

Availability

The Draft Toxicological Profiles are available online at <http://www.atsdr.cdc.gov/ToxProfiles> and at www.regulations.gov, Docket No. ATSDR-2014-0002.

Pamela I. Protzel Berman,

Director, Office of Policy, Planning and Evaluation, Agency for Toxic Substances and Disease Registry.

[FR Doc. 2017-12161 Filed 6-12-17; 8:45 am]

BILLING CODE 4163-70-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3343-PN]

Medicare and Medicaid Programs: Application From the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA-HFAP) for Continued CMS Approval of Its Ambulatory Surgical Center Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA-HFAP) for continued recognition as a national accrediting organization for Ambulatory Surgical Centers that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 13, 2017.

ADDRESSES: In commenting, please refer to file code CMS-3343-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3343-PN, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3343-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Monda Shaver, (410) 786-0310, Erin McCoy, (410) 786-2337, or Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search

instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from an Ambulatory Surgical Center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as an ASC. 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 416 specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ASCs.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416 of our Medicare regulations. Thereafter, the ASC 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 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. CMS Approval of Accreditation Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of an AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this notice of proposed recognition is to inform the public of the American Osteopathic Association/Healthcare Facilities Accreditation Program's (AOA-HFAP's) request for continued CMS approval of its ASC accreditation program. This notice also solicits public comment on whether AOA-HFAP's requirements meet or exceed the Medicare conditions for coverage (CfCs) for ASCs.

III. Evaluation of an AO's Accreditation Program

AOA-HFAP submitted all the necessary materials to enable us to make a determination concerning its request for continued CMS approval of its ASC accreditation program. This application was determined to be complete on April 14, 2017. Under section 1865(a)(2) of the Act and our regulations at § 488.5, our review and evaluation of AOA-HFAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AOA-HFAP's standards for ASCs as compared with Medicare's CfCs for ASCs.

- AOA-HFAP's survey process to determine the following:

- ++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

- ++ The comparability of AOA-HFAP's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ AOA-HFAP's processes and procedures for monitoring an ASC found out of compliance with AOA-HFAP's program requirements. These monitoring procedures are used only when AOA-HFAP identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).

- ++ AOA-HFAP's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- ++ AOA-HFAP's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ The adequacy of AOA-HFAP's staff and other resources, and its financial viability.

- ++ AOA-HFAP's capacity to adequately fund required surveys.

- ++ AOA-HFAP's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

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

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

IV. 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.*).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed

with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: June 7, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017-12193 Filed 6-12-17; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Dr. Natalie Greco, 301-761-7898;

Natalie.Greco@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Human and Veterinary Cancer Therapeutic Agent Utilizing Anthrax Toxin-Based Technology

Description of Technology

Due to the disorganized nature of blood vessels that run through tumors, chemotherapeutic agents often fail to penetrate tumors and kill cancer cells at the tumor's center. This can lead to ineffective chemotherapeutic treatments, because tumors can quickly grow back if the entire tumor is not destroyed. NIH researchers have developed a therapeutic agent that solves this problem facing current chemotherapy treatments. By elegantly