

the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of an existing information collection request; *Title of Information Collection:* Cooperative Agreements to Support Establishment of State-Operated Health Insurance Exchanges; *Use:* All States (including the 50 States, consortia of States, and the District of Columbia herein referred to as States) had the opportunity under Section 1311(b) of the Affordable Care to apply for three types of grants: (1) Planning grants; (2) Early Innovator grants for early development of information technology; and (3) Establishment grants to develop, implement and start-up Marketplaces. As of January 1st, 2017, the Secretary has disbursed over \$5.4 billion under this grant program and, as of that date, there were 19 active establishment grants awarded to 12 states. As the State-Based Marketplaces (SBM) and Small Business Health Options Program (SHOP) have matured and moved from the developmental phases to full-operation, the reporting requirements for the states have been modified and streamlined to insure only information necessary to provide effective oversight of their operations by CMS is collected.

Given the innovative nature of Exchanges and the statutorily-prescribed relationship between the Secretary and States in their development and operation, it is critical that the Secretary work closely with States to provide necessary guidance and technical assistance to ensure that States can meet the prescribed timelines, federal requirements, and goals of the statute and the grants awarded to them. *Form Number:* CMS-10371 (OMB Control Number: 0938-1119); *Frequency:* Once; *Affected Public:* State Government agencies, non-profit entities; *Number of Respondents:* 17; *Total Annual Responses:* 37; *Total Annual Hours:* 12,328. (For policy questions regarding this collection contact Nickom Sukachev at (301) 492-4400).

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved information collection; *Title of Information Collection:* State-based Marketplace Annual Reporting Tool (SMART); *Use:* The annual report is the primary vehicle to insure comprehensive compliance with all reporting requirements contained in the Affordable Care Act (ACA). It is specifically called for in Section 1313(a)(1) of the Act which requires an SBM to keep an accurate accounting of all activities, receipts, and expenditures, and to submit a report

annually to the Secretary concerning such accounting. CMS will use the information collected from States to assist in determining if a State is maintaining a compliant operational Exchange. *Form Number:* CMS-10507 (OMB Control Number: 0938-1244); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal governments; *Number of Respondents:* 17; *Total Annual Responses:* 17; *Total Annual Hours:* 1,173. (For policy questions regarding this collection contact Christy Woods at 301-492-5140).

3. *Title of Information Collection:* Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs; *Type of Information Collection Request:* Extension without change of a currently approved collection; *Use:* Under 45 CFR 156.122(d)(1)(2) and 156.230(c) and in the final rule, *Patient Protection and Affordable Care Act*; *HHS Notice of Benefit and Payment Parameters for 2018* (CMS-9934-F), standards for qualified health plan (QHP) issuers are established for the submission of provider and formulary data in a machine-readable format to the Department of Health and Human Services (HHS) and for posting on issuer Web sites. These standards provide greater transparency for consumers, including by allowing software developers to access formulary and provider data to create innovative and informative tools. This Information Collection Request (ICR) serves as a formal request for 3-year OMB approval. On September 30, 2015, the Office of Management and Budget (OMB) granted approval to the data collection *Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs*.

The burden estimates for the data collection requirements included in this package reflect the time and effort for QHP issuers to update and publish the appropriate data, and submit it to CMS. *Form Number:* CMS-10558 (OMB control number: 0938-1284); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 397; *Number of Responses:* 397; *Total Hours:* 208. (For questions regarding this collection, contact Joshua Annas at (301) 492-4407).

4. *Title of Information Collection:* State Permissions for Enrollment in Qualified Health Plans in the Federally Facilitated Exchange & Non-Exchange Entities; *Type of Information Collection Request:* Request for a new OMB control number; *Use:* The Patient Protection and Affordable Care Act, Public Law 111-

148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, "Affordable Care Act"), expand access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), also called Marketplaces, including the Small Business Health Options Program (SHOP). The Exchanges, which became operational on January 1, 2014, enhance competition in the health insurance market, expand access to affordable health insurance for millions of Americans, and provide consumers with a place to easily compare and shop for health insurance coverage.

This Information Collection Request (ICR) serves as the formal request for a new data collection associated with the HHS Notice of Benefit and Payment Parameters for 2018 Final Rule (2018 Payment Notice). This ICR includes information collection requirements related to the ability of states to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in Qualified Health Plans in the Federally Facilitated Exchange (§ 155.220) and ICRs related to non-exchange entities (§ 155.260). *Form Number:* CMS-10650 (OMB control number 0938-NEW); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 107,207; *Number of Responses:* 107,207; *Total Annual Hours:* 512,141. (For questions regarding this collection, contact Joshua Annas at (301-492-4407).

Dated: August 18, 2017.

Martique Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: Grant Reviewer Recruitment.

Title: Grant Reviewer Recruitment Form.

OMB No.: 0970-0455.

Description: The Administration for Children and Families' Children's

Bureau (CB) is responsible for administering the review of eligible grant applications submitted in response to funding opportunity announcements issued by CB. CB ensures that the objective review process is independent, efficient, effective, economical, and complies with the applicable statutes, regulations, and policies. Applications are reviewed by subject experts knowledgeable in child welfare and related fields. Review findings are advisory to CB; CB is responsible for making award decisions.

This announcement is a request for continued approval of the information collection system, the Reviewer Recruitment Module (RRM). CB uses a web-based data collection form and database to gather critical reviewer information in drop down menu format for data such as: Degree, occupation, affiliations with organizations and institutions that serve special populations, and demographic information that may be voluntarily provided by a potential reviewer.

These data elements help CB find and select expert grant reviewers for

objective review committees. The web-based system permits reviewers to access and update their information at will and as needed. The RRM is accessible by the general public via <https://rrm.grantsolutions.gov/AgencyPortal/cb.aspx>.

Respondents: Generally, our reviewers are current or retired professionals with backgrounds in child welfare and related fields and in some instances current or former foster care parents or clients.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|-----------------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Reviewer Recruitment Module | 500 | 1 | .25 | 125 |

Estimated Total Annual Burden Hours: 125.

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 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. 2017–17935 Filed 8–23–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–1956]

Identifying Trading Partners Under the Drug Supply Chain Security Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Identifying Trading Partners Under the Drug Supply Chain Security Act” (draft trading partner guidance). FDA is issuing this guidance to assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA). This guidance explains how to determine when certain statutory requirements will apply to entities that may be considered trading partners in the drug supply chain. FDA is also soliciting public input specific to the activities of “private-label distributors” of drug products and whether those activities fall within the definitions under DSCSA of the various trading partners.

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 October 23, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and