

for public written comments on these determinations on the CMS website by early September 2019. 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 2019, 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 2020 and reconsidered codes will be posted on the CMS website in November 2019, 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 Annual Public Meeting registration. Beginning April 8, 2019, and ending June 10, 2019, registration may be completed on-line at <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. Individuals must register by the date specified in the

DATES section of this notice. Registration is only required for individuals attending the meeting in person.

If not attending the CLFS Annual 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 CLFS Annual 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/>.

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 campus and parking facilities 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 8:00 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. We note that the public may not enter the CMS 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 15, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019-06148 Filed 3-29-19; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3369-FN]

Medicare and Medicaid Programs: Application From the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for Its Outpatient Physical Therapy and Speech Language Pathology Services Accreditation Program

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for continued recognition as a national accrediting organization for clinics, rehabilitation agencies, or public health agencies that furnish outpatient physical therapy and speech language pathology services that wish to participate in the Medicare or Medicaid programs.

DATES: The approval announced in this notice is effective on April 4, 2019 through April 4, 2025.

FOR FURTHER INFORMATION CONTACT: Erin Imhoff, (410) 786-2337; Monda Shaver, (410) 786-3410; or Tara Lemons, (410) 786-3030.

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 1861(p) of the Social Security Act (the Act), eligible beneficiaries may receive outpatient physical therapy and speech language pathology (OPT) services from a provider of services, a clinic, rehabilitation agency, a public health agency, or others, provided certain requirements are met. Section 1832(a)(2)(C) of the Act permits payment for OPT services. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 485 subpart H, specify the conditions that a clinic, rehabilitation agency or public health agency ("OPT providers") must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for OPT providers.

Generally, to enter into an agreement, an OPT provider must first be certified by a State survey agency as complying with the conditions of participation set forth in part 485, subpart H of our Medicare regulations. Thereafter, the OPT provider is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. An AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On October 30, 2018, we published a proposed notice in the **Federal Register** (83 FR 54591) announcing the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF's) request for continued approval of its Medicare OPT accreditation program. In the proposed notice, we detailed our evaluation criteria. Under Section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of AAAASF's Medicare OPT accreditation renewal application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of AAAASF's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its OPT surveyors; (4) ability to investigate and respond appropriately to complaints against accredited OPTs; and, (5) survey review and decision-making process for accreditation.

- The comparison of AAAASF's Medicare OPT accreditation program standards to our current Medicare OPT CoPs.

- A documentation review of AAAASF's survey process to:

- ++ Determine the composition of the survey team, surveyor qualifications, and AAAASF's ability to provide continuing surveyor training.

- ++ Compare AAAASF's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited OPTs.

- ++ Evaluate AAAASF's procedures for monitoring OPTs it has found to be

out of compliance with AAAASF's program requirements. (This pertains only to monitoring procedures when AAAASF identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c).)

- ++ Assess AAAASF's ability to report deficiencies to the surveyed OPT and respond to the OPT's plan of correction in a timely manner.

- ++ Establish AAAASF's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ Determine the adequacy of AAAASF's staff and other resources.

- ++ Confirm AAAASF's ability to provide adequate funding for performing required surveys.

- ++ Confirm AAAASF's policies with respect to surveys being unannounced.

- ++ Obtain AAAASF's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the October 30, 2018 proposed notice also solicited public comments regarding whether AAAASF's requirements met or exceeded the Medicare CoPs for OPTs. We received no comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between AAAASF's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared AAAASF's OPT accreditation program requirements and survey process with the Medicare CoPs at part 485 subpart H, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of AAAASF's OPT application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, AAAASF has revised its standards and certification processes in order to meet the requirements at:

- Section 485.701, to ensure AAAASF's standards appropriately reference the CMS standards;

- Section 485.703, definition of "supervision" at (2)(ii), to ensure AAAASF's standards appropriately reference the CMS standards;

- Section 485.705(a), to ensure AAAASF's standards appropriately reference the CMS standards;

- Section 485.705(c)(2) through (c)(6), to ensure AAAASF's standards appropriately reference the CMS standards;

- Section 485.719(b)(3), to ensure AAAASF's standards appropriately reference the statutory requirements;

- Section 488.5(a)(4)(ii), to ensure that an appropriate number of medical records are fully reviewed during the survey process and that survey record totals are accurately reflected in the overall deficiency statement;

- Section 488.5(a)(4)(iv), to ensure all deficiencies found on survey are cited in AAAASF's final survey report;

- Section 488.5(a)(4)(vii), to ensure appropriate monitoring of non-compliance correction;

- Section 488.5(a)(11)(ii), to ensure accurate survey findings are reported to CMS;

- Section 488.5(a)(13)(ii), to ensure AAAASF notifies CMS regarding any decision to revoke, withdraw, or revise the accreditation status of a deemed status supplier;

- Section 488.26(b) and (c), to ensure deficiencies are cited at the appropriate level based on manner and degree of findings;

- Section 488.28(a), to ensure AAAASF's policies for an acceptable plan of correction meet the CMS requirements;

- Section 488.28(d), to ensure that AAAASF's policies for correction of deficiencies in OPTs is comparable to CMS requirements, requiring that deficiencies normally must be corrected within 60 days; and

- Section 489.13(b)(1), to ensure all enrollment requirements are met prior to AAAASF surveying an initial applicant.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve AAAASF as a national accreditation organization for OPTs that request participation in the Medicare program, effective April 4, 2019 through April 4, 2025.

V. 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. Chapter 35).

Dated: March 15, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019-06149 Filed 3-29-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0895]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. On July 13, 2018, FDA determined that TPOXX (tecovirimat), manufactured by SIGA Technologies, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Office of Counterterrorism and Emerging Threats, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8510.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), which was added by the Cures Act, FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA has determined that TPOXX (tecovirimat), manufactured by SIGA Technologies, Inc., meets the criteria for a priority review voucher. TPOXX (tecovirimat) is indicated to treat human smallpox disease in adults and pediatric patients weighing at least 13 kilograms.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C

Act, go to <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm566498.htm#prv>. For further information about TPOXX (tecovirimat), go to the "Drugs@FDA" website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-06145 Filed 3-29-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0598]

Teva Women's Health, Inc., et al.; Withdrawal of Approval of 16 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 16 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of May 1, 2019.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.