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 new test codes, presenters should address all of the following items:

- New test code(s) and descriptor.
- Test purpose and method.
- Costs.
- Charges.
- A recommendation, with rationale, for one of the two bases (crosswalking or gapfilling) for determining payment for new tests.

Additionally, the presenters should provide the data which their recommendations are based. Written presentations from the public meeting will be available upon request, via email, to Glenn McGuirk at *Glenn.McGuirk@cms.hhs.gov*. Presentations regarding new test codes that do not address the above five items may be considered incomplete and may not be considered by CMS when making a determination. CMS may 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 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 which the determinations are based, and a request for public written comments on these determinations on the CMS Web site by early September 2014. This Web site can be accessed at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/*. We also will include a summary of all comments received by August 4, 2014 (15 business 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, 2014, 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 2015 and reconsidered codes will be posted on our Web site in November 2014, along with the rationale for each determination, the data 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 9, 2014, registration may be completed on-line at the following web address: *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. A confirmation will be sent upon receipt of the registration. Individuals must register by the date specified in the **DATES** section of this notice.

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: March 14, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–06515 Filed 3–24–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3292–N]

Medicare Program; Announcement of the Approval of the American Association for Laboratory Accreditation (A2LA) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

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

ACTION: Notice.

SUMMARY: This notice announces the application of the American Association for Laboratory Accreditation (A2LA) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for all specialty and subspecialty areas under CLIA. We have determined that the A2LA meets or

exceeds the applicable CLIA requirements. We are announcing the approval and granting the A2LA deeming authority for a period of 4 years.

DATES: *Effective Date:* This notice is effective from March 25, 2014 to March 26, 2018.

FOR FURTHER INFORMATION CONTACT: Cindy Flacks, (410) 786–6520.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of the A2LA as an Accreditation Organization

In this notice, we approve the American Association for Laboratory Accreditation (A2LA) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for all specialty and subspecialty areas under CLIA. We have examined the initial A2LA application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that the A2LA meets or exceeds the applicable CLIA requirements. We have also determined that the A2LA will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant the A2LA approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for all specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by the A2LA during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of the A2LA Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the A2LA accreditation program meets the necessary requirements to be approved by CMS and that, as such, CMS may approve the A2LA as an accreditation program with deeming authority under the CLIA program. The A2LA formally applied to CMS for approval as an accreditation organization under CLIA for all specialties and subspecialties under CLIA. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

The A2LA submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. The A2LA policies and procedures for oversight of laboratories performing laboratory testing for all CLIA specialties and subspecialties are equivalent to those of CLIA in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. The A2LA submitted requirements for monitoring and inspecting laboratories in the areas of accreditation organization, data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. The requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

Our evaluation identified the A2LA's requirements pertaining to waived testing, provider performed microscopy procedures, and moderate complexity testing that are more stringent than the CLIA requirements. The A2LA's requirements for high complexity testing are equivalent to the CLIA requirements. The A2LA will only accredit for waived tests or provider performed microscopy procedures if the laboratory is also applying for high or moderate complexity testing accreditation. Under the A2LA's requirements, laboratories performing any of these levels of testing will be held to the high complexity personnel requirements for all testing that the A2LA will accredit (high, moderate, waived or provider performed microscopy), as well as the requirements for nonwaived testing located in Subparts H, J, K, M, Q, and applicable parts of R.

In contrast, the CLIA requirements at § 493.15 only require that a laboratory performing waived testing follow the manufacturer's instructions and obtain a certificate of waiver. The CLIA requirements at § 493.19 require that a laboratory performing provider performed microscopy procedures meet personnel requirements located at § 493.1355 through § 493.1365. The CLIA requirements at § 493.20 require that a laboratory performing moderate complexity testing meet the personnel requirements located at § 493.1403 through § 493.1425.

B. Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

The A2LA's requirements are equal to or more stringent than the CLIA requirements at § 493.801 through § 493.865. For instance, the A2LA requires that laboratories conduct proficiency testing activities for both primary and secondary test systems for waived and non-waived testing. The CLIA requirement at § 493.801(b)(6) requires proficiency testing activities for the primary test system and for non-waived testing only.

C. Subpart J—Facility Administration for Nonwaived Testing

The A2LA requirements for the submitted subspecialties and specialties are equal to the CLIA requirements at § 493.1100 through § 493.1105.

D. Subpart K—Quality System for Nonwaived Testing

The A2LA requirements are equal to or more stringent than the CLIA requirements at § 493.1200 through § 493.1299. For instance, laboratories

that are performing waived testing in addition to moderate or high complexity testing will need to meet all requirements in subpart K, Quality System for Nonwaived Testing. The A2LA has more specific requirements for laboratory information systems than CLIA. In addition, prior to adding a new test to the laboratory's accreditation, the A2LA requires the laboratory to submit performance specifications for review and approval.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that the A2LA's requirements are equal to or more stringent than the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing. Under the A2LA's requirements, laboratories that perform moderate complexity testing must meet the personnel requirements for high complexity testing located at § 493.1441 through § 493.1495.

F. Subpart Q—Inspections

We have determined that the A2LA requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at § 493.1771 through § 493.1780. The A2LA requires a two day onsite surveillance visit one year after the initial accreditation is granted. The A2LA requires annual review of all accredited laboratories. The laboratory is required to submit any updates on information about its organization, facilities, key personnel and results of any proficiency testing. Laboratories may be required to undergo an onsite surveillance visit if they do not submit their annual review documentation to the A2LA by the established 30 day deadline, if significant changes to the facility or organization have occurred, or if proficiency testing results have been consistently poor. The CLIA regulations do not have this requirement.

G. Subpart R—Enforcement Procedures

The A2LA meets the requirements of subpart R to the extent that it applies to accreditation organizations. The A2LA policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the A2LA will deny, suspend, or revoke accreditation in a laboratory accredited by the A2LA and report that action to us within 30 days. The A2LA also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the A2LA's laboratory enforcement and appeal policies are equal to the requirements of part 493, subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by the A2LA may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the A2LA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the A2LA, for cause, before the end of the effective date of approval. If we determine that the A2LA has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the A2LA would be allowed to address any identified issues. Should the A2LA be unable to address the identified issues within that timeframe, we may, in accordance with the applicable regulations, revoke A2LA's deeming authority under CLIA.

Should circumstances result in our withdrawal of the A2LA's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938–0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: March 14, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–06512 Filed 3–24–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0250]

Draft Guidance for Industry on Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway.'' This draft guidance discusses FDA's recommendations for developing the indication and usage statements in the prescribing information for drugs approved under the accelerated approval regulatory pathway (hereafter ''accelerated approval''). The guidance also discusses labeling considerations for indications approved under accelerated approval when clinical benefit has been verified and FDA terminates the conditions of accelerated approval, or when FDA withdraws accelerated approval of an indication while other indications for the drug remain approved.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 27, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201,