conducted a review of CHAP's Medicare HHA application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of CHAP's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against HHAs; and (5) survey review and decision-making process for accreditation;
- A comparison of CHAP's HHA accreditation standards to our current Medicare HHA conditions for participation (CoPs);
- A documentation review of CHAP's survey processes to:

++ Determine the composition of the survey team, surveyor qualifications, and CHAP's ability to provide continuing surveyor training.

++ Compare CHAP's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited HHAs.

++ Evaluate CHAP's procedures for monitoring HHAs found to be out of compliance with CHAP program requirements. This pertains only to monitoring procedures when CHAP identifies non-compliance. If non-compliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c)➢

++ Assess CHAP's ability to report deficiencies to the surveyed HHAs and respond to the HHA's plan of correction in a timely manner.

++ Establish CHAP's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of CHAP's staff and other resources.

++ Confirm CHAP's ability to provide adequate funding for the completion of required surveys.

++ Confirm CHAP's policies for surveys being unannounced.

++ Obtain CHAP's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the October 20, 2017 proposed notice (82 FR 48817) also solicited public comments regarding whether CHAP's requirements met or exceeded the Medicare CoPs for HHAs. There were no comments submitted.

IV. Provisions of the Final Notice

A. Differences Between CHAP's Standards and Requirements for Accreditation and Medicare Conditions of Participation and Survey Requirements

We compared CHAP's accreditation requirements for HHAs and its survey process with the Medicare CoPs at 42 CFR part 484, and the survey and certification process requirements of 42 CFR parts 488 and 489. CHAP's standards crosswalk, which crosswalks CHAP standards to the corresponding Medicare requirements and regulations, was also examined to ensure that the appropriate CMS regulation would be included in citations as appropriate. Our review and evaluation of CHAP's HHA application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, CHAP has revised its survey processes so that its processes are comparable to CMS requirements:

- § 488.5(a)(4)(vii), to ensure plans of corrections (PoCs) address all non-compliant practices and include policy changes required to correct the deficient practice.
- § 488.5(a)(7) through (9), to ensure surveyors maintain current licensure, that new surveyors receive the minimum number of mentored surveys prior to surveying independently, and that all new surveyors receive a 90-day evaluation of performance.
- § 488.5(a)(12), to ensure the appropriate number of medical records are reviewed during complaint investigations.
- § 488.26(b), to ensure that survey documentation includes a detailed deficiency statement that clearly outlines the number of medical records reviewed, describes the manner and degree of non-compliance, and supports the appropriate level of deficiency citation.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that CHAP's requirements for HHAs meet or exceed our requirements. Therefore, we approve CHAP as a national accreditation organization for HHAs that request participation in the Medicare program, effective March 31, 2018 through March 31, 2024.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, record keeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: March 8, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–05891 Filed 3–22–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2397–FN]

RIN–0938–ZB29

Medicaid Program; Announcement of Medicaid Drug Rebate Program National Rebate Agreement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces changes to the Medicaid National Drug Rebate Agreement (NDRA, or Agreement) for use by the Secretary of the Department of Health and Human Services (HHS) and manufacturers under the Medicaid Drug Rebate Program (MDRP). We are updating the NDRA to incorporate legislative and regulatory changes that have occurred since the Agreement was published in the February 21, 1991 **Federal Register** (56 FR 7049). We are also updating the NDRA to make editorial and structural revisions, such as references to the updated Office of Management and Budget (OMB)-approved data collection forms and electronic data reporting.

DATES:

Applicability Date: The updated National Medicaid Drug Rebate Agreement (NDRA) provided in the Addendum to this final notice will be applicable on March 23, 2018.

Compliance Date: Publication of CMS–2397–FN serves as written notice of good cause to terminate all existing rebate agreements as of the first day of the full calendar quarter which begins at least 6 months after the effective date of the updated NDRA (October 1, 2018). Manufacturers with an existing active

NDRA will have at least 2 full calendar quarters as of the effective date of this notice to sign and submit the updated NDRA. We will publish further guidance on this soon.

FOR FURTHER INFORMATION CONTACT: Terry Simananda, (410) 786–8144.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicaid Program, states may provide coverage of outpatient drugs as part of the medical assistance furnished to eligible individuals as an optional benefit as described in sections 1902(a)(10) and (a)(54) and 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for federal financial participation (FFP) in state expenditures for these drugs. In general, for payment to be made available under section 1903 of the Act for most drugs, manufacturers must enter into, and have in effect, a Medicaid National Drug Rebate Agreement (NDRA, or Agreement) with the Secretary of the Department of Health and Human Services (HHS) as set forth in section 1927(a) of the Act. Additionally, in order to meet the requirement for a rebate agreement in section 1927(a) of the Act, manufacturers must also meet the requirements of section 1927(a)(5) of the Act, which require a manufacturer to enter into an agreement that meets the requirements of section 340B of the Public Health Service Act, as well as section 1927(a)(6) of the Act, which requires a manufacturer to enter into a master agreement with the Secretary of Veterans Affairs in compliance with 38 U.S.C. 8126 (see section 1927(a)(1) of the Act).

Authorized under section 1927 of the Act, the Medicaid Drug Rebate Program (MDRP) is a program that includes CMS, state Medicaid Agencies, and participating drug manufacturers that helps to partially offset the federal and state costs of most outpatient prescriptions drugs dispensed to Medicaid beneficiaries. Currently there are more than 650 drug manufacturers who participate in the MDRP. The NDRA provides that manufacturers are responsible for notifying states of a new drug's coverage. Manufacturers are required to report all covered outpatient drugs under their labeler code(s) to the MDRP and may not be selective in reporting their national drug codes (NDCs) to the program. Manufacturers are then responsible for paying a rebate on those drugs that were dispensed and/or paid for, as applicable, under the state plan. These rebates are paid by manufacturers on a quarterly basis to states and are shared between the states and the federal government to partially offset the overall cost of prescription drugs under the Medicaid Program.

Similarly, manufacturers that wish to terminate an NDRA that have active covered outpatient drugs must request termination for all associated labeler codes, and provide a reason for the request (for example, all covered outpatient drugs under the labeler code are terminated), or if the request for termination is only for certain labeler codes, provide justification for such request. Additionally, as with the current policy, for purposes of ensuring beneficiary access to single source drugs and/or drugs that are not otherwise available in the MDRP, we may choose to grant an exception to issuing or reinstating an NDRA for certain labeler codes of a manufacturer prior to issuing an NDRA for all of the labeler codes under the manufacturer, or terminating certain labeler codes as mentioned above.

II. Summary of Proposed Provisions and Analysis of and Responses to Public Comments on the Proposed Notice

In the proposed notice, published in the November 9, 2016 **Federal Register** (81 FR 78816), we provided a draft agreement updating the NDRA to reflect the changes in the Covered Outpatient Drug final rule with comment period that was published in the February 1, 2016 **Federal Register** (81 FR 5170), as well as operational and other legislative changes that have occurred over the last 20 plus years since the NDRA was first issued in 1991. We indicated in the proposed notice that a sample of the finalized NDRA would be posted on the CMS website after we considered the public comments and published the final notice.

In the proposed notice, we included in the Addendum, a draft of the updated NDRA for use in the MDRP, upon which we requested public comment. In the proposed notice, we indicated that if adopted, a drug manufacturer that seeks Medicaid coverage for its drugs would need to enter into the NDRA with the Secretary agreeing to provide the applicable rebate on those drugs for which payment was made under the state plan. The NDRA is not a contract. Rather, it should be viewed as an opt-in agreement that memorializes the statute and regulations. Therefore, we noted our intention to use the updated NDRA as a standard agreement that will not be subject to further revisions based on negotiations with individual manufacturers. For a complete and full description of the draft agreement of the NDRA, see the ''Addendum—Draft Agreement: National Drug Rebate Agreement Between the Secretary of Health and Human Services (Hereinafter referred to as ''the Secretary'') and the Manufacturer'' published in the proposed notice in the November 9, 2016 **Federal Register** (81 FR 78818 through 78835).

In response to the publication of the November 9, 2016 proposed notice, we received 13 timely public comments, some of which are beyond the scope of our proposals in that notice and will not be summarized and included in our responses below. Revisions made to the NDRA in response specific comments are noted in the applicable response to comments. Additionally, edits have been made to provide further clarity to the NDRA. A summary of revisions and edits made to the NDRA are provided as a summary to each section below. The following are a summary of the relevant public comments that we received related to the proposed notice, and our responses to the public comments.

A. Section I. Definitions

1. General Comments

Comment: One commenter is concerned that it may be overly cumbersome to require the user of the Agreement to look up the referenced regulations to determine the definitions of the terminology used in the Agreement. The commenter suggested that CMS update the text of the definitions and reference existing statute and regulations, rather than just putting forward the latter. In particular, the commenter noted that its recommendation would be most usefully applied to the definitions of the following terms: ''average manufacturer price (AMP),'' ''best price,'' ''covered outpatient drug,'' ''monthly AMP,'' ''quarterly AMP,'' and ''rebate period.''

Response: We disagree with the commenter that the text of the definitions, and references to the relevant statutory and/or regulatory citations, be included in the definitions. We prefer to refer to statute and/or regulations, as well as agency guidance, as opposed to repeating such language in the NDRA, as we believe this decreases the chance of inaccurate or conflicting NDRA text. Additionally, although the updated NDRA cites definitions implemented most recently in the Covered Outpatient Drug final rule with comment period (Final Rule) published in the **Federal Register** on February 1, 2016 (81 FR 5170), and codified in 42 CFR part 447, subpart I, we believe that subsequent statutory and/or regulatory changes are

incorporated by section VIII.(a). of the Agreement, which provides that the Agreement is subject to any changes in the Medicaid statute or regulations that affect the rebate program.

Restore Depot Price and Single Award Contract Price Definitions

Comment: A few commenters recommended that CMS not delete the definitions of ''Depot Price'' and ''Single-Award Contract Price'' from the Agreement as these terms are used but not defined in the MDRP statute and regulations. Specifically, the commenters stated that the MDRP statute defines best price to exclude ''Depot Price'' and ''Single-Award Contract Price.'' These same terms are used in the regulatory definitions of best price and AMP, however they are not defined anywhere except in the current NDRA. Therefore, the commenters recommended that CMS maintain the current definition of ''Depot Price'' and ''Single-Award Contract Price'' in the NDRA.

Response: We agree with the commenter that the definitions of ''Depot Price'' and ''Single-Award Contract Price'' should be retained in the NDRA as they are used in determination of best price and AMP but are not defined anywhere except for the NDRA. In addition, since we are retaining the definition of ''Single-Award Contract Price'', we will also retain the definition of ''Single-Award Contract.'' These definitions are being retained without any revisions. The definitions read as follows:

- ''*Depot Price*'' means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.
- ''*Single-Award Contract*'' means a contract between the federal government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.
- ''*Single-Award Contract Price*'' means a price established under a Single-Award Contract.

2. Marketed

Comment: One commenter recommended that CMS retain the original NDRA definition of ''marketed'' so that the base date AMP ties to a sales transaction from which pricing data can be captured. The commenter noted the phrase ''first available for sale'' could be interpreted in a number of ways, including the date the drug receives Food and Drug Administration (FDA) approval, or when finished goods are ready to ship. Furthermore, the commenter stated that a first sale transaction might not occur for some time after those dates.

Response: While the commenter used the phrase ''first available for sale'' in its comment, the definition of ''marketed'' in the proposed notice does not include the word ''first.'' Rather it states that marketed means that a covered outpatient drug is available for sale by the manufacturer in the states (81 FR 78818). We believe the use of the phrase ''available for sale'' in the definition of ''marketed'' is consistent with past operational guidance issued by us regarding manufacturer reporting of base date AMP (see Manufacturer Release #69, in the manufacturer frequently asked questions (FAQs) section where we provide information in the answer A3 concerning the correct reporting of Market Date.) Therefore, we are retaining and finalizing this definition as provided in the proposed notice. Program Releases are available on *www.Medicaid.gov*.

3. State Drug Utilization Data

Comment: A few commenters supported the proposed definition of State Drug Utilization Data because it described the utilization on which rebates are due, and explicitly specified that the state invoice data must exclude drugs purchased under the 340B program. However, the commenters recommended that CMS make the following changes:

- Add the phrase ''consistent with the Unit Type reported by the manufacturer, for the NDC'' to the definition to minimize the significant volume of Unit of Measure disputes generated by state submissions of claimed units in forms different from the types reported by the manufacturers.
- Delete the phrase ''state utilization data is supplied on the CMS–R–144 form (that is, the state rebate invoice)'' because the format and data provided by the states on CMS–R–144 are not sufficient for accurate and timely validation of state claimed units submitted for rebate payments.
- Clarify that such data must exclude any Part D drug utilization by dual eligible individuals, in accordance with section 1935(d)(1) of the Act because some states are reimbursing Part D copayments for dual eligible individuals and are including these copayments in state utilization data.

Accordingly, the commenters suggested modifying the definition of ''State Drug Utilization Data'' to read, ''the total number of both fee-for-service (FFS) and managed care organization (MCO) units of each dosage form and strength, consistent with the Unit Type reported by the manufacturer for the NDC, of the manufacturer's covered outpatient drugs reimbursed during a rebate period under a Medicaid State Plan, other than units dispensed to Medicaid beneficiaries that were purchased by covered entities through the drug discount program under section 340B of the Public Health Service Act and other than units of Part D drugs dispensed to Medicare and Medicaid dual eligibles.''

Response: We disagree with the commenter that the proposed definition of ''State Drug Utilization Data'' should be changed to read, ''consistent with the Unit Type reported by the manufacturer for the NDC.'' Manufacturers do not always report the correct Unit Type for an NDC, and the state's drug utilization data reporting may serve to open the necessary dialogue to make manufacturers aware of the need to report the correct Unit Type, or to discuss the need for the state or the manufacturer to perform a conversion prior to rebate billing or payment.

We further disagree with the commenter's suggestion to delete reference to the CMS–R–144 because that is the Office of Management and Budget (OMB)-approved format and fields to be included on the state's quarterly rebate invoice. The CMS–R–144 is not considered claims-level data (CLD), the exchange of which is sometimes necessary for rebate payment validation purposes.

Finally, we disagree that adding a specific Medicare Part D exclusion is necessary since manufacturers have the right to dispute claims they believe are ineligible for rebate. If states and manufacturers cannot resolve disputes on their own, either party may ask the MDRP Dispute Resolution Program (DRP) team to assist by contacting the CMS Regional Office (RO) DRP Coordinator (a list of the RO DRP Coordinators can be found on *www.Medicaid.gov*).

Comment: One commenter requested that the definition of State Drug Utilization Data be strengthened to explicitly exclude units dispensed to Medicaid beneficiaries that were purchased by covered entities through the 340B program and incorporate specifics into the definition including timeframe in which data must be provided, with cross references to later sections of the rebate agreement, and include the following data elements: Date of service (DOS), prescription number, and billed amount.

Response: We updated the language in the proposed NDRA to explicitly

exclude units dispensed to Medicaid beneficiaries that were purchased by covered entities through the drug discount program under section 340B of the Public Health Service Act (PHSA). We believe this reference is sufficient. As this is an agreement between the Secretary and the manufacturer, not the state, we do not believe it is necessary to include the statutory timeframe for states to transmit the CMS–R–144, or rebate invoice. However, section III.(a)., ''Secretary's Responsibilities'' does include reference to the 60-day timeframe for state reporting of utilization data. Additionally, DOS, prescription number, and billed amounts are not required to be reported on the CMS–R–144; however, manufacturers may request the minimum CLD required to validate the utilization data received from the state. As discussed in Manufacturer Release #95 and State Release #173, we continue to encourage the exchange of the minimum CLD in such situations. Program Releases are available on *www.Medicaid.gov.*

Comment: One commenter expressed concern that the exclusion of 340B-purchased drugs from the definition of State Drug Utilization Data may be misunderstood by 340B covered entities as absolving the covered entities of their responsibility to avoid duplicate discounts under the 340B program, and instead placing such responsibility exclusively on state Medicaid agencies. The commenter further recommended that when updating the definition of State Drug Utilization Data in the Agreement, CMS should express that the update in no way affects the covered entities obligation under the 340B program to avoid duplicate discounts. The commenter further noted that while the administration of the 340B program is primarily the responsibility of the Health Resources and Services Administration (HRSA), the commenter asserted that section 1927(a)(5)(C) of the Act indicates that CMS shares responsibility for providing guidance to 340B covered entities on how to avoid duplicate discounts. The commenter requested that CMS take additional steps to guide 340B covered entities by establishing, in the Medicaid managed care context, a uniform means for 340B claims to be identified, as well as establish specific procedures for states, Medicaid MCOs, and 340B covered entities to follow to ensure that 340B claims are excluded from the data submitted to manufacturers for request rebates.

Response: We disagree that we should discuss 340B covered entity requirements in the NDRA, because those requirements are appropriately communicated by HRSA, the agency that is responsible for administration and oversight of the 340B program. We continue to work with HRSA, manufacturers, states, data vendors, PBMs, and other interested parties to try to identify and ensure exclusion of 340B FFS and MCO units from rebate billing.

Comment: One commenter stated that CMS should revise the definition of State Drug Utilization Data to specifically refer to the statutory prohibition on duplicate discounts in section 340B(a)(5)(A) of the PHSA. The commenter further recommended that CMS reference the duplicate discount prohibition in every instance throughout the revised NDRA in which it is implicated, emphasizing the need for states to request rebates only on FFS and MCO covered outpatient drugs that have not been purchased under the 340B program.

Response: While we appreciate the commenter's concern regarding duplicate discounts, we do not believe that the NDRA is the appropriate avenue to remind states of their obligation to exclude both FFS and MCO 340B claims from their manufacturer rebate requests, as the NDRA is an agreement that applies to manufacturers, not the states. Furthermore, while we added reference to the specific exclusion of 340B units from State Drug Utilization Data, we do not believe that it is necessary, as suggested by the commenter, to add a specific reference to section 340B(a)(5)(A) of the PHSA.

Comment: One commenter recommended that CMS incorporate additional specifics into the definition of State Drug Utilization Data to guide its operationalization including both the applicable timeframe in which the state's drug utilization data must be provided—states are often able to provide drug utilization data within a 7-calendar day timeframe—and the following list of *minimum* claims-level data elements that should be provided: Provider ID; Provider Name and Address; Date of Service; Paid Date; Billed Amount; Prescription Number; and National Drug Code (NDC) 11. Other data elements that the commenter recommended CMS should include in this minimum set are: Original claim quantity; conversion factor; invoice quantity; Healthcare Common Procedure Coding System (HCPCS) code; claim type; days' supply; allowed amount; third-party amount reimbursed; Dispensed-As-Written (DAW) indicator; and Medicaid plan name and identification number (BIN/Processor Control Number). The commenter further recommended that these data be made available in a standardized, downloadable format, and should be provided in addition to those indispensable data elements that are already consistently made available by states.

Response: As this is an agreement between the Secretary and the manufacturer, and not the state, we do not believe it is necessary nor appropriate to include the statutory timeframe for states to transmit the CMS–R–144, or rebate invoice; however, section III.(a)., ''Secretary's Responsibilities'' does include reference to the 60-day timeframe for state reporting of utilization data. We disagree with the commenter that there is a minimum set of CLD that should be expected along with State Drug Utilization Data, as different CLD fields are needed depending on variables such as provider setting, third-party co-pays, and the type of dispute or potential dispute. We continue to encourage states to share the appropriate minimum CLD for payment validation purposes on a case-by-case basis.

4. Unit

Comment: A few commenters disagreed with our proposed change to the definition of ''unit'' from ''drug unit in the lowest identifiable amount'' to ''drug unit in the lowest dispensable amount'' and the removal of the examples in the current definition (for example, tablet, capsule, milliliter, and gram). The commenters stated that the change to ''lowest dispensable amount'' does not define nor clearly address the two product unit data elements reported by manufacturers to CMS and is not consistent with current CMS guidance, including Drug Data Reporting for Medicaid (DDR) system Data Guides, where CMS provides that manufacturers use eight unit types: Injectable anti-hemophilic factor; capsule; each; gram; milliliter; suppository; tablet; and transdermal patch. The commenters suggest renaming ''unit'' to ''unit type'' and adding the specific eight reporting types for consistency with CMS manufacturer product reporting requirements. Specifically, one commenter suggested that ''Unit Type'' means ''one of the eight possible unit types by which the covered outpatient drug, form, and strength will be dispensed, as reported by the manufacturer consistent with the product reporting instructions from CMS (CMS 367–c). The eight possible unit types are injectable anti-hemophilic factor, capsule, each, gram, milliliter, suppository, tablet, and transdermal patch.''

The commenter indicated that if CMS does not accept the suggested changes, then CMS should explain the purpose of the change and whether it implies any change in the unit types reported by manufacturers because the ''unit type'' selected by the manufacturer is the basis for the pricing metrics data and unit rebate amount (URA) calculation.

Response: While we appreciate the comments, we have decided to retain the changes to the definition of ''Unit,'' set forth in the proposed notice as we believe this is more accurate and descriptive of what states receive on their claim than ''lowest identifiable amount.'' We are not including any of the eight specific unit types that are currently used, as those are subject to being updated by operational instruction, including DDR system Data Guides. Our intent is to update the NDRA as appropriate and ensure that we are able to keep pace with the changes in drug delivery processes and manufacturer and drug innovation. We seek to ensure that manufacturers that need a change in unit types based on future products are able to participate in the MDRP and to report their prices accurately in conjunction with necessary unit types, and that our beneficiaries have access to such drugs. ''Unit'' is meant to identify the lowest dispensable ''Units Per Package Size'' field of the ''Unit Type'' reported on the CMS–367. This is meant to better clarify the manufacturer's drug product reporting requirements.

5. Unit Rebate Amount (URA)

Comment: One commenter agreed with the proposed definition of ''Unit Rebate Amount'' as ''the computed amount to which the state drug utilization data is applied by states in invoicing the manufacturer for the rebate payment due,'' but recommended that CMS include additional text indicating CMS's longstanding position that manufacturers remain solely responsible for calculating the URA that is necessary to pay a rebate. Similarly, another commenter suggested that CMS clarify in the definition of ''Unit Rebate Amount'' that this is the amount computed ''by CMS'' to which the State Drug Utilization Data is applied by states and that CMS provide this URA information to states as a courtesy and drug manufacturers remain responsible for correctly calculating the URA for their covered outpatient drugs. The commenter stated this is important because manufacturers face Civil Monetary Penalties and potential False Claims Act liability for any late or misreported prices, and that there are adequate safeguards in place to ensure manufacturer compliance.

Response: We do not believe it is necessary to add language to the definition of ''Unit Rebate Amount'' to specify the manufacturer's responsibility to calculate a URA for each covered outpatient drug for which a state made a payment, or was dispensed, in a rebate period. However, we agree that the manufacturer's responsibility to calculate a URA should be strengthened, and this is carried out in section II, ''Manufacturer's Responsibilities.'' Therefore, in this updated NDRA, we are revising section II.(b)., by changing the last sentence of the proposed paragraph to state that ''[f]urthermore, except as provided under section V.(b). of this agreement, manufacturers are required to calculate a URA and make a rebate payment in accordance with each calculated URA to each State Medicaid Agency for the manufacturer's covered outpatient drug(s) by NDC paid for by the state during a rebate period.'' Additionally, we have added the following sentence to the end of the paragraph to further clarify our calculation of the URA: ''CMS may calculate a URA based on manufacturer-submitted product and pricing data and provide the URA to states in order to facilitate rebate billing. However, CMS's URA calculation does not relieve the manufacturer of its responsibility to calculate the URA.''

B. Section II. Manufacturer's Responsibilities

1. Point of Contact

Comment: Several commenters suggested allowing manufacturers the flexibility to identify more than one contact related to rebate invoice issues. Another commenter recommended that CMS clarify that the reference to a single point of contact refers only to a contact for rebate invoice issues. The commenters suggested that CMS develop more flexible language to allow manufacturers to identify more than one point of contact or permit a general mailbox for communications. Another commenter indicated that CMS should consider establishing both primary and secondary points of contact to ensure consistency of communication between the state and manufacturers in the event the designated contact becomes unavailable. The commenters stated such flexibility would facilitate communication between states and manufacturers while allowing for differences in business models and accommodating the reality of turn-over and employee absences or non-availability.

Response: The CMS–367(d) allows the manufacturer to identify one main contact for each of the following issues: Legal, Invoice, and Technical, and the NDRA has been updated at section II.(a). to specify the three contacts required on the CMS–367(d). Therefore, section II.(a). will now specifically state that ''[t]he manufacturer shall identify an individual point of contact for the Legal, Invoice, and Technical contacts at a United States address to facilitate the necessary communications with states with respect to rebate invoice issues.''

The requirement of the three official manufacturer contacts is to ensure accountability and to facilitate communications between CMS, the states, and manufacturers regarding all aspects of the MDRP. Manufacturers and states often exchange additional contacts with each other; however, for purposes of the MDRP, only one official contact will be submitted for each of the manufacturer's roles. In an effort to ensure there are no delays regarding invoice processing and rebate payments, we allow a general email address to be listed for the invoice contact, but requires that a direct contact name and telephone number be submitted on the CMS–367(d) for the official contact. The official Legal and Technical Contacts are required to list their direct email address and telephone numbers. Although it is the manufacturer's responsibility to ensure that their official contacts on file with CMS are updated at all times, many manufacturers do not update the official contacts on file in a timely manner. It is especially important for manufacturers to notify CMS of Technical Contact changes since the CMS's MDRP staff includes the manufacturer's Technical Contact on all communications with the manufacturer to ensure that the manufacturer's Technical Contact is aware of what is being requested by others with respect to its data.

2. Manufacturer Price Reporting and Rebate Payments

Comment: A few commenters recommended that CMS clarify that a rebate payment under the NDRA is only due on covered outpatient drugs paid for by the state ''under a Medicaid State Plan or approved waiver program'' or ''under Medicaid'' since some states have multiple, non-Medicaid programs under which they pay for covered outpatient drugs.

Response: We agree with the commenter that rebates negotiated as part of a state-only pharmacy program are not subject to the rebate provisions. We believe that the introductory

language of section II., ''Manufacturer's Responsibilities,'' offers these assurances where it provides that ''[i]n order for the Secretary to authorize that a state receive payment for the manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 *et seq.,* the manufacturer agrees to the requirements as implemented by 42 CFR 447.510. . .'' Therefore, if a manufacturer receives a request for payment under this agreement that it does not believe is billed under federal Medicaid, we recommend the manufacturer contact the state for clarification.

3. Reporting Inner and Outer NDCs

Comment: A few commenters did not support the additional language that manufacturer drug product pricing reports must ''include all applicable NDCs identifying the drug product which may be dispensed to a beneficiary, including package NDCs (outer package NDCs and inner package NDCs).'' One commenter indicated that sales are based upon the outer NDC, therefore, CMS should remove the language indicating manufacturers have to report information on both inner and outer package NDCs. Another commenter disagreed with using the undefined and often misconstrued terms for describing product NDC–11s as ''outer package'' and ''inner package'' because reporting extraneous information increases the risk of potential error.

In particular, the commenter recommended that we delete the last sentence in section II.(c). which states, ''Reports to CMS should include all applicable NDCs identifying the drug product which may be dispensed to a beneficiary, including package NDCs (outer package NDCs and inner package NDCs)'' and replace it with the following, ''Manufacturer product data reporting to CMS should include all applicable NDCs identifying the drug product, as available for product sales in the states and as listed on the product label, which may be dispensed to a beneficiary.''

Response: We disagree with the comments summarized above in which commenters do not support the addition of the language in II.(c). regarding the inclusion of inner and outer NDCs for package NDCs be reported to us. We issued agency guidance clarifying the requirement for reporting of inner and outer NDCs in Manufacturer Release #106 and State Release #183. Manufacturer sales of NDCs do not determine whether the NDC is reported to us, or the NDC's status as a covered outpatient drug. As we indicated in the above releases, in accordance with section 1927(b)(3)(A) of the Act, manufacturers that have signed a rebate agreement are required to report certain pricing information for all covered outpatient drugs. As was stated in the aforementioned guidance, manufacturers must report all of their NDCs that meet the definition of a covered outpatient drug as described in statute at sections 1927(k)(2) through 1927(k)(4) of the Act, and regulation at § 447.502, to ensure compliance with the applicable reporting and payment requirements.

Also, in accordance with section 1927(b)(1)(A) of the Act, such manufacturers are required to make rebate payments for covered outpatient drugs dispensed after December 31, 1990, for which payment was made under the state plan for such a period. This includes drugs dispensed to Medicaid MCO enrollees. Additionally, per 1927(b)(2)(A) of the Act, states are required to report to manufacturers at the end of each rebate period, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made or which was dispensed under the plan, including information reported by each Medicaid managed care organization. Therefore, if a state has reimbursed a provider for FFS claims for an inner NDC, or if an inner NDC was dispensed for an MCO claim, the state is required to report or invoice the inner NDC to the manufacturer, and the manufacturer is subsequently required to pay rebates in accordance with section 1927(b)(1)(A) of the Act.

We further disagree that describing an NDC as an inner or outer NDC could be misconstrued, or that reporting information on both inner and outer NDCs is extraneous and could lead to potential errors. As noted above, we believe both NDCs may be evaluated as covered outpatient drugs, and if an NDC is a covered outpatient drug, then it should be reported as our guidance further clarifies. In other words, when states receive a claim from and pay a provider for dispensing an inner NDC, the state is required to invoice the manufacturer for that NDC and the manufacturer is subsequently required to pay rebates in accordance with 1927(b)(1)(A) of the Act. Program Releases are available on *www.Medicaid.gov.*

Comment: One commenter requested that CMS clarify the purpose of the following text, proposed for addition in section II.(c). to read, ''CMS uses drug information listed with FDA, such as Marketing Category and Drug Type, to be able to verify in some cases that an NDC meets the definition of a covered outpatient drug . . . [.]'' The commenter stated that this statement may be unnecessary and could lead to confusion if not omitted from the updated NDRA revision. In the absence of such a clarification, the commenter recommended CMS delete this clause.

Also with regard to section II.(c)., the commenter requested that CMS clarify whether the ''reports'' referenced in the text—that is, ''[r]eports to CMS should include all applicable NDCs identifying the drug product . . .''—are meant to be distinct from reports adding product information into the DDR system. The commenter noted this clarification is necessary given that, currently, products must be listed with the FDA before being added to the DDR system.

Response: We have decided to remove the phrase ''in some cases'' from the sentence regarding use of FDA information so that the provision now reads, ''CMS uses drug information listed with FDA, such as Marketing Category and Drug Type, to be able to verify that an NDC meets the definition of a covered outpatient drug . . . [.]'' We believe that the use of the phrase ''in some cases'' is neither necessary nor consistent with the discussion surrounding covered outpatient drugs in the final rule (81 FR 5184). We believe that when the entire sentence is considered (that is, ''CMS uses drug information listed with FDA, such as Marketing Category and Drug Type, to be able to verify that an NDC meets the definition of a covered outpatient drug, therefore, manufacturers should ensure that their NDCs are electronically listed with FDA.''), it is clear to manufacturers how we use drug information listed with FDA, and why it is in a manufacturer's best interests to ensure that their NDCs are electronically listed with FDA. Manufacturers should ensure that their NDCs are electronically listed with FDA for us to have access to information to be able to verify that an NDC meets the definition of a covered outpatient drug.

As for the commenter's request for clarification on the ''reports to CMS'' reference, this text is meant to instruct manufacturers to report all NDCs to CMS that may be dispensed to a beneficiary. This includes, but is not limited to NDCs on inner components within a larger container, if that NDC on the inner component represents a drug that meets the definition of a covered outpatient drug. NDCs must be listed with FDA in order for a manufacturer to be able to certify the product data in DDR. Manufacturers may contact

mdroperations@cms.hhs.gov if they encounter difficulty with this requirement.

4. Quarterly Pricing Adjustment Reporting

Comment: Several commenters stated that the proposed language in section II.(d). could be read to require that manufacturers restate their AMP, best price, customary prompt pay discount data, and nominal price data within 30 days of the end of each quarter in which any adjustment can be made in the last-reported figures. The commenters recommended that CMS not finalize this provision because a requirement to make restatements each quarter whenever an adjustment can be made conflicts with the current regulations at 42 CFR 447.510(b) which provide that ''a manufacturer must report to CMS any revision to AMP, best price, customary prompt discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due. Any revision request that exceeds 12 quarters will not be considered . . . A manufacturer must report revised AMP within the 12-quarter time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.''

The commenters noted that the regulation does not require that restatements be filed more than once within that 3-year window—only that the information must be restated by the end of the window. The commenters stated that our proposed language could conflict with the regulations and eliminate the flexibility the regulations provide to manufacturers regarding the timing of restatements, as it suggests that manufacturers would be required to make restatements more frequently than required by the regulations. To ensure that the Agreement aligns with the regulations, the commenters recommended that CMS not finalize this proposed change.

Response: We agree with the commenters that this phrase as originally worded could be misinterpreted. Therefore, we are revising the last sentence of section II.(d). to state that ''adjustments to all prior quarterly pricing data must be reported for a period not to exceed 12 quarters from when the pricing data were originally due as required under § 447.510(b).''

5. Increases and Decreases of Rebate Payment Amounts

Comment: Several commenters disagreed with our proposal to add the following sentence to section II.(f).: ''To the extent that changes in product, pricing, or related data cause increases to previously submitted total rebate amounts, the manufacturer will be responsible for timely payment of those increases in the same 30-day time frame as the current rebate invoice.'' The commenters stated that rebate payments must be adjusted when information changes causing either increases or decreases in previously submitted total rebate amounts and the Agreement must address both scenarios to be consistent with existing standards and that manufacturers continue to be entitled to recoup rebate overpayments as well.

Response: The purpose of this addition to section II.(f). is to state the manufacturers obligations when pricing or product data changes submitted by the manufacturer cause an increase in the amount owed to the state from previously paid rebate amounts. Manufacturer Release #58 provided guidance clarifying that interest applies when manufacturers fail to pay increases due to Prior Period Adjustments (PPAs) timely, and this is reflected in the proposed and updated NDRA. Program Releases are available on *www.Medicaid.gov.*

When PPAs cause a decrease to the amount of rebates previously paid by manufacturers, states will issue a credit upon agreement with the manufacturers about where the manufacturer would like the credit applied. To facilitate timely credits being applied by states, we encourage manufacturers to communicate which NDC line item(s) the credit(s) should be applied to with states. In response to public comment, and consistent with existing guidance, we have revised the updated NDRA at section II.(f). to add: ''To the extent that changes in product, pricing, or related data cause decreases to previously submitted total rebate amounts, the manufacturer should communicate with the states regarding where to apply the line-item (NDC-level) credit.'' to the end of the paragraph. Furthermore, we continue to encourage manufacturers and states to work together to ensure that appropriate payments are made, and credits applied, timely.

Comment: One commenter requested that CMS explain what changes cause decreases to previously submitted total rebate amounts.

Response: As previously stated, when PPAs cause a decrease to the amount of rebates previously paid by manufacturers, states will issue a credit upon agreement with the manufacturers about where the manufacturer would like the credit applied. We continue to encourage manufacturers and states to work together to ensure that appropriate payments are made, and credits applied, timely.

Comment: A few commenters urged CMS to clarify that the 30-day rebate does not conflict with the existing guidance provided under the Medicaid Rebate Data Guide for Labelers (April 2016), which provides that timely rebate payments must be made within 37 calendar days from the date a state receives the adjustment from CMS on the current quarterly URA data file. CMS should clarify that the existing policy permitting manufacturers to make rebate payments within 37 calendar days from the rebate invoice postmark date remain intact. Any confusion to the timeline for rebate payment could have a significant, negative operational impact on manufacturers and create additional administrative burden for manufactures, states, and CMS.

The commenters further noted that CMS recently reminded manufacturers of this ''38th day rule'' in a March 10, 2014 Program Notice, which stated that: ''[f]or purposes of calculating interest on late rebate payments, previously issued guidance (for example, Manufacturer Release #7 and State Release #29) has noted that manufacturers have 37 calendar days (as evidenced by the postmark by the U.S. Postal Service on the envelope) to pay rebates before interest begins to accrue.''

The commenters recommended that the updated NDRA include a new subsection (g) to follow the revised subsection (f) in which the 30-day payment requirement is stated (all other subsections re-lettered accordingly) to read, ''(g) For purposes of calculating interest on late rebate payments, manufacturers have 37 calendar days to pay rebates before interest begins to accrue. Based upon the state's invoice transmission method, manufacturers should use the state's email notification date, or the postmark by the U.S. Postal Service on the envelope.''

Response: While we appreciate the comment, we do not believe that the NDRA is the appropriate vehicle to relay such operational guidance. However, we are clarifying that the statutory requirements have not changed, nor has the language from the current rebate agreement, with respect to the rebate payment being made by the manufacturer in the proposed NDRA. The operational guidance relating to interest application after the 37th day from the postmark date of the invoice can be found in various Program Releases, including State Releases #29, and #166, as well as Manufacturer Release #7. Program Releases are available on *www.Medicaid.gov.*

Comment: One commenter requested revisions to section II.(f). to identify the parties' respective responsibility in the event that changes in product, pricing, or related data cause decreases to previously submitted total rebate amounts, and any credits to the manufacturer that may occur as a result of such decreases. The commenter noted CMS should clearly establish a single process and timeline for resolving changes in data regardless of whether they result in decreases or increases in the submitted total rebate amounts.

Response: As stated in previous responses to comments on decreases in rebate liability necessitated by manufacturer changes to pricing and/or product data, manufacturers are responsible for informing states to which line-item credits are to be applied. State responsibility is not included in the NDRA as the agreement is between the manufacturer and the Secretary and is not the appropriate vehicle for such guidance.

6. Comply With Statute, Regulation, Agency Guidance and Rebate Agreement

Comment: Several commenters noted that CMS should not include ''agency guidance'' among the items listed in section II.(g). as such a provision would circumvent the Administrative Procedures Act (APA), exceed the Secretary's authority under the Medicaid statute, be inconsistent with fundamental principles of contract law, fundamentally unfair, and over broad. The commenters further noted that under the APA, subregulatory guidance does not have the force of law and is not binding. Furthermore, commenters have indicated that the Medicaid rebate statute does not authorize CMS to override the APA, which serves to ensure that binding law is issued through a careful, deliberative process with stakeholder input.

Response: We do not believe that including a reference to agency guidance in this provision implicates the APA. Agency guidance is a reference to the interpretive guidance published by the agency, interpreting the Medicaid Drug Rebate statute and implementing regulations. Including a reference to ''agency guidance'' in this provision in the Agreement is simply a term of the Agreement, and does not suggest that agency guidance carries the force of law, as statutes and regulations do so. Therefore, we have retained ''agency guidance'' in section II.(g). of the rebate agreement.

Comment: A few commenters did not agree with our deletion of the requirement that CMS provide ''actual prior notice to the manufacturer'' before the manufacturer has to meet any change in its compliance obligations. The commenters were concerned that the lack of notice only exacerbates the concern over the addition of ''agency guidance'' to this provision in section II.(g). of the NDRA and as a result, even when manufacturers regularly check on their compliance obligations, they may not succeed in complying with all changes to agency guidance obligated to do under the updated NDRA. The commenters requested that CMS finalize the NDRA with such a notice requirement restored.

Response: We disagree with the commenters that this language remains necessary in the NDRA, as the laws and recently implemented final regulations provide the legal framework for the program. Furthermore, as stated previously, agency guidance is a reference to the interpretive guidance published by the agency, interpreting the Medicaid Drug Rebate statute and implementing regulations. Including a reference to ''agency guidance'' in this provision in the Agreement is simply a term of the Agreement, and does not suggest that agency guidance carries the force of law, as statutes and regulations do.

C. Section III. Secretary's Responsibilities

1. States' Reporting of Drug Utilization Information

Comment: Several commenters were concerned that the language CMS proposed in section III.(a). appears to weaken states' reporting requirements, could impact the reporting of state drug utilization data and conflicts with the Medicaid statute. While commenters acknowledged that CMS are the party to the NDRA, not states, and therefore could not bind states via the NDRA, they asserted that CMS must maintain consistency between the NDRA and the statute, which is binding on the states. Therefore, the commenters noted that CMS should incorporate state obligations by reference or specifically quote section 1927(b)(2)(A) of the Act instead of adopting language that differs substantively from the statute.

The commenters further noted that CMS should use the term ''shall,'' since it is consistent with the statutory requirement, rather than the draft revised NDRA's more permissive ''employ best efforts'' language. The commenters believe the revised text ''employ best efforts'' is open for broad interpretation, and as such lends significant uncertainty to the exact CMS activities that will be undertaken to ensure state compliance with rebate invoice reporting requirements. The commenters noted that CMS should strengthen the language to reflect our responsibility to ensure state's compliance with the applicable statutory provisions. However, if CMS continue to use the language ''employ best efforts'' in the updated NDRA, the commenters urged CMS to issue draft guidance simultaneously to the finalization of the NDRA to provide manufacturers with a more concrete definition of how the Agency will comply with existing statutory obligations.

