in the Code of Federal Regulations.

BILLING CODE 4120–01–P

Table A: Universe of Codes used in the Analysis of Co-morbidities (Developed by KECC)
Cancer (excludes non-melanoma skin cancer includes some benign CNS neoplasms)
141 MAL NEOPLASM TONGUE
141.0 MAL NEO TONGUE BASE
141.1 MAL NEO DORSAL TONGUE
141.2 MAL NEO TIP/LAT TONGUE
141.3 MAL NEO VENTRAL TONGUE
141.4 MAL NEO ANT 2/3 TONGUE
141.5 MAL NEO TONGUE JUNCTION
141.6 MAL NEO LINGUAL TONSIL
141.8 MALIG NEO TONGUE NEC
141.9 MALIG NEO TONGUE NOS
142 Malignant neoplasm maj salivary/parotid
142.0 MALIG NEO PAROTID
142.1 MALIG NEO SUBMANDIBULAR
142.2 MALIG NEO SUBLINGUAL
142.8 MAL NEO MAJ SALIVARY NEC
142.9 MAL NEO SALIVARY NOS
143 malignant neoplasm gum
143.0 MALIG NEO UPPER GUM
143.1 MALIG NEO LOWER GUM
143.8 MALIG NEO GUM NEC
143.9 MALIG NEO GUM NOS
144 malignant neoplasm floor of mouth
144.0 MAL NEO ANT FLOOR MOUTH

144.1 MAL NEO LAT FLOOR MOUTH
144.8 MAL NEO MOUTH FLOOR NEC
144.9 MAL NEO MOUTH FLOOR NOS
145 malignant neo other/unspec mouth parts
145.0 MAL NEO CHEEK MUCOSA
145.1 MAL NEO MOUTH VESTIBULE
145.2 MALIG NEO HARD PALATE
145.3 MALIG NEO SOFT PALATE
145.4 MALIGNANT NEOPLASM UVULA
145.5 MALIGNANT NEO PALATE NOS
145.6 MALIG NEO RETROMOLAR
145.8 MALIG NEOPLASM MOUTH NEC
145.9 MALIG NEOPLASM MOUTH NOS
146 malignant neoplasm oropharynx
146.0 MALIGNANT NEOPL TONSIL
146.1 MAL NEO TONSILLAR FOSSA
146.2 MAL NEO TONSIL PILLARS
146.3 MALIGN NEOPL VALLECULA
146.4 MAL NEO ANT EPIGLOTTIS
146.5 MAL NEO EPIGLOTTIS JUNCT
146.6 MAL NEO LAT OROPHARYNX
146.7 MAL NEO POST OROPHARYNX
146.8 MAL NEO OROPHARYNX NEC
146.9 MALIG NEO OROPHARYNX NOS
147 malignant neoplasm nasopharynx

147.0 MAL NEO SUPER NASOPHARYN
147.1 MAL NEO POST NASOPHARYNX
147.2 MAL NEO LAT NASOPHARYNX
147.3 MAL NEO ANT NASOPHARYNX
147.8 MAL NEO NASOPHARYNX NEC
147.9 MAL NEO NASOPHARYNX NOS
148 malignant neoplasm hypopharynx
148.0 MAL NEO POSTCRICOID
148.1 MAL NEO PYRIFORM SINUS
148.2 MAL NEO ARYEPIGLOTT FOLD
148.3 MAL NEO POST HYPOPHARYNX
148.8 MAL NEO HYPOPHARYNX NEC
148.9 MAL NEO HYPOPHARYNX NOS
149 mal neo other/ill-defined lip/oral cavity/pharynx
149.0 MAL NEO PHARYNX NOS
149.1 MAL NEO WALDEYER'S RING
149.8 MAL NEO ORAL/PHARYNX NEC
149.9 MAL NEO OROPHRYN ILL-DEF
150 malignant neoplasm esophagus
150.0 MAL NEO CERVICAL ESOPHAG
150.1 MAL NEO THORACIC ESOPHAG
150.2 MAL NEO ABDOMIN ESOPHAG
150.3 MAL NEO UPPER 3RD ESOPH
150.4 MAL NEO MIDDLE 3RD ESOPH
150.5 MAL NEO LOWER 3RD ESOPH

150.8 MAL NEO ESOPHAGUS NEC
150.9 MAL NEO ESOPHAGUS NOS
151 malignant neoplasm stomach
151.0 MAL NEO STOMACH CARDIA
151.1 MALIGNANT NEO PYLORUS
151.2 MAL NEO PYLORIC ANTRUM
151.3 MAL NEO STOMACH FUNDUS
151.4 MAL NEO STOMACH BODY
151.5 MAL NEO STOM LESSER CURV
151.6 MAL NEO STOM GREAT CURV
151.8 MALIG NEOPL STOMACH NEC
151.9 MALIG NEOPL STOMACH NOS
152 malignant neo sm intestine/duodenum
152.0 MALIGNANT NEOPL DUODENUM
152.1 MALIGNANT NEOPL JEJUNUM
152.2 MALIGNANT NEOPLASM ILEUM
152.3 MAL NEO MECKEL'S DIVERT
152.8 MAL NEO SMALL BOWEL NEC
152.9 MAL NEO SMALL BOWEL NOS
153 malignat neoplasm colon
153.0 MAL NEO HEPATIC FLEXURE
153.1 MAL NEO TRANSVERSE COLON
153.2 MAL NEO DESCEND COLON
153.3 MAL NEO SIGMOID COLON
153.4 MALIGNANT NEOPLASM CECUM

153.5 MALIGNANT NEO APPENDIX
153.6 MALIG NEO ASCEND COLON
153.7 MAL NEO SPLENIC FLEXURE
153.8 MALIGNANT NEO COLON NEC
153.9 MALIGNANT NEO COLON NOS
154 malig neo rectum/rectosigmoid junct/anus
154.0 MAL NEO RECTOSIGMOID JCT
154.1 MALIGNANT NEOPL RECTUM
154.2 MALIG NEOPL ANAL CANAL
154.3 MALIGNANT NEO ANUS NOS
154.8 MAL NEO RECTUM/ANUS NEC
155 mal neo liver/intrahepatic bile ducts
155.0 MAL NEO LIVER, PRIMARY
155.1 MAL NEO INTRAHEPAT DUCTS
155.2 MALIGNANT NEO LIVER NOS
156 mal neo gall bladder/Xhepatic bile ducts
156.0 MALIG NEO GALLBLADDER
156.1 MAL NEO EXTRAHEPAT DUCTS
156.2 MAL NEO AMPULLA OF VATER
156.8 MALIG NEO BILIARY NEC
156.9 MALIG NEO BILIARY NOS
157 malig neo pancreas
157.0 MAL NEO PANCREAS HEAD
157.1 MAL NEO PANCREAS BODY
157.2 MAL NEO PANCREAS TAIL

157.3 MAL NEO PANCREATIC DUCT
157.4 MAL NEO ISLET LANGERHANS
157.8 MALIG NEO PANCREAS NEC
157.9 MALIG NEO PANCREAS NOS
158 mal neo retroperitoneum/peritoneum
158.0 MAL NEO RETROPERITONEUM
158.8 MAL NEO PERITONEUM NEC
158.9 MAL NEO PERITONEUM NOS
159 mal neo other/ill-defined digest org/peritone
159.0 MALIG NEO INTESTINE NOS
159.1 MALIGNANT NEO SPLEEN NEC
159.8 MAL NEO GI/INTRA-ABD NEC
159.9 MAL NEO GI TRACT ILL-DEF
160 mal neo nas cavities/mid ear/access sinuses
160.0 MAL NEO NASAL CAVITIES
160.1 MALIG NEO MIDDLE EAR
160.2 MAL NEO MAXILLARY SINUS
160.3 MAL NEO ETHMOIDAL SINUS
160.4 MALIG NEO FRONTAL SINUS
160.5 MAL NEO SPHENOID SINUS
160.8 MAL NEO ACCESS SINUS NEC
160.9 MAL NEO ACCESS SINUS NOS
161 malignant neo larynx
161.0 MALIGNANT NEO GLOTTIS
161.1 MALIG NEO SUPRAGLOTTIS

161.2 MALIG NEO SUBGLOTTIS
161.3 MAL NEO CARTILAGE LARYNX
161.8 MALIGNANT NEO LARYNX NEC
161.9 MALIGNANT NEO LARYNX NOS
162 mal neo trachea/bronchus/lung
162.0 MALIGNANT NEO TRACHEA
162.2 MALIG NEO MAIN BRONCHUS
162.3 MAL NEO UPPER LOBE LUNG
162.4 MAL NEO MIDDLE LOBE LUNG
162.5 MAL NEO LOWER LOBE LUNG
162.8 MAL NEO BRONCH/LUNG NEC
162.9 MAL NEO BRONCH/LUNG NOS
163 malignant neo pleura
163.0 MAL NEO PARIETAL PLEURA
163.1 MAL NEO VISCERAL PLEURA
163.8 MALIG NEOPL PLEURA NEC
163.9 MALIG NEOPL PLEURA NOS
164 mal neo thymus/heart/mediastinum
164.0 MALIGNANT NEOPL THYMUS
164.1 MALIGNANT NEOPL HEART
164.2 MAL NEO ANT MEDIASTINUM
164.3 MAL NEO POST MEDIASTINUM
164.8 MAL NEO MEDIASTINUM NEC
164.9 MAL NEO MEDIASTINUM NOS
165 mal neo othr/ill-defined resp syst/intrathoracic

165.0 MAL NEO UPPER RESP NOS
165.8 MAL NEO THORAX/RESP NEC
165.9 MAL NEO RESP SYSTEM NOS
170 mal neo bone/articular cartilage
170.0 MAL NEO SKULL/FACE BONE
170.1 MALIGNANT NEO MANDIBLE
170.2 MALIG NEO VERTEBRAE
170.3 MAL NEO RIBS/STERN/CLAV
170.4 MAL NEO LONG BONES ARM
170.5 MAL NEO BONES WRIST/HAND
170.6 MAL NEO PELVIC GIRDLE
170.7 MAL NEO LONG BONES LEG
170.8 MAL NEO BONES ANKLE/FOOT
170.9 MALIG NEOPL BONE NOS
171 mal neo connective/other soft tissue
171.0 MAL NEO SOFT TISSUE HEAD
171.2 MAL NEO SOFT TISSUE ARM
171.3 MAL NEO SOFT TISSUE LEG
171.4 MAL NEO SOFT TIS THORAX
171.5 MAL NEO SOFT TIS ABDOMEN
171.6 MAL NEO SOFT TIS PELVIS
171.7 MAL NEOPL TRUNK NOS
171.8 MAL NEO SOFT TISSUE NEC
171.9 MAL NEO SOFT TISSUE NOS
172 mal melanoma skin

172.0 MALIG MELANOMA LIP
172.1 MALIG MELANOMA EYELID
172.2 MALIG MELANOMA EAR
172.3 MAL MELANOM FACE NEC/NOS
172.4 MAL MELANOMA SCALP/NECK
172.5 MALIG MELANOMA TRUNK
172.6 MALIG MELANOMA ARM
172.7 MALIG MELANOMA LEG
172.8 MALIG MELANOMA SKIN NEC
172.9 MALIG MELANOMA SKIN NOS
174 malignant neoplasm female breast
174.0 MALIG NEO NIPPLE
174.1 MAL NEO BREAST-CENTRAL
174.2 MAL NEO BREAST UP-INNER
174.3 MAL NEO BREAST LOW-INNER
174.4 MAL NEO BREAST UP-OUTER
174.5 MAL NEO BREAST LOW-OUTER
174.6 MAL NEO BREAST-AXILLARY
174.8 MALIGN NEOPL BREAST NEC
174.9 MALIGN NEOPL BREAST NOS
175 malignant neoplasm male breast
175.0 MAL NEO MALE NIPPLE
175.9 MAL NEO MALE BREAST NEC
176 Kaposi's sarcoma
176.0 SKIN - KAPOSI'S SARCOMA

