certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of Essential Community Providers (ECPs), and non-discrimination. The Exchange is responsible for ensuring that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR parts 155 and 156, based on the Affordable Care Act, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address Federal requirements that various entities must meet with respect to the establishment and operation of an Exchange; minimum requirements that health insurance issuers must meet with respect to participation in a State based or Federally-facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of the Affordable Care Act. Comments have been received, however; there were no comments that impacted the burden, and therefore no additional changes were made. *Form Number:* CMS–10593 (OMB Control Number: 0938–NEW); *Frequency:* Annually, Monthly; *Affected Public:* Private Sector; Business or other for-profit; *Number of Respondents:* 20; *Total Annual Responses:* 400; *Total Annual Hours:* 36,900. (For policy questions regarding this collection contact Christy Woods at 301–492–5140.)

Dated: March 1, 2016.

William N. Parham, III,

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

[FR Doc. 2016–04841 Filed 3–3–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10152]

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 require; 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 any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by May 3, 2016.

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' 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:

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–10152 Data Collection for Medicare Beneficiaries Receiving NaF–18 Positron Emission Tomography (PET) To Identify Bone Metastasis in Cancer

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.

1. *Type of Information Collection Request:* Extension of a previously approved collection; *Title:* Data Collection for Medicare Beneficiaries Receiving NaF–18 Positron Emission Tomography (PET) to Identify Bone Metastasis in Cancer; *Use:* In Decision Memorandum #CAG–00065R, issued on February 26, 2010, the Centers for Medicare and Medicaid Services (CMS) determined that the evidence is sufficient to conclude that for Medicare beneficiaries receiving NaF–18 PET scan to identify bone metastasis in cancer is reasonable and necessary only when the provider is participating in and patients are enrolled in a clinical study designed to information at the time of the scan to assist in initial antitumor treatment planning or to guide subsequent treatment strategy by the identification, location and quantification of bone metastases in beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and

providers accurately report data on all Medicare enrolled patients; and all patient confidentiality, privacy, and other Federal laws must be followed. Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meets specified standards and address the specified research questions. To qualify for payment, providers must prescribe certain NaF–18 PET scans for beneficiaries with a set of clinical criteria specific to each solid tumor. The statuary authority for this policy is section 1862(a)(1)(E) of the Act. The need to prospectively collect information at the time of the scan is to assist the provider in decision making for patient management. *Form Number:* CMS–10152 (OCN: 0938–0968); *Frequency:* Annual; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 25,000; *Total Annual Responses:* 25,000; *Total Annual Hours:* 2,084 hours. (For policy questions regarding this collection contact Stuart Caplan at 410–786–8564.)

Dated: March 1, 2016.

William N. Parham, III,

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

[FR Doc. 2016–04861 Filed 3–3–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0321]

Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting scientific data, information, and comments that would assist the Agency in its plan to develop a risk assessment for produce grown in fields or other growing areas amended with untreated biological soil amendments of animal origin (including raw manure). The risk assessment will evaluate and, if feasible, quantify the risk of human illness associated with consumption of produce grown in fields or other growing areas amended with untreated biological soil amendments of animal origin that are potentially contaminated with enteric pathogens, such as *Escherichia coli* O157:H7 or *Salmonella.* The risk assessment also will evaluate the impact of certain interventions, such as use of a time interval between application of the soil amendment and crop harvest, on the predicted risk. The risk assessment is intended to inform policy decisions with regard to produce safety.

DATES: Submit either electronic or written comments and scientific data and information by May 3, 2016.

ADDRESSES: You may submit comments and scientific data and information as follows:

Electronic Submissions

Submit electronic comments and scientific data and information in the following way:

- *Federal eRulemaking Portal*: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments and scientific data and information submitted electronically, including attachments, to *http://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 and scientific data and information, that information will be posted on *http://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)*: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments and scientific data and information submitted to the Division of Dockets Management, 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–2016–N–0321 for ''Risk Assessment of Foodborne Illness Associated with Pathogens from Produce Grown in Fields Amended with Untreated Biological Soil Amendments of Animal Origin; Request for Comments, Scientific Data, and Information''. Received comments and scientific data and information will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 and scientific data and information 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 and scientific data and information. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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 scientific data and information 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 and scientific data and information to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments and scientific data and information received, go to *http://*