DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10054 and CMS–10106]

Agency Information Collection Activities: Proposed Collection;
Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by December 18, 2017.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to http://www.regulations.gov. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number , Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:


2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see ADDRESSES).

CMSS–10054 New Technology Payments for APCs Under the Outpatient Prospective Payment System

CMS–10106 Medicare Authorization to Disclose Personal Health Information

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: New Technology Payments for APCs Under the Outpatient Prospective Payment System; Use: CMS needs to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner. It is necessary that we continue to collect appropriate information from interested parties such as hospitals, medical device manufacturers, pharmaceutical companies and others that bring to our attention specific services that they wish to evaluate for New Technology APC payment. We are making no changes to the information that we collect. The information that we seek to continue to collect is necessary to determine whether certain new services are eligible for payment in New Technology APCs, to determine appropriate coding and to set an appropriate 4 payment rate for the new technology service. The intent of these provisions is to ensure timely beneficiary access to new and appropriate technologies Form Number: CMS–10054 (OMB control number: 0938–0860); Frequency: Annually; Affected Public: Private Sector; Business or Other for–profits; Number of Respondents: 10; Total Annual Responses: 10; Total Annual Hours: 160. (For policy questions regarding this collection contact Joshua McFeeters at 410–786–9732).

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Authorization to Disclose Personal Health Information; Use: Unless permitted or required by law, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (§ 164.508) prohibits Medicare (a HIPAA covered entity) from disclosing an individual’s protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements. Medicare will make available to Medicare beneficiaries a standard, valid authorization to enable beneficiaries to request the disclosure of their protected health information. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for Medicare. Form CMS–10106, the Medicare Authorization to Disclose Personal Health Information, will be used by Medicare beneficiaries to authorize Medicare to disclose their protected health information to a third party. Form Number: CMS–10106 (OMB control number: 0938–0930); Frequency: Occasionally; Affected Public:

3. OMB Control Number: 0938–0062, Title of Information Collection: Medicare Authorization to Disclose Personal Health Information; Use: CMS needs to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner. It is necessary that we continue to collect appropriate information from interested parties such as hospitals, medical device manufacturers, pharmaceutical companies and others that bring to our attention specific services that they wish to evaluate for New Technology APC payment. We are making no changes to the information that we collect. The information that we seek to continue to collect is necessary to determine whether certain new services are eligible for payment in New Technology APCs, to determine appropriate coding and to set an appropriate 4 payment rate for the new technology service. The intent of these provisions is to ensure timely beneficiary access to new and appropriate technologies Form Number: CMS–10054 (OMB control number: 0938–0860); Frequency: Annually; Affected Public: Private Sector; Business or Other for–profits; Number of Respondents: 10; Total Annual Responses: 10; Total Annual Hours: 160. (For policy questions regarding this collection contact Joshua McFeeters at 410–786–9732).

4. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Authorization to Disclose Personal Health Information; Use: Unless permitted or required by law, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (§ 164.508) prohibits Medicare (a HIPAA covered entity) from disclosing an individual’s protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements. Medicare will make available to Medicare beneficiaries a standard, valid authorization to enable beneficiaries to request the disclosure of their protected health information. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for Medicare. Form CMS–10106, the Medicare Authorization to Disclose Personal Health Information, will be used by Medicare beneficiaries to authorize Medicare to disclose their protected health information to a third party. Form Number: CMS–10106 (OMB control number: 0938–0930); Frequency: Occasionally; Affected Public:

5. OMB Control Number: 0938–0848, Title of Information Collection: Amount of Medicare and Medicaid Payments for Services by Outpatient Prospective Payment System Hospitals for Services to Dually Eligible Beneficiaries; Use: CMS needs to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner. It is necessary that we continue to collect appropriate information from interested parties such as hospitals, medical device manufacturers, pharmaceutical companies and others that bring to our attention specific services that they wish to evaluate for New Technology APC payment. We are making no changes to the information that we collect. The information that we seek to continue to collect is necessary to determine whether certain new services are eligible for payment in New Technology APCs, to determine appropriate coding and to set an appropriate 4 payment rate for the new technology service. The intent of these provisions is to ensure timely beneficiary access to new and appropriate technologies Form Number: CMS–10054 (OMB control number: 0938–0860); Frequency: Annually; Affected Public: Private Sector; Business or Other for–profits; Number of Respondents: 10; Total Annual Responses: 10; Total Annual Hours: 160. (For policy questions regarding this collection contact Joshua McFeeters at 410–786–9732).

6. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Authorization to Disclose Personal Health Information; Use: Unless permitted or required by law, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (§ 164.508) prohibits Medicare (a HIPAA covered entity) from disclosing an individual’s protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements. Medicare will make available to Medicare beneficiaries a standard, valid authorization to enable beneficiaries to request the disclosure of their protected health information. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for Medicare. Form CMS–10106, the Medicare Authorization to Disclose Personal Health Information, will be used by Medicare beneficiaries to authorize Medicare to disclose their protected health information to a third party. Form Number: CMS–10106 (OMB control number: 0938–0930); Frequency: Occasionally; Affected Public:

7. OMB Control Number: 0938–0848, Title of Information Collection: Amount of Medicare and Medicaid Payments for Services by Outpatient Prospective Payment System Hospitals for Services to Dually Eligible Beneficiaries; Use: CMS needs to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner. It is necessary that we continue to collect appropriate information from interested parties such as hospitals, medical device manufacturers, pharmaceutical companies and others that bring to our attention specific services that they wish to evaluate for New Technology APC payment. We are making no changes to the information that we collect. The information that we seek to continue to collect is necessary to determine whether certain new services are eligible for payment in New Technology APCs, to determine appropriate coding and to set an appropriate 4 payment rate for the new technology service. The intent of these provisions is to ensure timely beneficiary access to new and appropriate technologies Form Number: CMS–10054 (OMB control number: 0938–0860); Frequency: Annually; Affected Public: Private Sector; Business or Other for–profits; Number of Respondents: 10; Total Annual Responses: 10; Total Annual Hours: 160. (For policy questions regarding this collection contact Joshua McFeeters at 410–786–9732).

8. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Authorization to Disclose Personal Health Information; Use: Unless permitted or required by law, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (§ 164.508) prohibits Medicare (a HIPAA covered entity) from disclosing an individual’s protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements. Medicare will make available to Medicare beneficiaries a standard, valid authorization to enable beneficiaries to request the disclosure of their protected health information. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for Medicare. Form CMS–10106, the Medicare Authorization to Disclose Personal Health Information, will be used by Medicare beneficiaries to authorize Medicare to disclose their protected health information to a third party. Form Number: CMS–10106 (OMB control number: 0938–0930); Frequency: Occasionally; Affected Public:
Individuals or Households; Number of Respondents: 2,200,000; Total Annual Responses: 2,200,000; Total Annual Hours: 550,000. (For policy questions regarding this collection contact Sam Jenkins at 410–786–3261.)

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–22630 Filed 10–17–17; 8:45 am] BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0426]

Submission for OMB Review; Comment Request; Child and Family Services Plan (CFSP), Annual Progress and Services Review (APSR), and Annual Budget Expenses Request and Estimated Expenditures (CFS–101)

Description: Under title IV–B, subparts 1 and 2, of the Social Security Act (the Act), States, Territories, and Tribes are required to submit a Child and Family Services Plan (CFSP). The CFSP lays the groundwork for a system of coordinated, integrated, and culturally relevant family services for the subsequent five years (45 CFR 1357.15(a)(1)). The CFSP outlines initiatives and activities the State, Territory, and Tribes will carry out in administering programs and services to promote the safety, permanency, and well-being of children and families, including, as applicable, those activities conducted under the John H. Chafee Foster Care Independence Program (Section 477 of the Act) and the State grant authorized by the Child Abuse Prevention and Treatment Act. By June 30 of each year, States, Territories, and Tribes are also required to submit an Annual Progress and Services Report (APSR) and a financial report called the CFS–101. The APSR is a yearly report that discusses progress made by a State, Territory or Tribe in accomplishing the goals and objectives cited in its CFSP (45 CFR 1357.16(a)). The APSR contains new and updated information about service needs and organizational capacities throughout the five-year plan period. The CFS–101 has three parts. Part I is an annual budget request for the upcoming fiscal year. Part II includes a summary of planned expenditures by program area for the upcoming fiscal year, the estimated number of individuals or families to be served, and the geographical service area. Part III includes actual expenditures by program area, numbers of families and individuals served by program area, and the geographic areas served for the last complete fiscal year.

Respondents: States, Territories, and Tribes must complete the CFSP, APSR, and CFS–101. States and Territories must also report data annually on caseworker visits with children in foster care. Tribes are exempted from the caseworker visits reporting requirement of the CFSP/APSR. There are approximately 189 Tribal entities that currently receive IV–B funding. There are 53 States (including Puerto Rico, the District of Columbia, and the U.S. Virgin Islands) that must complete the CFS, APSR, and CFS–101. There are a total of 242 possible respondents.

ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
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<tbody>
<tr>
<td>APSR</td>
<td>242</td>
<td>1</td>
<td>80</td>
<td>19,360</td>
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<td>CFSP</td>
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<tr>
<td>CFS–101, Parts I, II, and III</td>
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<td>5</td>
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<tr>
<td>Caseworker Visits</td>
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<td>1</td>
<td>99.33</td>
<td>5,264.48</td>
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</tbody>
</table>

Estimated Total Annual Burden Hours: 31,654.59.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information within 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA

SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Mary Jones,
ACF/OPRE Certifying Officer.


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1003]

Center for Devices and Radiological Health: Experiential Learning Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH or Center) is announcing the 2018 Experiential Learning Program (ELP). This training is intended to provide CDRH and other FDA staff with an opportunity to understand laboratory practices, quality system management, patient perspective/input, and challenges that impact the medical device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities, and others to participate in this formal training program for CDRH and other FDA staff, or to contact CDRH for more information regarding the ELP.

DATES: Submit electronic proposals for participation in the ELP within the dates provided at the ELP Web site at: https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.

ADDRESSES: For access to the docket to read background documents, go to https://www.regulations.gov and insert