176.1 SFT TISUE - KPSI'S SRCMA
176.2 PALATE - KPSI'S SARCOMA
176.3 GI SITES - KPSI'S SRCOMA
176.4 LUNG - KAPOSI'S SARCOMA
176.5 LYM NDS - KPSI'S SARCOMA
176.8 SPF STS - KPSI'S SARCOMA
176.9 KAPOSI'S SARCOMA NOS
179 MALIG NEOPL UTERUS NOS
180 malignant neoplasm cervix uteri
180.0 MALIG NEO ENDOCERVIX
180.1 MALIG NEO EXOCERVIX
180.8 MALIG NEO CERVIX NEC
180.9 MAL NEO CERVIX UTERI NOS
181 MALIGNANT NEOPL PLACENTA
182 malignant neoplasm uterine body
182.0 MALIG NEO CORPUS UTERI
182.1 MAL NEO UTERINE ISTHMUS
182.8 MAL NEO BODY UTERUS NEC
183 malignant neo ovary/other uterine adnexa
183.0 MALIGN NEOPL OVARY
183.2 MAL NEO FALLOPIAN TUBE
183.3 MAL NEO BROAD LIGAMENT
183.4 MALIG NEO PARAMETRIUM
183.5 MAL NEO ROUND LIGAMENT
183.8 MAL NEO ADNEXA NEC

183.9 MAL NEO ADNEXA NOS
184 malignant neo other/unspec female genitals
184.0 MALIGN NEOPL VAGINA
184.1 MAL NEO LABIA MAJORA
184.2 MAL NEO LABIA MINORA
184.3 MALIGN NEOPL CLITORIS
184.4 MALIGN NEOPL VULVA NOS
184.8 MAL NEO FEMALE GENIT NEC
184.9 MAL NEO FEMALE GENIT NOS
185 MALIGN NEOPL PROSTATE
186 malignant neoplasm testis
186.0 MAL NEO UNDESCEND TESTIS
186.9 MALIG NEO TESTIS NEC
187 malignant neo penis/other male genitals
187.1 MALIGN NEOPL PREPUCE
187.2 MALIG NEO GLANS PENIS
187.3 MALIG NEO PENIS BODY
187.4 MALIG NEO PENIS NOS
187.5 MALIG NEO EPIDIDYMIS
187.6 MAL NEO SPERMATIC CORD
187.7 MALIGN NEOPL SCROTUM
187.8 MAL NEO MALE GENITAL NEC
187.9 MAL NEO MALE GENITAL NOS
188 malignant neoplasm bladder
188.0 MAL NEO BLADDER-TRIGONE

188.1 MAL NEO BLADDER-DOME
188.2 MAL NEO BLADDER-LATERAL
188.3 MAL NEO BLADDER-ANTERIOR
188.4 MAL NEO BLADDER-POST
188.5 MAL NEO BLADDER NECK
188.6 MAL NEO URETERIC ORIFICE
188.7 MALIG NEO URACHUS
188.8 MALIG NEO BLADDER NEC
188.9 MALIG NEO BLADDER NOS
189 mal neo kidney/other/unspec urinary organs
189.0 MALIG NEOPL KIDNEY
189.1 MALIG NEO RENAL PELVIS
189.2 MALIGN NEOPL URETER
189.3 MALIGN NEOPL URETHRA
189.4 MAL NEO PARAURETHRAL
189.8 MAL NEO URINARY NEC
189.9 MAL NEO URINARY NOS
190 malignant neoplasm eye
190.0 MALIGN NEOPL EYEBALL
190.1 MALIGN NEOPL ORBIT
190.2 MAL NEO LACRIMAL GLAND
190.3 MAL NEO CONJUNCTIVA
190.4 MALIGN NEOPL CORNEA
190.5 MALIGN NEOPL RETINA
190.6 MALIGN NEOPL CHOROID

190.7 MAL NEO LACRIMAL DUCT
190.8 MALIGN NEOPL EYE NEC
190.9 MALIGN NEOPL EYE NOS
191 malignant neoplasm brain
191.0 MALIGN NEOPL CEREBRUM
191.1 MALIG NEO FRONTAL LOBE
191.2 MAL NEO TEMPORAL LOBE
191.3 MAL NEO PARIETAL LOBE
191.4 MAL NEO OCCIPITAL LOBE
191.5 MAL NEO CEREB VENTRICLE
191.6 MAL NEO CEREBELLUM NOS
191.7 MAL NEO BRAIN STEM
191.8 MALIG NEO BRAIN NEC
191.9 MALIG NEO BRAIN NOS
192 mal neo other/unspec nervous system
192.0 MAL NEO CRANIAL NERVES
192.1 MAL NEO CEREBRAL MENING
192.2 MAL NEO SPINAL CORD
192.3 MAL NEO SPINAL MENINGES
192.8 MAL NEO NERVOUS SYST NEC
192.9 MAL NEO NERVOUS SYST NOS
193 MALIGN NEOPL THYROID
194 mal neo other endocrine/related structures
194.0 MALIGN NEOPL ADRENAL
194.1 MALIG NEO PARATHYROID

194.3 MALIG NEO PITUITARY
194.4 MALIGN NEO PINEAL GLAND
194.5 MAL NEO CAROTID BODY
194.6 MAL NEO PARAGANGLIA NEC
194.8 MAL NEO ENDOCRINE NEC
194.9 MAL NEO ENDOCRINE NOS
195 mal neo other/ill-defined sites
195.0 MAL NEO HEAD/FACE/NECK
195.1 MALIGN NEOPL THORAX
195.2 MALIG NEO ABDOMEN
195.3 MALIGN NEOPL PELVIS
195.4 MALIGN NEOPL ARM
195.5 MALIGN NEOPL LEG
195.8 MALIG NEO SITE NEC
196 secondry/unspec mal neo lymph nodes
196.0 MAL NEO LYMPH-HEAD/NECK
196.1 MAL NEO LYMPH-INTRATHOR
196.2 MAL NEO LYMPH INTRA-ABD
196.3 MAL NEO LYMPH-AXILLA/ARM
196.5 MAL NEO LYMPH-INGUIN/LEG
196.6 MAL NEO LYMPH-INTRAPELV
196.8 MAL NEO LYMPH NODE-MULT
196.9 MAL NEO LYMPH NODE NOS
197 secondary mal neo resp/digestive systems
197.0 SECONDARY MALIG NEO LUNG

197.1 SEC MAL NEO MEDIASTINUM
197.2 SECOND MALIG NEO PLEURA
197.3 SEC MALIG NEO RESP NEC
197.4 SEC MALIG NEO SM BOWEL
197.5 SEC MALIG NEO LG BOWEL
197.6 SEC MAL NEO PERITONEUM
197.7 SECOND MALIG NEO LIVER
197.8 SEC MAL NEO GI NEC
198 secondary mal neo other spec sites
198.0 SECOND MALIG NEO KIDNEY
198.1 SEC MALIG NEO URIN NEC
198.2 SECONDARY MALIG NEO SKIN
198.3 SEC MAL NEO BRAIN/SPINE
198.4 SEC MALIG NEO NERVE NEC
198.5 SECONDARY MALIG NEO BONE
198.6 SECOND MALIG NEO OVARY
198.7 SECOND MALIG NEO ADRENAL
198.81 SECOND MALIG NEO BREAST
198.82 SECOND MALIG NEO GENITAL
198.89 SECONDARY MALIG NEO NEC
199 mal neo w/o site specification
199.0 MALIG NEO DISSEMINATED
199.1 MALIGNANT NEOPLASM NOS
199.2 MAL NEO ASSOC W/ TRANSPLANT ORG
200 lymphosarcoma & reticulosarcoma

200.00 RETCLSRC UNSP XTRNDL ORG
200.01 RETICULOSARCOMA HEAD
200.02 RETICULOSARCOMA THORAX
200.03 RETICULOSARCOMA ABDOM
200.04 RETICULOSARCOMA AXILLA
200.05 RETICULOSARCOMA INGUIN
200.06 RETICULOSARCOMA PELVIC
200.07 RETICULOSARCOMA SPLEEN
200.08 RETICULOSARCOMA MULT
200.1 lymphosarcoma/reticulosarcoma/lymphosarc
200.10 LYMPHSRC UNSP XTRNDL ORG
200.11 LYMPHOSARCOMA HEAD
200.12 LYMPHOSARCOMA THORAX
200.13 LYMPHOSARCOMA ABDOM
200.14 LYMPHOSARCOMA AXILLA
200.15 LYMPHOSARCOMA INGUIN
200.16 LYMPHOSARCOMA PELVIC
200.17 LYMPHOSARCOMA SPLEEN
200.18 LYMPHOSARCOMA MULT
200.2 lymphosarc/reticulosarc, Brkt tmr/lymphoma
200.20 BRKT TMR UNSP XTRNDL ORG
200.21 BURKITT'S TUMOR HEAD
200.22 BURKITT'S TUMOR THORAX
200.23 BURKITT'S TUMOR ABDOM
200.24 BURKITT'S TUMOR AXILLA

200.25 BURKITT'S TUMOR INGUIN
200.26 BURKITT'S TUMOR PELVIC
200.27 BURKITT'S TUMOR SPLEEN
200.28 BURKITT'S TUMOR MULT
200.8 lymphosarcoma/reticulsarcoma other variants
200.80 OTH VARN UNSP XTRNDL ORG
200.81 MIXED LYMPHOSARC HEAD
200.82 MIXED LYMPHOSARC THORAX
200.83 MIXED LYMPHOSARC ABDOM
200.84 MIXED LYMPHOSARC AXILLA
200.85 MIXED LYMPHOSARC INGUIN
200.86 MIXED LYMPHOSARC PELVIC
200.87 MIXED LYMPHOSARC SPLEEN
200.88 MIXED LYMPHOSARC MULT
201 Hodgkin's disease
201.0 Hodgkin's disease Hodgkin's paragranuloma
201.00 HDGK PRG UNSP XTRNDL ORG
201.01 HODGKINS PARAGRAN HEAD
201.02 HODGKINS PARAGRAN THORAX
201.03 HODGKINS PARAGRAN ABDOM
201.04 HODGKINS PARAGRAN AXILLA
201.05 HODGKINS PARAGRAN INGUIN
201.06 HODGKINS PARAGRAN PELVIC
201.07 HODGKINS PARAGRAN SPLEEN
201.08 HODGKINS PARAGRAN MULT

201.1 Hodgkin's disease Hodgkin's granuloma
201.11 HODGKINS GRANULOM HEAD
201.10 H's dis H's granuloma unspec/Xnodal/sol org
201.12 HODGKINS GRANULOM THORAX
201.13 HODGKINS GRANULOM ABDOM
201.14 HODGKINS GRANULOM AXILLA
201.15 HODGKINS GRANULOM INGUIN
201.16 HODGKINS GRANULOM PELVIC
201.17 HODGKINS GRANULOM SPLEEN
201.18 HODGKINS GRANULOM MULT
201.2 Hodgkin's disease Hodgkin's sarcoma
201.20 HDGK SRC UNSP XTRNDL ORG
201.21 HODGKINS SARCOMA HEAD
201.22 HODGKINS SARCOMA THORAX
201.23 HODGKINS SARCOMA ABDOM
201.24 HODGKINS SARCOMA AXILLA
201.25 HODGKINS SARCOMA INGUIN
201.26 HODGKINS SARCOMA PELVIC
201.27 HODGKINS SARCOMA SPLEEN
201.28 HODGKINS SARCOMA MULT
201.4 Hodgkin's disease lymphocystic-histiocytic
201.40 LYM-HST UNSP XTRNDL ORGN
201.41 HODG LYMPH-HISTIO HEAD
201.42 HODG LYMPH-HISTIO THORAX
201.43 HODG LYMPH-HISTIO ABDOM

