For Further Information Contact: Laurel Garrison, M.P.H., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 5555 Ridge Avenue, Cincinnati, Ohio 45213. Telephone: (513) 533–8324; Email: *LGarrison@cdc.gov.*

The Director, Office of Strategic Business Initiatives, Office of 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.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–07961 Filed 4–15–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1819–N]

Public Meeting on June 25, 2024 Regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2025

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting to receive comments and recommendations (including data on which recommendations are based) on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System codes being considered for Medicare payment under the Clinical Laboratory Fee Schedule for calendar year 2025. This meeting also provides a forum for those who submitted certain reconsideration requests regarding final determinations made last year on new test codes and for the public to provide comment on the requests.

DATES:

Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting Date: The public meeting is scheduled for Tuesday, June 25, 2024 from 9:00 a.m. to 5:00 p.m., Eastern Daylight Time (E.D.T.).

Deadline for Submission of Presentations and Written Comments: All presenters for the CLFS Annual Public Meeting must register and submit their presentations electronically to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov,* by May 30, 2024 at 5:00 p.m., E.D.T. All written comments (non-presenter comments) must also be submitted electronically to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov,* by May 30, 2024, at 5:00 p.m., E.D.T. Any presentations or written comments received after that date and time will not be included in the meeting and will not be reviewed.

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received no later than May 30, 2024 at 5:00 p.m. E.D.T.

Publication of Proposed Determinations: We intend to publish our proposed determinations for new test codes and our proposed determinations for reconsidered codes (as described later in section II, ''Format'' of this notice) for calendar year 2025 by early September 2024.

Deadline for Submission of Written Comments Related to Proposed Determinations: Comments in response to the proposed determinations will be due by early October 2024.

ADDRESSES: The CLFS Annual Public Meeting will be held virtually and in-person at the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Where to Submit Written Comments: Interested parties should submit all written comments on presentations and proposed determinations electronically to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov* (the specific date for the publication of these determinations and the deadline for submitting comments regarding these determinations will be published on the CMS website).

FOR FURTHER INFORMATION CONTACT: Rasheeda Arthur, (410) 786–3434.

The CLFS Policy Team and submit all inquiries to the CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov* with the subject entitled ''CLFS Annual Public Meeting Inquiry.''

SUPPLEMENTARY INFORMATION:

I. Background

Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) required the Secretary of the Department of Health and Human Services (the Secretary) to establish procedures for coding and payment determinations for new clinical diagnostic laboratory tests under part B of title XVIII of the Social Security Act (the Act) that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM). The procedures and Clinical Laboratory Fee Schedule (CLFS) public meeting announced in this notice for new tests are in accordance with the procedures published on November 23, 2001 in the **Federal Register** (66 FR 58743) to implement section 531(b) of BIPA.

Section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added section 1833(h)(8) of the Act. Section 1833(h)(8)(A) of the Act requires the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any clinical diagnostic laboratory test (CDLT) for which a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code is assigned on or after January 1, 2005. A code is considered to be substantially revised if there is a substantive change to the definition of the test or procedure to which the code applies (for example, a new analyte or a new methodology for measuring an existing analyte-specific test). (See section 1833(h)(8)(E)(ii) of the Act and 42 CFR 414.502)).

Section 1833(h)(8)(B) of the Act sets forth the process for determining the basis for, and the amount of, payment for new tests. Pertinent to this notice, sections 1833(h)(8)(B)(i) and (ii) of the Act require the Secretary to make available to the public a list that includes any such test for which establishment of a payment amount is being considered for a year and, on the same day that the list is made available, cause to have published in the **Federal Register** notice of a meeting to receive comments and recommendations (including data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for the tests on such list. This list of codes for which the establishment of a payment amount under the CLFS is being considered for calendar year (CY) 2025 will be posted on the Centers for Medicare & Medicaid Services (CMS) website concurrent with the publication of this notice and may be updated prior to the CLFS Annual Public Meeting. The

CLFS Annual Public Meeting list of codes can be found on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/.* Section 1833(h)(8)(B)(iii) of the Act requires that we convene the public meeting not less than 30 days after publication of the notice in the **Federal Register**. The CLFS requirements regarding public consultation are codified at 42 CFR 414.506.

Two bases of payment are used to establish payment amounts for new CDLTs. The first basis, called ''crosswalking,'' is used when a new CDLT is determined to be comparable to an existing test, multiple existing test codes, or a portion of an existing test code. New CDLTs that were assigned new or substantially revised codes prior to January 1, 2018, are subject to provisions set forth under § 414.508(a). For a new CDLT that is assigned a new or significantly revised code on or after January 1, 2018, CMS assigns to the new CDLT code the payment amount established under § 414.507 of the comparable existing CDLT. Payment for the new CDLT code is made at the payment amount established under § 414.507. (See § 414.508(b)(1)).

The second basis, called ''gapfilling,'' is used when no comparable existing CDLT is available. When using this method, instructions are provided to each Medicare Administrative Contractor (MAC) to determine a payment amount for its part B geographic area for use in the first year. In the first year, for a new CDLT that is assigned a new or substantially revised code on or after January 1, 2018, the MAC-specific amounts are established using the following sources of information, if available: (1) charges for the test and routine discounts to charges; (2) resources required to perform the test; (3) payment amounts determined by other payers; (4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and (5) other criteria CMS determines appropriate. In the second year, the test code is paid at the median of the MAC-specific amounts. (See § 414.508(b)(2)).

Under section 1833(h)(8)(B)(iv) of the Act and § 414.506(d)(1) CMS, taking into account the comments and recommendations (and accompanying data) received at the CLFS Annual Public Meeting, develops and makes available to the public a list of proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on the proposed determinations. Under section 1833(h)(8)(B)(v) of the Act and § 414.506(d)(2), taking into account the comments received on the proposed determinations during the public comment period, CMS then develops and makes available to the public a list of final determinations of payment amounts for tests along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) added section 1834A to the Act. The statute requires extensive revisions to the Medicare payment, coding, and coverage requirements for CDLTs. Pertinent to this notice, section 1834A(c)(3) of the Act requires the Secretary to consider recommendations from the expert outside advisory panel established under section 1834A(f)(1) of the Act when determining payment using crosswalking or gapfilling processes. In addition, section 1834A(c)(4) of the Act requires the Secretary to make available to the public an explanation of the payment rates for the new test codes, including an explanation of how the gapfilling criteria and panel recommendations are applied. These requirements are codified in § 414.506(d) and (e).

After the final determinations have been posted on the CMS website, the public may request reconsideration of the basis and amount of payment for a new CDLT as set forth in § 414.509. Pertinent to this notice, those requesting that we reconsider the basis for payment or the payment amount as set forth in § 414.509(a) and (b), may present their reconsideration requests at the following year's CLFS Annual Public Meeting provided the requestor made the request to present at the CLFS Annual Public Meeting in the written reconsideration request. For purposes of this notice, we refer to these codes as the ''reconsidered codes.'' The public may comment on the reconsideration requests. (See the CY 2008 Physician Fee Schedule final rule with comment period published in the **Federal Register** on November 27, 2007 (72 FR 66275 through 66280) for more information on these procedures.)

II. Format

We are following our usual process, including an annual public meeting to determine the appropriate basis and payment amount for new and reconsidered codes under the CLFS for CY 2025. The public hybrid meeting will be conducted virtually and will occur on-site at the CMS Central Building.

This meeting is open to the public. Registration is only required for those interested in presenting public comments during the meeting or attending the meeting in-person at the CMS campus at the address specified in the **ADDRESSES** section of this notice. If attending the meeting in-person, on-site check-in for visitors will be held from 8:30 a.m. to 9:00 a.m. E.D.T., followed by opening remarks.

During this hybrid meeting, registered persons from the public may discuss and make recommendations for specific new and reconsidered codes for the CY 2025 CLFS. The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (Advisory Panel on CDLTs) will participate in this CLFS Annual Public Meeting by gathering information and asking questions to presenters, and will hold its next public meeting, virtually and in-person, on July 25 and 26, 2024. The public meeting for the Advisory Panel on CDLTs will focus on the discussion of and recommendations for test codes presented during the June 25, 2024 CLFS Annual Public Meeting. The Panel meeting also will address any other CY 2025 CLFS issues that are designated in the Panel's charter and specified on the meeting agenda. The announcement for the next meeting of the Advisory Panel on CDLTs is included in a separate notice published elsewhere in this issue of the **Federal Register**.

Due to time constraints, presentations must be brief, lasting no longer than 10 minutes. Written presentations must be electronically submitted to CMS on or before May 30, 2024. In addition, if presenting in-person, presenters should make copies available for approximately 50 meeting participants, since CMS will not be providing additional copies to the public. Presentation slots will generally be assigned based upon chronological order of receipt of presentation materials. In the event there is not enough time for presentations by everyone who is interested in presenting, we will only accept written presentations from those who submitted written presentations within the submission window and were unable to present due to time constraints. Presentations should be sent via email to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov.* In addition, individuals may also submit requests after the CLFS Annual Public Meeting to obtain electronic versions of the

presentations. Requests for electronic copies of the presentations after the public meeting should be sent via email to our CLFS dedicated email box, noted above.

Presenters should submit all presentations using a standard PowerPoint template. In addition to the standard PowerPoint template available, presenters may also provide the same information from the PowerPoint presentation into a provided Excel worksheet template. Submitting the same information that is requested for the PowerPoint presentation into the Excel worksheet template will aid with triaging and reviewing recommendation information during the meeting and after the meeting, during the code review process. The standard PowerPoint presentation and Excel worksheet templates are available on the CMS website, at *https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/annual-public-meetings,* under the ''Meeting Notice and Agenda'' heading.

