program, known as the Voluntary Prescription Drug Benefit Program. As required by 42 CFR 423.32(a) and (b), a Part D-eligible individual who wishes to enroll in a Medicare prescription drug plan (PDP) may enroll during the enrollment periods specified in § 423.38, by completing an enrollment form with the PDP, or enrolling through other mechanisms CMS determines are appropriate. *Form Number:* CMS–10718 (OMB control number: 0938–New); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 14,749,256; *Total Annual Responses:* 14,749,256; *Total Annual Hours:* 10,324,481. (For policy questions regarding this collection contact Deme Umo at (410) 786–8854.)

5. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage; *Use:* The purpose of this notice is to provide 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.

CMS requests approval of changes to a currently approved collection under section 1860D–4(g)(1) of the Social Security Act which requires Part D plan sponsors that deny prescription drug coverage to provide a written notice of the denial to the enrollee. The written notice must include a statement, in understandable language, of the reasons for the denial and a description of the appeals process.

Medicare beneficiaries who are enrolled in a Part D plan will be informed of adverse decisions related to their prescription drug coverage and their right to appeal these decisions. The notice provides all ways that the beneficiary can file an appeal under one section. The Part D instructions have also been revised to include a paragraph informing providers that in the case that a request for a coverage determination is denied under Part B due to step therapy requirements, a different notice should be given.

This denial notice is primarily issued to Part D plan enrollees (Medicare beneficiaries) and is most commonly sent to enrollees by mail. Relying on electronic transmission of this notice to beneficiaries is impractical. Plans are required by regulation to maintain a website by which beneficiaries can request an appeal. In this version of the notice, website information is more prominently displayed. *Form Number:* CMS–10146 (OMB control number: 0938–0976); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 525; *Total Annual Responses:* 2,887,866; *Total Annual Hours:* 721,967. (For policy questions regarding this collection contact Sara Klotz at (410) 786–1984.)

Dated: November 13, 2019.

William N. Parham, III,

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

[FR Doc. 2019–24930 Filed 11–15–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3392–CN]

Medicare Program; Request for Nominations for Members for the Medicare Evidence Development & Coverage Advisory Committee; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction notice.

SUMMARY: This document corrects a typographical error that appeared in the notice published in the **Federal Register** on October 21, 2019 entitled ''Request for Nominations for Members for the Medicare Evidence Development & Coverage Advisory Committee.''

DATES: This correcting document is effective on November 15, 2019.

FOR FURTHER INFORMATION CONTACT: Leah Cromwell, (410) 786–2243.

SUPPLEMENTARY INFORMATION:

I. Background and Summary of Errors

In FR Doc. 2019–22947 of October 21, 2019 (84 FR 56193), there was a typographical error that is identified in the **FOR FURTHER INFORMATION CONTACT** section.

On page 56193, we inadvertently made a typographical error in the email address of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) coordinator.

II. Correction of Errors

In FR Doc. 2019–22947 of October 21, 2019 (84 FR 56193), make the following corrections:

1. On page 56193, second column, third full paragraph, last line, the email address ''*Leah.Cromwell@cms.hhs.gov*'' is corrected to read ''*Leah.Cromwell1@cms.hhs.gov*''.

Dated: November 4, 2019.

Kate Goodrich.

Director, Center for Clinical Standards and Quality, Chief Medical Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–24934 Filed 11–15–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10611, CMS–R–282 and CMS–R–235]

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 18, 2019.

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 website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. 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:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Outpatient Observation Notice (MOON); *Use:* On August 6, 2015, Congress enacted the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) Public Law 114–42, amending Section 1866(a)(1) of the Social Security Act (the Act) (42 U.S.C. 1395cc(a)(1)), by adding a new subparagraph (Y). The NOTICE Act requires hospitals and CAHs to provide written notification and oral explanation to individuals who receive observation services as outpatients for more than 24 hours.

The MOON is a standardized notice delivered to persons entitled to Medicare benefits under Title XVIII of the Act who receive more than 24 hours of observation services, informing them that their hospital stay is outpatient and not inpatient, and the implications of being an outpatient. This information collection applies to beneficiaries in Original Medicare and enrollees in Medicare health plans.

The Medicare Outpatient Observation Notice (MOON) serves as the written notice component of this mandatory notification process. The standardized content of the MOON includes all informational elements required by statute, in language understandable to beneficiaries, and fulfils the regulatory requirements at 42 CFR part 489.20(y).