201.44 HODG LYMPH-HISTIO AXILLA
201.45 HODG LYMPH-HISTIO INGUIN
201.46 HODG LYMPH-HISTIO PELVIC
201.47 HODG LYMPH-HISTIO SPLEEN
201.48 HODG LYMPH-HISTIO MULT
201.5 Hodgkin's disease nodular sclerosis
201.50 NDR SCLR UNSP XTRNDL ORG
201.51 HODG NODUL SCLERO HEAD
201.52 HODG NODUL SCLERO THORAX
201.53 HODG NODUL SCLERO ABDOM
201.54 HODG NODUL SCLERO AXILLA
20155 HODG NODUL SCLERO INGUIN
201.56 HODG NODUL SCLERO PELVIC
201.57 HODG NODUL SCLERO SPLEEN
201.58 HODG NODUL SCLERO MULT
201.6 Hodgkin's disease mixed cellularity
201.60 MXD CELR UNSP XTRNDL ORG
201.61 HODGKINS MIX CELL HEAD
201.62 HODGKINS MIX CELL THORAX
201.63 HODGKINS MIX CELL ABDOM
201.64 HODGKINS MIX CELL AXILLA
201.66 HODGKINS MIX CELL PELVIC
201.67 HODGKINS MIX CELL SPLEEN
201.68 HODGKINS MIX CELL MULT
201.7 Hodgkin's disease lymphocytic depletion

201.70 LYM DPLT UNSP XTRNDL ORG
201.71 HODG LYMPH DEPLET HEAD
201.72 HODG LYMPH DEPLET THORAX
201.73 HODG LYMPH DEPLET ABDOM
201.74 HODG LYMPH DEPLET AXILLA
201.75 HODG LYMPH DEPLET INGUIN
201.76 HODG LYMPH DEPLET PELVIC
201.77 HODG LYMPH DEPLET SPLEEN
201.78 HODG LYMPH DEPLET MULT
201.9 Hodgkin's disease unspec
201.90 HDGK DIS UNSP XTRNDL ORG
201.91 HODGKINS DIS NOS HEAD
201.92 HODGKINS DIS NOS THORAX
201.93 HODGKINS DIS NOS ABDOM
201.94 HODGKINS DIS NOS AXILLA
201.95 HODGKINS DIS NOS INGUIN
201.96 HODGKINS DIS NOS PELVIC
201.97 HODGKINS DIS NOS SPLEEN
201.98 HODGKINS DIS NOS MULT
202 other mal neo lymphoid/histiocytic tissue
202.0 nodular lymphoma
202.00 NDLR LYM UNSP XTRNDL ORG
202.01 NODULAR LYMPHOMA HEAD
202.02 NODULAR LYMPHOMA THORAX
202.03 NODULAR LYMPHOMA ABDOM

202.04 NODULAR LYMPHOMA AXILLA
202.05 NODULAR LYMPHOMA INGUIN
202.06 NODULAR LYMPHOMA PELVIC
202.07 NODULAR LYMPHOMA SPLEEN
202.08 NODULAR LYMPHOMA MULT
202.1 other mal neo lymphoid/histiocytic tissue; mycosis fungoides
202.10 MYCS FNG UNSP XTRNDL ORG
202.11 MYCOSIS FUNGOIDES HEAD
202.12 MYCOSIS FUNGOIDES THORAX
202.13 MYCOSIS FUNGOIDES ABDOM
202.14 MYCOSIS FUNGOIDES AXILLA
202.15 MYCOSIS FUNGOIDES INGUIN
202.16 MYCOSIS FUNGOIDES PELVIC
202.17 MYCOSIS FUNGOIDES SPLEEN
202.18 MYCOSIS FUNGOIDES MULT
202.2 other mal neo lymphoid/histiocytic tissue; SZRY's disease
202.20 SZRY DIS UNSP XTRNDL ORG
202.21 SEZARY'S DISEASE HEAD
202.22 SEZARY'S DISEASE THORAX
202.23 SEZARY'S DISEASE ABDOM
202.24 SEZARY'S DISEASE AXILLA
202.25 SEZARY'S DISEASE INGUIN
202.26 SEZARY'S DISEASE PELVIC
202.27 SEZARY'S DISEASE SPLEEN
202.28 SEZARY'S DISEASE MULT

202.3 other mal neo lymphoid/histiocytic tissue; mal histiocytosis
202.30 MLG HIST UNSP XTRNDL ORG
202.31 MAL HISTIOCYTOSIS HEAD
202.32 MAL HISTIOCYTOSIS THORAX
202.33 MAL HISTIOCYTOSIS ABDOM
202.34 MAL HISTIOCYTOSIS AXILLA
202.35 MAL HISTIOCYTOSIS INGUIN
202.36 MAL HISTIOCYTOSIS PELVIC
202.37 MAL HISTIOCYTOSIS SPLEEN
202.38 MAL HISTIOCYTOSIS MULT
202.4 other mal neo lymphoid/histiocytic tis, leukemic reticuloendotheliosis
202.40 LK RTCTL UNSP XTRNDL ORG
202.41 HAIRY-CELL LEUKEM HEAD
202.42 HAIRY-CELL LEUKEM THORAX
202.43 HAIRY-CELL LEUKEM ABDOM
202.44 HAIRY-CELL LEUKEM AXILLA
202.45 HAIRY-CELL LEUKEM INGUIN
202.46 HAIRY-CELL LEUKEM PELVIC
202.47 HAIRY-CELL LEUKEM SPLEEN
202.48 HAIRY-CELL LEUKEM MULT
202.5 other mal neo lymphoid/histiocytic tis, LTR-SIWE dis
202.50 LTR-SIWE UNSP XTRNDL ORG
202.51 LETTERER-SIWE DIS HEAD
202.52 LETTERER-SIWE DIS THORAX
202.53 LETTERER-SIWE DIS ABDOM

202.54 LETTERER-SIWE DIS AXILLA
202.55 LETTERER-SIWE DIS INGUIN
202.56 LETTERER-SIWE DIS PELVIC
202.57 LETTERER-SIWE DIS SPLEEN
202.58 LETTERER-SIWE DIS MULT
202.6 other mal neo lymphoid/histiocytic tis, mal mast cell tumors
202.60 MLG MAST UNSP XTRNDL ORG
202.61 MAL MASTOCYTOSIS HEAD
202.62 MAL MASTOCYTOSIS THORAX
202.63 MAL MASTOCYTOSIS ABDOM
202.64 MAL MASTOCYTOSIS AXILLA
202.65 MAL MASTOCYTOSIS INGUIN
202.66 MAL MASTOCYTOSIS PELVIC
202.67 MAL MASTOCYTOSIS SPLEEN
202.68 MAL MASTOCYTOSIS MULT
202.8 other lymphomas
202.80 OTH LYMP UNSP XTRNDL ORG
202.81 LYMPHOMAS NEC HEAD
202.82 LYMPHOMAS NEC THORAX
202.83 LYMPHOMAS NEC ABDOM
202.84 LYMPHOMAS NEC AXILLA
202.85 LYMPHOMAS NEC INGUIN
202.86 LYMPHOMAS NEC PELVIC
202.87 LYMPHOMAS NEC SPLEEN
202.88 LYMPHOMAS NEC MULT

202.9 othr mal neo lymphoid/histiocytic tis, othr/unspec
202.90 UNSP LYM UNSP XTRNDL ORG
202.91 LYMPHOID MAL NEC HEAD
202.92 LYMPHOID MAL NEC THORAX
202.93 LYMPHOID MAL NEC ABDOM
202.94 LYMPHOID MAL NEC AXILLA
202.95 LYMPHOID MAL NEC INGUIN
202.96 LYMPHOID MAL NEC PELVIC
202.97 LYMPHOID MAL NEC SPLEEN
202.98 LYMPHOID MAL NEC MULT
203 mult myeloma/immunoproliferative neoplasms
203.0 multiple myeloma
203.00 MULT MYELM W/O REMISSION
203.01 MULT MYELM W REMISSION
203.1 plasma cell leukemia
203.10 PLSM CELL LEUK W/O RMSON
203.11 PLSM CELL LEUK W RMSON
203.8 other immunoproliferative neoplasms
203.80 OTH IMNPRFL NPL W/O RMSN
203.81 OTH IMNPRFL NPL W RMSN
204 lymphoid leukemia
204.0 acute lymphoid leukemia
204.00 ACT LYM LEUK W/O RMSION
204.01 ACT LYM LEUK W RMSION
204.02 AC LYMPHOID LEUKEMIA, IN RELAPSE

204.1 chronic lymphoid leukemia
204.10 CHR LYM LEUK W/O RMSION
204.11 CHR LYM LEUK W RMSION
204.12 CHR LYM LEUK, IN RELAPSE
204.2 subacute lymphoid leukemia
204.20 SBAC LYM LEUK W/O RMSION
204.21 SBAC LYM LEUK W RMSION
204.8 lymphoid leukemia other
204.80 OTH LYM LEUK W/O RMSION
204.81 OTH LYM LEUK W RMSION
204.9 lymphoid leukemia unspec
204.90 UNS LYM LEUK W/O RMSION
204.91 UNS LYM LEUK W RMSION
205 myeloid leukemia
205.0 acute myeloid leukemia
205.00 ACT MYL LEUK W/O RMSION
205.01 ACT MYL LEUK W RMSION
205.1 chronic myeloid leukemia
205.10 CHR MYL LEUK W/O RMSION
205.11 CHR MYL LEUK W RMSION
205.2 subacute myeloid leukemia
205.20 SBAC MYL LEUK W/O RMSION
205.21 SBAC MYL LEUK W RMSION
205.22 SBAC MYL LEUK, IN RELAPSE
205.3 myeloid leukemia, myeloid sarcoma

205.30 MYL SRCOMA W/O RMSION
205.31 MYL SRCOMA W RMSION
205.8 myeloid leukemia other
205.80 OTH MYL LEUK W/O RMSION
205.81 OTH MYL LEUK W RMSION
205.9 myeloid leukemia unspec
205.90 UNS MYL LEUK W/O RMSION
205.91 UNS MYL LEUK W RMSION
206 monocytic leukemia
206.0 acute monocytic leukemia
206.00 ACT MONO LEUK W/O RMSION
206.01 ACT MONO LEUK W RMSION
206.1 chronic monocytic leukemia
206.10 CHR MONO LEUK W/O RMSION
206.11 CHR MONO LEUK W RMSION
206.2 subacute monocytic leukemia
206.20 SBAC MONO LEUK W/O RMSON
206.21 SBAC MONO LEUK W RMSION
206.8 monocytic leukemia other
206.80 OTH MONO LEUK W/O RMSION
206.81 OTH MONO LEUK W RMSION
206.9 monocytic leukemia unspec
206.90 UNS MONO LEUK W/O RMSION
206.91 UNS MONO LEUK W RMSION
207 other spec leukemia

207.0 other specif leukemia, ac erythremia/erythroleukemia
207.00 ACT ERTH/ERYLK W/O RMSON
207.01 ACT ERTH/ERYLK W RMSON
207.1 other specif leukemia, chronic erythremia
207.10 CHR ERYTHRM W/O REMISION
207.11 CHR ERYTHRM W REMISION
207.2 other specif leukemia, megakaryocytic leuk
207.20 MGKRYCYT LEUK W/O RMSION
207.21 MGKRYCYT LEUK W RMSION
207.8 other specif leukemia other
207.80 OTH SPF LEUK W/O REMSION
207.81 OTH SPF LEUK W REMSION
208 leukemia unspecified cell type
208.0 acute leukemia unspecified cell type
208.00 ACT LEUK UNS CL W/O RMSN
208.01 ACT LEUK UNS CL W RMSON
208.1 chronic leukemia unspec cell type
208.10 CHR LEUK UNS CL W/O RMSN
208.11 CHR LEUK UNS CL W RMSON
208.2 subacute leukemia unspec cell type
208.20 SBAC LEUK UNS CL W/O RMS
208.21 SBAC LEUK UNS CL W RMSON
208.8 leukemia unspecified cell type other
208.80 OTH LEUK UNS CL W/O RMSN
208.81 OTH LEUK UNS CL W RMSON

208.9 leukemia unspec cell type unspec
208.90 LEUKEMIA NOS W/O REMSION
208.91 LEUKEMIA NOS W REMISSION
209.00 Mal carcinoid tmr sm intest, unspec portion
209.01 Malignant carcinoid tumor of the duodenum
209.02 Malignant carcinoid tumor of the jejunum
209.03 Malignant carcinoid tumor of the ileum
209.10 Mal carcinoid tmr lge intest, unspec portion
209.11 Malignant carcinoid tumor of the appendix
209.12 Malignant carcinoid tumor of the cecum
209.13 Malig carcinoid tumor of the ascend colon
209.14 Mal carcinoid tumor of the transverse colon
209.15 Mal carcinoid tumor of the descending colon
209.16 Mal carcinoid tumor of the sigmoid colon
209.17 Malignant carcinoid tumor of the rectum
209.20 Mal carcinoid tumor of unknown primary site
209.21 Mal carcinoid tumor of the bronchus and lung
209.22 Malignant carcinoid tumor of the thymus
209.23 Malignant carcinoid tumor of the stomach
209.24 Malignant carcinoid tumor of the kidney
209.25 Mal carcinoid tumor of foregut, NOS
209.26 Malignant carcinoid tumor of midgut, NOS
209.27 Malignant carcinoid tumor of hindgut, NOS
209.29 Malignant carcinoid tumor of other sites
209.30 Mal poorly differentiat neuroendo Ca, any site

209.40 Ben carcinoid tmr sm intest, unspec portion
209.41 Benign carcinoid tumor of the duodenum
209.42 Benign carcinoid tumor of the jejunum
209.43 Benign carcinoid tumor of the ileum
209.50 Ben carcinoid tmr lge intest, unspec portion
209.51 Benign carcinoid tumor of the appendix
209.52 Benign carcinoid tumor of the cecum
209.53 Benign carcinoid tumor ascend colon
209.54 Ben carcinoid tumor of the transverse colon
209.55 Benign carcinoid tumor descend colon
209.56 Benign carcinoid tumor of the sigmoid colon
209.57 Benign carcinoid tumor of the rectum
209.60 Benign carcinoid tumor unknown primary site
209.61 Benign carcinoid tumor bronchus/lung
209.62 Benign carcinoid tumor thymus
209.63 Benign carcinoid tumor of the stomach
209.64 Benign carcinoid tumor of the kidney
209.65 Benign carcinoid tumor of foregut, NOS
209.66 Benign carcinoid tumor of midgut, NOS
209.67 Benign carcinoid tumor of hindgut, NOS
209.69 Benign carcinoid tumor of other sites
22.5 benign neo brain/other nervous system parts
225.0 BENIGN NEOPLASM BRAIN
225.1 BENIGN NEO CRANIAL NERVE
225.2 BEN NEO CEREBR MENINGES

225.3 BENIGN NEO SPINAL CORD
225.4 BEN NEO SPINAL MENINGES
225.8 BENIGN NEO NERV SYS NEC
225.9 BENIGN NEO NERV SYS NOS
226 BENIGN NEOPLASM THYROID
227.3 BENIGN NEO PITUITARY
227.4 BEN NEOPL PINEAL GLAND
228.02 HEMANGIOMA INTRACRANIAL
237.0 UNC BEHAV NEO PITUITARY
237.1 UNC BEHAV NEO PINEAL
237.3 UNC BEHAV NEO PARAGANG
237.5 UNC BEH NEO BRAIN/SPINAL
237.6 UNC BEHAV NEO MENINGES
237.7 neurofibromatosis
237.70 NEUROFIBROMATOSIS NOS
237.71 NEUROFIBROMATOSIS TYPE I
237.72 NEUROFIBROMATOSIS TYP II
237.9 UNC BEH NEO NERV SYS NEC
239.6 BRAIN NEOPLASM NOS
259.2 other endocr disorders, carcinoid syndrome
Drug and/or Alcohol Induced Mental Disorders
291 Alcoholic psychosis
291.0 DELIRIUM TREMENS
291.1 Alcohol psychosis, alcoh amnestic syndrome

291.2 Alcoholic psychosis, other alcohol dementia
291.3 Alcoh psychosis, alc withdrawal hallucinosis
291.4 Alcoh psycho, idiosyncratic alcoh intoxicat
291.5 Alcoholic psychoses, alcohol jealousy
291.8 Alcoh psychoses, other spec alcoh psycho
291.81 Alc psych othr spec alco psych/alc wthdrwl
291.89 Alco psych, other spec alco psycho, other
291.9 Alcoholic psychoses/unspec alcoh psycho
292 Drug psychoses
292.0 DRUG WITHDRAWAL
292.1 Paranoid/hallucinatory induced by drugs
292.11 Paranoid/hallucinatory drgs induced, drg-induced organic delusion syndrome
292.12 DRUG PSY DIS W HALLUCIN
292.2 PATHOLOGIC DRUG INTOX
292.8 other spec drug-induced mental disorders
292.81 othr spec drg-induced ment disorders, drg-induced delirium
292.82 other specified drug-induced mental disorders, drug-induced dementia
292.84 other specified drug-induced mental disorders, drug-induced organic affective syndrome
292.89 othr spec drg-induced ment disorders, othr
292.9 unspecified drug-induced mental disorders
303 alcohol dependence syndrome
303.0 alco depend syndrome, ac alcoho intox
303.00 AC ALCOHOL INTOX-UNSPEC
303.01 alco depend syndr, ac alcoho intox, contin
303.02 alc depend syndr, ac alco intox, episodic

303.03 alc depend syndr, ac alc intox, in remission
303.9 alc depend syndr, othr & unspec alc depend
303.90 alco depend syndr, othr & unspec alc depend unspec
303.91 alcohol dependence syndrome, other & unspecified alcohol dependence, continuous
303.92 alcohol dependence syndrome, other & unspecified alcohol dependence, episodic
303.93 alcohol dependence syndrome, other & unspecified alcohol dependence, in remission
304 drug dependence
304.0 drug dependence, opioid
304.00 drug dependence, opioid, unspecified
304.01 drug dependence, opioid, continuous
304.02 drug dependence, opioid, episodic
304.03 drug dependence, opioid, in remission
304.1 drg depend barbit/similarly acting sdtv/hypnotic depend
304.10 drug dependence barbiturate/similarly acting sedative/hypnotic dependence unspec
304.11 drug dependence barbiturate/similarly acting sedative/hypnotic dependence continuous
304.12 drug dependence barbiturate/similarly acting sedative/hypnotic dependence episodic
304.13 drug dependence barbiturate/similarly acting sedative/hypnotic dependence in remission
304.2 drug dependence, cocaine
304.20 drug dependence, cocaine unspecified
304.21 drug dependence, cocaine continuous
304.22 drug dependence, cocaine episodic
304.23 drug dependence, cocaine in remission
304.3 drug dependence, cannabis
304.30 drug dependence, cannabis unspecified
304.31 drug dependence, cannibis continuous

304.32 drug dependence, cannabis episodic
304.33 drug dependence, cannabis in remission
304.4 drg depend, amphetamine/othr psychostim
304.40 drg depend amphetamine/othr psychostim unspec
304.41 drg depend amphetamine/othr psychostim contin
304.42 drug dependence, amphetamine/other psychostimulant episodic
304.43 drug dependence, amphetamine/other psychostimulant episodic in remission
304.5 drug dependence hallucinogen
304.50 drug dependence hallucinogen unspec
304.51 drug dependence hallucinogen continuous
304.52 drug dependence hallucinogen episodic
304.53 drug depend hallucinogen in remission
304.6 other specified drug dependence
304.60 other specified drug dependence unspec
304.61 other specified drug dependence continuous
304.62 other specified drug dependence episodic
304.63 other spec drug dependence in remission
304.7 drug dependence opioid type w/other drug
304.70 drug depend opioid type w/other drug unspec
304.71 drug depend opioid type w/other drug contin
304.72 drug depend opioid type w/other drug episod
304.73 drg depend opioid w/othr drg in remission
304.8 drug depend combination w/o opioid
304.80 drug depend comb w/o opioid type unspec
304.81 drug depend comb w/o opioid type contin

304.82 drug depend comb w/o opioid type episodic
304.83 drug depend comb w/o opioid type episodic
304.9 drug dependence unspec dependence
304.90 drug dependence unspec depend unspec
304.91 drug depend unspec depend continuous
304.92 drug depend unspec dependence episodic
304.93 drug depend unspec depend in remission
305.0 nondependence drug abuse alcohol
305.00 nondependence drug abuse alcohol unspec
305.01 nondependence drug abuse alcohol contin
305.02 nondependence drug abuse alcohol episodic
305.03 nondepend drug abuse alcohol in remission
571.0 Alcoholic fatty liver
571.1 Acute alcoholic hepatitis
571.2 Alcoholic cirrhosis of liver
571.3 Alcoholic liver damage unspecified
V11.3 personal mental disorder history alcoholism
Cardiac Conditions
425.5 Alcoholic cardiomyeopathy
427.5 cardiac arrest
Pericarditis
420 acute pericarditis
420.0 ac pericarditis in dis classified elsewhere

420.9 other/unspec pericarditis
420.90 other/unspec pericard, ac pericard unspec
420.91 other/unspec pericard, ac idiopathic pericard
420.99 other/unspec pericarditis other
HIV/AIDS
042 HIV w/spec cond includes AIDS
V08 asymptotic HIV infection status
079.53 HIV-2 INFECTION OTH DIS
Hepatitis B
070.2 viral hepatitis B w/hepatic coma
070.20 viral hep B w/hep coma ac or unspec w/o hep delta
070.21 viral hepatitis B w/hepatic coma acute or unspec w/ hepatitis delta
070.22 viral hepatitis B w/hepatic coma chronic w/o hepatitis delta
070.23 viral hepatitis B w/hepatic coma chronic w/hepatitis delta
070.3 viral hepatitis B w/o hepatic coma
070.30 viral hepatitis B w/o hepatic coma acute or unspec w/o hepatitis delta
070.31 viral hepatitis B w/o hepatic coma acute or unspec w/ hepatitis delta
070.32 viral hepatitis B w/o hepatic coma chronic w/o hepatitis delta
070.33 viral hepatitis B w/ohepatic coma chronic w/ hepatitis delta
Septicemia and Shock
020.2 SEPTICEMIC PLAGUE
020.3 PRIMARY PNEUMONIC PLAGUE

031 diseases due to other mycobacteria
036.2 meningococcemia
038 septicemia
038.0 septicemia, streptococcal
038.1 septicemia, staphylococcal
038.10 septicemia, staphylococcal unspec
038.11 septicemia, staphylococcal staph aureus
038.19 septicemia, staphylococcal other
038.2 septicemia pneumococcal septicemia
038.3 septicemia due to anaerobes
038.4 septicemia due to other gram neg organisms
038.41 septicemia d/t othr gram neg hemophilus influenza
038.42 septicemia d/t othr gram neg org E coli
038.43 septice d/t othr gram neg org pseudomonas
038.44 septicemia d/t othr gram neg org serratia
038.49 septicemia d/t othr gram neg organism othr
038.8 septicemia other specified
038.9 septicemia other unspecified
040.82 toxic shock syndrome
054.5 herpetic septicemia
771.81 newborn septicemia
785.59 othr shock: endotox, gram neg hypovolem
Bacterial pneumonias/opportunistic infections/pneumococcal pneumonias
003.22 salmonella pneumonia

006.4 amebic lung abcess
007.4 cryptosporidosis
020.3 primary pneumonia
020.4 SECONDARY PNEUMON PLAGUE
020.5 pneumonic unspecified
021.2 PULMONARY TULAREMIA
022.1 PULMONARY ANTHRAX
031.2 disseminated mycobacteria
039.1 PULMONARY ACTINOMYCOSIS
078.5 CYTOMEGALOVIRAL DISEASE
112.4 candidiasis lung
112.5 candidiasis disseminated
112.84 candidal esophagitis
114.0 primary coccidioidomycosis pulmonary
114.4 chronic pulmonary coccidioidomycosis
114.5 primary coccidioidomycosis unspecified
115.05 histoplasma capsulatum pneumonia
115.15 histoplasma duboisii pneumonia
115.95 histoplasmosis unspecified pneumonia
117.3 aspergillosis
117.5 cryptococcosis
117.7 zygomycosis (phycomycosis/mucomycosis)
121.2 paragonimiais
122.1 echinoccus granulosis lung
130.0 toxoplasmosis meningoencephalitis

130.4 toxoplasmosis pneumonitis (strep pneumoniae pneumonia)
130.8 multisystemic disseminated toxoplasmosis
136.3 pneumocytosis
321.0 cryptococcal meningitis
481 pneumococcal pneumonia (streptococcus pneumoniae pneumonia)
482 other bacterial pneumonias
482.0 pneumonia due to Klebsiella pneumoniae
482.1 pneumonia due to pseudomonas
482.2 hemophilus influenzae pneumonia
482.3 streptococcus pneumonia
482.30 streptococcus pneumonia unspecified
482.31 streptococcus Group A pneumonia
482.32 streptococcus Group B pneumonia
482.39 streptococcus other strep pneumonia
482.4 pneumonia due to staphlococcus
482.40 pneumonia due to staphlococcus unspec
482.41 pneumonia due to staphlococcus aureus
482.49 pneumonia due to other staph pneumonia
482.8 pneumonia due to other specified bacteria
482.81 pneumonia due to anaerobes
482.82 pneumonia due to E. coli
482.83 pneumonia due to other gram neg bacteria
482.84 Legionnaires' disease
482.89 pneumonia due to other specified bacteria
484.1 cytomegalic inclusion disease pneumonia

484.6 aspergillosis pneumonia
484.7 other systemic mycoses pneumonia
507 pneumonitis due to solids & liquids
507.0 pneumonia due to inhalation of food/vomitus
507.1 pneumonia due to inhalation of oils/essences
507.8 pneumonitis due to other solids & liquids
510 empyema
510.0 empyema with fistula
510.9 empyema without fistula
513 lung/mediastinum abscess
513.0 lung abscess
513.1 mediastinal abscess
Gastrointestinal Tract Bleeding
530.21 esophageal ulcer w/bleeding
531.0 acute gastric ulcer w/hemorrhage
531.00 acute gastric ulcer w/hemorrhage w/o obst
531.01 acute gastric ulcer w/hemorrhage w/obstruct
531.2 acute gastric ulcer w/hemorrhage/perforation
531.20 ac gastric ulcer w/hemorrhage/perf w/obst
531.21 ac gastric ulcer w/hemorrhage/perf w/o obst
531.4 chronic/unspec gastric ulcer w/hemorrhage
531.40 chr/unspec gastric ulcer w/hemorrhage w/o obst
531.41 chr/unspec gastric ulcer w/hemorrhage w/obst
531.6 chr/unspec gastric ulcer w/hemorrhage/perf

531.60 chronic/unspec gastric ulcer w/hemorrhage/perforation w/o obstruct
531.61 chronic/unspec gastric ulcer w/hemorrhage/perforation w/obstruct
532.0 acute duodenal ulcer w/hemorrhage
532.00 acute duodenal ulcer w/hemorrhage w/o obst
532.01 acute duodenal ulcer w/hemorrhage w/obst
532.2 ac duodenal ulcer w/hemorrhage/perforation
532.20 ac duodenal ulcer w/hemorrhage/perforation w/obstruction
532.21 ac duodenal ulcer w/hemorrhage/perforation w/o obstruction
532.4 chr/unspec duodenal ulcer w/hemmorhage
532.40 chr/unspec duodenal ulcer w/hemmorhage w/o obstruction
532.41 chr/unspec duodenal ulcer w/hemmorhage w/obstruction
532.6 chr/unspec duodenal ulcer w/hemmorhage/perforation
532.60 chr/unspec duodenal ulcer w/hemmorhage/perforation w/o obstruction
532.61 chr/unspec duodenal ulcer w/hemmorhage/perforation w/obstruction
533.0 acute peptic ulcer w/hemorrhage
533.00 acute peptic ulcer w/hemorrhage w/o obst
533.01 acute peptic ulcer w/hemorrhage w/obstruct
533.2 acute peptic ulcer w/hemorrhage/perforation
533.20 ac peptic ulcer w/hemorrhage/perf w/obstr
533.21 ac peptic ulcer w/hemorrhage/perf w/obst
533.4 chronic/unspec peptic ulcer w/hemorrhage
533.40 chr/unspec pep ulc w/hemorrhage w/o obst
533.41 chr/unspec pep ulcer w/hemorrhage w/obst
533.6 chronic/unspec peptic ulcer w/hemorrhage/perforation
533.60 chr/unspec pep ulc w/hemorr/perf w/o obs

533.61 chr/unspec pep ulc w/hemorr/perf w/obs
534.0 acute gastrojejunal ulcer w/hemorrhage
534.00 ac gastrojejunal ulcer w/hemorrhage w/o obs
534.01 ac gastrojejunal ulcer w/hemorrhage w/obst
534.2 ac gastrojejunal ulcer w/hemorrhage/perf
534.20 ac gastrojejunal ulcr w/hemorr/perf w/obst
534.21 ac gastrojejunal ulc w/hemorr/perf w/o obst
534.4 chr/unspec gastrojejunal ulcer w/hemorrhage
534.40 chr/unspec gastrojejunal ulc w/hemo w/o obs
534.41 chr/unspec gastrojejunal ulc w/hemorr w/obs
534.6 chronic/unspec gastrojejunal ulcer w/hemorrhage/perforation
534.60 chr/unspec gastrojejunal ulcer w/hemorrhage/perf w/o obst
534.61 chr/unspec gastrojejunal ulcer w/hemorrhage/perf w/obst
537.83 angiodysplagia stomach/duod w/hemorrhage
562.02 diverticulosis small intest w/hemorrhage
562.03 diverticulitis small intest w/hemorrhage
562.12 diverticulosis colon w/hemorrhage
562.13 diverticulitis colon w/hemorrhage
569.85 angiodysplagia intestine w/hemorrhage
Hereditary hemollytic anemias/sickle cell anemias
282 hereditary hemolytic anemias
282.0 hereditary spherocytosis
282.1 hereditary elliptocytosis
282.2 anemias d/to glutathione metabolism disorder

282.3 othr hemolytic anemias d/t enzyme def
282.4 Thalassemias
282.41 sickle cell thalassemia w/o crisis
282.42 sickle cell thalassemia w/crisis
282.49 other thalassemia
282.5 sickle-cell trait
282.6 sickle-cell disease
282.61 sickle-cell dis Hb-SS disease w/o crisis
282.62 sickle-cell dis Hb-SS disease w/crisis
282.63 sickle-cell dis sickle-cell Hb-C dis w/o crisis
282.64 sickle-cell dis sickle-cell Hb-C dis w/crisis
282.68 sickle-cell dis other sickle-cell dis w/o crisis
282.69 sickle-cell dis other sickle-cell dis w/crisis
282.7 other hemoglobinopathies
282.8 other spec hereditary hemolytic anemias
282.9 hereditary hemolytic anemia unspec
Myelodysplastic Syndrome
238.7 neoplasm other lymphatic/hematopoietic tissues (includes myelodysplastic syndrome)
Monoclonial Gammopathy
273.1 monoclonial paraproteinemia (includes monoclonial gammopathy)

Table B: ICD-9 Codes eligible for a Co-Morbidity Payment Adjustment
Cancer (excludes non-melanoma skin cancer)
141.0 malignant neoplasm tongue base
141.1 malignant neoplasm dorsal tongue
141.2 malignant neoplasm tip/lateral tongue
141.3 malignant neoplasm ventral tongue
141.4 malignant neoplasm anterior 2/3 tongue
141.5 malignant neoplasm tongue junction
141.6 malignant neoplasm lingual tonsil
141.8 malignant neoplasm tongue nec
142.0 malignant neoplasm parotid
142.1 malignant neoplasm submandibular
142.2 malignant neoplasm sublingual gland
143.0 malignant neoplasm upper gum
143.1 malignant neoplasm lower gum
144.0 malignant neoplasm anterior floor mouth
144. malignant neoplasm lateral floor mouth
144.8 malignant neoplasm mouth floor nec
145.0 malignant neoplasm cheek mucosa
145.1 malignant neoplasm vestibule
145.2 malignant neoplasm hard palate

145.3 malignant neoplasm soft palate
145.4 malignant neoplasm uvula
145.6 malignant neoplasm retromolar
145.8 malignant neoplasm mouth nec
146.0 malignant neoplasm tonsil
146.1 malignant neoplasm tonsillar fossa
146.2 malignant neoplasm tonsil pillars
146.3 malignant neoplasm vallecula
146.4 malignant neoplasm anterior epiglottis
146.5 malignant neoplasm epiglottis junction
146.6 malignant neoplasm lateral oropharynx
146.7 malignant neoplasm posterior oropharynx
146.8 malignant neoplasm oropharynx nec
147.0 malignant neoplasm superior nasopharyn
147.1 malignant neoplasm posterior nasopharynx
147.2 malignant neoplasm lateral nasopharynx
147.3 malignant neoplasm anterior nasopharynx
148.0 malignant neoplasm postcricoid
148.1 malignant neoplasm pyriform sinus
148.2 malignant neoplasm aryepiglottic fold
148.3 malignant neoplasm posterior hypopharynx
148.8 malignant neoplasm hypopharynx nec

149.1 malignant neoplasm waldeyer's ring
149.8 malignant neoplasm oral/pharynx nec
149.9 malignant neoplasm orophryn ill-defined
150.0 malignant neoplasm cervical esophagus
150.1 malignant neoplasm thoracic esophagus
150.2 malignant neoplasm abdomin esophagus
150.3 malignant neoplasm upper 3rd esoph
150.4 malignant neoplasm middle 3rd esoph
150.5 malignant neoplasm lower 3rd esoph
151.0 malignant neoplasm stomach cardia
151.1 malignant neoplasm pylorus
151.2 malignant neoplasm pyloric antrum
151.3 malignant neoplasm stomach fundus
151.4 malignant neoplasm stomach body
151.5 malignant neoplasm stomach lesser curvature
151.6 malignant neoplasm stomach greater curvature
152.0 malignant neoplasm duodenum
152.1 malignant neoplasm jejunum
152.2 malignant neoplasm ileum
152.3 malignant neoplasm meckel's diverticulum
152.8 malignant neoplasm small bowel nec
153.0 malignant neoplasm hepatic flexure

153.1 malignant neoplasm transverse colon
153.2 malignant neoplasm descending colon
153.3 malignant neoplasm sigmoid colon
153.4 malignant neoplasm cecum
153.5 malignant neoplasm appendix
153.6 malignant neoplasm ascending colon
153.7 malignant neoplasm splenic flexure
154.0 malignant neoplasm rectosigmoid junction
154.1 malignant neoplasm rectum
154.2 malignant neoplasm anal canal
155.0 malignant neoplasm liver, primary
155.1 malignant neoplasm intrahepat ducts
156.0 malignant neoplasm gallbladder
156.1 malignant neoplasm extrahepatic ducts
156.2 malignant neoplasm ampulla of vater
156.8 malignant neoplasm biliary nec
157.0 malignant neoplasm pancreas head
157.1 malignant neoplasm pancreas body
157.2 malignant neoplasm pancreas tail
157.3 malignant neoplasm pancreatic duct
157.4 malignant neoplasm islet langerhans
157.8 malignant neoplasm pancreas nec

158.0 malignant neoplasm retroperitoneum
158.8 malignant neoplasm peritoneum nec
160.0 malignant neoplasm nasal cavities
160.1 malignant neoplasm middle ear
160.2 malignant neoplasm maxillary sinus
160.3 malignant neoplasm ethmoidal sinus
160.4 malignant neoplasm frontal sinus
160.5 malignant neoplasm sphenoid sinus
160.8 malignant neoplasm access sinus nec
161.0 malignant neoplasm glottis
161.1 malignant neoplasm supraglottis
161.2 malignant neoplasm subglottis
161.3 malignant neoplasm cartilage larynx
161.8 malignant neoplasm larynx nec
162.0 malignant neoplasm trachea
162.2 malignant neoplasm main bronchus
162.3 malignant neoplasm upper lobe lung
162.4 malignant neoplasm middle lobe lung
162.5 malignant neoplasm lower lobe lung
163.0 malignant neoplasm parietal pleura
163.1 malignant neoplasm visceral pleura
164.0 malignant neoplasm thymus

