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, physicians, and nursing home administrators or directors of nursing in nursing homes. 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. *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: July 16, 2018.

William N. Parham, III,

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

[FR Doc. 2018–15466 Filed 7–19–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: ORR–6, ORR Requirements for Refugee Cash Assistance; and Refugee Medical Assistance (45 CFR part 400).

OMB No.: 0970–0036.

Description: As required by section 412(e) of the Immigration and Nationality Act, the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is requesting the information from Form ORR–6 to determine the effectiveness of the State cash and medical assistance, and social services programs. State-by-State Refugee Cash Assistance (RCA) and Refugee Medical Assistance (RMA) utilization rates derived from Form ORR–6 are calculated for use in formulating program initiatives, priorities, standards, budget requests, and assistance policies. ORR regulations

require that State Refugee Resettlement and Wilson-Fish agencies, and local and Tribal governments complete Form ORR–6 in order to participate in the above-mentioned programs.

Respondents: State governments, Replacement Designees, and Wilson/Fish Alternative Projects.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–6 Performance Report	57	2	8	912

Estimated Total Annual Burden Hours: 912.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention 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. 2018–15537 Filed 7–19–18; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0052]

Documenting Electronic Data Files and Statistical Analysis Programs; Draft Guidance for Industry; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period for the notice of availability that published in the **Federal Register** on May 21, 2018. In that document, FDA requested comments on the draft revised guidance for industry (GFI) #197 entitled ''Documenting Electronic Data Files and Statistical Analysis Programs.'' The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published May 21, 2018 (83 FR 23468). Submit either electronic or written comments on the draft revised guidance by October 18, 2018, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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 Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2009–D–0052 for ''Documenting Electronic Data Files and Statistical Analysis Programs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed