following information must be submitted when registering:
- Stand-by Speaker name.
- Organization or company name.
- Email addresses that will be used by the speaker in order to connect to the virtual meeting.
- New or Reconsidered Code (s) for which the company or organization you are representing submitted a comment or presentation.

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 an organization entry. Also, each individual may only register one person at a time. That is, one individual may not register multiple individuals at the same time.

After registering, a confirmation email will be sent upon receipt of the registration. The email will provide information to the speaker in preparation for the meeting. Registration is only required for stand-by speakers and must be submitted by the deadline specified in the DATES section of this notice. Note: No registration is required for prepared speakers. 

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received no later than June 1, 2023 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 Submission of Written Comments Related to Proposed Determinations: Comments in response to the proposed determinations will be due by early October 2023.

ADDRESS: The CLFS Annual Public Meeting will be held virtually and will not occur at the campus of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244–1650. 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: 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) 2024 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 2024. The public meeting will be conducted virtually and will not 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. During the virtual meeting, registered persons from the public may discuss and make recommendations for specific new and reconsidered codes for the CY 2024 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 on July 19 and 20, 2023. The public meeting for the Advisory Panel on CDLTs will focus on the discussion of and recommendations for test codes presented during the June 22, 2023 CLFS Annual Public Meeting. The Panel meeting also will address any other CY 2024 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 June 1, 2023. 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 that is available on the CMS website, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=ClinicalLabFeeSched/. Interested parties may submit written comments on the proposed determinations for new and reconsidered codes by early October 2023, 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 2024 and reconsidered codes will be posted our website in November 2023, 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, 2023 and ending June 1, 2023, registration may be completed by presenters only. Individuals who intend to view and/or listen to the meeting do not need to register. Presenter registration may be completed by sending an email to our CLFS dedicated email box, CLFS_Annual_Public_Meeting@cms.hhs.gov. The subject of the email should state “Presenter Registration for CY 2024 CLFS Annual Laboratory Meeting.” All of the following information must be submitted when registering:

- Speaker name
- Organization or company name
- Telephone numbers
- Email address that will be used by the presenter in order to connect to the virtual meeting
- New or Reconsidered Code (s) for which presentation is being submitted
- Presentation
- 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 an organization entry. Also, each individual may only register one person at a time. That is, one individual may not register multiple individuals at the same time.

After registering, a confirmation email will be sent upon receipt of the registration. The email will provide information to the presenter in preparation for the meeting. Registration is only required for individuals giving a presentation during the meeting. Presenters must register by the deadline specified in the Dates section of this notice.

If you are not presenting during the CLFS Annual Public Meeting, 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
V. 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 Evel J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the Federal Register.


Evel J. Barco Holland,
Federal Register Liaison, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3438–PN]

Medicare and Medicaid Programs: Application From the Accreditation Commission for Healthcare (ACHC) for Continued CMS-Approval of Its Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice with comment.

SUMMARY: This notice acknowledges the receipt of an application from the Accreditation Commission for Healthcare for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by May 15, 2023.

ADDRESSES: In commenting, please refer to file code CMS–3438–PN.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to https://www.regulations.gov. Follow the “Submit a comment” instructions.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3438–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

   Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3438–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Danielle Adams, (410) 786–8818; or Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: https://www.regulations.gov. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicate comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital provided certain requirements are met. Sections 1861(e) of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as a hospital. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482 specify the minimum conditions that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a state survey agency (SA) as complying with the conditions or requirements set forth in part 482 of our regulations. Thereafter, the hospital is subject to regular surveys by a SA to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by SAs.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body’s approved program would be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

Our regulations concerning the approval of AOs are set forth at §§ 488.4, 488.5 and 488.3(e)(2)(i). The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The Accreditation Commission for Healthcare’s (ACHC) current term of approval for their hospital accreditation program expires September 25, 2023.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a national AO’s