164.1 malignant neoplasm heart
164.2 malignant neoplasm anterior mediastinum
164.3 malignant neoplasm posterior mediastinum
165.8 malignant neoplasm thorax/resp nec
170.0 malignant neoplasm skull/face bone
170.1 malignant neoplasm mandible
170.2 malignant neoplasm vertebrae
170.3 malignant neoplasm ribs/sternum/clavicle
170.4 malignant neoplasm long bones arm
170.5 malignant neoplasm bones wrist/hand
170.6 malignant neoplasm pelvic girdle
170.7 malignant neoplasm long bones leg
170.8 malignant neoplasm bones ankle/foot
171.0 malignant neoplasm soft tissue head
171.2 malignant neoplasm soft tissue arm
171.3 malignant neoplasm soft tissue leg
171.4 malignant neoplasm soft tissue thorax
171.5 malignant neoplasm soft tis abdomen
171.6 malignant neoplasm soft tissue pelvis
172.0 malignant melanoma lip
172.1 malignant melanoma eyelid
172.2 malignant melanoma ear

172.4 malignant melanoma scalp/neck
172.5 malignant melanoma trunk
172.6 malignant melanoma arm
172.7 malignant melanoma leg
174.0 malignant neoplasm nipple
174.1 malignant neoplasm breast-central
174.2 malignant neoplasm breast upper-inner
174.3 malignant neoplasm breast lower-inner
174.4 malignant neoplasm breast upper-outer
174.5 malignant neoplasm breast lower-outer
174.6 malignant neoplasm breast-axillary
175.0 malignant neoplasm male nipple
176.0 skin - kaposi's sarcoma
176.1 sft tisue - kaposi's sarcoma
176.2 palate - kaposi's sarcoma
176.3 gi sites - kaposi's sarcoma
176.4 lung - kaposi's sarcoma
176.5 lymph nodes - kaposi's sarcoma
176.8 specified sites - kaposi's sarcoma
180.0 malignant neoplasm endocervix
180.1 malignant neoplasm exocervix
180.8 malignant neoplasm cervix nec

182.0 malignant neoplasm corpus uteri
182.1 malignant neoplasm uterine isthmus
182.8 malignant neoplasm body uterus nec
183.0 malignant neoplasm ovary
183.2 malignant neoplasm fallopian tube
183.3 malignant neoplasm broad ligament
183.4 malignant neoplasm parametrium
183.5 malignant neoplasm round ligament
184.0 malignant neoplasm vagina
184.1 malignant neoplasm labia majora
184. 2 malignant neoplasm labia minora
184.3 malignant neoplasm clitoris
186.0 malignant neoplasm undescend testis
186.9 malignant neoplasm testis nec
187.1 malignant neoplasm prepuce
187.2 malignant neoplasm glans penis
187.3 malignant neoplasm penis body
187.5 malignant neoplasm epididymis
187.6 malignant neoplasm spermatic cord
187.7 malignant neoplasm scrotum
188.0 malignant neoplasm bladder-trigone
188.1 malignant neoplasm bladder-dome

188.2 malignant neoplasm bladder-lateral
188.3 malignant neoplasm bladder-anterior
188.4 malignant neoplasm bladder-post
188.5 malignant neoplasm bladder neck
188.6 malignant neoplasm ureteric orifice
188.7 malignant neoplasm urachus
189.0 malignant neoplasm kidney
189.1 malignant neoplasm renal pelvis
189.2 malignant neoplasm ureter
189.3 malignant neoplasm urethra
189.4 malignant neoplasm paraurethral
190.0 malignant neoplasm eyeball
190.1 malignant neoplasm orbit
190.2 malignant neoplasm lacrimal gland
190.3 malignant neoplasm conjunctiva
190.4 malignant neoplasm cornea
190.5 malignant neoplasm retina
190.6 malignant neoplasm choroid
190.7 malignant neoplasm lacrimal duct
190.8 malignant neoplasm eye nec
191.0 malign neopl cerebrum
191.1 malignant neoplasm frontal lobe

191.2 malignant neoplasm temporal lobe
191.3 malignant neoplasm parietal lobe
191.4 malignant neoplasm occipital lobe
191.5 malignant neoplasm cereb ventricle
191.7 malignant neoplasm brain stem
192.0 malignant neoplasm cranial nerves
192.1 malignant neoplasm cerebral meninges
192.2 malignant neoplasm spinal cord
192.3 malignant neoplasm spinal meninges
194.0 malignant neoplasm adrenal
194.1 malignant neoplasm parathyroid
194.3 malignant neoplasm pituitary
194.4 malignant neoplasm pineal gland
194.5 malignant neoplasm carotid body
194.6 malignant neoplasm paraganglia nec
195.0 malignant neoplasm head/face/neck
195.1 malignant neoplasm thorax
195.2 malignant neoplasm abdomen
195.3 malignant neoplasm pelvis
195.4 malignant neoplasm arm
195.5 malignant neoplasm leg
196.0 malignant neoplasm lymph-head/neck

196.1 malignant neoplasm lymph-intrathoracic
196.2 malignant neoplasm lymph intra-abdoman
196.3 malignant neoplasm lymph-axilla/arm
196.5 malignant neoplasm lymph-inguin/leg
196.6 malignant neoplasm lymph-intrapelvic
196.8 malignant neoplasm lymph node-multiple
197.0 secondary malignant neoplasm lung
197.1 secondary malignant neoplasm mediastinum
197.2 secondary malignant neoplasm pleura
197.4 secondary malignant neoplasm small bowel
197.5 secondary malignant neoplasm large bowel
197.6 secondary malignant neoplasm peritoneum
197.7 secondary malignant neoplasm liver
198.0 secondary malignant neoplasm kidney
198.1 secondary malignant neoplasm urinary nec
198.2 secondary malignant neoplasm skin
198.3 secondary malignant neoplasm brain/spine
198.4 secondary malignant neoplasm nerve nec
198.5 secondary malignant neoplasm bone
198.6 secondary malignant neoplasm ovary
198.7 secondary malignant neoplasm adrenal
198.81 secondary malignant neoplasm breast

199.0 malignant neoplasm disseminated
199.2 malignant neoplasm associated with transplant
200.00 reticulosarcoma unsppecified extrandodal
200.01 reticulosarcoma head
200.02 reticulosarcoma thorax
200.03 reticulosarcoma abdoman
200.04 reticulosarcoma axilla
200.05 reticulosarcoma inguinal
200.06 reticulosarcoma pelvic
200.07 reticulosarcoma spleen
200.08 reticulosarcoma multiple
200.10 lymphosarcoma unspecified xtranodal
200.11 lymphosarcoma head
200.12 lymphosarcoma thorax
200.13 lymphosarcoma abdoman
200.14 lymphosarcoma axilla
200.15 lymphosarcoma inguinal
200.16 lymphosarcoma pelvic
200.17 lymphosarcoma spleen
200.18 lymphosarcoma multiple
200.20 burkitt's tumor unspecified xtranodal
200.21 burkitt's tumor head

200.22 burkitt's tumor thorax
200.23 burkitt's tumor abdom
200.24 burkitt's tumor axilla
200.25 burkitt's tumor inguin
200.26 burkitt's tumor pelvic
200.27 burkitt's tumor spleen
200.28 burkitt's tumor multiple
200.81 mixed lymphosarcoma head
200.82 mixed lymphosarcoma thorax
200.83 mixed lymphosarc abdoman
200.84 mixed lymphosarcoma axilla
200.85 mixed lymphosarcoma inguinal
200.86 mixed lymphosarcoma pelvic
200.87 mixed lymphosarcoma spleen
200.88 mixed lymphosarcoma multiple
201.00 hodgkins paragran unspecified extranodal origin
201.01 hodgkins paragran head
201.02 hodgkins paragran thorax
201.03 hodgkins paragran abdom
201.04 hodgkins paragran axilla
201.05 hodgkins paragran inguinal
201.06 hodgkins paragran pelvic

201.07 hodgkins paragran spleen
201.08 hodgkins paragran multiple
201.11 hodgkins granuloma head
201.10 hodgkins granuloma unspecified/extranodal/solitary organ
201.12 hodgkins granuloma thorax
201.13 hodgkins granuloma abdom
201.14 hodgkins granuloma axilla
201.15 hodgkins granuloma inguin
201.16 hodgkins granuloma pelvic
201.17 hodgkins granuloma spleen
201.18 hodgkins granuloma mult
201.20 hodgkins sarcoma unspecified/extranodal
201.21 hodgkins sarcoma head
201.22 hodgkins sarcoma thorax
201.23 hodgkins sarcoma abdom
201.24 hodgkins sarcoma axilla
201.25 hodgkins sarcoma inguinal
201.26 hodgkins sarcoma pelvic
201.27 hodgkins sarcoma spleen
201.28 hodgkins sarcoma multiple
201.40 lymphocytic-histiocytic unspecified extranodal
201.41 hodgkins lymphocytic-histiocytic head

201.42 hodgkins lymphocytic-histiocytic thorax
201.43 hodgkins lymphocytic-histiocytic abdoman
201.44 hodgkins lymphocytic-histiocytic axilla
201.45 hodgkins lymphocytic-histiocytic inguinal
201.46 hodgkins lymphocytic-histiocytic pelvic
201.47 hodgkins lymphocytic-histiocytic spleen
201.48 hodgkins lymphocytic-histiocytic multiple
201.50 nodular sclerosis unspecified extranodal
201.51 hodgkins nodular sclerosis head
201.52 hodgkins nodular sclerosis thorax
201.53 hodgkins nodular sclerosis abdoman
201.54 hodgkins nodular sclerosis axilla
201.55 hodgkins nodular sclerosis inguinal
201.56 hodgkins nodular sclerosis pelvic
201.57 hodgkins nodular sclerosis spleen
201.58 hodgkins nodular sclerosis multiple
201.60 mixed cellular unspecified extranodal
201.61 hodgkins mixed cell head
201.62 hodgkins mixed cell thorax
201.63 hodgkins mixed cell abdom
201.64 hodgkins mixed cell axilla
201.66 hodgkins mixed cell pelvic

201.67 hodgkins mixed cell spleen
201.68 hodgkins mixed cell multiple
201.70 lymphocytic depletion unspecified extranodal origin
201.71 hodgkins lymphocytic depletion head
201.72 hodgkins lymphocytic depletion thorax
201.73 hodgkins lymphocytic depletion abdoman
201.74 hodgkins lymphocytic depletion axilla
201.75 hodgkins lymphocytic depletion inguinal
201.76 hodgkins lymphocytic depletion pelvic
201.77 hodgkins lymphocytic depletion spleen
201.78 hodgkins lymphocytic depletion multiple
201.90 hodgkins disease unspecified extrananodal origin
201.91 hodgkins disease nos head
201.92 hodgkins disease nos thorax
201.93 hodgkins disease nos abdom
201.94 hodgkins disease nos axilla
201.95 hodgkins disease nos inguin
201.96 hodgkins disease nos pelvic
201.97 hodgkins disease nos spleen
201.98 hodgkins disease nos multiple
202.00 nodular lymphoma unspecified extrananodal origin
202.01 nodular lymphoma head

202.02 nodular lymphoma thorax
202.03 nodular lymphoma abdoman
202.04 nodular lymphoma axilla
202.05 nodular lymphoma inguinal
202.06 nodular lymphoma pelvic
202.07 nodular lymphoma spleen
202.08 nodular lymphoma multiple
202.10 mycosis fungoides unspecified extrananodal origin
202.11 mycosis fungoides head
202.12 mycosis fungoides thorax
202.13 mycosis fungoides abdom
202.14 mycosis fungoides axilla
202.15 mycosis fungoides inguinal
202.16 mycosis fungoides pelvic
202.17 mycosis fungoides spleen
202.18 mycosis fungoides multiple
202.20 sezary's disease unspecified extrananodal origin
202.21 sezary's disease head
202.22 sezary's disease thorax
202.23 sezary's disease abdom
202.24 sezary's disease axilla
202.25 sezary's disease inguinal

202.26 sezary's disease pelvic
202.27 sezary's disease spleen
202.28 sezary's disease multiple
202.30 malignant histiocytosis unspecified extrananodal origin
202.31 malignant histiocytosis head
202.32 malignant histiocytosis thorax
202.33 malignant histiocytosis abdoman
202.34 malignant histiocytosis axilla
202.35 malignant histiocytosis inguinal
202.36 malignant histiocytosis pelvic
202.37 malignant histiocytosis spleen
202.38 malignant histiocytosis multiple
202.40 leukemic reticuloendotheleosis unspecified extrananodal origin
202.41 hairy-cell leukemia head
202.42 hairy-cell leukemia thorax
202.43 hairy-cell leukemia abdoman
202.44 hairy-cell leukemia axilla
202.45 hairy-cell leukemia inguinal
202.46 hairy-cell leukemia pelvic
202.47 hairy-cell leukemia spleen
202.48 hairy-cell leukemia multiple
202.50 letterer-siwe unspecified extrananodal origin

202.51 letterer-siwe dis head
202.52 letterer-siwe dis thorax
202.53 letterer-siwe dis abdoman
202.54 letterer-siwe dis axilla
202.55 letterer-siwe dis inguinal
202.56 letterer-siwe dis pelvic
202.57 letterer-siwe dis spleen
202.58 letterer-siwe dis multiple
202.60 malignant mast unspecified extrananodal origin
202.61 malignant mastocytosis head
202.62 malignant mastocytosis thorax
202.63 malignant mastocytosis abdoman
202.64 malignant mastocytosis axilla
202.65 malignant mastocytosis inguinal
202.66 malignant mastocytosis pelvic
202.67 malignant mastocytosis spleen
202.68 malignant mastocytosis multiplr
202.80 other lymphomas unspecified extrananodal origin
202.81 lymphomas nec head
202.82 lymphomas nec thorax
202.83 lymphomas nec abdom
202.84 lymphomas nec axilla

202.85 lymphomas nec inguin
202.86 lymphomas nec pelvic
202.87 lymphomas nec spleen
202.88 lymphomas nec multiple
202.90 unspecified lymphoma unspecified extrananodal origin
202.91 lymphoid malignancy nec head
202.92 lymphoid malignancy nec thorax
202.93 lymphoid malignancy nec abdoman
202.94 lymphoid malignancy nec axilla
202.95 lymphoid malignancy nec inguinal
202.96 lymphoid malignancy nec pelvic
202.97 lymphoid malignancy nec spleen
202.98 lymphoid malignancy nec multiple
203.00 multiple myeloma w/o remission
203.01 multiple myeloma w remission
203.10 plasma cell leukemia without remission
203.11 plasma cell leukemia with remission
203.80 other immunoproliferative neoplasm without remission
203.81 other immunoproliferative neoplasm with remission
204.00 acute lymphoid leukemia without remission
204.01 acute lymphoid leukemia with remission
204.02 acute lymphoid leukemia, in relapse

204.10 chronic lymphoid leukemia without remission
204.11 chronic lymphoid leukemia with remission
204.12 chronic lymphoid leukemia, in relapse
204.20 subacute lymphoid leukemia without remission
204.21 subacute lymphoid leukemia with remission
204.80 other lymphoid leukemia without remission
204.81 other lymphoid leukemia with remission
204.90 unspecified lymphoid leukemia without remission
204.91 unspecified lymphoid leukemia with remission
205.00 acute myeloid leukemia without remission
205.01 acute myeloid leukemia with remission
205.10 chronic myeloid leukemia without remission
205.11 chronic myeloid leukemia with remission
205.20 subacute myeloid leukemia without remission
205.21 subacute myeloid leukemia with remission
205.22 subacute myeloid leukemia, in relapse
205.30 myeloid sarcoma without remission
205.31 myeloid sarcoma with remission
205.80 other myeloid sarcoma without remission
205.81 other myeloid sarcoma with remission
205.90 unspecified myeloid sarcoma without remission
205.91 unspecified myeloid sarcoma with remission

206.00 acute monocytic leukemia without remission
206.01 acute monocytic leukemia with remission
206.10 chronic monocytic leukemia without remission
206.11 chronic monocytic leukemia with remission
206.20 subacute monocytic leukemia without remission
206.21 subacute monocytic leukemia with remission
206.80 other monocytic leukemia without remission
206.81 other monocytic leukemia with remission
206.90 unspecified monocytic leukemia without remission
206.91 unspecified monocytic leukemia with remission
207.00 acute erythremia/erythroleukemia without remission
207.01 acute erythremia/erythroleukemia with remission
207.10 chronic erythremia/erythroleukemia without remission
207.11 chronic erythremia/erythroleukemia with remission
207.20 megakaryocytic leukemia without remission
207.21 megakaryocytic leukemia with remission
207.80 other specified leukemia without remission
207.81 other specified leukemia without remission
208.00 acute leukemia unspecified cell without remission
208.01 acute leukemia unspecified cell remission
208.10 chronic leukemia unspecified cell without remission
208.11 chronic leukemia unspecified cell with remission

209.01 malignant carcinoid tumor of the duodenum
209.02 malignant carcinoid tumor of the jejunum
209.03 malignant carcinoid tumor of the ileum
209.11 malignant carcinoid tumor of the apendix
209.12 malignant carcinoid tumor of the cecum
209.13 malignant carcinoid tumor of the ascending colon
209.14 malignant carcinoid tumor of the transverse colon
209.15 malignant carcinoid tumor of the descending colon
209.16 malignant carcinoid tumor of the sigmoid colon
209.17 malignant carcinoid tumor of the rectum
209.21 malignant carcinoid tumor of the bronchus and lung
209.22 malignant carcinoid tumor of the thymus
209.23 malignant carcinoid tumor of the stomach
209.24 malignant carcinoid tumor of the kidney
228.02 hemangioma intracranial
237.0 uncharacteristic behavior neoplasm of the pituitary
237.1 uncharacteristic behavior neoplasm of the pineal
237.3 uncharacteristic behavior neoplasm of the paragang
237.5 uncharacteristic behavior neoplasm of the brain/spinal
237.6 uncharacteristic behavior neoplasm of the meninges
237.71 neurofibromatosis type i
237.72 neurofibromatosis type ii

Drug and/or Alcohol Induced Mental Disorders
303.02 alcoholic dependence syndrome, acute alcoholic intoxication, episodic
303. alcoholic dependence syndrome, acute alcoholic intoxication, episodic, in remission
303.91 alcoholic dependence syndrome, acute alcoholic intoxication, episodic, continuous
303.92 alcohol dependence syndrome, other & unspecified alcohol dependence, episodic
303.93 alcohol dependence syndrome, other & unspecified alcohol dependence, in remission
304.01 drug dependence, opioid, continuous
304.02 drug dependence, opioid, episodic
304.03 drug dependence, opioid, in remission
304.11 drug dependence barbiturate/similarly acting sedative/hypnotic dependence continuous
304.12 drug dependence barbiturate/similarly acting sedative/hypnotic dependence episodic
304.13 drug dependence barbiturate/similarly acting sedative/hypnotic dependence in remission
304.21 drug dependence, cocaine continuous
304.22 drug dependence, cocaine episodic
304.23 drug dependence, cocaine in remission
304.31 drug dependence, cannibis continuous
304.32 drug dependence, cannabis episodic
304.33 drug dependence, cannabis in remission
304.41 drug depend amphetamine/othr psychostim contin
304.42 drug dependence, amphetamine/other psychostimulant episodic
304.43 drug dependence, amphetamine/other psychostimulant episodic in remission

304.51 drug dependence hallucinogen continuous
304.52 drug dependence hallucinogen episodic
304.53 drug depend hallucinogen in remission
304.61 other specified drug dependence continuous
304.62 other specified drug dependence episodic
304.63 other spec drug dependence in remission
304.71 drug dependence opioid type with other drug continuous
304.72 drug dependence opioid type with other drug episod
304.73 drug dependence opioid with othr drug in remission
304.81 drug dependence comb without opioid type continuous
304.82 drug dependence comb without opioid type episodic
304.83 drug dependence comb without opioid type episodic
304.91 drug dependence unspecified dependence continuous
304.92 drug dependence unspecified dependence episodic
304.93 drug dependence unspecified depend in remission
305.01 nondependence drug abuse alcohol continuous
305.02 nondependence drug abuse alcohol episodic
305.03 nondepend drug abuse alcohol in remission
571.0 alcoholic fatty liver
571.1 acute alcoholic hepatitis
571.2 alcoholic cirrhosis of liver

Cardiac Conditions
425.5 alcoholic cardiomyeopathy
427.5 cardiac arrest
Pericarditis
420.90 other/unspecified pericarditis, acute pericarditis unspecified
420.91 other/unspecified pericarditis, acute idiopathic pericarditis
HIV/AIDS
042 hiv w/spec cond includes aids
v08 asymptotic hiv infection status
Hepatitis B
070.30 viral hepatitis b without hepatic coma acute or unspecified without hepatitis delta
070.31 viral hepatitis b without hepatic coma acute or unspecified w/ hepatitis delta
070.32 viral hepatitis b without hepatic coma chronic without hepatitis delta
070.33 viral hepatitis b without hepatic coma chronic w/ hepatitis delta
Septicemia and Shock
038.0 septicemia, streptococcal
038.11 septicemia, staphylococcal staphlococcus aureus
038.2 septicemia pneumococcal septicemia

038.3 septicemia due to anaerobes
038.41 septicemia due to other gram negative hemophilus influenza
038.42 septicemia due to other gram negative organism e coli
038.43 septice due to other gram negative organism pseudomonas
038.44 septicemia due to other gram negative organism serratia
038.49 septicemia due to othr gram negative organism other
038.8 septicemia other specified
Bacterial Pneumonias/Opportunistic Infections/Pneumococcal Pneumonias
020.3 primary pneumonia
020.5 pneumonic unspecified
112.84 candidal esophagitis
114.5 primary coccidioidomycosis unspecified
321.0 cryptococcal meningitis
481 pneumococcal pneumonia (streptococcus pneumoniae pneumonia)
482.0 pneumonia due to klebsiella pneumoniae
482.1 pneumonia due to pseudomonas
482.2 hemophilus influenzae pneumonia
482.31 streptococcus group a pneumonia
482.32 streptococcus group b pneumonia
482.41 pneumonia due to staphlococcus aureus
482.81 pneumonia due to anaerobes

482.82 pneumonia due to e. coli
482.84 legionnaires' disease
484.1 cytomegalic inclusion disease pneumonia
484.6 aspergillosis pneumonia
507.0 pneumonia due to inhalation of food/vomitus
507.1 pneumonia due to inhalation of oils/essences
507.8 pneumonitis due to other solids & liquids
510.0 empyema with fistula
510.9 empyema without fistula
513.0 lung abscess
513.1 mediastinal abscess
Gastrointestinal Tract Bleeding
530.21 esophageal ulcer with bleeding
531.00 acute gastric ulcer with hemorrhage without obstruction
531.01 acute gastric ulcer with hemorrhage with obstructtion
531.20 acute gastric ulcer with hemorrhage/perf with obst
531.21 acute gastric ulcer with hemorrhage/perf without obst
532.00 acute duodenal ulcer with hemorrhage without obst
532.01 acute duodenal ulcer with hemorrhage with obst
532.20 acute duodenal ulcer with hemorrhage/perforation with obstruction
532.21 acute duodenal ulcer with hemorrhage/perforation without obstruction

