

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](mailto: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 on-going 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. Leppla (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

- Chen KH, *et al.*, Selection of anthrax toxin protective antigen variants that discriminate between the cellular receptors tem8 and cmg2 and achieve targeting of tumor cells. *J Biol Chem.* 2007 Mar 30; 282(13): 9834–9845 [PMID: 17251181 PMCID: PMC2530824]
- Liu S, *et al.*, Solid tumor therapy by selectively targeting stromal endothelial cells. *Proc Natl Acad Sci U S A.* 2016 Jul 12; 113(28): E4079–E4087 [PMID: 27357689 PMCID: PMC4948345]
- Wein AN, *et al.*, An anthrax toxin variant with an improved activity in tumor targeting. *Sci Rep.* 2015; 5: 16267 [PMID: 26584669 PMCID: PMC4653645]
- 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; 279(2): 220–229 [PMID: 24971906 PMCID: PMC4137396]
- Bachran C, *et al.*, Cytolethal distending toxin B as a cell-killing component of tumor-targeted anthrax toxin fusion proteins. *Cell Death Dis.* 2014 Jan; 5(1): e1003 [PMID: 24434511 PMCID: PMC4040664]
- Wein AN, *et al.*, Tumor therapy with a urokinase plasminogen activator-activated anthrax lethal toxin alone and in combination with paclitaxel. *Invest New Drugs.* 2013 Feb; 31(1): 206–212 [PMID: 22843210 PMCID: PMC3757568]
- Phillips DD, *et al.*, Engineering Anthrax Toxin Variants That Exclusively Form Octamers and Their Application to Targeting Tumors. *J Biol Chem.* 2013 Mar 29; 288(13): 9058–9065 [PMID: 23393143 PMCID: PMC3610978]
- Liu S, *et al.*, Intermolecular complementation achieves high specificity tumor targeting by anthrax toxin. *Nat Biotechnol.* 2005 Jun; 23(6): 725–730 [PMID: 15895075 PMCID: PMC2405912]

#### Intellectual Property

- HHS E–256–2015—US Application Nos. 62/210,771, filed 27 Aug 2015; 62/323,218, filed 15 Apr 2016; PCT App. No. PCT/US16/48706, filed 25 Aug 2016.
- HHS E–120–2013—US App. No. 14/898,248, filed 14 Dec 2015; PCT App. No. PCT/US2014/043131, filed 19 Jun 2014.
- HHS E–246–2012—US App. No. 14/423,408, filed 23 Feb 2015; PCT App. No. PCT/US13/56205
- HHS E–059–2004—US Patent No. 7,947,289, filed 09 Feb 2005.

HHS E–293–1999—US Patent Nos. 7,468,352, filed 22 Mar 2002; 8,791,074, filed 20 Oct 2008, and 9,403,872 filed 24 Jun 2014.

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

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**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Advisory Committee to the Director, National Institutes of Health, was renewed for an additional two-year period on May 31, 2017.

It is determined that the Advisory Committee to the Director, National Institutes of Health, is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or [spaethj@od.nih.gov](mailto:spaethj@od.nih.gov).

Dated: June 7, 2017.

#### Jennifer Spaeth,

*Director, Office of Federal Advisory Committee Policy.*

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