Response: We agree with the commenter and are updating section III. of the NDRA to reflect that state utilization data are due no later than 60 days from the end of the rebate period. While we appreciate the comments, we do not believe that the description in section III.(a). of the proposed NDRA of the Secretary's responsibilities in regards to states reporting requirements to manufacturers conflicts with the statute. Section 1927(b)(2)(A) of the Act provides the 60-day timeframe for the states reporting obligations under the MDRP to provide relevant information in a format established by the Secretary and section III.(a). reflects that requirement. The rebate invoice (CMS–R–144) or alternative information described is that established format. Furthermore, we believe that the updated section III.(a). does not weaken states' reporting requirements because states are not subject to the agreement. States that opt to cover drugs are subject to applicable statutory, regulatory and sub-regulatory guidance. While we updated the paragraph in the proposed NDRA to be more inclusive of details, we have not changed or noted a change in state process. Additionally, we disagree that retaining the language that the Secretary ''. . . will employ best efforts,'' which is similar to language in the current rebate agreement, is contradictory to the statute or that it will lead to confusion and be open for misinterpretation. The NDRA is an agreement between the Secretary and the manufacturer, and is not the appropriate vehicle to specifically address state reporting requirements.

Comment: One commenter urged CMS to revise the new language at section III.(a). to eliminate any perception that the timeliness requirements apply only to FFS rebate claims since the new language refers to information about Medicaid utilization of covered outpatient drugs that were ''paid for'' during the rebate period. The commenter noted that CMS distinguishes between manufacturer

rebate obligations which accrue for FFS units based on the date of payment to pharmacies and MCO units based on the date of dispensing to Medicaid enrollees. The commenter further noted that the statute refers back to the number of units ''dispensed . . . for which payment was made under the plan during the period, including such information reported by MCOs . . . .'' Accordingly, the commenter recommended that section III.(a). be revised to read, ''. . . that is, information about Medicaid utilization of covered outpatient drugs that were dispensed and for which payment was made under a Medicaid State plan or approved waiver during the rebate period.''

Response: We agree with the commenter that the language in section III.(a). could be misinterpreted to apply only to FFS rebate claims. Therefore, we are revising section III.(a). to state ''. . . information about Medicaid utilization of covered outpatient drugs that were dispensed and/or paid for, as applicable during the rebate period'' to clarify that timeliness requirements apply to both FFS and MCO rebate claims.

D. Section IV. Penalty Provisions

1. Civil Monetary Penalties (CMPs)

Comment: One commenter recommended that CMS keep the phrase ''in connection with a survey'' in the provision of the NDRA on Civil Monetary Penalties (CMPs) in section IV.(a). because the underlying statutory authority only authorizes the Secretary to impose CMPs on a manufacturer that refuses a request for information in connection with a survey about drug charges or prices. The commenter noted that the Medicaid rebate statute states at section 1927(b)(3)(B) of the Act that:

''The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information.''

The commenter believes that the language in the NDRA should accurately reflect this statutory authority.

Response: We agree that the language in the NDRA should accurately reflect the statutory language. Therefore, we are adding back in to this section the phrase ''in connection with a survey''. Section IV.(a). now reads as follows: ''The Secretary may impose a civil monetary penalty under section III.(b)., as set forth in 1927(b)(3)(B) of the Act and applicable regulations, on a wholesaler, manufacturer, or direct seller of a covered outpatient drug, if a wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request by the Secretary, or the Secretary's designee, for information about covered outpatient drug charges or prices in connection with a survey or knowingly provides false information, including in any of its quarterly reports to the Secretary. The provisions of section 1128A of the Act (other than section (a) (for amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B) of the Act and applicable regulations.''

Comment: One commenter appreciated our reference to existing statute and regulations in updating the penalty provisions of the NDRA, but questioned the proposal to only cite relevant statute/regulation without reference or summary of the text to which the user is referred. In particular, the commenter noted that these revisions may prove overly cumbersome in section IV.(c). that describes the CMPs that may be imposed for failure to provide timely information on AMP, best price, or base date AMP, and if CMS included only a reference to the relevant statute, users would need to separately look up the different penalty amounts referenced in the NDRA text, rather than be able to reference them without requiring a document other than the NDRA itself. Thus, the commenter requested that CMS update the text of the provisions with specific dollar values and reference existing statute and regulations, rather than just putting forward the latter.

Response: We disagree that the statutory and/or regulatory text be restated in section IV.(c). of the NDRA, and that otherwise the provision is overly cumbersome. As stated previously in response to comments, our approach in the proposed and updated NDRA is to refer to statute and/or regulations, as well as agency guidance, as opposed to repeating such language in the NDRA, as we believe this decreases the chance of inaccurate or conflicting NDRA text. The general provisions of the NDRA incorporate such statutory requirements not explicitly referenced in the NDRA. We have added language in the general provisions to reflect this approach.

2. Remedies Available for Violations of the Agreement

Comment: One commenter recommended that CMS revise the language in section IV.(d). to be even-handed and provide the same protection to manufacturers. The commenter specifically recommended revising this sentence to add ''or manufacturers'' to read, ''[n]othing in this Agreement shall be construed to limit the remedies available to the United States, states, or manufacturers for a violation of this Agreement or any other provision of law.''

Response: Manufacturers are afforded protections under section V. of the NDRA, which addresses dispute resolution procedures in the event a manufacturer wishes to dispute state drug utilization data on the rebate invoice. Therefore, we are not adding the reference to ''or manufacturers'' as requested by the commenter.

E. Section V. Dispute Resolution Process

1. Timing of Dispute

Comment: One commenter requested greater clarification around the timing and process of dispute resolution.

Response: We agree with the commenter with respect to clarifying the timing of dispute resolution. Based on many years of experience in assisting with dispute resolution efforts when asked by manufacturers and states, we realize that 60 days is not enough time for a typical dispute to be resolved. Therefore, section V.(c). of the updated NDRA is changed from requiring a dispute to be resolved within 60 days before moving to the state hearing process, to being resolved ''within a reasonable time frame.'' Additionally, as noted in previous responses, we encourage interested parties to go to our DRP web page, *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/dispute-resolution/index.html,* for more information about our suggestions and information regarding dispute resolution.

2. Audit of State Drug Utilization Data

Comment: A few commenters noted the importance of manufacturers' access to CLD and the need to ensure the accuracy of state-reported data as critical mechanisms to avoid disputes in the first place, and where they cannot be avoided, resolve them more efficiently and expeditiously for all program participants. The commenter noted that CMS requires that state invoices to manufacturers include certain information but permit states to furnish that data at an aggregate level in the rebate invoice. Commenters noted further that CMS also makes it clear in the Final Rule that ''states will need to have detailed, prescription-level information or other mutually-agreeable

data available for dispute resolution purposes, if requested by a manufacturer in accordance with the state provision of information requirements of section 1927(b)(2)(A) of the Act'' (81 FR 5272).

The commenters suggested that CMS specify in the NDRA that minimum CLD elements needed to facilitate dispute resolution include (in addition to the NDC, period covered, and whether the prescription is fee-for-service or managed care) elements such as the pharmacy ID (including pharmacy name and address), units, dispense date, 340B identifier, unit of measure, provider ID (NPI) and any third party payment. Commenters also recommended that CMS specify that states provide CLD in a standard format, and electronically or in a downloadable format on a quarterly basis.

Response: We disagree with the commenters' suggestions to revise the updated NDRA to include specific requirements related to the CLD that may be requested of states and used for payment validation. We also do not believe that it is appropriate to include such detail in the NDRA as it is an agreement between the Secretary and the manufacturer, and is not the appropriate vehicle to specifically address these issues. Manufacturers retain the right to request the minimum CLD required to validate the utilization data received from the state. We further disagree with the commenter that there is a minimum set of CLD that should be expected along with State Drug Utilization Data, as different CLD fields are needed depending on variables such as provider setting, third-party co-pays, and the type of dispute or potential dispute. Consistent with Manufacturer Release #95 and State Release #173, we continue to encourage states to share the appropriate minimum CLD for payment validation purposes on a case-by-case basis. Program Releases are available on *www.Medicaid.gov.*

Comment: One commenter suggested that CMS recognize the need for states to acknowledge disputes within a specified time period and to provide relevant CLD to manufacturers within a specified time frame and that CMS should revise our changes to section V.(d). so that it reads as follows: ''Nothing in this section shall preclude the right of the manufacturer to audit the state drug utilization data reported (or required to be reported) by the state. The Secretary encourages the manufacturer and the state to develop mutually beneficial audit procedures.'' Commenters further suggested that at a minimum, however, CMS shall require the state to make available to the manufacturer claim-level data necessary to review or audit the State drug utilization data.

Response: As the NDRA is an agreement between the Secretary and the manufacturer, we disagree that we should incorporate a state's obligation into the NDRA. However, as referenced in Manufacturer Release #95 and State Release #173, as well as the ''Medicaid Drug Rebate Data Guide for Labelers'' and ''Medicaid Drug Rebate Data Guide for States'' (available as a download in the DDR system), we encourage both manufacturers and states to share such information with others involved in rebate payment and disputes. Official disputes must be entered into by manufacturers via the Reconciliation of State Invoice (ROSI) (Form CMS–304) or Prior Quarter Adjustment Statement (PQAS) (Form CMS–304a), and operational instructions for the ROSI and PQAS are provided in these data guides. Program Releases are available on *www.Medicaid.gov.*

3. State Hearing Process

Comment: One commenter stated it is critical that CMS provide more transparency about the state hearing process that is supposed to be used to resolve disputes that cannot be resolved in good faith within 60 days. The commenter indicated that under current section V.(c). of the current Rebate Agreement, if disputes cannot be resolved after this 60-day period, CMS shall require the state to make available to the manufacturer the state hearing mechanism available under 42 CFR 447.253(e). However, the proposed rebate agreement deletes the reference to § 447.253(e) and instead refers to the state hearing mechanism ''available to providers for Medicaid payment disputes.'' The commenter indicated that this deletion may have been intended to be a substantive change, since § 447.253(e) concerns the appeal procedure for providers to receive administrative review of ''payment rates'' and would appreciate CMS clarifying whether the change it proposes is substantive and (if so) what effect it would have.

The commenter further stated it is difficult to determine what the process is that CMS are referencing with its proposed language and is not certain whether CMS confirmed that such a process exists in each state. The commenter further recommended that if CMS does not intend for the proposed language to constitute a substantive change, CMS should provide more clarity around the practical details regarding how the dispute process available under § 447.253(e) would work, such as how a manufacturer would begin the dispute process, what procedures would be used to facilitate dispute resolution, and where to look for guidance on the process. Even if the proposed changes to section V.(c). are meant to constitute a substantive change, the commenter indicated it would still appreciate receiving guidance about the process ''available to providers for Medicaid payment disputes.''

Response: The current NDRA references the incorrect paragraph for state hearings as § 447.253(c); the commenter is correct that § 447.253(e) is the correct provider hearing reference. The deletion of the reference to the CFR cite was not intended to be a substantive change. We have added the correct CFR cite (§ 447.253(e)) to section V.(c). in the updated NDRA. Furthermore, we have issued guidance for the state hearing process via State Release #181 and Manufacturer Release #105. In these releases, we reminded states and manufacturers that the state hearing process is an option available to both states and manufacturers when they have reached an impasse through the normal dispute resolution process, or when one of the parties is not being responsive to another's efforts to engage in dispute resolution. Given the variability in the states' hearing processes, we recommended that each state make manufacturers aware of the process to request such a hearing in that state. Program Releases are available on *www.Medicaid.gov.*

4. Retain Section V.(e). From Current NDRA

Comment: A few commenters questioned the intent of removing section V.(e). of the existing rebate agreement, which states, ''adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.'' One commenter questioned if it means disputed amounts are not subject to adjustment (either an increase or decrease). Another commenter recommended that CMS retain the current section (e) in the current section V and make adjustments to the language to allow for adjustments that constitute both increases and decreases in the rebate amount since § 447.510(b)(1) requires that ''a manufacturer must report to CMS any revision to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due.'' Another commenter specifically also

recommended including section (e) from the current NDRA but also suggested that CMS revise the sentence to read, ''[t]o the extent that changes in product, pricing, or related data cause increases or decreases to previously submitted total rebate amounts, the manufacturer will make appropriate payment adjustments in the same timeframe as the current rebate invoice (that is, 38 days after the state mails the state utilization data).''

Response: We do not believe that any revisions are necessary, as we believe section V.(b). of the updated NDRA captures these concerns and addresses these issues. As stated earlier in response to comments, we updated language in section II.(f). regarding increases and decreases in rebate amount, and believe that this provides sufficient information on processing rebate increases and decreases.

5. General Request for DRP Guidance

Comment: One commenter recommended that CMS take this opportunity to issue additional guidance that can facilitate dispute resolution. Currently, this process can be costly for manufacturers and states, and can delay payment of rebates in cases where disputed utilization data turns out to be correct. The commenter further noted that the HHS Office of Inspector General (OIG) has recommended additional steps to prevent and resolve disputes and found that certain disputes occur frequently due to poor-quality data (disputes over drugs with complicated unit-of-measure conversions, physician-administered drugs, 340B purchased drugs, and terminated drugs). The commenter stated that CMS could accelerate dispute resolution by revising the NDRA to identify minimum steps that states could take to facilitate dispute resolution and to provide that manufacturers will not be responsible for interest payments during periods before these minimum steps are taken.

Response: While we appreciate the comments, we disagree that additional guidance on the dispute resolution process be set forth in the NDRA. Dispute resolution is an alternative to the state hearing mechanism, and is a process between the state and manufacturer. We have no formal role in dispute resolution, but continue to assist to the extent possible, when manufacturers and/or states request support in resolving a dispute. Therefore, we will continue in our role as facilitator when practical, and we encourage interested parties to review our DRP web page, *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/dispute-resolution/index.html,* for more information about our suggestions regarding dispute resolution.

Comment: One commenter requested more information about our role in facilitating dispute resolution between states and manufacturers. More specifically, the commenter requested additional clarity around our voluntary dispute resolution program process for states and manufacturers such as how the (dispute) program works, how a manufacturer can facilitate use of the program, our role in the dispute process, and our point of contact for the program.

Response: As noted previously, this type of information is generally distributed through operational guidance. In this case, we release information about our role in dispute resolution, the process to request our facilitation of disputes, and our points of contact on our website at *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/dispute-resolution/index.html.*

6. Retain Section VI. From Current NDRA

Comment: Several commenters stated CMS should not finalize the deletion of section VI.(a). of the current NDRA, which pertains to patient access to outpatient prescription drugs. The commenters stated this provision recognizes that the access requirements in the rebate statute are the reason that manufacturers sign the Medicaid rebate agreement, and CMS has a responsibility to take action if states do not fulfill their obligations under the rebate statute. One commenter suggested that rather than deleting this provision, it should be reinforced and further strengthened in the updated NDRA to conform to the drug access requirements of section 1927 of the Act. The commenter noted that CMS reaffirmed the states' statutory obligation to cover covered outpatient drugs for which the relevant manufacturer has a Medicaid drug rebate agreement in State Release #172 (*https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf*) in response to Hepatitis C virus (HCV) therapies being unreasonably restricted by the states. This commenter suggested CMS explicitly refer to the text of State Release #172 that states provide Medicaid beneficiaries with access to prescribed medicines as described under section 1927 of the Act. The commenter stated that CMS may choose to continue to include this text in the ''dispute resolution'' section of the NDRA, or include the text under section III, ''Secretary's Responsibilities[.]''

Response: As stated previously in response to comments, our approach in the proposed and updated NDRA is to refer to or cite statute and/or regulations, as well as agency guidance, as opposed to repeating such language expressly in the NDRA, as we believe this decreases the chance of inaccurate or conflicting NDRA text. We believe section VIII, the General Provisions section of the NDRA incorporates such statutory requirements not explicitly referenced in other sections of the NDRA. However, in order to ensure clarity on this point, we have updated paragraph (a) of Section VIII, General Provisions to add an introductory sentence that reads: ''This agreement is authorized by the applicable provisions in sections 1902, 1903, 1905, and 1927 of the Act, and the implementing regulations at 42 CFR part 447.'' Therefore, in updating the NDRA we do not believe that the current section VI is necessary. Moreover, the drug access requirements in section 1927 of the Act continue to be binding on states, regardless of the inclusion of the state requirement in the NDRA between the Secretary and manufacturers. As the commenter noted, when specific drug access issues arise, as most recently on the HCV drugs referenced in State Release #172, we release agency guidance reminding states of drug access requirements. We have published such guidance over the years, such as State Release #38, about coverage of a new multiple sclerosis drug. Also, we issued State Release #51, in response to proposed state legislation that would limit drug coverage for states seeking to leverage discounts from manufacturers, clarifying that such legislation would not supersede drug coverage requirements in section 1927 of the Act. We will continue, when circumstances arise, to remind states of their coverage requirements under the MDRP. Program Releases are available on *www.Medicaid.gov.*

F. Section VI. Confidentiality Provisions

Comment: One commenter agreed with our updated section VI.(b)., which states that, ''[t]he manufacturer will hold state drug utilization data confidential. If the manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or Agreement, the

manufacturer will observe confidentiality statutes, regulations, and other properly promulgated policy concerning such data.'' However, the commenter recommended that CMS amend the section to recognize the reality that manufacturers must often share drug utilization data with contractors for various business reasons by adding language to section VI.(b). to read, ''[t]his confidentiality provision does not prevent a manufacturer from sharing drug utilization data with a contractor or other agent that helps the manufacturer perform audits or otherwise assess drug utilization data, provided that the contractor or agent agrees to treat the drug utilization data confidentially.''

Another commenter requested that CMS clarify how the confidentiality provisions relate to a manufacturers' use of third parties for dispute resolution and outsourcing claims processing.

Response: We do not believe that the edits suggested by the commenter are necessary as section VIII.(g). of the updated NDRA provides for the incorporation of contractors in the terms ''State Medicaid Agency'' and ''Manufacturer.'' However, we are revising section VIII.(g). to provide further clarification on this matter. Therefore, section VIII.(g). is being revised to read as follows: ''[t]he terms ''State Medicaid Agency'' and ''Manufacturer'' incorporate any contractors which fulfill responsibilities pursuant to the agreement unless such contractors are specifically excluded in the rebate agreement or such exclusion is specifically agreed to by an appropriate CMS official.''

G. Section VII. Nonrenewal and Termination

1. Re-Entrance After Termination

Comment: One commenter is concerned that the language in section VII.(d). which states that the manufacturer must make ''good faith efforts to appeal or resolve matters pending with the OIG'' could be misinterpreted to include ''matters pending with the OIG'' that are unrelated to violations of a previous Medicaid rebate agreement. Therefore, the commenter suggested revising the sentence to say that a manufacturer may not enter into another rebate agreement until at least one rebate period from the effective date of termination, ''and provided that the manufacturer has addressed to the satisfaction of CMS any outstanding violations from any previous rebate agreements, including but not limited to payment of any outstanding rebates and good faith efforts to appeal or resolve any disputes pending with the OIG concerning violations of a previous rebate agreement.''

Response: We understand the commenter's concerns and have revised the language in section VII.(d). to create two sentences which now reads: If this rebate agreement is terminated, the manufacturer is prohibited from entering into another rebate agreement as set forth in section 1927(b)(4)(C) of the Act for at least one rebate period from the effective date of the termination. The manufacturer must also address to the satisfaction of CMS any outstanding violations from any previous rebate agreement(s), including, but not limited to, payment of any outstanding rebates and also make good faith efforts to appeal or resolve matters pending with the OIG relating to the MDRP or exclusion as referenced in subsection (c) of this section, unless the Secretary finds good cause for earlier reinstatement.

H. Section VIII. General Provisions

1. Transfer of Ownership

Comment: One commenter requested that CMS make it clear that the automatic assignment of rebate liability (as specified in section VIII.(c). applies only when there is a transfer of ownership of the manufacturer as a whole, and not a transfer of specific products or product lines.

Response: Section VIII.(c). of the General Provisions section only speaks to transfer of ownership of the manufacturer, and does not reference transfer of specific products or product lines. We do not believe any revisions to section VIII.(c). of the updated NDRA are necessary.

2. Due Date Falls on Weekend or Federal Holiday

Comment: One commenter sought clarification from CMS regarding what is meant by ''other item'' in the section that reads, ''In the event that a due date falls on a weekend or federal holiday, the report or other item will be due on the first business day following that weekend or federal holiday.''

Response: The reference to ''other item'' is intended to refer to anything due from the manufacturer to us per the rebate agreement.

3. Request for New Subsection: Rebate Payment Deadline

Comment: One commenter recommended that CMS include a new subsection under section VIII in the NDRA to clarify the number of days manufacturers have to pay late rebates before interest begins to accrue. The commenter stated that this subsection should incorporate the guidance CMS provided to manufacturers in Manufacturer Release #7 and #89, which states that, ''[i]nterest will begin accruing on disputed or unpaid amounts 38 calendar days from the date the state mails the state utilization data, as evidenced by the postmark by the United States Postal Service or other common mail carrier on the envelope (not a postage stamp).''

Response: As stated in response to previous comments, statute, regulation, and agency guidance, such as Program Releases, are incorporated by reference in section VIII, General Provisions. As stated previously, we have updated paragraph (a) of Section VIII, to add an introductory sentence that reads: ''This agreement is authorized by the applicable sections of 1902, 1903, 1905 and 1927 of the Act, and the implementing regulations at 42 CFR part 447.'' Therefore, we do not believe it is necessary to specifically incorporate the language suggested by the manufacturer in the updated NDRA.

I. Section IX. CMS–367 Forms of the Drug Rebate Agreement

Comment: One commenter stated that CMS should amend any forms referenced in or attached to the NDRA through the same process by which CMS is required to amend the NDRA itself (bilaterally). For example, CMS proposed that the NDRA would include as an attachment certain CMS forms (CMS–367a, CMS–367b, CMS–367c, and CMS–367d) that are used for reporting data required by the NDRA. Additionally, CMS incorporated by reference in section I.(t). of the proposed NDRA the CMS–R–144 form (state rebate invoice).

While the commenter recognized that CMS has changed these forms in the past through the Paperwork Reduction Act process, without officially amending the rebate agreement, the commenter recommended that CMS amend all forms associated with this NDRA in the same way that CMS amend the NDRA itself. The commenter noted that section VIII.(h). of the proposed NDRA states that ''except for the conditions specified in sections II.(g). and VIII.(a). (which concern changes to the rebate statute or implementing regulations), this agreement will not be altered except by an amendment in writing signed by both parties . . . ,'' which means that (apart from changes associated with statutory and regulatory changes) any changes made to the NDRA, including its attachments, must be in writing and signed by both parties.

The commenter recommended that CMS extend these same requirements to any forms that CMS choose to incorporate by reference, to ensure that the substance of the NDRA cannot be altered by changes in standard CMS forms that technically are not considered part of the NDRA itself.

Response: OMB-approved forms, when changed, are subject to a notice and comment period as required by the Paperwork Reduction Act. We have complied with these requirements and will continue to comply for future updates to these forms. Therefore, we believe it is appropriate to revise section VIII.(h). to include as part of the exclusions all applicable OMB-approved forms. We have revised VIII.(h). to state that ''[e]xcept for the conditions specified in II.(g). and VIII.(a)., as well as all applicable OMB-approved forms, this agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the manufacturer.''

J. Miscellaneous Comments

Comment: One commenter urged CMS to include in the updated NDRA the existing mechanism that permits manufacturers to notify CMS of state Medicaid program compliance concerns regarding drug coverage requirements or if there is a pattern or history of inaccuracy in Medicaid utilization reporting.

Response: We disagree with the commenter's suggestion that we memorialize in the NDRA the details of how a manufacturer may contact us regarding concerns with compliance with drug coverage requirements or patterns/historical inaccuracies in state drug utilization data reporting. We will continue to update any operational instructions on the options available or suggestions for manufacturers to communicate such issues to us.

Comment: Several commenters requested that CMS revise the NDRA to more specifically enumerate state requirements with regard to the MDRP.

Response: We disagree that state requirements be enumerated in the NDRA, as this is an agreement between the manufacturers and the Secretary and is not the appropriate vehicle to specifically address state requirements.

III. Provisions of the Final Notice

As stated previously, we are updating the NDRA to reflect the changes in the Covered Outpatient Drugs final rule with comment period that was published in the February 1, 2016 **Federal Register** (81 FR 5170), as well as operational and other legislative changes that have occurred over the last 20 plus years since the NDRA was first issued in 1991. A sample of the finalized NDRA will be posted on the *www.Medicaid.gov.* The publication of the final notice in the **Federal Register** constitutes written notice of good cause to terminate all old rebate agreements as of the first day of the full calendar quarter which begins at least 6 months after the effective date of the updated NDRA. As noted in the proposed notice, the updated NDRA will need to be signed by all participating manufacturers, as well as new manufacturers joining the program (81 FR 78817). Therefore, all currently participating manufacturers wishing to maintain their participation in the MDRP will need to work with CMS to sign and effectuate an updated NDRA for each labeler code by the compliance date specified in the **DATES** section of this public notice. For any current manufacturer that does not sign and effectuate an updated NDRA within the time frame specified above, the result would be termination of the existing NDRA. Per section 1927(b)(4)(B)(iii) of the Act, termination of a rebate agreement does not affect rebates due under that agreement before the effective date of its termination. We will be providing additional instructions and guidance pertaining to how to sign and effectuate the updated NDRA through subregulatory guidance.

Furthermore, prospective manufacturers that request a new NDRA, or reinstatement of a previously active NDRA once the updated NDRA is available, would be subject to the current process of data submission and verification prior to the execution of a NDRA.

Additionally, we are further clarifying that, in keeping with the requirements in the previous and updated NDRA and CMS's policy guidance in Manufacturer Releases #13 and #48, manufacturers that wish to participate in the MDRP are required to report all their covered outpatient drugs to CMS, regardless of labeler code. Therefore, in an effort to prevent selective reporting of NDCs, manufacturers must ensure that all associated labeler codes with covered outpatient drugs enter into a rebate agreement in order to comply with the terms of the NDRA. This requirement is found under section II, Manufacturer's Responsibilities, subsection (a) of the previous NDRA, and in section II, Manufacturer's Responsibilities, subsection (b) of the updated NDRA. When a participating manufacturer requests an agreement for a newly acquired labeler code that has covered outpatient drugs, that NDRA request will be subject to verification of their proposed covered outpatient drug list. Program releases are available at *www.Medicaid.gov.*

A copy of the updated NDRA is included in the Addendum of this notice. Below is a summary of the revisions and edits to the updated NDRA that have been made as a result of comments or to provide conforming or clarifying edits.

A. Definitions

- In response to a comment, we are retaining the definitions of ''Depot Price,'' ''Single-Award Contract,'' and ''Single-Award Contract Price,'' without any revisions to the definitions. As such all numbering is adjusted to account for the retention of these definitions.
- We are adding an opening quotation mark to the definition of ''Marketed'' as it was omitted from the draft NDRA.
- The definition of ''Rebate Period'' is revised to add ''section 1927(k)(8) of the Act as implemented by'' after the word ''in'' and before ''42 CFR 447.502.''
- The definition of ''State Drug Utilization Data'' is revised to replace the word ''reimbursed'' with ''dispensed and/or paid for, as applicable'' so that it now reads: ''. . . covered outpatient drugs dispensed and/or paid for, as applicable during a rebate period. . . .''
- The definition of ''State Drug Utilization Data'' is also revised to add ''(OMB control number: 0938–0582)'' after ''CMS–R–144'' in order to properly identify the form as being OMB approved.
- The definition of ''State Medicaid Agency'' is revised to add ''and 1927(k)(9) of the Act'' after ''sections 1902(a)(5)'' and before ''to administer'' so that it now reads ''. . . under sections 1902(a)(5) and 1927(k)(9) of the Act to administer . . .''.
- The definition of ''Unit'' is revised to add ''(OMB control number 0938–0578)'' after ''CMS–367c form'' in order to properly identify the form as being OMB approved.

