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 (CICs) 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 CICs 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 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.

[PR Doc. 2017–12193 Filed 6–12–17; 8:45 am]

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
exploiting cell surface proteases present at high levels in tumors, they have developed a tumor-targeted anthrax based toxin that inactivates the blood vessels within tumors. While in some cases cancer cells are also killed by the tumor-targeted toxin, the primary mechanism of action is thought to be a decrease in blood flow to the center of tumors, causing cancer cell death and tumor necrosis. Preliminary and ongoing studies have demonstrated that the targeted toxins have antitumor effects on melanomas, lung cancers and colon cancer in mouse models, and on feline and canine oral tumors. Interestingly, this therapy does not target a specific type of cancer cell, rather it targets the vasculature in and around tumors. Therefore, it has great potential to treat a wide range of solid tumors. Additionally, because few non-surgical treatments are available to treat many human and veterinary solid tumors, this technology would fill an unmet need in cancer therapy.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

**Potential Commercial Applications**

Therapeutic agent for a wide range of human and veterinary solid tumors, including:

- Melanomas
- Lung and colon cancers
- Oral squamous carcinomas

**Competitive Advantages**

- Proven effective in a variety of models, including models of important veterinary cancers.
- Agent is only active in tumor micro-environments, resulting in low toxicity to healthy tissue.
- Cancer cells are not directly targeted, so this agent can be used to treat a broad spectrum of solid tumors and resistance is unlikely to arise.
- Fills an unmet need in cancer therapy, because few non-surgical treatments exist.

**Development Stage**

- in vitro data available
- in vivo data available (animal)
- prototype

**Inventors:** S. Leplaa (NIAID); S.-H. Liu (NIAID); T. Bugge (NIDCR); A. Wein (NIAID); D. Peters (NIDCR); J. Liu (NHLBI); K.-H. Chen (NIAID); H. Birkedal-Hansen (NIDCR); S. Netzel-Arnett (NIDCR); D. Phillips (NIAID); C. Leysath (NIAID); C. Bachran (NIAID)

**Publications**


Peters DE, et al., Comparative toxicity and efficacy of engineered anthrax lethal toxin variants with broad anti-tumor activities. Toxicol Appl Pharmacol. 2014 Sep 1; 270(2): 220–229 [PMID: 24971906 PMCID: PMC4137396]


**Intellectual Property**


**Licensing Contact:** Dr. Natalie Greco, 301–761–7898; Natalie.Greco@nih.gov

**Collaborative Research Opportunity:** The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize anthrax toxin-based cancer therapeutics. For collaboration opportunities, please contact Dr. Natalie Greco, 301–761–7898; Natalie.Greco@nih.gov.

Dated: June 1, 2017.

**Suzanne Frisbie,**
Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[PR Doc. 2017–12147 Filed 6–12–17; 8:45 am]

**BILLING CODE 4140–01–P**