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/formats 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/ahrqviews/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.

[FR Doc. 2018–25971 Filed 11–28–18; 8:45 am]

BILLING CODE 4160–90–P

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 *OR*, Email: *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 *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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.

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 currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2020 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application. The information will

be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, Program of All Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) Ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number:* CMS–10137 (OMB control number: 0938–0936); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 243; *Total Annual Responses:* 256; *Total Annual Hours:* 2,351.08. (For policy questions regarding this collection contact Arianne Spaccarelli, at 410–786–5715.)

2. *Type of Information Collection Request:* New c (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the CMS Quality Improvement Organizations: Medication Safety and Adverse Drug Event Prevention; *Use:* The purpose of this Information Collection Request (ICR) is to collect data to inform the program evaluation of the Centers for Medicare & Medicaid Services (CMS) Quality Improvement Organizations (QIO) current contract known as the 11th Scope of Work (SOW). The current ICR focuses on evaluating one component of the quality improvement activities of the Quality Innovation Network Quality Improvement Organizations (QIN–QIOs) and is part of a larger evaluation of the overall impact of the QIO program. This ICR aims to assess the QIN–QIO Task which focuses on Medication Safety and Adverse Drug Event Prevention. For this evaluation, we are using a mixed-methods design to compare quality improvement activities of community-based pharmacists and physician practices participating in the QIN–QIO program (participating) with those not participating in the QIN–QIO program (non-participating).

As mandated by Sections 1152–1154 of the Social Security Act, CMS directs the QIO program, which is one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries. QIOs are groups of health quality experts, clinicians, and consumers who work to assist Medicare providers with quality improvement throughout the spectrum of care and to review quality concerns for the protection of beneficiaries and the Medicare Trust Fund. This program is a key component of the U.S. Department of Health and Human Services' (HHS) National Quality Strategy and the CMS Quality Strategy. The work is aligned with the current HHS and CMS administration priorities to empower patients and doctors to make decisions about their health care; usher in a new era of state flexibility and local leadership; support innovative approaches to improve quality, accessibility, and affordability; and improve the CMS customer experience. In the current SOW, 14 QIN–QIOs coordinate the work in 53 U.S. states and territories.

CMS evaluates the quality and effectiveness of the QIO program as authorized in Part B of Title XI of the Social Security Act. CMS created the Independent Evaluation Center (IEC) to provide CMS and its stakeholders with an independent and objective program evaluation of the 11th SOW.

For the program to improve medication safety and prevent adverse drug events (ADEs), QIN–QIOs provide technical assistance to providers, practitioners, organizations offering Medicare Advantage plans under Medicare Part C, and prescription drug sponsors offering drug plans under Part D. ADEs are defined as ''injury resulting from medical intervention related to a drug,'' and cause the majority of preventable deaths in hospitals. ADEs escalate healthcare costs and utilization, increasing admission and readmission rates, emergency department (ED) visits, and physician visits. ADEs are particularly problematic for older adults who have multiple chronic conditions and interact with many care settings.

Opioid misuse and overdose is a significant cause of ADEs and was declared a public health emergency by the White House in 2017. In 2016, over 14 million Medicare Part D beneficiaries received opioid prescriptions, and many of these beneficiaries received extreme amounts of the drugs. The Medicare population has one of the highest and fastest-growing rates of diagnosed opioid use disorder.

As part of the HHS Opioid Initiative launched in March 2015, CMS developed a multipronged approach to combat misuse and promote programs that support treatment and recovery support services for clinicians, beneficiaries, and families. CMS also worked with HHS and other health agencies to develop a *National Action Plan for Adverse Drug Prevention* (2014). In addition to opioids, the Action Plan focused on ADEs caused by other high-risk medication (HRM) groups: Anticoagulants and diabetic medications. Given the burden of ADEs caused by these three classes of drugs, focusing prevention efforts in these areas could have a significant impact on reducing harm and improving population health among Medicare beneficiaries.

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 410–786–1294.)

Dated: November 26, 2018.

William N. Parham, III,

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

[FR Doc. 2018–25978 Filed 11–28–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

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.

SUMMARY: As required by section 423(c) of the Social Security Act, the Department is publishing the allotment percentage 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.

FOR FURTHER INFORMATION CONTACT: Daniel Jackson, Grants Fiscal Management Specialist, Office of Grants Management, Office of Administration, Administration for Children and Families, 330 C St. SW, Washington, DC 20201. Telephone: (202) 401–3446. Email: *daniel.jackson@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The allotment percentage for each State is determined on the basis of paragraphs (b) and (c) of section 423 of the Social Security Act. These figures are available on the ACF internet homepage at *https://www.acf.hhs.gov/cb.* The allotment percentage for each State is as follows:

ALLOTMENT

State	Percentage
Alabama	60.54
Alaska	43.36
Arizona	59.19
Arkansas	60.16
California	42.50
Colorado	47.06
Connecticut	30.25
Delaware	51.62
District of Columbia	30.00
Florida	53.73
Georgia	57.38
Hawaii	49.16
Idaho	59.41
Illinois	47.37
Indiana	56.44
Iowa	53.57
Kansas	52.37
Kentucky	60.43
Louisiana	57.09
Maine	55.15
Maryland	41.34
Massachusetts	34.73
Michigan	55.31
Minnesota	47.14
Mississippi	64.24
Missouri	56.32
Montana	55.77
Nebraska	49.84
Nevada	55.23
New Hampshire	42.83
New Jersey	37.84
New Mexico	61.06
New York	38.63
North Carolina	57.20
North Dakota	47.32
Ohio	54.67
Oklahoma	56.55
Oregon	53.59
Pennsylvania	48.50
Rhode Island	48.88
South Carolina	59.65
South Dakota	51.47
Tennessee	56.03
Texas	53.39

ALLOTMENT—Continued

State	Percentage
Utah	57.96
Vermont	49.37
Virginia	46.44
Washington	44.42
West Virginia	62.68
Wisconsin	52.48
Wyoming	43.49
America Samoa	70.00
Guam	70.00
Puerto Rico	70.00
N. Mariana Islands	70.00
Virgin Islands	70.00

Statutory Authority: 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

Food and Drug Administration

[Docket No. FDA–2018–N–4337]

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.