they cannot benefit from the federal confidentiality and privilege protections of the Patient Safety Act.

Since February 2005, AHRQ has convened the Federal Patient Safety Work Group (PSWG) to assist with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS as well as the Departments of Defense and Veterans Affairs. The PSWG helps assure the consistency of definitions/forms with those of relevant government agencies. In addition, AHRQ has solicited comments from the private and public sectors regarding proposed versions of the Common Formats through a contract, since 2008, with the National Quality Forum (NQF), which is a non-profit organization focused on health care quality. After receiving comments, the NQF solicits review of the formats by its Common Formats Expert Panel. Subsequently, NQF provides this input to AHRQ who then uses it to refine the formats.

Previously, AHRQ’s primary focus with the Common Formats has been to support traditional event reporting. For the Common Formats, it should be noted that AHRQ uses the term “surveillance” to refer to the improved detection of events and calculation of adverse event rates in populations reviewed that will allow for collection of comparable performance data over time and across settings. These formats are designed to provide, through retrospective review of medical records, information that is complementary to that derived from event reporting systems. For more information on AHRQ’s efforts measuring patient safety in this area, please go to: https://www.ahrq.gov/news/blog/ahrqvews/new-system-aims-to-improve-patient-safety-monitoring.html.

AHRQ announced the availability of the Common Formats for Surveillance—Hospital Version 0.2 Beta, for review and comment on May 9, 2018 in the Federal Register (83 FR 21295–21296). After obtaining feedback, the Agency revised and finalized the formats through the development of event descriptions which are definitions of patient safety events, near misses, and unsafe conditions. The Common Formats for Surveillance—Hospital Version 0.2 Beta will be posted at the PSOPPC website: https://www.psoppc.org/psoppc_web.

Additional information about the Common Formats can be obtained through AHRQ’s PSO website: https://pso.ahrq.gov/.

Francis D. Chesley, Jr.,
Acting Deputy Director.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10137 and CMS–10675]

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 December 31, 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 OB, Email: OIRA_submission@omb.eop.gov.
The QIO program provides technical assistance to reduce ADEs in beneficiaries resulting from polypharmacy, specifically those who use three or more medications including a prescription in a HRM drug groups. In the 11th SOW, specific interventions include training providers through Learning Action Networks; developing collaborations among local providers across care settings; providing materials and information resources; and helping providers collect data to monitor prescribing practices.

To evaluate the effectiveness of this program, we will use a mixed method evaluation combining secondary data analysis of Medicare claims with a community provider survey. We plan to conduct an online survey of 1,200 community-based pharmacists and physician practices. These participants were selected based on their role in prescribing HRM and treating ADEs.

The proposed survey assesses the extent to which the National Action Plan for Adverse Drug Prevention strategies have been used, the level of engagement with the QIO, and other influences that can help explain progress towards the goals of the QIN–QIO SOW. The questions used for these constructs related to program and non-program influences have been adopted from previously used and/or validated instruments, including the IEC Nursing Home Survey that was approved under OMB control number 0938–1330.

The survey will also provide estimates of the attribution of the QIN–QIO program for improving ADE prevention, and reported impact of the QIN–QIO program from the perspective of healthcare providers. The perceived influence on quality improvement efforts will be quantified and, along with econometric modeling methods, will be used to assess program attribution. Estimating attribution is a contract requirement for the IEC and helps provide evidence of impact of the QIN–QIO program. Since current analytical methods do not adequately address the overlap of quality improvement initiatives targeting medication safety and ADE prevention, the IEC developed an innovative approach, combining survey input with modeling, to estimate the relative importance of the QIN–QIO program. The concept is supported at the highest level of administration for Quality Improvement at CMS and has been presented at national conferences and to CMS/CCSQ leadership. The survey data.
is an essential component of this analytic method.

The information collected through the survey will complement the existing data by helping identify factors associated with ADE outcomes of interest from existing data sets such as Medicare claims. For example, claims data can provide information on whether the number of prescriptions for opioids has decreased, but not what has helped to facilitate the decrease.

Subsequent to the 60-day Federal Register notice which published on July 20, 2018 (83 FR 34593), the collection instrument was revised to clarify wording on questions, adjust the methods for measuring attribution, and nursing homes were removed from the originally-proposed sample. These changes did not result in changes to burden, as additional respondents will be recruited from the pharmacy and practice settings. Form Number: CMS–10675 (OMB control number: 0938–NEW); Frequency: Annually; Affected Public: Private sector (Business or other for-profits); Number of Respondents: 1,200; Total Annual Responses: 1,200; Total Annual Hours: 300. (For policy questions regarding this collection contact Nancy Sonnenfeld at 410–786–3446. Email: daniel.jackson@acf.hhs.gov.

SUMMARY: The allotment percentages for each State under the Title IV–B Subpart 1, Stephanie Tubbs Jones Child Welfare Services Program. Under section 423(a), the allotment percentages are one of the factors used in the computation of the Federal grants awarded under the Program.

DATES: The allotment percentages will be effective for Federal Fiscal Years 2020 and 2021.


SUPPLEMENTARY INFORMATION: The allotment percentage for each State under the Title IV–B Subpart 1, Stephanie Tubbs Jones Child Welfare Services Program. Under Section 423(c) of the Social Security Act (42 U.S.C. 623(c)).

Elizabeth Leo,
Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2018–25932 Filed 11–28–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Regulations; Final

Notice of Allotment Percentages to States for Child Welfare Services State Grants; CFDA Number: 93.645

AGENCY: Children’s Bureau, Administration on Children, Youth and Families, Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of biennial publication of allotment percentages for States under the Title IV–B Subpart 1, Stephanie Tubbs Jones Child Welfare Services Program. Under Section 423(c) of the Social Security Act (42 U.S.C. 623(c)), the allotment percentages are one of the factors used in the computation of the Federal grants awarded under the Program.

DATES: The allotment percentages will be effective for Federal Fiscal Years 2020 and 2021.


SUPPLEMENTARY INFORMATION: The allotment percentage for each State under the Title IV–B Subpart 1, Stephanie Tubbs Jones Child Welfare Services Program. Under Section 423(c) of the Social Security Act (42 U.S.C. 623(c)).

Elizabeth Leo,
Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2018–25932 Filed 11–28–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards; Announcement of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the following public meeting entitled “Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.” FDA is also requesting public comments on the subject. The purpose of the meeting and the request for comments is to fulfill FDA’s commitment to seek stakeholder input related to data standards and the electronic submission system’s past performance, future targets, emerging industry needs, and technology initiatives. FDA will use the information from the public meeting as well as from comments submitted to the docket to provide input into data standards initiatives, the FDA Information Technology (IT) Strategic Plan, and electronic submissions gateway target timeframes.

DATES: The public meeting will be held on April 10, 2019, from 9 a.m. to 4 p.m. Submit either electronic or written comments by April 10, 2019. See the SUPPLEMENTARY INFORMATION section for registration date and information.