

The application process is open to all health plans that want to participate in the MA program. The application is distinct and separate from the bid process, and CMS issues a determination on the application prior to bid submissions, or before the first Monday in June. *Form Number:* CMS–10137 (OMB control number: 0938–0935); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 380; *Total Annual Responses:* 400; *Total Annual Hours:* 6,106. (For policy questions regarding this collection contact Keith Penn-Jones, at 410–786–3104.)

9. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS); *Use:* The CMS has had longstanding concerns about the improper payments related to DMEPOS items. The Department of Health and Human Services' Office of the Inspector General and the U.S. Government Accountability Office have published multiple reports indicating questionable billing practices by suppliers, inappropriate Medicare payments, and questionable utilization of DMEPOS items. The fiscal year (FY) 2017 Medicare FFS program improper payment rate for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) was 44.6%, accounting for over \$3.7 billion in projected improper payments. The CMS has implemented several initiatives in recent years to address these issues, such as the DMEPOS Competitive Bidding Program, as well as heightened screening of suppliers, as authorized by the Affordable Care Act. In addition to those actions, CMS is continuing the use of prior authorization in fee for service Medicare. Prior authorization is a process through which a request for provisional affirmation of coverage is submitted for review before an item is rendered to a Medicare patient and before a claim is submitted for payment. Prior authorization helps make sure that applicable Medicare coverage, payment, and coding rules are met before item(s) are rendered. Prior to furnishing the item to the beneficiary and prior to submitting the claim for processing, a requester must submit a prior authorization request that includes evidence that the item complies with all

applicable Medicare coverage, coding, and payment rules. Consistent with § 414.234(d), such evidence must include the order, relevant information from the beneficiary's medical record, and relevant supplier-produced documentation. After receipt of all applicable required Medicare documentation, CMS or one of its review contractors will conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request. A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the DMEPOS item likely meets Medicare's coverage, coding, and payment requirements. Suppliers who receive a non-affirmative decision have unlimited resubmission opportunities. *Form Number:* CMS–10524 (OMB control number: 0938–1293); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 321,551; *Total Annual Responses:* 321,551; *Total Annual Hours:* 160,775.68 (For policy questions regarding this collection contact Yuliya Cook at (410) 786–0157.)

10. *Type of Information Collection Request:* Reinstatement; *Title of Information Collection:* Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage; *Use:* Section 1862(m) of the Social Security Act (and regulations at 42 CFR Subpart B (sections 405.201–405.215) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. Medicare does not cover the Category A device itself because Category A (Experimental) devices do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary. Medicare may cover Category B (Non-experimental) devices, and associated routine costs of care, if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Under the current centralized review process, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies have a centralized point of contact for submission, review

and determination of Medicare coverage IDE study requests. In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are met, as described in our regulations, CMS (or its designated entity) must review documents submitted by interested parties or study sponsors. Such information submitted will be a FDA IDE approval letter, IDE study protocol, IRB approval letter, National Clinical Trials (NCT) number, and Supporting materials as needed. *Form Number:* CMS–10511 (OMB control number: 0938–1250); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours:* 200. (For policy questions regarding this collection contact Cheryl Gilbreath at 410–786–5919.)

Dated: January 28, 2019.

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

[FR Doc. 2019–00411 Filed 1–30–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Self-Assessment Review and Report.

OMB No.: 0970–0223.

Description: Section 454(15)(A) of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Act of 1996, requires each State to annually assess the performance of its child support enforcement program in accordance with standards specified by the Secretary of the Department of Health and Human Services, and to provide a report of the findings to the Secretary. This information is required to determine if States are complying with Federal child support mandates and providing the best services possible. The report is also intended to be used as management tool to help States evaluate their programs and assess performance.

Respondents: State Child Support Enforcement Agencies or Department/Agency/Bureau responsible for Child Support Enforcement in each State.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Self-assessment report	54	1	4	216

Estimated Total Annual Burden Hours: 216.

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. Attention 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 between 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 B. Jones,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970-0114]

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Child Care and Development Fund Plan for States/Territories for FFY 2019–2021 (ACF–118).

Description: The Child Care and Development Fund (CCDF) Plan (the Plan) for States and Territories is required from each CCDF Lead agency in accordance with Section 658E of the Child Care and Development Block Grant Act of 1990 (CCDBG Act), as amended, CCDBG Act of 2014 (Pub. L. 113–186), and 42 U.S.C 9858. The Plan, submitted on the ACF–118, is required triennially, and remains in effect for three years. The Plan provides ACF and the public with a description of, and assurance about the States’ and Territories’ child care programs. These Plans are the applications for CCDF funds. The ACF–118 is currently approved through December 31, 2018.

This Notice is required by the Paperwork Reduction Act (PRA). The PRA requires Federal agencies to request approval from the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) for any information collection that will ask the same question of ten or more persons. The process includes publication of an initial **Federal**

Register Notice (FRN) allowing 60 days for public comments on the initial plan for information collection, the publication of a second FRN allowing 30 days for public comment on the final proposed information collection, and review and approval by the OMB Office of Information and Regulatory Affairs.

Due to unanticipated events, the Office of Child Care (OCC) could not comply with the regular PRA clearance process that calls for two **Federal Register** Notices (60- and 30-day) and comment periods by the July 1, 2018 CCDF Plan submission deadline. The OCC requested and was granted clearance for this FY 2019–2021 CCDF Plan Preprint from OMB under emergency clearance procedure for six months with an expiration date of December 31, 2018. Because the CCDF Plan covers three year effective period, we are initiating the full clearance process to obtain OMB approval to use this document for the entire three year period.

The Office of Child Care (OCC) gave thoughtful consideration to the comments received from the 30-day emergency Public Notice. OCC revised the document to reflect some of the changes made to minimize the administrative burden of the collection of information on respondents. The revised document contains revisions to improve the accuracy and clarity of policy questions, definitions, and guidance in order to improve the quality of information that is collected.

Respondents: State and Territory CCDF Lead Agencies (56).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–118	56	0.33	200	3,696

Estimated Total Annual Burden Hours: 3,696.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

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

requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the