B. Manufacturer Responsibilities

- Subsection (a)—Has been revised to add ''for the Legal, Invoice, and Technical contacts'' between the words ''contact'' and ''at'' so that it now reads: ''. . . point of contact for the Legal, Invoice, and Technical contacts at a United States address . . . .''
- Subsection (b)—Is revised to add ''for all covered outpatient drugs in all labeler codes of a manufacturer'' after ''is signed'' and before ''calculated'' so that it now reads ''. . . Beginning with

the quarter in which the National Drug Rebate Agreement (rebate agreement) is signed for all covered outpatient drugs of all labeler codes of a manufacturer, calculate, and report . . .''. It is also revised to add the words ''calculate a URA and'' after ''required to'' and before ''make'' so that it now reads ''. . . manufacturers are required to calculate a URA and make a rebate payment . . . ,'' and is revised to add the following sentences to the end of the subsection: ''CMS may calculate a URA based on manufacturer-submitted product and pricing data and provide the URA to states in order to facilitate rebate billing. However, CMS's URA calculation does not relieve the manufacturer of its responsibility to calculate the URA.''

• Subsection (c)—Has been revised to remove the phrase ''in some cases'' from the third sentence so that it now reads, ''CMS uses drug information listed with FDA, such as Marketing Category and Drug Type, to be able to verify that an NDC meets the definition of a covered outpatient drug, therefore, manufacturers should ensure that their NDCs are electronically listed with FDA.''

• Subsection (d)—First, the first sentence is revised to add ''(OMB control number 0938–0578)'' after ''CMS–367a form'' in order to properly identify the form as being OMB approved. Second, the third sentence is revised to read, ''[t]he manufacturer agrees to provide such information not later than 30 days after the end of each rebate period beginning with the effective date quarter.'' Third, the fourth sentence is revised to read, ''[a]djustments to all prior quarterly pricing data must be reported for a period not to exceed 12 quarters from when the pricing data were originally due as required under 42 CFR 447.510(b).''

• Subsection (e)—First, the first sentence is revised to add ''(OMB control number 0938–0578)'' after ''CMS–367b form'' in order to properly identify the form as being OMB approved. Second, the second sentence is revised to read, ''[t]he manufacturer agrees to provide such information not later than 30 days after the end of the month of the effective date, and not later than 30 days after the end of each month thereafter.''

• Subsection (f)—First, in accordance with section 1927(b)(3)(A) of the Act, the first sentence is revised to replace the word ''within'' with ''not later than'' after ''payments'' and before ''30 days'' so that it now reads ''Except as provided under V.(b)., to make rebate payments not later than 30 days after receiving the state rebate invoice.'' Second, it is revised to add the following sentence to the end of the subsection: ''To the extent that changes in product, pricing, or related data cause decreases to previously submitted total rebate amounts, the manufacturer should communicate with the states regarding where to apply the line-item (NDC-level) credit.''

• Subsection (i)—Is revised to add ''(OMB control number 0938–0578)'' after ''CMS–367d form'' in order to properly identify the form as being OMB approved.

• Subsection (k)—The reference to ''42 CFR 447.534'' in the last sentence of the subsection is replaced with ''42 CFR 447.510'' as this is the valid regulatory reference.

C. Secretary Responsibilities

• Subsection (a)—In accordance with section 1927(b)(2)(A) of the Act, the first sentence is revised to replace the word ''within'' with ''not later than'' after ''manufacturer,'' and ''60 days'' and to add ''dispensed and/or'' before ''paid for,'' and to add the ''as applicable'' after ''paid for'' so that it now reads: ''The Secretary will employ best efforts to ensure the State Medicaid Agency shall report to the manufacturer, no later than 60 days of the last day of each rebate period, the rebate invoice (CMS–R–144) or the minimum utilization information as described in section II.(f). of this agreement, that is, information about Medicaid utilization of covered outpatient drugs that were dispensed and/or paid for, as applicable, during the rebate period.''.

D. Penalty Provisions

• Subsection (a)—Is revised to add ''in connection with a survey'' after ''prices'' and before ''or'' in the first sentence.

• Subsection (d)—Is revised to add ''government'' after ''United States.''

E. Dispute Resolutions

• Subsection (a)—Is revised to add the OMB Control number associated with CMS–304 and CMS–304(a) forms after the reference to each form. The paragraph now read: ''In the event a manufacturer discovers a potential discrepancy with state drug utilization data on the rebate invoice, which the manufacturer and state in good faith are unable to resolve prior to the payment due date, the manufacturer will submit a Reconciliation of State Invoice (ROSI) form, the CMS–304 (OMB control number: 0938–0676), to the state. If such a discrepancy is discovered for a prior rebate period's invoice, the manufacturer will submit a Prior Quarter Adjustment Statement (PQAS) form, CMS–304a (OMB control number: 0938–0676), to the state.''

• Subsection (c)—The phrase ''shall require'' is replaced with ''will employ best efforts to ensure,'' and the phrase ''within 60 days'' is replaced by ''within a reasonable time frame'' in both instances, and the reference to ''42 CFR 447.253(e)'' is added in parentheses to the end of the subsection so that it now reads: ''The state and the manufacturer will use their best efforts to resolve a dispute arising under (a) or (b) above within a reasonable time frame after the state's receipt of the manufacturer's ROSI/PQAS. In the event that the state and manufacturer are not able to resolve the dispute within a reasonable time frame, CMS will employ best efforts to ensure the state makes available to the manufacturer the same state hearing mechanism available to providers for Medicaid payment disputes (42 CFR 447.253(e)).''.

F. Confidentiality Provisions

This section is finalized as proposed.

G. Nonrenewal and Termination

• Subsection (a)—Is revised to add ''from the date specified in section II.(h).,'' between ''year'' and ''unless'' so that in now reads: ''. . . successive terms of one year from the date specified in section II.(h)., unless the manufacturer . . . .''

• Subsection (b)—The first paragraph is revised to add ''and section 1927(b)(4)(B)(ii) of the Act'' after ''this agreement'' and before ''the manufacturer'' so that it now reads: ''In accordance with section VII.(a). of this agreement and section 1927(b)(4) of the Act, the manufacturer may terminate the agreement for any reason . . .''. The second paragraph, is revised to add an ''s'' to the end of ''cause'' to make it plural in both instances.

• Subsection (d)—Is revised to add a period after the word ''termination'' and create a new sentence that begins ''The manufacturer must also address . . .''

• Subsection (d)—Is also revised to add ''also make'' before ''good faith efforts in this new second sentence.

• Subsection (d)—Is further revised to add ''per subsection (c) of this section'' between ''the OIG'' and ''unless'' so it now reads ''. . . resolve matters pending with the OIG per subsection (c) of this section, unless the Secretary finds . . .''.

H. General Provisions

• Subsection (a)—Is revised to add the following sentence to the beginning of the subsection: ''This agreement is authorized by the applicable provisions

of sections 1902, 1903, 1905, and 1927 of the Act, and the implementing regulations at 42 CFR part 447.''.

• Subsection (f)—Is changed to replace the word ''scheme'' with ''construct''.

• Subsection (g)—Is revised to add ''such contractors are'' between ''unless'' and ''specifically,'' to replace ''provided for'' with ''excluded,'' and to add ''such exclusion is'' between ''or'' and ''specifically'' so that it now reads: The terms ''State Medicaid Agency'' and ''Manufacturer'' incorporate any contractors which fulfill responsibilities pursuant to the agreement unless such contractors are specifically excluded in the rebate agreement or such exclusion is specifically agreed to by an appropriate CMS official.

• Subsection (h)—Is revised to add ''as well as applicable OMB-approved forms,'' between ''VIII.(a).,'' and ''this agreement'' and to remove ''except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the manufacturer.'' so that it now reads: ''(h) Except for the conditions specified in II.(g). and VIII.(a)., as well as applicable OMB-approved forms, this agreement will not be altered.''.

I. CMS–367

This section is finalized as proposed.

J. Signatures

This section is finalized as proposed.

IV. Collection of Information Requirements

As stated in section 4711(f) of the Omnibus Budget Reconciliation Act of 1990, Chapter 35 of title 44, United States Code, and Executive Order 12291 shall not apply to information and regulations required for purposes of carrying out this Act and implementing the amendments made by this Act. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

As discussed in sections I and II of this final notice, we have revised the NDRA to add references to the appropriate CMS forms, consisting of: CMS–R–144 (OMB control number: 0938–0582), CMS–367 (OMB control number 0938–0578), and CMS–304 (OMB control number: 0938–0676). While the forms are referenced within the NDRA, there are no new or revised collection of information requirements or burden resulting from the updated NDRA. The forms are simply being referenced for clarity.

Addendum—Updated Agreement:

National Drug Rebate Agreement Between the Secretary of Health and Human Services (Hereinafter Referred to as ''the Secretary'') and the Manufacturer

The Secretary, on behalf of the U.S. Department of Health and Human Services and all states which have a Medicaid State Plan approved under 42 U.S.C. 1396a, and the manufacturer, on its own behalf, for purposes of section 1927 of the Social Security Act (''the Act''), 42 U.S.C. 1396r–8, hereby agree to the following:

I. Definitions

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act and implementing Federal regulations, as interpreted and applied herein:

(a) ''*Average Manufacturer Price (AMP)*'' will have the meaning set forth in section 1927(k)(1) of the Act as implemented by 42 CFR 447.504.

(b) ''*Base Consumer Price Index-Urban (CPI–U)*'' is the CPI–U for September, 1990. For drugs approved by the Food and Drug Administration (FDA) after October 1, 1990, ''Base CPI–U'' means the CPI–U for the month before the month in which the drug was first marketed.

(c) ''*Base Date AMP*'' will have the meaning set forth in sections 1927(c)(2)(A)(ii)(II) and 1927(c)(2)(B) of the Act.

(d) ''*Best Price*'' will have the meaning set forth in section 1927(c)(1)(C) of the Act as implemented by 42 CFR 447.505.

(e) ''*Bundled Sale*'' will have the meaning set forth in 42 CFR 447.502.

(f) ''*Centers for Medicare & Medicaid Services (CMS)*'' means the agency of the U.S. Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g) ''*Consumer Price Index-Urban (CPI–U)*'' will have the meaning set forth in 42 CFR 447.502.

(h) ''*Covered Outpatient Drug*'' will have the meaning set forth in sections 1927(k)(2), (k)(3) and (k)(4) of the Act as implemented by 42 CFR 447.502.

(i) ''*Depot Price*'' means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(j) ''*Innovator Multiple Source Drug*'' will have the meaning as set forth in section 1927(k)(7)(A)(ii) of the Act as implemented by 42 CFR 447.502.

(k) ''*Manufacturer*'' will have the meaning as set forth in section 1927(k)(5) of the Act as implemented by 42 CFR 447.502.

(l) ''*Marketed*'' means that a covered outpatient drug is available for sale by a manufacturer in the states.

(m) ''*Monthly AMP*'' will have the meaning as set forth in 42 CFR 447.510.

(n) ''*Multiple Source Drug*'' will have the meaning as set forth in section 1927(k)(7)(A)(i) of the Act as implemented by 42 CFR 447.502.

(o) ''*National Drug Code (NDC)*'' will have the meaning as set forth in 42 CFR 447.502.

(p) ''*Non-innovator Multiple Source Drug*'' will have the meaning as set forth in section 1927(k)(7)(A)(iii) of the Act as implemented by 42 CFR 447.502.

(q) ''*Quarterly AMP*'' will have the meaning as set forth in 42 CFR 447.504.

(r) ''*Rebate period*'' will have the meaning as set forth in section 1927(k)(8) of the Act as implemented by 42 CFR 447.502.

(s) ''*Secretary*'' means the Secretary of the U.S. Department of Health and Human Services, or any successor thereto, or any officer or employee of the U.S. Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated. In this agreement, references to CMS indicate such successor authority.

(t) ''*Single-Award Contract*'' means a contract between the federal government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(u) ''*Single-Award Contract Price*'' means a price established under a Single-Award Contract.

(v) ''*Single Source Drug*'' will have the meaning set forth in section 1927(k)(7)(A)(iv) of the Act as implemented by 42 CFR 447.502.

(w) ''*State Drug Utilization Data*'' means the total number of both fee-for-service (FFS) and managed care organization (MCO) units of each dosage form and strength of the manufacturer's covered outpatient drugs dispensed and/or paid for, as applicable during a rebate period under a Medicaid State Plan, other than units dispensed to Medicaid beneficiaries that were purchased by covered entities through the drug discount program under section 340B of the Public Health Service Act; state utilization data is supplied on the CMS–R–144 form (OMB control number: 0938–0582) (that is, the state rebate invoice).

(x) ''*States*'' will have the meaning as set forth in 42 CFR 447.502.

(y) ''*State Medicaid Agency*'' means the agency designated by a state under sections 1902(a)(5) and 1927(k)(9) of the Act to administer or supervise the administration of the Medicaid program.

(z) ''*Unit*'' means drug unit in the lowest dispensable amount. The manufacturer will specify the unit information associated with each covered outpatient drug per the instructions provided in CMS–367c (OMB control number 0938–0578).

(aa) ''*Unit Rebate Amount (URA)*'' means the computed amount to which the state drug utilization data is applied by states in invoicing the manufacturer for the rebate payment due.

(bb) ''*United States*'' will have the meaning as set forth in 42 CFR 447.502.

(cc) ''*Wholesaler*'' will have the meaning as set forth in section 1927(k)(11) of the Act as implemented by 42 CFR 447.502.

II. Manufacturer's Responsibilities

In order for the Secretary to authorize that a state receive payment for the

manufacturer's drugs under Title XIX of the Act, 42 U.S.C. 1396 *et seq.,* the manufacturer agrees to the requirements as implemented by 42 CFR 447.510 and the following:

(a) The manufacturer shall identify an individual point of contact for the Legal, Invoice, and Technical contacts at a United States address to facilitate the necessary communications with states with respect to rebate invoice issues.

(b) Beginning with the quarter in which the National Drug Rebate Agreement (rebate agreement) is signed for all covered outpatient drugs of all labeler codes of a manufacturer, calculate, and report all required pricing data on every covered outpatient drug by NDC in accordance with section 1927 of the Act and as implemented by 42 CFR 447.510. Furthermore, except as provided under section V.(b). of this agreement, manufacturers are required to calculate a URA and make a rebate payment in accordance with each calculated URA to each State Medicaid Agency for the manufacturer's covered outpatient drug(s) by NDC paid for by the state during a rebate period. CMS may calculate a URA based on manufacturer-submitted product and pricing data and provide the URA to states in order to facilitate rebate billing. However, CMS's URA calculation does not relieve the manufacturer of its responsibility to calculate the URA.

