

of Responses: 2,138; Total Annual Hours: 170,589. (For policy questions regarding this collection contact Kevin Young at 410-786-6133 or Ashley Stedding at 410-786-4250).

### 3. Type of Information Collection

**Request:** Extension of a currently approved collection; **Title of Information Collection:** Income and Eligibility Verification System Reporting and Supporting Regulations; **Use:** Section 1137 of the Social Security Act requires that States verify the income and eligibility information contained on the applicant's application and in the applicant's case file through data matches with the agencies and entities identified in this section. The State Medicaid/CHIP agency will report the existence of a system to collect all information needed to determine and redetermine eligibility for Medicaid and CHIP. The State Medicaid/CHIP agency will attest to using the PARIS system in determining beneficiary eligibility in Medicaid or CHIP benefit programs. **Form Number:** CMS-R-74 (OMB control number: 0938-0467); **Frequency:** Occasionally; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 55; **Total Annual Responses:** 3,241; **Total Annual Hours:** 1,071. (For policy questions regarding this collection contact Stephanie Bell at 410-786-0617.)

Dated: October 23, 2018.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2018-23576 Filed 10-26-18; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10494]

#### Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by November 28, 2018.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

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:

1. Access CMS' website address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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:** Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

#### 1. Type of Information Collection

**Request:** Revision of a previously approved collection; **Title of Information Collection:** Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel—CAC; **Use:** Section 1321(a)(1) of the Affordable Care Act directs and authorizes the Secretary to issue regulations setting standards for meeting the requirements under title I of the Affordable Care Act, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to this authority, regulations establishing the certified application counselor program have been finalized at 45 CFR 155.225. In accordance with 155.225(d)(1) and (7), certified application counselors in all Exchanges are required to be initially certified and recertified on at least an annual basis and successfully complete Exchange-required training. **Form Number:** CMS-10494 (OMB control number: 0938-1205); **Frequency:** On Occasion; **Affected Public:** State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); individuals or households; **Number of Respondents:** 30,000; **Total Annual Responses:** 30,000; **Total Annual Hours:** 7,500. (For policy questions regarding this collection contact Deborah Bryant at 301-492-5213.)

Dated: October 24, 2018.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2018-23590 Filed 10-26-18; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

**Proposed Projects:** Office of Child Care CCDF Onsite Monitoring.

**Title:** Child Care and Development Fund (CCDF) State Monitoring Compliance Demonstration Packet.

**OMB No.:** New.

*Description:* This is a new proposed data collection from the Office of Child Care (OCC) for the Onsite Monitoring System.

Section 658I of the Child Care and Development Block Grant Act and Subpart J of 45 CFR, part 98 of the Child Care and Development Fund requires the monitoring of programs funded under the CCDF for compliance with:

- (1) The Act;
- (2) CCDF Regulations; and
- (3) The State/Territory CCDF approved Plan.

The proposed data collection will be used by the Office of Child Care (OCC) to monitor State CCDF Lead Agencies to determine and validate compliance with CCDF regulations and the approved State Plan. The data collection is designed to provide States with the flexibility to propose an approach that is feasible and sufficient to demonstrate compliance based on State circumstances and processes. State Lead Agencies will participate in onsite monitoring based on a 3-year cohort; submitting data once every three years.

OCC will begin monitoring for compliance in FY 2019.

The data collection for the first 3-years will focus on 11 topical areas: (1) Disaster Preparedness, Response and Recovery; (2) Consumer Education: Dissemination of Information to Parents, Providers, and General Public (Monitoring Reports and Annual Aggregate Data); (3) Twelve-Month Eligibility; (4) Child: Staff Ratios and Group Sizes; (5) Health and Safety Requirements for Providers (11 Health and Safety Topics); (6) Pre-Service/Orientation and Ongoing Training Requirements for Providers; (7) Inspections for CCDF Licensed Providers; (8) Inspections for License-Exempt CCDF Providers; (9) Ratios for Licensing Inspectors; (10) Child Abuse and Neglect Reporting; and (11) Program Integrity.

In developing the Onsite Monitoring System, OCC convened a workgroup of states to provide feedback and input on the design of the Onsite Monitoring System. As part of the workgroup discussions, states emphasized the need for individualized monitoring because

of the complexity of each state's CCDF structure and variance in implementation strategies. As a response, OCC developed the Compliance Demonstration Packet that offers states the opportunity to propose their approach to demonstrating compliance based on how their CCDF program is administered. OCC also consulted other federal programs and monitoring experts on the Onsite Monitoring System's development and incorporated their feedback regarding the efficiency and efficacy of the proposed process.

During the development of the Onsite Monitoring System, OCC conducted pilots in a number of States. Feedback received from pilot States and the pilot results were used to enhance the monitoring process and data collection method. Burden estimates below are based on an analysis of data collected through all of the pilot visits while accounting for variance in state documentation.

*Respondents:* State grantees and the District of Columbia.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Compliance Demonstration Chart .....	17	1	16	272
Document Submission Chart .....	17	1	80	1,360

**Estimated Total Annual Burden Hours:** 1,632 hours.

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](mailto: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 agency's estimate of the burden of the proposed collection of information; (c)

the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**  
*Reports Clearance Officer.*  
 [FR Doc. 2018-23536 Filed 10-26-18; 8:45 am]  
**BILLING CODE 4184-43-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-3647]

**Endo Pharmaceuticals, Inc., et al.;  
 Withdrawal of Approval of 10 New  
 Drug Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 10 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of November 28, 2018.

**FOR FURTHER INFORMATION CONTACT:** Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993-0002, 301-796-3601.

**SUPPLEMENTARY INFORMATION:** The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing.