other aspect of this collection of information, including any of the following subjects: 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 on the collection(s) of information must be received by the OMB desk officer by November 2, 2015.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 or Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of the following:


2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated Billing; Use: We are requesting approval of a reinstatement of a Change of Therapy OMRA for Skilled Nursing Facilities (SNFs). As described in CMS–1351–F, we finalized the assessment effective October 1, 2011. The SNFs are required to submit this assessment. The COT OMRA is comprised of a subset of resident assessment information developed for use by SNFs to satisfy a Medicare payment requirement. The burden associated with this is the SNF staff time required to complete the COT OMRA, SNF staff time to encode the data, and SNF staff time spent in transmitting the data. The SNFs are required to complete a COT OMRA when a SNF resident was receiving a sufficient level of rehabilitation therapy to qualify for an Ultra High, Very High, High, Medium, or Low Rehabilitation category and when the intensity of therapy (as indicated by the total reimbursable therapy minutes (RTM) delivered, and other therapy qualifiers such as number of therapy days and disciplines providing therapy) changes to such a degree that it would no longer reflect the RUG–IV classification and payment assigned for a given SNF resident based on the most recent assessment used for Medicare payment. The COT OMRA is a type of required PPS assessment which uses the same item set as the End of Therapy (EOT) OMRA. Form Number: CMS–10387 (OMB Control Number: 0938–1149); Frequency: Yearly; Affected Public: Private sector (Business or other For-profits and Not-for-profit institutions); Number of Respondents: 15,421; Total Annual Responses: 678,524; Total Annual Hours: 701,119. (For policy questions regarding this collection contact Penny Gershman at 410–786–6643).

2. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologics; Use: In accordance with Section 1847A of the Social Security Act (the Act), Medicare Part B covered drugs and biologics not paid on a cost or cost basis are paid based on the average sales price (ASP) of the drug or biological, beginning in Calendar Year (CY) 2005. The ASP data reporting requirements are specified in Section 1927 of the Act. The reported ASP data are used to establish the Medicare payment amounts. The reporting template was revised in CY 2011 in order to facilitate accurate collection of ASP data. An accompanying user guide with instructions on the template’s use was also created and included an explanation of the data elements in the template. Form Number: CMS–10110 (OMB Control Number: 0938–0921); Frequency: Quarterly; Affected Public: Private sector (Business or other For-profits); Number of Respondents: 180; Total Annual Responses: 720; Total Annual Hours: 34,560. (For policy questions regarding this collection contact Amy Gruber at 410–786–1542).


William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–25109 Filed 10–1–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1657–N]

Medicare, Medicaid, and Children’s Health Insurance Programs; Announcement of the Advisory Panel on Clinical Diagnostic Laboratory Tests Meeting on October 19, 2015

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

ACTION: Notice.

SUMMARY: This notice announces the next meeting date of the Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on Monday, October 19, 2015. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) on issues related to clinical diagnostic laboratory tests.

DATES: Meeting Date: The meeting of the Panel is scheduled to take place at CMS’s headquarters in Baltimore, MD on Monday, October 19, 2015, beginning at 9:00 a.m., Eastern Daylight Time (EDT). The Panel will address issues relating to the CY 2016 clinical laboratory fee schedule (CLFS) preliminary determinations of new and
reconsidered test codes, as well as provide input on other CY2016 CLFS issues that are designated in the Panel’s charter.

Meeting Registration:

The public may attend the meeting in-person, view via webcast, or listen via teleconference. Beginning Friday, October 2, 2015, and ending Tuesday, October 13, 2015 at 5:00 p.m. EDT, registration to attend the meeting in-person may be completed on-line at http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html. On this Web page, under “Related Links,” double-click the “Clinical Diagnostic Laboratory Tests FACA Panel Meeting Registration” link and enter the required information. All the following information must be submitted when registering:

- Name
- Company name
- Address
- Email addresses.

Note: Participants who do not plan to attend the meeting in-person on October 19, 2015 should not register. No registration is required for participants who plan to view the meeting via webcast or listen via teleconference.

Presenter Registration and Submission of Presentations and Comments

We are interested in submitted comments or in person presentations at the meeting concerning the issues described in the SUPPLEMENTARY INFORMATION section of this notice and clarified in the agenda to be published approximately 2 weeks before the meeting. The comments and presentations should not address issues not before the Panel. The deadline to register to be a presenter and to submit written presentations for the meeting is 5:00 p.m. EDT, Tuesday, October 13, 2015. Presenters may register by email by contacting the person listed in the FOR FURTHER INFORMATION CONTACT section of this notice. Presentations should be sent via email to the same person’s email address.

Meeting Location, Webcast, and Teleconference

The meetings will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244–1850. Alternately, the public may either view the meetings via a webcast or listen by teleconference. During the scheduled meeting, webcasting is accessible online at http://cms.gov/live. Teleconference dial-in information will appear on the final meeting agenda, which will be posted on the CMS Web site when available at http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

Meeting Format

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. on Monday, October 19, 2015. Following the opening remarks, the Panel will address any issues relating to the CY 2016 CLFS preliminary determinations of new and reconsidered test codes, as well as provide input on other CY 2016 CLFS issues that are designated in the Panel’s charter. The Panel will hear oral presentations from the public for no more than 1 hour during each of two sessions. During session one, registered persons from the public may present recommendations on preliminary determinations of new and reconsidered codes for the CY 2016 CLFS. During session two, registered persons from the public may present recommendations on CLFS issues that are designated in the Panel’s charter and outlined in the Agenda.


FOR FURTHER INFORMATION CONTACT:

Glenn C. McGuirk, Designated Federal Official (DFO), Center for Medicare, Division of Ambulatory Services, CMS, 7500 Security Boulevard, Mail Stop C4–01–26, Baltimore, MD 21244, 410–786–5723, email CDLTPanel@cms.hhs.gov or Glenn.McGuirk@cms.hhs.gov. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background

The Advisory Panel on Clinical Diagnostic Laboratory Tests is authorized by section 1834A(f)(1) of the Social Security Act (the Act) (42 U.S.C. 1395m–1), as established by section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014). The Panel is subject to the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels. Section 1834A(f)(1) of the Act directs the Secretary of the Department of Health and Human Services (Secretary) to consult with an expert outside advisory panel, established by the Secretary, composed of an appropriate selection of individuals with expertise in issues related to clinical diagnostic laboratory tests. Such individuals may include molecular pathologists, clinical laboratory researchers, and individuals with expertise in laboratory science or health economics.

The Panel will provide input and recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS), on the following:

- The establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test;
- The factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests; and
- Other aspects of the new payment system under section 1834A of the Act.

A notice announcing the establishment of the Panel and soliciting nominations for members was published in the October 27, 2014 Federal Register (79 FR 63919 through 63920). In the August 7, 2015 Federal Register (80 FR 47491), CMS announced membership appointments to the Panel along with the first public meeting date for the Panel, which was held on August 26, 2015.

The Panel charter provides that panel meetings will be held up to four times annually. The Panel consists of 15 individuals and a Chair. The Panel Chair facilitates the meeting and the DFO or DFO’s designee must be present at all meetings.

II. Agenda

The Agenda for the October 19, 2015, meeting will provide for discussion and comment on the following topics as designated in the Panel’s Charter:

- CY 2016 CLFS preliminary determinations of new and reconsidered test codes which were posted on September 25, 2015 on our Web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ ClinicalLabFeeSched/Laboratory_Public_Meetings.html.
- Other CY 2016 CLFS issues designated in the Panel’s charter and further described on our Agenda.

A detailed Agenda will be posted approximately 2 weeks before the meeting, on the CMS Web site at http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

III. Meeting Attendance

The Panel’s meeting on October 19, 2015, is open to the public; however,
attendance is limited to space available. Priority will be given to those who pre-register and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on federal property, must register by following the instructions in the “Meeting Registration” section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

IV. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
- Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
- Attendees must present a government-issued photo identification to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid photo ID, persons may not be permitted entry to the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, for example, laptops and cell phones are subject to physical inspection.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.

V. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

VI. Panel Recommendations and Discussions

The Panel’s recommendations will be posted after the meeting on our Web site at http://cmsgov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

VIII. Copies of the Charter

The Secretary’s Charter for the Advisory Panel on Clinical Diagnostic Laboratory Tests is available on the CMS Web site at http://cmsgov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html or you may obtain a copy of the charter by submitting a request to the contact listed in the FOR FURTHER INFORMATION CONTACT section of this notice.

IX. 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.).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

OMB No.: 0970–0416.

Description: Collection of these data will assist legislators and policymakers in determining how effective their policymaking efforts have been over time in applying the various child support legislation to the overall child support enforcement picture. This information will help policymakers determine to what extent individuals on welfare would be removed from the welfare rolls as a result of more stringent child support enforcement efforts.

Respondents: Individuals and households.

### ANNUAL BURDEN ESTIMATES

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<th>Instrument</th>
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<th>Number of responses per respondent</th>
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Estimated Total Annual Burden Hours: 1,239.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L’Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.