(c) In accordance with the specifications pursuant to Office of Management and Budget (OMB)-approved CMS–367c form, report all covered outpatient drugs and corresponding drug product, pricing, and related data to the Secretary, upon entering into this agreement. This information is to be updated as necessary to include new NDCs and updates to existing NDCs. CMS uses drug information listed with FDA, such as Marketing Category and Drug Type, to be able to verify that an NDC meets the definition of a covered outpatient drug, therefore, manufacturers should ensure that their NDCs are electronically listed with FDA. Reports to CMS should include all applicable NDCs identifying the drug product which may be dispensed to a beneficiary, including package NDCs (outer package NDCs and inner package NDCs).

(d) Beginning with the effective date quarter and in accordance with the specifications pursuant to OMB-approved CMS–367a form (OMB control number 0938–0578), report quarterly pricing data to the Secretary for all covered outpatient drugs in accordance with 42 CFR 447.510. This includes reporting for any package size which may be dispensed to the beneficiary. The manufacturer agrees to provide such information not later than 30 days after the end of each rebate period beginning with the effective date quarter. Adjustments to all prior quarterly pricing data must be reported for a period not to exceed 12 quarters from when the pricing data were originally due as required under 42 CFR 447.510(b).

(e) In accordance with the OMB-approved CMS–367b form (OMB control number 0938–0578), report information including monthly AMPs and monthly AMP units for all covered outpatient drugs in accordance with 42 CFR 447.510. The manufacturer agrees to provide such information not later than 30 days after the end of the month of the effective date, and not later than 30 days after the end of each month thereafter.

(f) Except as provided under V.(b)., to make rebate payments not later than 30 days after receiving the state rebate invoice. The manufacturer is responsible for timely payment of the rebate within 30 days so long as the state invoice contains, at a minimum, the number of units paid by NDC in accordance with 1927(b)(1) of the Act. To the extent that changes in product, pricing, or related data cause increases to previously-submitted total rebate amounts, the manufacturer will be responsible for timely payment of those increases in the same 30-day time frame as the current rebate invoice. To the extent that changes in product, pricing, or related data cause decreases to previously-submitted total rebate amounts, the manufacturer should communicate with the states regarding where to apply the line-item (NDC-level) credit.

(g) To comply with the conditions of 42 U.S.C. 1396r–8, changes thereto, implementing regulations, agency guidance and this Agreement.

(h) In accordance with 1927(a)(1) of the Act, rebate agreements between the Secretary and the manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall have a mandatory effective date equal to the first day of the rebate period that begins more than 60 days after the date the agreement is entered into. Rebate agreements entered into on or after November 29, 1999 will also have an effective date equal to the date the rebate agreement is entered into that will permit optional state coverage of the manufacturer's NDCs as of that date.

(i) To obtain and maintain access to the system used by the Medicaid Drug Rebate program, use that system to report required data to CMS, and ensure that their contact information is kept updated as required in the OMB-approved CMS–367d form (OMB control number 0938–0578).

(j) To continue to make a rebate payment on all of its covered outpatient drugs for as long as an agreement with the Secretary is in force and state utilization data reports that payment was made for that drug, regardless of whether the manufacturer continues to market that drug. If there are no sales by the manufacturer during a rebate period, the AMP and best price reported in the prior rebate period should be used in calculating rebates.

(k) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and best price were derived in accordance with 42 CFR 447.510, and make such records available to the Secretary upon request. In the absence of specific guidance in section 1927 of the Act, federal regulations and the terms of this agreement, the manufacturer may make reasonable assumptions in its calculations of AMP and best price, consistent with the purpose of section 1927 of the Act, federal regulations and the terms of this agreement. A record (written or electronic) explaining these assumptions must also be maintained by the manufacturer in accordance with the recordkeeping requirements in 42 CFR 447.510, and such records must be made available to the Secretary upon request.

(l) To notify CMS of any filing of bankruptcy, and to transmit such filing to CMS within seven days of the date of filing.

III. Secretary's Responsibilities

(a) The Secretary will employ best efforts to ensure the State Medicaid Agency shall report to the manufacturer, not later than 60 days after the last day of each rebate period, the rebate invoice (CMS–R–144) or the minimum utilization information as described in section II.(f). of this agreement, that is, information about Medicaid utilization of covered outpatient drugs that were dispensed and/or paid for, as applicable, during the rebate period. Additionally, the Secretary will expect any changes to prior quarterly state drug utilization data to be reported at the same time.

(b) The Secretary may survey those wholesalers and manufacturers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as set forth in section 1927(b)(3)(B) of the Act and section IV of this agreement.

(c) The Secretary may audit manufacturer information reported under section 1927(b)(3)(A) of the Act.

IV. Penalty Provisions

(a) The Secretary may impose a civil monetary penalty under section III.(b). as set forth in 1927(b)(3)(B) of the Act and applicable regulations, on a wholesaler, manufacturer, or direct seller of a covered outpatient drug, if a wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request by the Secretary, or the Secretary's designee, for information about covered outpatient drug charges or prices in connection with a survey or knowingly provides false information, including in any of its quarterly reports to the Secretary. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B) of the Act and applicable regulations.

(b) The Secretary may impose a civil monetary penalty, for each item of false information as set forth in 1927(b)(3)(C)(ii) of the Act and applicable regulations.

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, best price or base date AMP. The amount of the penalty shall be determined as set forth in 1927(b)(3)(C)(i) of the Act and applicable regulations.

(d) Nothing in this Agreement shall be construed to limit the remedies available to the United States government or the states for a violation of this Agreement or any other provision of law.

V. Dispute Resolution

(a) In the event a manufacturer discovers a potential discrepancy with state drug utilization data on the rebate invoice, which the manufacturer and state in good faith are

unable to resolve prior to the payment due date, the manufacturer will submit a Reconciliation of State Invoice (ROSI) form, the CMS–304 (OMB control number: 0938–0676), to the state. If such a discrepancy is discovered for a prior rebate period's invoice, the manufacturer will submit a Prior Quarter Adjustment Statement (PQAS) form, CMS–304a (OMB control number: 0938–0676), to the state.

(b) If the manufacturer disputes in good faith any part of the state drug utilization data on the rebate invoice, the manufacturer shall pay the state for the rebate units not in dispute within the required due date in II.(f). Upon resolution of the dispute, the manufacturer will either pay the balance due, if any, plus interest as set forth in section 1903(d)(5) of the Act, or be issued a credit by the state by the due date of the next quarterly payment in II(f).

(c) The state and the manufacturer will use their best efforts to resolve a dispute arising under (a) or (b) above within a reasonable time frame after the state's receipt of the manufacturer's ROSI/PQAS. In the event that the state and manufacturer are not able to resolve the dispute within a reasonable time frame, CMS will employ best efforts to ensure the state makes available to the manufacturer the same state hearing mechanism available to providers for Medicaid payment disputes (42 CFR 447.253(e)).

(d) Nothing in this section shall preclude the right of the manufacturer to audit the state drug utilization data reported (or required to be reported) by the state. The Secretary encourages the manufacturer and the state to develop mutually beneficial audit procedures.

(e) The state hearing mechanism is not binding on the Secretary for purposes of the Secretary's authority to implement the civil money penalty provisions of the statute or this agreement.

VI. Confidentiality Provisions

(a) Pursuant to section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the manufacturer in connection with this agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the manufacturer, or prices charged by the manufacturer, except as authorized under section 1927(b)(3)(D).

(b) The manufacturer will hold state drug utilization data confidential. If the manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the manufacturer will observe confidentiality statutes, regulations, and other properly promulgated policy concerning such data.

(c) Notwithstanding the nonrenewal or termination of this agreement for any reason, these confidentiality provisions will remain in full force and effect.

VII. Nonrenewal and Termination

(a) Unless otherwise terminated by either party pursuant to the terms of this agreement, the agreement shall be effective beginning on the date specified in section II.(h). of this agreement and shall be automatically renewed for additional successive terms of one year from the date specified in section II.(h)., unless the manufacturer gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) In accordance with section VII.(a). of this agreement and section 1927(b)(4)(B)(ii) of the Act, the manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first rebate period beginning 60 days after the manufacturer gives written notice requesting termination, or CMS initiates termination via written notice to the manufacturer.

The Secretary may terminate the agreement for failure of a manufacturer to make rebate payments to the state(s), failure to report required data, for other violations of this agreement, or other good causes upon 60 days prior written notice to the manufacturer of the existence of such violation or other good causes. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(c) Manufacturers on the Office of Inspector General's (OIG's) List of Excluded Individuals/Entities (Exclusion List) will be subject to immediate termination from the Medicaid drug rebate program unless and until the manufacturer is reinstated by the OIG. Appeals of exclusion and any reinstatement will be handled in accordance with section 1128 of the Act and applicable regulations. Manufacturers that are on the OIG Exclusion List and are reinstated by the OIG under certain circumstances may be evaluated for reinstatement to the Medicaid drug rebate program by CMS. Reinstatement to the Medicaid drug rebate program would be for the next rebate period that begins more than 60 days from the date of the OIG's reinstatement of the manufacturer after exclusion.

(d) If this rebate agreement is terminated, the manufacturer is prohibited from entering into another rebate agreement as set forth in section 1927(b)(4)(C) of the Act for at least one rebate period from the effective date of the termination. The manufacturer must also address to the satisfaction of CMS any outstanding violations from any previous rebate agreement(s), including, but not limited to, payment of any outstanding rebates and also make good faith efforts to appeal or resolve matters pending with the OIG relating to the MDRP or exclusion as referenced in subsection (c) of this section, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

VIII. General Provisions

(a) This agreement is authorized by the applicable provisions of sections 1902, 1903, 1905, and 1927 of the Act, and the implementing regulations at 42 CFR part 447. This agreement is subject to any changes in the Medicaid statute or regulations that affect the rebate program.

(b) Any notice required to be given pursuant to the terms and provisions of this agreement will be permitted in writing or electronically.

Notice to the Secretary will be sent to: Centers for Medicaid and CHIP Services, Disabled & Elderly Health Programs Group, Division of Pharmacy, Mail Stop S2–14–26, 7500 Security Blvd., Baltimore, MD 21244.

The CMS address may be updated upon notice to the manufacturer.

Notice to the manufacturer will be sent to the email and/or physical mailing address as provided under section X of this agreement and updated upon manufacturer notification to CMS at the email and/or address in this agreement.

(c) In the event of a transfer in ownership of the manufacturer, this agreement and any outstanding rebate liability are automatically assigned to the new owner subject to the conditions as set forth in section 1927 of the Act.

(d) Nothing in this agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this agreement is found to be invalid by a court of law, this agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(e) Nothing in this agreement shall be construed as a waiver or relinquishment of any legal rights of the manufacturer or the Secretary under the Constitution, the Act, other federal laws, or state laws.

(f) The rebate agreement shall be construed in accordance with Federal law and ambiguities shall be interpreted in the manner which best effectuates the statutory construct.

(g) The terms ''State Medicaid Agency'' and ''Manufacturer'' incorporate any contractors which fulfill responsibilities pursuant to the agreement unless such contractors are specifically excluded in the rebate agreement or such exclusion is specifically agreed to by an appropriate CMS official.

(h) Except for the conditions specified in II.(g). and VIII.(a)., as well as applicable OMB-approved forms, this agreement will not be altered.

(i) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

IX. CMS–367

CMS–367 attached hereto is part of this agreement.

X. Signatures

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ Date: _____
(signature)

Title: Director
Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: _____ _____
(signature) (please print name)
Title: _____
Name of Manufacturer: _____
Manufacturer Address _____
_____

Manufacturer Labeler Code(s): _____
Date: _____

CMS-367a

CMS RECORD SPECIFICATION
DDR QUARTERLY PRICING DATA
TEXT FILE FOR TRANSFER TO CMS

Source: Drug Manufacturers
Target: CMS

Field	Size	Position	Remarks
Record ID	1	1 - 1	Constant of "Q"
Labeler Code	5	2 - 6	NDC #1
Product Code	4	7 - 10	NDC #2
Package Size	2	11 – 12	NDC #3
Period Covered	5	13 – 17	QYYYY (Qtr/Yr)
Average Mfr Price	12	18 – 29	99999.999999
Best Price	12	30 – 41	99999.999999
Nominal Price	9	42 – 50	***999999999***
Customary Prompt Pay Disc.	9	51 – 59	***999999999***
Initial Drug Available for LE	1	60-60	***Y, N, X or Z***
Initial Drug	9	61-69	***9 digits alpha-numeric***

CMS-367a According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578 (Expires: 12/31/2019). The time required to complete this information collection is estimated to average 34.8 hours per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

QUARTERLY PRICING DATA FIELDS – CMS-367a

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled.

Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.

Period Covered: Calendar quarter and year covered by data submission. Numeric 5-digit field, QYYYY.

Valid values for Q:

1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31

Valid values for YYYY: 4-digit calendar year.

Average Manufacturer's Price (AMP): The AMP per unit per product code for the period covered. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which is the same for all package sizes. Compute to 7 decimal places, and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal place ('.') and 6 decimal places; right-justified, zero-filled.

Best Price: Per the statute and rebate agreement, the lowest price available per product code, regardless of package size. Compute to 7 decimal places and round to 6 decimal places. Zero-fill for Non-Innovator Multiple Source drugs. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled.

Nominal Price (NP): Sales that meet the statutory/regulatory definition of NP. Total dollar figure per 11-digit NDC, rounded to nearest dollar. 9-digit field; 9 whole numbers; right-justified, 0-filled. If no sales for a package size, fill with all zeroes.

