DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Centers for Medicare & Medicaid
Services

[CMS–1646–N]

Medicare Program; Public Meeting on
July 18, 2016 Regarding New and
Reconsidered Clinical Diagnostic
Laboratory Test Codes for the Clinical
Laboratory Fee Schedule for Calendar
Year 2017

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) 2017. 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: Meeting Date: The public meeting is
scheduled for Monday, July 18, 2016 from 9:00 a.m. to 3:00 p.m., Eastern
Daylight Savings Time (E.D.T.).

Deadline for Registration of Presenters

Deadline for Submission of Presentations: All
presenters for the public meeting must register and submit their presentations electronically to Glenn McGuirk at
Glenn.McGuirk@cms.hhs.gov by July 1, 2016 E.D.T.

Deadline for Submitting Requests for
Special Accommodations: Requests for
special accommodations must be received no later than 5:00 p.m. on July 1, 2016 E.D.T.

Deadline for Submission of Written
Comments: We intend to publish our
proposed determinations for new test
codes and our preliminary
determinations for reconsidered codes
(as described below in section II.
Format) for CY 2017 by early September
2016. Interested parties may submit
written comments on these
determinations by early October, 2016,
to the address specified in the

ADDRESSES section of this notice or
electronically to Glenn McGuirk at
Glenn.McGuirk@cms.hhs.gov (the
specific date for the publication of these
determinations on the CMS Web site, as
well as the deadline for submitting
comments regarding these
determinations will be published on the
CMS Web site).

ADDRESSES: The 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) requires the Secretary of the 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). The procedures and 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
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 with respect to 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.)

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,
section 1833(h)(8)(B)(i) and (ii) of the Act
requires that procedures be 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 clinical laboratory fee schedule (CLFS) is being considered for calendar year (CY) 2017 is posted on the CMS Web site 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. The new test code is assigned the local fee schedule amount 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 amount, or the national limitation amount. (See § 414.508(a).)

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. The contractor-specific amounts are established for the new test code 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. (See § 414.508(b) and § 414.509 for more information regarding the gapfilling process.)

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 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 Web site, 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, for crosswalking, reconsider the payment amount as set forth in § 414.509(a) and (b)(1) may present their reconsideration requests at the following year’s public meeting provided that the requestor made the request to present at the 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 test codes under the CLFS for CY 2017. 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., followed by opening remarks. Registered persons from the public may discuss and make recommendations for specific new and reconsidered test codes for the CY 2017 CLFS.

We note that the July 2016 Clinical Diagnostic Laboratory Tests (CDLT) Advisory Panel meeting and the laboratory public meeting will be a joint meeting this year, on July 18, 2016. The announcement for the CDLT Advisory Panel meeting will be included in a separate Federal Register notice. Because of this, 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 1, 2016. Presentation slots will be assigned on a first-come, first-served basis. In the event that there is not enough time for presentations by everyone who is interested in presenting, CMS will gladly accept written presentations from those who were unable to present due to time constraints. Presentations should be sent via email to Glenn McGuirk, at Glenn.McGuirk@cms.hhs.gov. For reconsidered and new test codes, presenters should address all of the following 5 items:

1. Reconsidered or new test codes and descriptor.
2. Test purpose and method.
3. Costs.
5. Recommendation with rationale (including accompanying data on which the determinations are based, and responses to comments and suggestions received from the public).
days after the meeting). Interested parties may submit written comments on the proposed determinations for new test codes or the preliminary determinations for reconsidered codes by early October, 2016, to the address specified in the ADDRESSES section of this notice or electronically to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov (the specific date for the publication of the determinations on the CMS Web site, as well as the deadline for submitting comments regarding the determinations, will be published on the CMS Web site). Final determinations for new test codes to be included for payment on the CLFS for CY 2017 and reconsidered codes will be posted on the CMS Web site in November 2016, 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 public meeting registration. Beginning June 6, 2016, registration may be completed on-line at the following Web site: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/. 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, which new test codes they will be presenting comments on the proposed determinations for new test codes or the preliminary determinations for reconsidered codes by early October, 2016, to the address specified in the ADDRESSES section of this notice or electronically to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov (the specific date for the publication of the determinations on the CMS Web site, as well as the deadline for submitting comments regarding the determinations, will be published on the CMS Web site). Final determinations for new test codes to be included for payment on the CLFS for CY 2017 and reconsidered codes will be posted on the CMS Web site in November 2016, 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.

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. It is suggested that you arrive at the CMS facility between 8:15 a.m. and 8:30 a.m., so that you will be able to arrive promptly at the meeting by 9:00 a.m. 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. (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: April 11, 2016.

Andrew M. Slavitt,
Acting Administrator, Centers for Medicare & Medicaid Services.

[PR Doc. 2016–11269 Filed 5–12–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

**Title:** Tribal Child Support Enforcement Direct Funding Request: 45 CFR 309—Plan.

**OMB No.:** 0970–0218.

**Description:** The final rule within 45 CFR part 309, published in the Federal Register on March 30, 2004, contains a regulatory reporting requirement that, in order to receive funding for a Tribal IV–D program a Tribe or Tribal organization must submit a plan describing how the Tribe or Tribal organization meets or plans to meet the objectives of section 455(f) of the Social Security Act, including establishing paternity, establishing, modifying, and enforcing support orders, and locating noncustodial parents. The plan is required for all Tribes requesting funding; however, once a Tribe has met the requirements to operate a comprehensive program, a new plan is not required annually unless a Tribe makes changes to its title IV–D program. Tribes and Tribal organizations must respond if they wish to operate a fully funded program. This paperwork collection activity is set to expire in December 31, 2016.

**Respondents:** Tribes and Tribal Organizations.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
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<td>45 CFR 309—Plan</td>
<td>60</td>
<td>2</td>
<td>480</td>
<td>57,600</td>
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**Estimated Total Annual Burden Hours:** 57,600.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing...