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 May 7, 2020.

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:

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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 with change of a currently approved collection; *Title of Information Collection:* Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3); *Use:* Pursuant to disclosure requirements set out in sections 1851(d)(2)(A) and 1860D–1(c) of the Social Security Act (the Act), and cited in §§ 422.111(a)(3) and 423.128(a)(3), Medicare Advantage (MA) organizations and Part D sponsors must provide notice to plan members of impending changes to plan benefits, premiums and cost sharing in the coming year. To this effect, members will be in the best position to make an informed choice on continued enrollment or disenrollment from that plan at least 15 days before the Annual Election Period (AEP) using the Annual Notice of Change (ANOC) and before the first day of the AEP for the Evidence of Coverage (EOC). MA organizations and Part D sponsors must notify plan members of the coming year changes using the standardized ANOC. Plans must disseminate the EOC at the time of enrollment and at least annually thereafter.

CMS requires MA organizations and Part D sponsors to use the standardized documents being submitted for OMB approval to satisfy disclosure requirements mandated by section 1851 (d)(3)(A) of the Act and § 422.111 for MA organizations and section 1860D–1(c) of the Act and § 423.128(a)(3) for Part D sponsors.

Sections 1851(h)(1) and (2) of the Act require MA organizations and Part D sponsors to obtain CMS approval of marketing materials to ensure that MA organizations and Part D sponsors disclose correct information to current and potential enrollees. CMS collects and retains the MA organization and Part D plan marketing materials via the Health Plan Management System (HPMS). MA organizations and Part D plans submit marketing materials to the CMS marketing material review process using HPMS. Both current and potential enrollees can review other marketing materials to find plan benefits, premiums, and cost sharing for the coming year (after October 1) and the current year to be in a better position to make.

MA organizations and Part D sponsors use the information discussed in the Medicare Communication and Marketing Guidelines (MCMG) to comply with the requirements to seek CMS approval on marketing materials under MA and Part D law and regulations, as described above. CMS requires MA organizations and Part D sponsors to obtain CMS approval of marketing materials to ensure that MA organizations and Part D sponsors disclose correct information to current and potential enrollees. Both current and potential enrollees can review other marketing materials to find plan benefits, premiums, and cost sharing for the coming year (after October 1) and the current year to be in a better position to make informed and educated plan selections. *Form Number:* CMS–10260 (OMB control number: 0938–1051); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 795; *Total Annual Responses:* 47,962; *Total Annual Hours:* 33,124. (For policy questions regarding this collection contact Timothy Roe at 410–786–2006.)

Dated: April 1, 2020

William N. Parham, III,

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

[FR Doc. 2020–07181 Filed 4–6–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10636 and CMS–10592]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by June 8, 2020.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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.*

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 N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10636 Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans

CMS–10592 Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans; *Use:* CMS regulations at 42 CFR 417.414, 417.416, 422.112(a)(1)(i), and 422.114(a)(3)(ii) require that all Medicare Advantage organizations (MAOs) offering coordinated care plans, network-based private fee-for-service (PFFS) plans, and as well as section 1876 cost organizations, maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. To enforce this requirement, CMS developed network adequacy criteria which set forth the minimum number of providers and maximum travel time and distance from enrollees to providers, for required provider specialty types in each county in the United States and its territories. Organizations must be in compliance with the current CMS network adequacy criteria guidance, which is updated and published annually on CMS's website. Additional network policy guidance is also located in chapter 4 of the Medicare Managed Care Manual. This collection of information is essential to appropriate and timely compliance monitoring by CMS, in order to ensure that all active contracts offering network-based plans maintain an adequate network.

CMS verifies that organizations are compliant with the CMS network adequacy criteria by performing a contract-level network review, which occurs when CMS requests an organization upload provider and facility Health Service Delivery (HSD) tables for a given contract to the Health Plan Management System (HPMS). CMS reviews networks on a three-year cycle, unless there is an event that triggers an intermediate full network review, thus resetting the organization's triennial review. The triennial review cycle will help ensure a consistent process for network oversight and monitoring.

Once CMS staff reviews the ACC reports and any Exception Requests and/or Partial County Justifications, CMS then makes its final determination on whether the organization is operating in compliance with current CMS network adequacy criteria. If the organization passes its network review for a given contract, then CMS will take no further action. If the organization fails its network review for a given contract, then CMS will take appropriate compliance actions. CMS has developed a compliance methodology for network adequacy reviews that will ensure a consistent approach across all organizations. *Form Number:* CMS–10636 (OMB control number: 0938–1346); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 140; *Total Annual Responses:* 1,416; *Total Annual Hours:* 12,772. (For policy questions regarding this collection contact Amber Casserly at 410–786–5530.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; *Use:* Section 1321(a) requires HHS to issue regulations setting standards for meeting the requirements under Title I of the Affordable Care Act including the offering of Qualified Health Plans (QHPs) through the Exchanges. On March 27, 2012, HHS published the rule CMS–9989–F: Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers. The Exchange rule contains provisions that

mandate reporting and data collections necessary to ensure that health insurance issuers are meeting the requirements of the Affordable Care Act. These information collection requirements are set forth in 45 CFR part 156.

Information collected by the Exchanges or Medicaid and CHIP agencies will be used to determine eligibility for coverage through the Exchange and insurance affordability programs (*i.e.,* Medicaid, CHIP, and advance payment of the premium tax credits); evaluate how CMS can best communicate eligibility and enrollment updates to issuers; and assist consumers in enrolling in a QHP if eligible. Applicants include anyone who may be eligible for coverage through any of these programs. *Form Number:* CMS–10592 (OMB control number: 0938–1341); *Frequency:* Annually, Monthly, Occasionally; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 250; *Total Annual Responses:* 250; *Total Annual Hours:* 131,750. (For policy questions regarding this collection contact Anne Pesto at 443–844–9966.)

Dated: April 1, 2020.

William N. Parham, III,

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

[FR Doc. 2020–07185 Filed 4–6–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0016]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Records Access Requirements for Food Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our recordkeeping and records access requirements for food facilities.

DATES: Submit either electronic or written comments on the collection of information by June 8, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 8, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 8, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2011–N–0016 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Records Access Requirements for Food Facilities.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 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.govinfo.gov/content/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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three