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:* Extension of a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations; *Use:* We use this report to compare actual data to the approved waiver estimates. In conjunction with the waiver compliance review reports, the information provided will be compared to that in the Medicaid Statistical Information System (MSIS) (CMS–R–284; OMB control number 0938–0345) report and FFP claimed on a state's Quarterly Expenditure Report (CMS–64; OMB control number 0938–1265), to determine whether to continue the state's home and community-based services waiver. States' estimates of cost and utilization for renewal purposes are based upon the data compiled in the CMS–372(S) reports. *Form Number:* CMS–372(S) (OMB Control Number: 0938–0272); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 48; *Total Annual Responses:* 315; *Total Annual Hours:* 13,545. (For policy questions regarding this collection contact Ralph Lollar at 410–786–0777).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Outpatient/Ambulatory Surgery Patient Experience of Care Survey (O/ASPECS); *Use:* The information collected in the national implementation of Outpatient/Ambulatory Surgery Patient Experience of Care Survey (A/ASPECS) will be used to: (1) Provide a source of information from which selected measures can be publicly reported to beneficiaries to help them make informed decisions for outpatient surgery facility selection; (2) aid facilities with their internal quality improvement efforts and external benchmarking with other facilities; and (3) provide us with information for monitoring and public reporting purposes. *Form Number:* CMS–10500 (OMB Control Number: 0938–1240); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 2,813,610; *Total Annual Responses:* 2,813,610; *Total Annual Hours:* 365,769. (For policy questions regarding this collection contact Memuna Ifedirah at 410–786–6849).

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Site Investigation for Independent Diagnostic Testing Facilities (IDTFs); *Use:* We enroll Independent Diagnostic Testing Facilities (IDTFs) into the Medicare program via a uniform application, the CMS 855B. Implementation of enhanced procedures for verifying the enrollment information has improved the enrollment process as well as identified and prevented fraudulent IDTFs from entering the Medicare program. As part of this process, verification of compliance with IDTF performance standards is necessary. The primary function of the site investigation form for IDTFs is to provide a standardized, uniform tool to gather information from an IDTF that tells us whether it meets certain standards to be a IDTF (as found in 42 CFR 410.33(g)) and where it practices or renders its services. The site investigation form has been used in the past to aid in verifying compliance with the required performance standards found in 42 CFR 410.33(g). No revisions have been made to this form since the last submission for OMB approval. *Form Number:* CMS–10221 (OMB Control Number: 0938–1029); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 900; *Total Annual Responses:* 900; *Total Annual Hours:* 1,800. (For policy questions regarding this collection contact Kim McPhillips at 410–786–5374).

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); *Use:* We enroll suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) into the Medicare program via a uniform application, the CMS 855S. Implementation of enhanced procedures for verifying the enrollment information has improved the enrollment process as well as identified and prevented fraudulent DMEPOS suppliers from entering the Medicare program. As part of this process, verification of compliance with supplier standards is necessary. The primary function of the site investigation form is to provide a standardized, uniform tool to gather information from a DMEPOS supplier that tells us whether it meets certain qualifications to be a DMEPOS supplier (as found in 42 CFR 424.57(c)) and where it practices or renders its services. The site investigation form has been used in the past to aid in verifying compliance with the required supplier standards found in 42 CFR 424.57(c). No revisions have been made to this form since the last submission for OMB approval. *Form Number:* CMS–R–263 (OMB Control Number: 0938–0749); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 30,000; *Total Annual Responses:* 30,000; *Total Annual Hours:* 15,000. (For policy questions regarding this collection contact Kim McPhillips at 410–786–5374).

Dated: January 13, 2015.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–00627 Filed 1–15–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0167]

Submission for OMB Review; Comment Request: Child Care Quarterly Case Record Report—ACF–801

Description: Section 658K of the Child Care and Development Block Grant Act (42 U.S.C. 9858) requires that States and Territories submit monthly case-level data on the children and families receiving direct services under the Child Care and Development Fund (CCDF). The implementing regulations for the statutorily required reporting are at 45 CFR 98.70. Case-level reports, submitted quarterly or monthly (at grantee option), include monthly sample or full population case-level data. The data elements to be included in these reports are represented in the ACF–801. ACF uses disaggregate data to determine program and participant characteristics as well as costs and levels of child care services provided. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research. On November 19, 2014, the President signed the Child Care and Development Block Grant Act of 2014

(Pub. L. 113–86) which reauthorized the CCDF program and made some changes to ACF–801 reporting requirements. Owing to the need to consult with CCDF administrators and other interested parties on these changes, and a limited amount of time before the current ACF–801 form expires, ACF is not proposing changes to the ACF–801 at this time. We request to extend the ACF–801 without changes in order to ensure the form does not expire. In the near future, ACF plans to initiate a new clearance process under the Paperwork Reduction Act to implement the data reporting changes in the newly-reauthorized law.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Marianna Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–801	56	4	25	5,600

Estimated Total Annual Burden Hours: 5,600.

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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–00560 Filed 1–15–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2300]

Evaluating Drug Effects on the Ability To Operate a Motor Vehicle; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Evaluating Drug Effects on the Ability to Operate a Motor Vehicle.'' The purpose of this guidance is to assist sponsors in the evaluation of the effects of psychoactive drugs on the ability to operate a motor vehicle. Driving is a complex activity involving a wide range of cognitive, perceptual, and motor activities. Reducing the incidence of motor vehicle accidents (MVAs) that occur because of drug-impaired driving is a public health priority. This draft guidance recommends using a systematic effort to identify drugs that increase the risk of MVAs as a critical component of assessing drug risk and designing strategies to reduce this risk.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 17, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aaron Sherman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4339, Silver Spring, MD 20993–0002, 240–402–0493.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Evaluating Drug Effects on the Ability to Operate a Motor Vehicle.'' The purpose of this guidance is to assist sponsors in the evaluation of the effects of psychoactive drugs on the ability to operate a motor vehicle.

Driving is a complex activity involving a wide range of cognitive, perceptual, and motor activities that can be adversely affected by therapeutic drugs. Reducing the incidence of MVAs that occur because of drug-impaired driving is a public health priority.[1]

Drugs that impair driving ability may also impair the ability to judge the extent of one's own impairment. This increases the need for objective evaluation of the presence and degree of driving impairment, with risk mitigation strategies based on that information. This guidance recommends a systematic effort to identify drugs for which evaluation of effects on driving abilities may be needed, and the types of studies that such an evaluation entails.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on evaluating drug effects on the ability to operate a motor vehicle. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

[1] See the Drugged Driving Web page on the Office of National Drug Control Policy Web site at *http://www.whitehouse.gov/ondcp/drugged-driving.*