

CDC announces the following meeting for the Clinical Laboratory Improvement Advisory Committee (CLIAC). This meeting is open to the public, limited only by the space available. The meeting room accommodates approximately 100 people. The public is also welcome to view the meeting by webcast. Check the CLIAC website on the day of the meeting for the webcast link <http://cdclabtraining.adobeconnect.com/cliac/>.

DATES: The meeting will be held on November 7, 2018, 8:30 a.m. to 5:30 p.m., EST and November 8, 2018, 8:30 a.m. to 1:00 p.m., EST.

ADDRESSES: CDC, 2500 Century Parkway NE, Rooms 1200/1201, Atlanta, Georgia 30345 and <http://cdclabtraining.adobeconnect.com/cliac/>.

FOR FURTHER INFORMATION CONTACT: Nancy Anderson, MMSc, MT(ASCP), Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop F-11, Atlanta, Georgia 30329-4027, telephone (404) 498-2741; NAnderson@cdc.gov.

SUPPLEMENTARY INFORMATION: All people attending the CLIAC meeting in-person are required to register for the meeting online at least five business days in advance for U.S. citizens and at least 15 business days in advance for international registrants. Register at: <https://wwwn.cdc.gov/cliac/>. Register by scrolling down and clicking the "Register for this Meeting" button and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than October 30, 2018 for U.S. registrants and October 20, 2018 for international registrants.

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments on agenda items. Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item. In general, each individual or group requesting to make oral comments will be limited to a total time of five minutes (unless otherwise indicated). To assure adequate time is scheduled for public comments, speakers should notify the contact person below at least five business days prior to the meeting date. For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated).

However, it is requested that comments be submitted at least five business days prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be provided to the contact person at the mailing or email address below, and will be included in the meeting's Summary Report.

The CLIAC meeting materials will be made available to the Committee and the public in electronic format (PDF) on the internet instead of by printed copy. Check the CLIAC website on the day of the meeting for materials: <https://wwwn.cdc.gov/cliac/>.

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendment (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

Matters To Be Considered: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will focus on an update from the CDC's Office of Infectious Diseases Board of Scientific Counselors meeting; updates on laboratory interoperability; updates on antibiotic resistance activities; the Clinical Laboratory Improvement Amendments personnel requirements; the role of the laboratory in the opioid crisis; and the role of the laboratory in improving diagnoses. Agenda items are subject to change as priorities dictate.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10599]

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 October 29, 2018.

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 <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: 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 of a currently approved collection; *Title of Information Collection:* Pre-Claim Review Demonstration for Home Health Services; *Use:* Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) authorizes the Secretary to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act)." Pursuant to this authority, the CMS seeks to develop and implement a Medicare demonstration project, which CMS believes will help assist in developing improved procedures for the

identification, investigation, and prosecution of Medicare fraud occurring among Home Health Agencies (HHA) providing services to Medicare beneficiaries.

This revised demonstration would help assist in developing improved procedures for the identification, investigation, and prosecution of potential Medicare fraud. The demonstration would help make sure that payments for home health services are appropriate through either pre-claim or postpayment review, thereby working towards the prevention and identification of potential fraud, waste, and abuse; the protection of Medicare Trust Funds from improper payments; and the reduction of Medicare appeals. CMS proposes initially implementing the demonstration in Illinois, Ohio, North Carolina, Florida, and Texas with the option to expand to other states in the Palmetto/JM jurisdiction. CMS proposes starting the demonstration in Illinois on December 10, 2018. Under this demonstration, CMS proposes to offer choices for providers to demonstrate their compliance with CMS' home health policies. Providers in the demonstration states may participate in either 100 percent pre-claim review or 100 percent postpayment review. These providers will continue to be subject to a review method until the HHA reaches the target affirmation or claim approval rate. Once a HHA reaches the target pre-claim review affirmation or post-payment review claim approval rate, it may choose to be relieved from claim reviews, except for a spot check of their claims to ensure continued compliance. Providers who do not wish to participate in either 100 percent pre-claim or postpayment reviews have the option to furnish home health services and submit the associated claim for payment without undergoing such reviews; however, they will receive a 25 percent payment reduction on all claims submitted for home health services and may be eligible for review by the Recovery Audit Contractor.

The information required under this collection is required by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Under the pre-claim review option, HHA will send the pre-claim review request along with all required documentation to the Medicare contractor for review prior to submitting the final claim for payment. If a claim is submitted without a pre-claim review decision on file, the Medicare contractor will request the information from the HHA to determine if payment is appropriate. For the postpayment

review option, the Medicare contractor will also request the information from the HHA that submitted the claim for payment, to determine if payment was appropriate. Comments were received in response to the 60-day notice. *Form Number:* CMS-10599 (OMB control number: 0938-1311); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profits); *Number of Respondents:* 941,287; *Total Annual Responses:* 1,330,980; *Total Annual Hours:* 670,375. (For questions regarding this collection contact Jennifer McMullen (410) 786-7635).

Dated: September 21, 2018.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0280]

Agency Information Collection Activities; Proposed Collection; Comment Request; Financial Disclosure by Clinical Investigators

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 information collections regarding financial disclosure by clinical investigators.

DATES: Submit either electronic or written comments on the collection of information by November 26, 2018.

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 November 26, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time