The MOON is not given every time items and services are furnished in a hospital or CAH. Rather, hospitals are only required to deliver the MOON to individuals receiving observation services as outpatients for more than 24 hours. *Form Number:* CMS–10611 (OMB control number: 0938–1308); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 4,373; *Total Annual Responses:* 946,209; *Total Annual Hours:* 236,552. (For policy questions regarding this collection contact Janet Miller at *Janet.Miller@cms.hhs.gov.*)

2. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Health Plan Appeals and Grievance Data Collection and Reporting Requirements, Data Disclosure Requirements under section 422.111; *Use:* Part 422 of Title 42 of the Code of Federal Regulations (CFR) distinguishes between certain information a Medicare Advantage (MA) organization must provide to each enrollee (on an annual basis) and information that the MA organization must disclose to any MA eligible individual (upon request). This requirement can be found in § 1852(c)(2)(C) of the Social Security Act and in 42 CFR 422.111(c)(3) which states that MA organizations must disclose information pertaining to the number of disputes, and their disposition in the aggregate, with the categories of grievances and appeals, to any individual eligible to elect an MA organization who requests this information.

The appeals and grievance data form is an OMB approved form for use by Medicare Advantage organizations to disclose grievance and appeal data, upon request, to individuals eligible to elect an MA organization. By utilizing the form, MA organizations will meet the disclosure requirements set forth in regulations at 42 CFR 422.111(c)(3).

In an effort to identify opportunities to reduce burden for this collection, we compared data provided by plans to CMS in Part C reporting requirements (OMB 0938–1054) with the requirements to provide aggregate grievance and appeals data to MA eligible beneficiaries. We found that data reported to CMS in the Part C reporting requirements was data that would meet the disclosure requirements at § 1852(c)(2)(C) of the Social Security Act and 42 CFR 422.111(c).

We are proposing to revise this form by allowing plans to use data collected for Part C reporting requirements (OMB 0938–1054) that also meet requirements for this collection. This change merges and aligns the collection and reporting periods, so MA plans do not need to keep two separate sets of data and reports each year.

For CMS Part C reporting requirements, data is collected quarterly, but only reported annually. To match this and reduce plan burden, CMS is revising this form to use the data reported annually to CMS, and that data be valid for one year versus creating a new report every six months. Further, data provided to enrollees would be consistent with data provided to CMS. *Form Number:* CMS–R–282 (OMB control number: 0938–0778); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 733; *Total Annual Responses:* 59,133; *Total Annual Hours:* 5,405. (For policy questions regarding this collection contact Staci Paige at 410–786–2045.)

3. *Type of Information Collection Request:* Reinstatement with change of a currently approved collection; *Title of Information Collection:* Data Use Agreement (DUA) Form; *Use:* The Privacy Act of 1974 allows for discretionary releases of data maintained in Privacy Act protected systems of records under § 552a(b) (Conditions of Disclosure). The mandate to account for disclosures of data under the Privacy Act is found at § 552a(c)(Accounting of Certain Disclosures). This section states that certain information must be maintained regarding disclosures made by each agency. This information is: Date, Nature, Purpose, and Name/Address of Recipient. Section 552a(e) sets the overall Agency Requirements that each agency must meet in order to maintain records under the Privacy Act.

The Data Use Agreement (DUA) form is needed as part of the review of each CMS data request to ensure compliance with the requirements of the Privacy Act

for disclosures that contain PII. The DUA form also provides data requestors and custodians with a formal means to agree to the data protection and destruction statutory and regulatory requirements of CMS' PII data.

When entities, such as academic, federal or state agency researchers or CMS contractors request CMS PII/PHI data, they enter into a Data Use Agreement (DUA) with CMS. The DUA stipulates that the recipient of CMS data must properly protect the data according to all applicable data security standards and also provide for its appropriate destruction at the completion of the project/study or the expiration date of the DUA. The DUA form enables the data recipient and CMS to document the request and approval for release of CMS data. *Form Number:* CMS–R–235 (OMB control number: 0938–0734); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 9,200; *Total Annual Responses:* 9,200; *Total Annual Hours:* 2,900. (For policy questions regarding this collection contact Kari A Gaare at 410–786–8612.)

Dated: November 13, 2019.

William N. Parham, III,

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

[FR Doc. 2019–24929 Filed 11–15–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1835]

Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention; 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 final guidance for industry entitled ''Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for treating or preventing smallpox (variola virus) infection. This guidance finalizes the draft guidance of the same name issued on July 11, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on November 18, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2018–D–1835 for ''Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention.'' 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 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 except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled