DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services [CMS–1697–N]

Medicare Program; Public Meeting on June 25, 2018 Regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2019

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) 2019. 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 Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (Advisory Panel on CDLTs) will participate in this Annual Laboratory Public Meeting by gathering information and asking questions to presenters, and will hold its next public meeting on July 16 and 17, 2018. The public meeting for the Advisory Panel on CDLTs will focus on discussion of and recommendations for test codes presented during the June 25, 2018 Annual Laboratory Public Meeting. The Panel meeting will also address other CY 2019 CLFS issues that are designated in the Panel’s charter and specified on the meeting agenda may also be discussed.

DATES: Annual Laboratory Public Meeting Date: The meeting is scheduled for Monday, June 25, 2018 from 8:00 a.m. to 5:00 p.m., E.D.T.

Deadline for Registration of Presenters and Submission of Presentations: All presenters for the Annual Laboratory Public Meeting must register and submit their presentations electronically to our CLFS dedicated email box, CLFS_Annual_Public_Meeting@cms.hhs.gov, by June 11, 2018 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 June 11, 2018.

Deadline for Submission of Written Comments Related to the Annual Laboratory Public Meeting: Written comments regarding the presentations must be received by July 9, 2018 at 5:00 p.m. E.D.T. (2 weeks after the meeting).

Publication of Proposed Determinations: 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”) 1833(h)(8)(B)(i) and (ii) of the Act and 42 CFR 414.502). 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)(B)(iii) of the Act and 42 CFR 414.502).

For further information contact: Glenn McGuirk, (410) 786–5723.
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 clinical diagnostic laboratory tests (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, the new CDLT code is assigned the payment amount established under §414.507 of the comparable existing CDLT. Payment for the new CDLT is made at the payment amount established under §414.507. (See §414.506(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 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; (4) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and (5) Other criteria that 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)(4)(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 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.

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.

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 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 2019.

This meeting is open to the public. The on-site check-in for visitors will be held from 7:30 a.m. to 8:00 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 2019 CLFS.

As stated in the SUMMARY section of this notice, the Advisory Panel on CDLTs will participate in the Annual Laboratory Public Meeting by gathering information and asking questions to presenters on June 25, 2018, and will hold a public meeting in July 16 and 17, 2018 to discuss matters of the Panel and make recommendations regarding the test codes presented at the Annual Laboratory Public Meeting. The announcement for the Advisory Panel on CDLTs meeting is included in a separate Federal Register notice.

Due to 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 June 11, 2018. 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.

Presenters are required 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
### III. Registration Instructions

The Division of Ambulatory Services in the CMS Center for Medicare is coordinating the CLFS public meeting registration. Beginning April 4, 2018, and ending June 11, 2017, registration may be completed on-line 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/). On this web page, 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.
- Email addresses.

When registering, individuals who want to make a presentation must also specify the new test codes on which they will be presenting comments. A confirmation will be sent upon receipt of the registration.

If not attending the Annual Laboratory 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](http://cms.gov/live). Teleconference dial-in information will appear on the final Annual Laboratory 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/](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 7:00 a.m. and 8:00 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 7:15 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.

### 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.).

Dated: March 20, 2018.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1706–N]

Medicare Program; Membership and Meeting Announcement for the Advisory Panel on Clinical Diagnostic Laboratory Tests

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

ACTION: Notice.

SUMMARY: This notice announces the appointment of three new members to the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) and the next public meeting for the Panel, which is scheduled on Monday, July 16, 2018 and Tuesday, July 17, 2018.