person requesting the Protected Health Information (PHI) and the person's authority to have access to Medicare eligibility information. Furthermore, CMS requires that trading partners who wish to conduct eligibility transactions on a real-time basis with CMS provide certain assurances as a condition of receiving access to the Medicare eligibility information for the purpose of conducting real-time 270/271 inquiry/response transactions. *Form Number:* CMS–10157 (OMB control number: 0938–0960); *Frequency:* Quarterly; *Affected Public:* Private sector (Business or other For-profits and Not-For-Profits); *Number of Respondents:* 2,000; *Total Annual Responses:* 2,000; *Total Annual Hours:* 250. (For policy questions regarding this collection contact Rupinder Singh at 410–786–7484).

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Issuer Reporting Requirements for Selecting a Cost-Sharing Reductions Reconciliation Methodology; *Use:* Sections 1402 and 1412 of the Affordable Care Act provide for reductions in cost sharing on essential health benefits for low- and moderate-income enrollees in silver level qualified health plans (QHP) on individual market Exchanges. It also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level. These cost-sharing reductions will help eligible individuals and families afford the out-of-pocket spending associated with health care services provided through Exchange-based QHP coverage.

The law directs QHP issuers to notify the Secretary of the Department of Health and Human Services (HHS) of cost-sharing reductions made under the statute for qualified individuals, and directs the Secretary to make periodic and timely payments to the QHP issuer equal to the value of those reductions. Further, the law permits advance payment of the cost-sharing reduction amounts to QHP issuers based upon amounts specified by the Secretary.

Under established HHS regulations, QHP issuers will receive advance payments of the cost-sharing reductions throughout the year. Each issuer will then be subject to one of two reconciliation processes after the year to ensure that HHS reimbursed each issuer the correct advance cost-sharing amount. This information collection request establishes the data collection requirements for a QHP issuer to report to HHS which reconciliation reporting option the issuer will be subject to for a given benefit year. *Form Number:* CMS–10469 (OMB control number: 0938–1214); *Frequency:* Annually; *Affected Public:* Private sector (Businesses or other for-profits); *Number of Respondents:* 575; *Total Annual Responses:* 575; *Total Annual Hours:* 13,200. (For policy questions regarding this collection contact Pat Meisol at 410–786–1917.)

Dated: May 11, 2016.

William N. Parham, III,

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

[FR Doc. 2016–11499 Filed 5–13–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10409]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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 a 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: (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 on the collection(s) of information must be received by the OMB desk officer by June 15, 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:* Extension of a currently approved collection; *Title of Information Collection:* Long Term Care Hospital (LCTH) Continuity Assessment Record and Evaluation (CARE) Data Set; *Use:* Section 3004 of the Affordable Care Act authorized the establishment of quality reporting program for long term care hospitals (LTCHs). Beginning in FY 2014, LTCHs that fail to submit quality measure data may be subject to a 2 percentage point reduction in their annual update to the standard Federal rate for discharges occurring during a rate year. The LTCH CARE Data Set was developed specifically for use in LTCHs for data collection of NQF #0678 Pressure Ulcer measures beginning

October 1, 2012, with the understanding that the data set would expand in future rulemaking years with the adoption of additional quality measures. Relevant data elements contained in other well-known and clinically established data sets, including but not limited to the Minimum Data Set 3.0 (MDS 3.0) and CARE, were incorporated into the LTCH CARE Data Set V1.01, V2.00 and V2.01. LTCH CARE Data Set V3.00 will be implemented April 1, 2016. *Form Number:* CMS–10409 (OMB control number: 0938–1163); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 424; *Total Annual Responses:* 405,344; *Total Annual Hours:* 328,346. (For policy questions regarding this collection contact Staci Payne at 410–786–2838.)

Dated: May 11, 2016.

William N. Parham, III,

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

[FR Doc. 2016–11500 Filed 5–13–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0872]

Considerations for Use of Histopathology and Its Associated Methodologies To Support Biomarker Qualification; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Considerations for Use of Histopathology and Its Associated Methodologies to Support Biomarker Qualification.'' This guidance is intended to assist submitters of a biomarker for qualification that conduct nonclinical biomarker qualification studies in which histopathology is used as a reference or truth standard. This guidance discusses the processes that we recommend be considered when generating histopathology data to be included in biomarker studies and outlines the scientific standards recommended for histopathology used in nonclinical biomarker characterization and qualification. The recommendations in this guidance are intended for confirmatory studies in nonclinical biomarker qualification that justify the proposed context of use, where scientifically rigorous evaluation of biomarker performance in relation to histopathologic changes is essential. The principles outlined in this guidance are also applicable to exploratory nonclinical biomarker studies. This guidance finalizes the draft guidance ''Use of Histology in Biomarker Qualification Studies,'' issued in December 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments 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, 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 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–2011–D–0872 for ''Considerations for Use of Histopathology and Its Associated Methodologies to Support Biomarker Qualification; Guidance for Industry; Availability.'' Received comments 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 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 *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 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: *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 received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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