Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910–0755
56	Institutional Review Boards	0910–0130

Dated: June 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13554 Filed 6–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0514]

Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Procedures for Clinical Laboratory Improvement Amendments Categorization

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 administrative procedures for Clinical Laboratory Improvement Amendments of 1988 (CLIA) categorization of certain in vitro diagnostic tests.

DATES: Submit either electronic or written comments on the collection of information by August 26, 2019.

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 August 26, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 26, 2019. 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–2013–N–0514 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Procedures for Clinical Laboratory Improvement Amendments Categorization.'' 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.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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Administrative Procedures for CLIA Categorization—42 CFR 493.17

OMB Control Number 0910–0607—Extension

FDA's ''*Guidance for Administrative Procedures for CLIA Categorization*'' [1] describes procedures FDA uses to assign the complexity category to a device, which affects what type of CLIA certificate the laboratory obtains. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (*e.g.,* name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA categorization	80	5	400	1	400	$2,000

[1] There are no capital costs associated with this collection of information.

Based on recent receipt data for requests for CLIA categorization separate from a product application, the number of respondents is approximately 80. On average, each respondent requests such categorizations five times per year.

The cost, not including personnel, is estimated at $5 per submission (5 × 400), totaling $2,000. This includes the cost of copying and mailing copies of package inserts and a cover letter. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (*e.g.,* paper). Upon review of this information collection, we have adjusted the estimated cost per submission (previously $52). Because the submissions are typically only a few pages per package insert and copying or printing and postage for a few pages is not expected to be more than $5, we believe this is a more appropriate cost burden estimate.

Our estimated burden for the information collection reflects an overall decrease of 500 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years. Also, upon review of this information collection, we believe the previous estimate may have included requests for categorization associated with a premarket submission, the burden estimate of which is included under the OMB approval for the applicable premarket submission. We have therefore revised the number of respondents/responses to include only those that are separate from a product application, consistent with the scope of this information collection.

[1] Available at *https://www.fda.gov/media/71065/download.*

Dated: June 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13561 Filed 6–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CMS–3365–N]

Secretarial Review and Publication of the National Quality Forum 2018 Activities Report to Congress and the Secretary of the Department of Health and Human Services

AGENCY: Office of the Secretary of Health and Human Services, HHS.

ACTION: Notice.

SUMMARY: This notice acknowledges the Secretary of the Department of Health and Human Services' (the Secretary) receipt and review of the National Quality Forum 2018 Annual Activities Report to Congress and the Secretary submitted by the consensus-based entity under contract with the Secretary in accordance with the Social Security Act. The Secretary has reviewed and is publishing the report in the **Federal Register** together with the Secretary's comments on the report not later than 6 months after receiving the report in accordance with section 1890(b)(5)(B) of the Social Security Act.

FOR FURTHER INFORMATION CONTACT: Sophia Chan, (410) 786–5050.

SUPPLEMENTARY INFORMATION:

I. Background

The United States Department of Health and Human Services (HHS) has long recognized that a high functioning health care system that provides higher quality care requires accurate, valid, and reliable measurements of quality and efficiency. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) added section 1890 of the Social Security Act (the Act), which requires the Secretary to contract with the consensus-based entity (CBE) to perform multiple duties designed to help improve performance measurement. Section 3014 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148) expanded the duties of the CBE to help in the identification of gaps in available measures and to improve the selection of measures used in health care programs.

HHS awarded a competitive contract to the National Quality Forum (NQF) in January 2009 to fulfill the requirements of section 1890 of the Act. A second, multi-year contract was awarded to NQF after an open competition in 2012. A third, multi-year contract was awarded again to NQF after an open competition in 2017. Section 1890(b) of the Act requires the following:

Priority Setting Process: Formulation of a National Strategy and Priorities for Health Care Performance Measurement. The CBE must synthesize evidence and convene key stakeholders to make recommendations on an integrated national strategy and priorities for health care performance measurement in all applicable settings. In doing so, the CBE is to give priority to measures that: (1) Address the health care provided to patients with prevalent, high-cost chronic diseases; (2) have the greatest potential for improving quality, efficiency, and patient-centered health care; and (3) may be implemented rapidly due to existing evidence, standards of care, or other reasons. Additionally, the CBE must take into account measures that: (1) May assist consumers and patients in making informed health care decisions; (2) address health disparities across groups and areas; and (3) address the continuum of care across multiple providers, practitioners and settings.

Endorsement of Measures: The CBE must provide for the endorsement of standardized health care performance measures. This process must consider whether measures are evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, responsive to variations in patient characteristics such as health status, language capabilities, race or ethnicity, and income level, and are consistent across types of health care providers, including hospitals and physicians.

Maintenance of CBE Endorsed Measures: The CBE is required to establish and implement a process to ensure that endorsed measures are updated (or retired if obsolete) as new evidence is developed.

Review and Endorsement of an Episode Grouper Under the Physician Feedback Program: The CBE must provide for the review and, as appropriate, the endorsement of the episode grouper developed by the Secretary on an expedited basis.

Convening Multi-Stakeholder Groups: The CBE must convene multi-stakeholder groups to provide input on: (1) The selection of certain categories of quality and efficiency measures, from among such measures that have been endorsed by the entity; (2) such measures that have not been considered for endorsement by such entity but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures; and (3) national priorities for improvement in population health and in the delivery of health care services for consideration under the national strategy. The CBE provides input on measures for use in certain specific Medicare programs, for use in programs that report performance information to the public, and for use in health care programs that are not included under the Act. The multi-stakeholder groups provide input on quality and efficiency measures for various federal health care quality reporting and quality improvement programs including those that address certain Medicare services provided through hospices, hospital inpatient and outpatient facilities, physician offices, cancer hospitals, end stage renal disease (ESRD) facilities, inpatient rehabilitation facilities, long-term care hospitals, psychiatric hospitals, and home health care programs.

Transmission of Multi-Stakeholder Input: Not later than February 1 of each year, the CBE must transmit to the Secretary the input of multi-stakeholder groups.

Annual Report to Congress and the Secretary: Not later than March 1 of each year, the CBE is required to submit to Congress and the Secretary an annual report. The report must describe:

- The implementation of quality and efficiency measurement initiatives and the coordination of such initiatives with quality and efficiency initiatives implemented by other payers;
- Recommendations on an integrated national strategy and priorities for health care performance measurement;
- Performance of the CBE's duties required under its contract with the Secretary;
- Gaps in endorsed quality and efficiency measures, including measures that are within priority areas identified by the Secretary under the national strategy established under section 399HH of the Public Health Service Act (National Quality Strategy), and where quality and efficiency measures are unavailable or inadequate to identify or address such gaps;
- Areas in which evidence is insufficient to support endorsement of quality and efficiency measures in priority areas identified by the Secretary under the National Quality Strategy, and where targeted research may address such gaps; and
- The convening of multi-stakeholder groups to provide input on: (1) The selection of quality and efficiency measures from among such measures that have been endorsed by the CBE and