Respondents will include individuals who call poison centers about exposures related to the select public health emergencies. These respondents include adults, 18 years and older; adolescents, 15 to less than 18 years; and parents or guardians on behalf of their children less than 15 years of age.

The total estimate of 300 annual respondents is based on poison center experience which assumes two incidents per year with approximately 150 respondents per event. The average burden per respondent is approximately 40 minutes for the call-back questionnaire. We anticipate a total annualized burden of 200 hours.

There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adult Poison Center Callers	Sample Questionnaire—Adults	210	1	40/60
Adolescent Poison Center Callers	Sample Questionnaire—Adolescent	30	1	40/60
Parent or Guardian Poison Center Callers	Sample Questionnaire—Parent or Guardian	60	1	40/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–588, CMS–10146, CMS–10185, CMS–10261, and CMS–10631]

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 any of the following subjects: 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 *October 12, 2016.*

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' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

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: Reports Clearance Office at (410) 786–1326.

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:* Electronic Funds Transfer Authorization Agreement; *Use:* The information is needed to allow providers to receive funds electronically in their bank accounts. *Form Number:* CMS–588 (OMB control number: 0938–0626); *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 45,807; *Total Annual Responses:* 45,807; *Total Annual Hours:* 22,906. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–4645.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements and Supporting Regulations; *Use:* Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. For all reporting sections, data are reported electronically to CMS. Each reporting section is reported at one of the following levels: Contract (data should be entered at the H#, S#, R#, or E# level) or Plan (data

should be entered at the Plan Benefit Package (PBP level, *e.g.* Plan 001 for contract H#, R#, S#, or E). Sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit and C&D Data Group. If outliers or other data anomalies are detected, DCOP will work in collaboration with other Divisions within CMS for follow-up and resolution. For CY2017 Reporting Requirements, the following 7 reporting sections will be reported and collected at the Contract-level or Plan-level: Enrollment and Disenrollment, Retail, Home Infusion, and Long-Term Care Pharmacy Access, Medication Therapy Management (MTM) Programs, Grievances, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, and Employer/Union Sponsored Sponsors. *Form Number:* CMS–10185 (OMB control number: 0938–0992); *Frequency:* Annually and semi-annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 561; *Total Annual Responses:* 11,438; *Total Annual Hours:* 14,750. (For policy questions regarding this collection contact Chanelle Jones at 410–786–8008.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a); *Use:* Medicare Advantage Organizations (MAOs) must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to: The cost of its operations; the patterns of service utilization; the availability, accessibility, and acceptability of its services; to the extent practical, developments in the health status of its enrollees; information demonstrating that the MAO has a fiscally sound operation; and other matters that CMS may require. CMS also has oversight authority over cost plans which includes establishment of reporting requirements. This revision would add five new data elements to the reporting section: Organization Determinations and Reconsiderations. These new data elements are needed to obtain more information about case reopenings. The revision would also suspend the Sponsor Oversight of Agents reporting section beginning 2017 so that the reporting section can be reassessed based on burden and usage. *Form Number:* CMS–10261 (OMB control number: 0938–1054); *Frequency:* Yearly and Semi-annually; *Affected Public:* Private sector (Business or other For-profits); *Number of Respondents:* 544; *Total Annual Responses:* 3,508; *Total Annual Hours:* 160,215. (For policy questions regarding this collection contact Terry Lied at 410–786–8973.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage; *Use:* The notice provides information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process. *Form Number:* CMS–10146 (OMB control number: 0938–0976); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 580; *Total Annual Responses:* 1,902,055; *Total Annual Hours:* 475,514. (For policy questions regarding this collection contact Amber Casserly at 410–786–0976.)

5. *Type of Information Collection Request:* New collection (request for a new OMB control number); *Title of Information Collection:* The PACE Organization Application Process in 42 CFR part 460; *Use:* In general, Programs of All-Inclusive Care for the Elderly (PACE) services are provided through a PACE Organization (PO). An entity wishing to become a PO must submit an application to CMS that describes how the entity meets all the requirements in the PACE program. An entity's application must be accompanied by an assurance from the State Administering Agency (SAA) of the State in which the PO is going to be located.

Initial application requirements for the PACE program are currently set forth in 42 CFR 460.12 and in the PACE Manual, Ch. 17. Until recently, the submission of initial and service area expansion (SAE) PACE applications and supporting information was in paper format. These applications are often hundreds of pages long, expensive to reproduce and transmit, and administratively inefficient, as staff reviewing different parts of the application are located in different physical locations and must receive hard copies of the material. However, beginning in 2016, initial PACE applications are being submitted via a new automated, electronic submission process. As with initial applications, an application also must be submitted for a PO that seeks to expand its service area and/or add a new service site, and with OMB approval, an automated application process will now also be required of PACE organizations submitting service area expansion applications.

While this collection is being submitted to OMB as a ''New'' package, the collection is not new. The collection is currently approved by OMB under control number 0938–0790 (CMS–R–244). Based on internal review we intend to remove the application from that package but, before doing so, we need approval of the application under a new OMB control number. This will avoid lapses in OMB's approval along with any violations of the PRA.

As is, the currently approved CMS–R–244 package is lengthy and somewhat time consuming to review. We believe the change will help streamline the public and OMB's review of the application as well as the remaining requirements and burden under CMS–R–244. The 60-day notice published in the **Federal Register** on December 8, 2015 (80 FR 76193). The 30-day notice published on May 2, 2016 (81 FR 26234). Both published under CMS–R–244. We are republishing the 30-day notice under the new CMS ID number (CMS–10631) and the tentative OMB control number (0938–New). Otherwise, all changes are nonsubstantive.

Form Number: CMS–10631 (OMB control number: 0938–New); *Frequency:* Once and occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions) and State, Local, or Tribal Governments; *Number of Respondents:* 730; *Total Annual Responses:* 84; *Total Annual Hours:* 4,576. (For policy questions regarding this collection contact Debbie Vanhoven at 410–786–6625.)

Dated: September 7, 2016.

William N. Parham, III,

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

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