For reconsidered and new codes, presenters should address all of the following five items:

- Reconsidered or new code(s) with the most current code descriptor.
- Test purpose and method with a brief comment on how the new test is different from other similar analyte or methodologies found in tests already on the CLFS.
- Test costs.
- Charges.
- Recommendation with rationale for one of the two bases (crosswalking or gapfilling) for determining payment for reconsidered and new tests.

Additionally, presenters should provide the data on which their recommendations are based. Presentations regarding reconsidered and new test codes that do not address the above five items for presenters may be considered incomplete and may not be considered by CMS when making a determination. However, we may request missing information following the meeting to prevent a recommendation from being considered incomplete.

Taking into account the comments and recommendations (and accompanying data) received at the CLFS Annual Public Meeting, we intend to post our proposed determinations with respect to the appropriate basis for establishing a payment amount for each new test code and our proposed determinations with respect to the reconsidered codes along with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on these determinations on our website by early September 2024. The CMS website is *https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/annual-public-meetings.* Interested parties may submit written comments on the proposed determinations for new and reconsidered codes by early October 2024, electronically to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov* (the specific date for the publication of the determinations on the CMS website, as well as the deadline for submitting comments regarding the determinations, will be published on the CMS website). Final determinations for new test codes to be included for payment on the CLFS for CY 2025 and reconsidered codes will be posted our website in November 2024, along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public. The final determinations with respect to reconsidered codes are not subject to further reconsideration. With respect to the final determinations for new test codes, the public may request reconsideration of the basis and amount of payment as set forth in § 414.509.

III. Registration Instructions

The Division of Ambulatory Services in the CMS Center for Medicare is coordinating the CLFS Annual Public Meeting registration. Beginning May 1, 2024 and ending May 30, 2024, registration may be completed by presenters and in-person attendees. Individuals who intend to view and/or listen to the meeting virtually do not need to register. Presenter registration and individuals who intend to attend the meeting at the CMS campus must register by sending an email to CMS's CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov.* The subject of the email should state ''Presenter or In-Person Attendee Registration for CY 2024 CLFS Annual Laboratory Meeting.'' All of the following information must be submitted when registering:

- Speaker or In-Person Attendee name.
- Organization or company name.
- Telephone numbers.
- Email address that will be used by the presenter to connect to the virtual meeting.
- New or Reconsidered Code (s) for which presentation is being submitted (if applicable).
- Presentation (if applicable).
- Excel Worksheet (if applicable).

Registration details may not be revised once they are submitted. If registration details require changes, a new registration entry must be submitted by the date specified in the **DATES** section of this notice. Additionally, registration information must reflect individual-level content and not reflect the name of an organization. For example, an organization cannot request to register a group of individuals without specifying registration details for each individual being registered. See section V for further information.

After registering, a confirmation email will be sent upon receipt of the registration. The email will provide information to the presenter or in-person attendee in preparation for the meeting. Registration is only required for individuals giving a presentation during the meeting or attending the meeting at the CMS campus. Presenters or in-person attendees must register by the deadline specified in the **DATES** section of this notice.

If you are not presenting during the CLFS Annual Public Meeting or cannot attend in person, you may view the meeting via webinar or listen-only by teleconference. If you would like to listen to or view the meeting, teleconference dial-in and webinar information will appear on the final CLFS Annual Public Meeting agenda, which will be posted on the CMS website when available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/.*

IV. Special Accommodations

Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the CMS resource box (*CDLT_Annual_Public_Meeting@cms.hhs.gov*). The deadline for submitting this request is listed in the **DATES** section of this notice.

V. Security, Building, and Parking Guidelines

This hybrid meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. We suggest that you arrive at the CMS campus and parking facilities between 8:00 a.m. and 8:45 a.m. E.D.T., so that you will be able to arrive promptly at the meeting by 9:00 a.m. E.D.T. Individuals who are not registered in

advance will not be permitted to enter the building and will be unable to attend the meeting. We note that the public may not enter the CMS building earlier than 8:15 a.m. E.D.T. (45 minutes before the convening of the meeting).

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–08005 Filed 4–15–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10573]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 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 17, 2024.

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, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

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–10573 Reform of Requirements for Long-Term Care Facilities

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 of a currently approved collection; *Title of Information Collection:* Reform of Requirements for Long-Term Care Facilities; *Use:* The purpose of this package is to request Office of Management and Budget (OMB) approval of the collection of information requirements for the requirements of participation for Long-Term Care (LTC) facilities that must be met in order to participate in the Medicare and Medicaid Programs. LTC facilities include skilled nursing facilities (SNFs) as defined in section 1819(a) of the Social Security Act in the Medicare program and nursing facilities (NFs) as defined in 1919(a) of the Act in the