Customary Prompt Pay Discount (CPP): Labelers may 1) allocate an individual CPP discount dollar amount per 11-digit NDC in each package size's record, or 2) report an aggregate discount dollar amount, by adding up all package sizes, and report this aggregate CPP discount dollar amount in one package size record and zero-fill the remaining package sizes. 9-digit field; 9 whole numbers; right-justified, 0-filled.

Initial Drug Available for LE: Identifies whether a line extension drug has an Initial Drug available for the quarter/year being reported.

Valid Values:

Y = Yes
N = No
X = X-Not an LE Drug
Z = Not Applicable (for quarters prior to 2Q2016, or for quarters in which the NDC or labeler was not active).

Initial Drug: Identifies the drug (from which a line extension drug is derived) with the highest additional rebate ratio (calculated as a percentage of AMP) for the quarter/year being reported. The Initial Drug's additional rebate ratio is then used in the alternative URA calculation for the line extension drug. The Initial Drug should fall under the same corporation as the corresponding line extension drug, and must be active within the MDR Program at the time it is reported as an Initial Drug. Numeric values only, 9-digit field, right-justified and zero-filled.

CMS-367b

CMS RECORD SPECIFICATION
DDR MONTHLY PRICING DATA
TEXT FILE FOR TRANSFER TO CMS

Source: Drug Manufacturers
Target: CMS

Field	Size	Position	Remarks
Record ID	1	1 – 1	Constant of "M"
Labeler Code	5	2 – 6	NDC #1
Product Code	4	7 – 10	NDC #2
Package Size	2	11 – 12	NDC #3
Month	2	13 – 14	MM
Year	4	15 – 18	YYYY
Average Mfr Price	12	19 – 30	99999.999999
AMP Units	14	31 – 44	99999999999.99
5i Threshold	1	45 - 45	Y, N, X, or Z

CMS-367b According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578 (Expires: 12/31/2019). The time required to complete this information collection is estimated to average 44.8 hours per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

CMS-367c

CMS RECORD SPECIFICATION
DDR DRUG PRODUCT DATA
TEXT FILE FOR TRANFER TO CMS

Source: Drug Manufacturers

Target: CMS

Field	Size	Position	Remarks
Record ID	1	1 – 1	Constant of "P"
Labeler Code	5	2 – 6	NDC #1
Product Code	4	7 – 10	NDC #2
Package Size Code	2	11 - 12	NDC #3
Drug Category	1	13 - 13	See Data Element Definitions
Unit Type	3	14 - 16	See Data Element Definitions
FDA Approval Date	8	17 - 24	MMDDYYYY
FDA Thera. Eq. Code	2	25 - 26	See Data Element Definitions
Market Date	8	27 - 34	MMDDYYYY
Termination Date	8	35 - 42	MMDDYYYY
Drug Type Indicator	1	43 – 43	See Data Element Definitions
OBRA'90 Baseline AMP	12	44 – 55	99999.999999
Units Per Pkg Size	11	56 – 66	9999999.999
FDA Product Name	63	67 – 129	FDA Product Name
DRA Baseline AMP	12	130 – 141	99999.999999
Package Size Intro Date	8	142 – 149	MMDDYYYY
Purchased Product Date	8	150 – 157	MMDDYYYY
5i Drug Indicator	1	158 – 158	See Data Element Definitions
5i Route of Administration	3	159 – 161	See Data Element Definitions
ACA Baseline AMP	12	162 - 173	99999.999999
COD Status	2	174 – 175	See Data Element Definitions
FDA Appl. No./OTC Mono. No.	7	176 – 182	See Data Element Definitions
Line Extension Drug Indicator	1	183 – 183	See Data Element Definitions

*Reactivation Date	*n/a	*n/a	*This field may only be submitted online via DDR. See Data Element Definitions

CMS-367c According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578 (Expires: 12/31/2019). The time required to complete this information collection is estimated to average 53.5 hours per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

DRUG PRODUCT DATA FIELDS – CMS-367c

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled.

Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.

Drug Category: Alpha-numeric values, 1 character.

Valid values:

S = Single source
I = Innovator multiple source
N = Non-innovator multiple source

Unit Type: One of the 8 unit types by which the drug is dispensed. Alpha-numeric values, 3-character field, left justified.

Valid values:

AHF = Injectable Anti-Hemophilic Factor
CAP = Capsule
SUP = Suppository
GM = Gram
ML = Milliliter
TAB = Tablet
TDP = Transdermal Patch
EA = EACH

FDA Approval Date: NDA or monograph approval date. Numeric values, 8-digit field, format: MMDDYYYY.

FDA TEC: FDA-assigned Therapeutic Equivalence Codes. Alpha-numeric values, 2 character field.

Valid values:

AA	BC	BS
AB	BD	BT
AN	BE	BX
AO	BN	NR - Not rated
AP	BP	A1 thru A9 = AB value
AT	BR	

Market Date: For S and I drugs, the date the drug was first marketed by the original labeler (i.e., NDA holder). For N drugs, the date the drug was first marketed under the labeler's rebate agreement. If a Market Date falls on a date that is earlier than 9/30/1990, CMS will change it to 9/30/1990 in both the Medicaid Drug Rebate (MDR) system and the Drug Data Reporting for Medicaid (DDR) system since dates earlier than the start of the Drug Rebate Program have no bearing on the program. Numeric values, 8-digit field, format: MMDDYYYY.

Termination Date: The date a drug is withdrawn from the market or the drug's last lot expiration date. (Note: Initial termination date submissions may be provided via file transfer; however, subsequent changes to this field may only be submitted online via DDR.) Zero or blank fill if not present. Numeric values, 8-digit field, format: MMDDYYYY.

Drug Type Indicator: Identifies a drug as prescription (Rx) or over-the-counter (OTC).

Valid Values:
1 = Rx
2 = OTC

OBRA'90 Baseline AMP: The AMP per unit for the period that establishes the OBRA'90 Baseline AMP for innovator drugs. There will be one weighted baseline AMP for the product, which will be the same for all package sizes. Compute to 7 decimal places and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled.

Units Per Package Size: Total number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values, 11-digit field: 7 whole numbers, the decimal ('.') and 3 decimal places; right-justified, zero-filled.

FDA Product Name: Drug name as it appears on FDA listing form. Alpha-numeric values, 63 characters, left justified, blank-fill unused positions.

DRA Baseline AMP (optional): For active innovator drugs with a Market Date less than July 1, 2007, the OBRA'90 or OBRA'93 Baseline AMP revised in accordance with relevant regulations and program guidance. There will be one weighted DRA Baseline AMP for the product, which will be the same for all package sizes. Per CMS-2238-FC, labelers had 4 quarters (i.e., January 2, 2008 – October 30, 2008) to report this optional field. Numeric values, 12-digit field; 5 whole numbers, the decimal ('.') and 6 decimal places, right- justified, zero-filled. Compute to 7 decimal places and round to 6 decimal places.

Package Size Introduction Date: The date the package size is first available on the market. Numeric values, 8-digit field, format: MMDDYYYY

Purchased Product Date: The date the company currently holding legal title to the NDC first markets the drug under this NDC (this date can result, for example, from the purchase of an NDC from one company by another company, the re-designation of an NDC from one of a company's labeler codes to another of that same company's labeler codes, cross-licensing arrangements, etc.). Zero or blank fill if not applicable. Numeric values, 8-digit field, format: MMDDYYYY

5i Drug Indicator: Identifies whether a product is a 5i Drug. Alpha-numeric values; 1-digit field.

Valid Values:

Y = Yes
N = No

5i Route of Administration: Identifies the method by which the 5i drug is administered to a patient. If a product is not a 5i drug, a value of "000" (Not Applicable) should be entered. Numeric values; 3-digit field.

Valid Values:

000 = Not Applicable
001 = Implanted
002 = Infused
003 = Inhaled
004 = Injected
005 = Instilled

ACA Baseline AMP (Optional): For active innovator drugs, the OBRA'90, OBRA'93 or DRA Baseline AMP revised in accordance with the statute and relevant program guidance. There will be one weighted ACA Baseline AMP for the product, which will be the same for all package sizes. Numeric values, 12-digit field; 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified; zero-filled. Compute to 7 decimal places and round to 6 decimal places.

Covered Outpatient Drug (COD) Status: A category that identifies whether or not a product meets the statutory definition of a covered outpatient drug in accordance with sections

1927(k)(2) to 1927(k)(4) of the Social Security Act. Numeric values, 2-character field.

Valid Values:

01 = Abbreviated New Drug Application (ANDA)
02 = Biologics License Application (BLA)
03 = New Drug Application (NDA)
04 = NDA Authorized Generic
05 = DESI 5* – LTE/IRS drug for all indications
06 = DESI 6* – LTE/IRS drug withdrawn from market
07 = Prescription Pre-Natal Vitamin or Fluoride
08 = Prescription Dietary Supplement/Vitamin/Mineral (Other than Prescription Pre-Natal Vitamin or Fluoride)
09 = OTC Monograph Tentative
10 = OTC Monograph Final
11 = Unapproved Drug – Drug Shortage
12 = Unapproved Drug – Per 1927(k)(2)(A)(ii)
13 = Unapproved Drug – Per 1927(k)(2)(A)(iii)

*NDCs with a COD Status of DESI 5/6 are not eligible for coverage or rebates under the Medicaid Drug Rebate Program.

FDA Application Number/OTC Monograph Number: For drugs with a COD status of ANDA, BLA, NDA, or NDA Authorized Generic, this is the seven-digit application number that is assigned by the FDA for approval to market a generic drug or new drug in the United States. Numeric field; 7 characters, fill with leading zeros as needed.

For drugs with a COD status of OTC Monograph Tentative or Final, this is the FDA's regulatory citation for the OTC. 7 alpha-numeric characters. For drugs with a COD Status of OTC Monograph Final, the first four characters are a constant of "PART"; the last three characters are the numeric values for the appropriate regulatory citation for the product (for example, "225"). For drugs with a COD Status of OTC Monograph Tentative, the first four characters are a constant of "PART"; the last three characters are the numeric values for the appropriate regulatory citation for the product, or 3 zeros if a Monograph Number is not available.

For drugs with a COD Status other than ANDA, BLA, NDA, NDA Authorized Generic, OTC Monograph Final, or OTC Monograph Tentative, the FDA Application No./OTC Monograph No. field should be zero-filled.

Reactivation Date: The date on which a terminated product is re-introduced to the market. (Note: This field may only be submitted online via DDR and is **NOT** part of the actual File Transfer Layout.)

Line Extension Drug Indicator: Identifies whether a product is a line extension drug as defined in Section 1927 (c)(2)(C) of the Social Security Act.

Valid Values:

Y = Yes
N = No

CMS-367d

MEDICAID DRUG REBATE AGREEMENT

ENCLOSURE B (PAGE 1 OF 2)
SUPPLEMENTAL DATA

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

LEGAL CONTACT – Person to contact for legal issues concerning the rebate agreement

NAME OF CONTACT

AREA PHONE NUMBER EXTENSION

EMAIL ADDRESS:

NAME OF CORPORATION

STREET ADDRESS

CITY STATE ZIP CODE

INVOICE CONTACT – Person responsible for processing invoice utilization data

NAME OF CONTACT

AREA PHONE NUMBER EXTENSION

EMAIL ADDRESS:

NAME OF CORPORATION

STREET ADDRESS

CITY STATE ZIP CODE

Note: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

CMS-367d According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578 (Expires: 12/31/2019). The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

MEDICAID DRUG REBATE AGREEMENT

ENCLOSURE B (PAGE 2 OF 2)
SUPPLEMENTAL DATA

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

TECHNICAL CONTACT – Person responsible for sending and receiving data

NAME OF CONTACT

AREA PHONE NUMBER EXTENSION

FAX #

EMAIL ADDRESS:

NAME OF CORPORATION

STREET ADDRESS

CITY STATE ZIP CODE

Note: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

CMS-367d According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578 (Expires: 12/31/2019) . The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Dated: February 20, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 16, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–05947 Filed 3–22–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3352–N]

Medicare Program; Announcement of the Approval of the American Association for Laboratory Accreditation (A2LA) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the approval of the application of the American Association for Laboratory Accreditation (A2LA) as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for all specialty and subspecialty areas under CLIA. We have determined that the A2LA meets or exceeds the applicable CLIA requirements. We are announcing the approval and granting the A2LA deeming authority for a period of 4 years.

DATES: *Applicable Date:* This notice is applicable from March 23, 2018 to March 23, 2022.

FOR FURTHER INFORMATION CONTACT: Cindy Flacks, (410) 786–6520.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of the A2LA as an Accreditation Organization

In this notice, we approve the American Association for Laboratory Accreditation (A2LA) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for all specialty and subspecialty areas under CLIA. We have examined the initial A2LA application and all subsequent submissions to determine the equivalency of its accreditation program with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that the A2LA meets or exceeds the applicable CLIA requirements. We have also determined that the A2LA will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R.

Therefore, we grant the A2LA approval as an accreditation organization under 42 CFR part 493, subpart E for the period stated in the **DATES** section of this notice for all specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by the A2LA during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of the A2LA Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the A2LA accreditation program meets the necessary requirements to be approved by CMS and that, as such, CMS may approve the A2LA as an accreditation program with deeming authority under the CLIA program. The A2LA formally applied to CMS for approval as an accreditation organization under CLIA for all specialties and subspecialties under CLIA. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

The A2LA submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. The A2LA policies and procedures for oversight of laboratories performing laboratory testing for all CLIA specialties and subspecialties are equivalent to those of CLIA in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. The A2LA submitted requirements for monitoring and inspecting laboratories in the areas of accreditation organization, data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. The requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

B. Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

The A2LA's requirements are equal to or more stringent than the CLIA requirements at §§ 493.801 through 493.865. For instance, the A2LA requires that laboratories conduct proficiency testing activities for both primary and secondary test systems for waived and non-waived testing. The CLIA requirement at § 493.801(b)(6) requires proficiency testing activities for the primary test system and for non-waived testing only.

C. Subpart J—Facility Administration for Nonwaived Testing

The A2LA requirements for the submitted subspecialties and specialties are equal to the CLIA requirements at §§ 493.1100 through 493.1105.