



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1668-N]

Medicare Program; Public Meeting on July 31, 2017 Regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2018

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting to receive comments and recommendations (including accompanying data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System (HCPCS) codes being considered for Medicare payment under the clinical laboratory fee schedule (CLFS) for calendar year (CY) 2018. 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.

The Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel will participate in this meeting by gathering information and asking questions to presenters on July 31, 2017, and will hold a public meeting on August 1, 2017 to discuss matters of the Panel and make recommendations regarding the test codes presented at the CLFS public meeting. In the event the CLFS public meeting needs to extend to August 1, 2017, the CDLT Advisory Panel will convene its public meeting immediately following the CLFS public meeting, rather than starting at 9:00 a.m. Eastern Daylight Savings Time (E.D.T.) as currently planned.

DATES: Meeting Date: The CLFS public meeting is scheduled for Monday, July 31, 2017 from 9:00 a.m. to 5:00 p.m., E.D.T. If needed, the meeting will resume on Tuesday, August 1, 2017, beginning at 9:00 a.m. E.D.T.

Deadline for Registration of Presenters and Submission of Presentations: All presenters for the CLFS public meeting must register and submit their presentations electronically to our CLFS dedicated email box, CLFS_Annual_Public_Meeting@cms.hhs.gov, by July 14, 2017 at 5:00 p.m. E.D.T.

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received no later than 5:00 p.m. E.D.T. on July 14, 2017.

Deadline for Submission of Written Comments: Written comments regarding the presentations must be received by August 11, 2017 at 5:00 p.m. E.D.T. (10 days after the meeting). We intend to publish our proposed determinations for new test codes and our preliminary determinations for reconsidered codes (as described later in this notice in section II. "Format") for CY 2018 by early September 2017. Comments in response to the preliminary determinations will be due by early October 2017. Interested parties should submit all written comments on presentations and preliminary determinations to the address specified in the "**ADDRESSES**" section of this notice or electronically to our CLFS dedicated email box, CLFS_Annual_Public_Meeting@cms.hhs.gov (the specific date for the publication of these determinations on the CMS website, as well as the deadline for submitting comments regarding these determinations, will be published on the CMS website).

ADDRESSES: The CLFS public meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT:

Glenn McGuirk, (410) 786-5723.

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 (ICD-9-CM) (now, 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 for which a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code is assigned on or after January 1, 2005 (hereinafter referred to as “new tests”). 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 (such as, 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 prior to Calendar Year (CY) 2018 (Beginning January 1, 2018, payments for tests will be set in accordance with the methodologies specified in section 1834A of the Act.). 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, causes to have published a notice in the **Federal Register** of a meeting to receive comments and recommendations (including accompanying 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 CY 2018 is posted 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**. These requirements are codified at 42 CFR part 414, subpart G.

Two bases of payment are used to establish payment amounts for new tests. The first basis, called “crosswalking,” is used when a new test code is determined to be comparable to an existing test code, multiple existing test codes, or a portion of an existing test code. For a new CDLT that is assigned a new or significantly revised code before January 1, 2018, the new test code is assigned the local fee schedule amounts and the national limitation amount of the existing test. Payment for the new test is made at the lesser of the billed amount, the local fee schedule amounts, or the national limitation amount. (See §414.508(a)(1)).

The second basis, called “gapfilling,” is used when no comparable existing test is available. When using this method, instructions are provided to each Part A and Part B 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 before January 1, 2018, the contractor-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; and (4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. In the second year, the test code is paid at the national limitation amount. (See §414.508(a)(2)).

Under section 1833(h)(8)(B)(iv) of the Act, the Secretary, taking into account the comments and recommendations (and accompanying data) received at the CLFS 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, taking into account the comments received on the proposed determinations during the public comment period, the Secretary then develops and makes available to the public a list of final determinations of final payment amounts for new test codes 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.

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 test as set forth in

§414.509. Pertinent to this notice, those requesting that CMS 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 public meeting provided the requestor made the request to present at the CLFS 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 November 27, 2007 CY 2008 Physician Fee Schedule final rule with comment period (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 2018.

This meeting is open to the public. The 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. Registered persons from the public may discuss and make recommendations for specific new and reconsidered codes for the CY 2018 CLFS.

As stated in the "**SUMMARY**" section of this notice, the Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel will participate in the CLFS public meeting by gathering information and asking questions to presenters on July 31, 2017, and will hold a public meeting on August 1, 2017 to discuss matters of the Panel and make recommendations regarding the test codes presented at the CLFS public meeting. The announcement for the CDLT Advisory Panel meeting is included in a separate **Federal Register** notice.

Because of time constraints, presentations must be brief, lasting no longer than 10 minutes, and must be accompanied by three written copies. In addition, presenters should make copies available for approximately 50 meeting participants, since CMS will not be providing additional copies. Written presentations must be electronically submitted to CMS on or before July 14, 2017. Presentation slots will be assigned on a first-come, first-served basis. In the event there is not enough time for presentations by everyone who is interested in presenting, CMS will accept written presentations from those who 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 public meeting to obtain electronic versions of the presentations. Requests for electronic copies of the presentations post public meeting should be sent via email to our CLFS dedicated email box, noted above.

We are standardizing the presentation format for the CLFS public meeting. As a result, this year we are requiring presenters to 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/Laboratory_Public_Meetings.html, under the “Meeting Notice and Agenda” heading.

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

- (1) Reconsidered or new codes and descriptor.
- (2) Test purpose and method.
- (3) Costs.
- (4) Charges.

(5) Recommendation with rationale for one of the two bases (crosswalking or gapfilling) for determining payment for reconsidered and new tests.

Additionally, the 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. We may, however, 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 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 preliminary 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 the CMS website by early September 2017. This website can be accessed at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. Interested parties may submit written comments on the preliminary determinations for new and reconsidered codes by early October 2017, to the address specified in the “**ADDRESSES**” section of this notice or 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 2018 and reconsidered codes will be posted on the CMS website in November 2017, 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 public meeting registration. Beginning June 19, 2017, and ending July 14, 2017, registration may be completed on-line at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. On this webpage, under the heading “Meeting Notice, Registration and Agenda,” you will find a link entitled “Register for CLFS Annual Meeting.” Click this link and enter the required information. All the following information must be submitted when registering:

- Name.
- Company name.
- Address.
- Telephone numbers.
- E-mail addresses.

When registering, individuals who want to make a presentation must also specify which new test codes they will be presenting comments. A confirmation will be sent upon receipt of the registration. Individuals must register by the date specified in the “**DATES**” section of this notice.

If not attending the CLFS public meeting in person, the public may view the meeting via webcast or listen by teleconference. During the public meeting, webcasting is accessible online at <http://cms.gov/live>. Teleconference dial-in information will appear on the final Panel 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/](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/).

IV. Security, Building, and Parking Guidelines

The 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 facility between 8:15 a.m. and 8:30 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. The public may not enter the 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.

V. Special Accommodations

Individuals attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should provide that information upon registering for the meeting. The deadline for registration is listed in the “**DATES**” section of this notice.

Dated: June 2, 2017.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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