533.00 acute peptic ulcer with hemorrhage without obstruction
533.01 acute peptic ulcer with hemorrhage with obstruction
533.20 acute peptic ulcer with hemorrhage/perforation with obstruction
533.21 acute peptic ulcer with hemorrhage/perforation with obstruction
534.00 acute gastrojejunal ulcer with hemorrhage without obstruction
534.01 acute gastrojejunal ulcer with hemorrhage with obstruction
534.20 acute gastrojejunal ulcer with hemorrhage/perforation with obstruction
534.21 acute gastrojejunal ulcer with hemorrhage/perforation without obstruction
537.83 angiodysplagia stomach/duod with hemorrhage
562.02 diverticulosis small intestine with hemorrhage
562.03 diverticulitis small intestine with hemorrhage
562.12 diverticulosis colon with hemorrhage
562.13 diverticulitis colon with hemorrhage
569.85 angiodysplagia intestine with hemorrhage
Hereditary Hemollytic Anemias/Sickle Cell Anemias
282.0 hereditary spherocytosis
282.1 hereditary elliptocytosis
282.2 anemias due to glutathione metabolism disorder
282.3 other hemolytic anemias due to enzyme deficiency
282.41 sickle cell thalassemia without crisis
282.42 sickle cell thalassemia with crisis

282.49 other thalassemia
282.5 sickle-cell trait
282.61 sickle-cell disease hb-ss disease without crisis
282.62 sickle-cell disease hb-ss disease with crisis
282.63 sickle-cell disease sickle-cell hb-c disease without crisis
282.64 sickle-cell disease sickle-cell hb-c disease with crisis
282.68 sickle-cell disease other sickle-cell disease without crisis
282.7 other hemoglobinopathies
282.8 other spec hereditary hemolytic anemias
Monoclonial Gammopathy
273.1 monoclonial paraproteinemia (includes monoclonial gammopathy)

Table C			
List of National Drug Codes Used to Identify Part D Drugs for the Expanded ESRD PPS			
Drug Class: Vitamin D Analogs			
Ingredient Name	**NDC**	**Strength**	**Trade Name**
Calcitriol	260530051	.25 MCG	Calcitriol Capsules
	540007	.25 MCG	Calcitriol Capsules
	930657	.25MCG	Calcitriol Capsules
	930658	0.5MCG	Calcitriol Capsules
	1791578	0.25MG	Calcitriol Capsules

Table C			
List of National Drug Codes Used to Identify Part D Drugs for the Expanded ESRD PPS			
	1791603	0.5MCG	Calcitriol Capsules
	4800657	0.25 MCG	Calcitriol Capsules
	4800658	0.5 MCG	Calcitriol Capsules
	110140011	0.25 MCG	Calcitriol Capsules
	142880007	.25 MCG	Calcitriol Capsules
	178560007	0.25 MCG	Calcitriol Capsules
	548684584	0.25 MCG	Calcitriol Capsules
	551548251	0.25 MCG	Calcitriol Capsules
	647250048	0.25 MG	Calcitriol Capsules
	647250049	0.5 MG	Calcitriol Capsules
	543120	1 MCG/ML	Calcitriol Oral Solution
	682589030	0.5 MCG	Calcitriol Capsules
	548683461	.25 MCG	Rocaltrol Capsules
	604910562	0.5 MCG	Rocaltrol Capsules
	49115	1 MCG/ML	Rocaltrol Oral Solution
Paricalcitol	744314	2 MCG	Zemplar Capsules
	744315	4 MCG	
	744317	1 MCG	
	110140056	2 MCG	
	110140057	4 MCG	
	242360664	1 MCG	
	511294272	1 MCG	
	551540001	1 MCG	
	551546971	1 MCG	

Table C			
List of National Drug Codes Used to Identify Part D Drugs for the Expanded ESRD PPS			
Doxercalciferol	110140017	0.5 MCG	Hectorol Capsules
	110140018	2.5 MCG	
	511293550	2.5 MCG	
	584680120	0.5 MCG	
	584680122		
	584680121	2.5 MCG	
Drug Class: Calcimimetic			
Ingredient Name	**NDC**	**Strength**	**Trade Name**
Cinacalcet Hydrochloride	682589225	30 MG	Cinacalcet HCL Tablet
	632850074	66 MG	Sensipak Tablets
	1791845	30 MG	Sensipar Tablets
	548685616	30 MG	Sensipar Tablets
	555130073	33 MG	Sensipar Tablets
	555130074	66 MG	Sensipar Tablets
	555130075	99 MG	Sensipar Tablets
	632850073	30 MG	Sensipar Tablets
	632850075	K99 MG	Sensipar Tablets
Drug Class: Oral Phosphate Binder			
Ingredient Name	**NDC**	**Strength**	**Trade Name**
Lanthanum Carbonate	540920252	500 MG	Fosrenol Chewable Tablets
	540920253	750 MG	
	540920254	1000 MG	
	635520250	750 MG	
	635520251	1000 MG	

Table C			
List of National Drug Codes Used to Identify Part D Drugs for the Expanded ESRD PPS			
	635520252	500 MG	
Calcium Acetate	540026	667 MG	Calcium Acetate Capsules
	142880954	667 MG	Calcium Acetate Capsules
	597306402	667 MG	PhosLo Gelcaps
	1791371	667 MG	PhosLo Tablets
	1791934		PhosLo Tablets
	522680200	667 MG	PhosLo Tablets
	548683460	667 MG	PhosLo Tablets
	548685691		PhosLo Tablets
	647250260	667 MG	PhosLo Tablets
Sevelamer Hydrochloride	178560020	400 MG	Crenagel Tablets
	260530308	800 MG	Renagel Tablet
	260530394	400 MG	Renagel Tablet
	6155613	800 MG	Renagel Tablets
	178560021	800 MG	Renagel Tablets
	242360660	400 MG	Renagel Tablets
	511293461	800 MG	Renagel Tablets
	548685615	800 MG	Renagel Tablets
	551549726	400 MG	Renagel Tablets
	551549727	800 MG	Renagel Tablets
	580160778	800 MG	Renagel Tablets
	584680020	400 MG	Renagel Tablets
	584680021	800 MG	Renagel Tablets
	613920721	400 MG	Renagel Tablets

Table C			
List of National Drug Codes Used to Identify Part D Drugs for the Expanded ESRD PPS			
	647250284	400 MG	Renagel Tablets
	647250285	800 MG	Renagel Tablets
	654970020	400 MG	Renagel Tablets
	654970021	800 MG	Renagel Tablets
	675440656	800 MG	Renagel Tablets
	682990002	400 MG	Renagel Tablets
	682990021	800 MG	Renagel Tablets
	584680130	800 MG	Renvela Tablets
	711144207	403 MG	Sevelamer Hydrochloride Capsules
	68258-9013	800 MG	Sevelamer Hydrochloride Tablets
	68258-9070	400 MG	Sevelamer Hydrochloride Tablets
Sevelamer Carbonate	68299-0130	800 MG	Renvela Tablets

[FR Doc. E9–22486 Filed 9–15–09; 4:15 pm]
BILLING CODE 4120–01–C

Notices

Federal Register

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Tuesday, September 29, 2009

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1508–N]

Medicare Program; Town Hall Meeting on End-Stage Renal Disease Prospective Payment System

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the date, time, and location of the town hall meeting to discuss the Medicare End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) proposed rule. This meeting provides a forum for interested parties including, but not limited to beneficiaries, caregivers, providers, and other industry representatives to make oral statements in response to the ESRD PPS proposed rule. The meeting is open to the public, but registration is required and attendance is limited to space available.

DATES: *Meeting Date:* The town hall meeting will be held on Wednesday, October 23, 2009, from 9 a.m. to 12 p.m., eastern daylight time (e.d.t.).

Deadline for Registrations: Registrations must be received by October 2, 2009 by 5 p.m., e.d.t.

Deadline for Special Accommodations: Special accommodations must be made by October 5, 2009. Special arrangements for medical equipment or medical devices must be made by October 9, 2009.

ADDRESSES: *Meeting Location:* The meeting will be held in the main auditorium at the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Meeting Registration: All individuals interested in attending the meeting must register at the following Web site: *http://www.cms.hhs.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3.* Scroll down to the town hall meeting for the ESRD PPS Proposed Rule and select the register button to complete the required registration.

Individuals interested in making oral presentations at the meeting must also register as attendees and register at the following Web site: *http://www.cms.hhs.gov/esrdpayment/20_town_hall_speaker.asp.* Scroll down to the town hall meeting for the ESRD PPS Proposed Rule and select the town hall speaker register URL link to complete the required registration.

FOR FURTHER INFORMATION CONTACT: Jean-Marie Moore or Brenda Hudson at 410–786–8974.

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) was enacted on July 15, 2008. Section 153(b) of MIPPA amended section 1881(b) of the Social Security Act to require the implementation of an end-stage renal disease (ESRD) bundled payment system effective January 1, 2011 (herein referred to as the ''ESRD PPS'').

The ESRD PPS proposed rule, which appears elsewhere in this **Federal Register**, would implement a case-mix adjusted bundled prospective payment system (PPS) for Medicare outpatient ESRD dialysis facilities beginning January 1, 2011, in compliance with section 153(b) of MIPPA. The proposed ESRD PPS would replace the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

II. Meeting Format

The meeting will begin with a brief overview of the ESRD PPS proposed rule. The majority of the time allotted will be reserved for oral presentations from registered speakers.

Individuals who wish to make an oral presentation must not only register to attend, but must also register to speak at the town hall meeting. In general, speaker registration will be accepted on a first come, first served basis. However, in the event, the number of speaker requests exceed the allotted timeframe for the town hall meeting, we reserve the right to select those speakers that will offer the broadest array of topics and viewpoints.

The CMS meeting host will establish the sequencing order in which presentations will be delivered. All speakers will be working with a compact time limitation that will be enforced to permit as many presentations as possible. Registered speakers may not assign time to, or accept time from another speaker or attendee at the meeting. Speakers that choose to use handouts must bring 500 paper copies of any handout to the meeting.

III. Registration Instructions

The Division of Chronic Care Management in the Center for Medicare Management is coordinating the town hall meeting registration. While there is no registration fee, for security purposes, individuals are required to register to attend. We note that prospective speakers are required to register separately as an attendee and speaker as specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice.

Once seating capacity has been reached, individuals attempting to register will be notified that the meeting has reached capacity and given the option to listen to the proceedings by a toll-free phone line (as available slots permit).

Registrants will receive separate confirmations regarding acceptance as an attendee and as a speaker. Speaker confirmations will also indicate the time allocations for speaking (anticipate approximately 5 minutes). In the event that a registered speaker becomes unable to attend, we request that the individual notify CMS as soon as possible using the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice so that their time may be reallocated.

IV. Security, Building, and Parking Guidelines

This meeting is being held in a Federal government facility; therefore, in planning your arrival, we recommend allowing additional time to clear security. In order to gain access to the building and grounds, participants must have with them a government issued photo identification (for example, driver's license or passport), and a copy of their written meeting registration

confirmation(s). In addition, participants must be listed on an approved security list before persons are permitted entrance. Persons without proper identification will be denied access.

Individuals who are not registered in advance will not be permitted to enter the facility and will be unable to attend the meeting. Registered participants may not enter the building earlier than 7 a.m., e.d.t. on October 23, 2009. However, we encourage individuals to arrive no later than 8:15 a.m., e.d.t. to allow sufficient time to go through the security checkpoints at the gate to the compound, and to the Central Building lobby.

Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, including personal items such as desktops, cell phones, and palm pilots, are subject to physical inspection.

CMS cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the Designated Federal Office specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

It is possible that requests made in advance of the public meeting may be denied because of unique safety, security or handling concerns.

Parking permits and instructions are issued upon arrival by guards at the Security Boulevard main entrance.

All visitors must be escorted in areas other than the lower level lobby, cafeteria, auditorium and first-floor lobby in the Central Building. All visitors are responsible for making their own travel arrangements for both arrival at and departure from the town hall meeting.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 3, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–22484 Filed 9–15–09; 4:15 pm]

BILLING CODE 4120–01–P

Reader Aids

Federal Register

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CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

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