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Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3393–PN]

Medicare Program; Application From Community Health Accreditation Partner (CHAP) for Initial CMS-Approval of Its Home Infusion Therapy 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 Community Health Accreditation Partner for initial recognition as a national accrediting organization for suppliers of home infusion therapy services that wish to participate in the Medicare program. The statute requires that within 60 days of receipt of an organization's complete application, the Centers for Medicare & Medicaid Services (CMS) publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 27, 2020.

ADDRESSES: In commenting, please refer to file code CMS–3393–PN.

Comments, including mass comment submissions, must be submitted in one of the following three 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–3393–PN, P.O. Box 8016, 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–3393–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT: Christina Mister-Ward, (410)786–2441. Shannon Freeland, (410) 786- 4348.

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 website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

Home infusion therapy (HIT) is a treatment option for Medicare beneficiaries with a wide range of acute and chronic conditions. Section 5012 of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016) added section 1861(iii) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines ''home infusion therapy'' as professional services, including nursing services; training and education not otherwise covered under the Durable Medical Equipment (DME) benefit; remote monitoring; and other monitoring services. Home infusion therapy must be furnished by a qualified HIT supplier and furnished in the individual's home. The individual must:

- Be under the care of an applicable provider (that is, physician, nurse practitioner, or physician assistant); and
- Have a plan of care established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs under Part B, that prescribes the type, amount, and duration of infusion therapy services that are to be furnished.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that a qualified HIT supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and in reviewing and modifying the list of designated AOs. These statutory factors are as follows:

- The ability of the organization to conduct timely reviews of accreditation applications.
- The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act).
- Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.
- Such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit HIT suppliers furnishing HIT not later than January 1, 2021. Section 1861(iii)(3)(D)(i)(III) of the Act requires a ''qualified home infusion therapy supplier'' to be accredited by a CMS-approved AO, pursuant to section 1834(u)(5) of the Act.

On March 1, 2019, we published a solicitation notice entitled, ''Medicare Program; Solicitation of Independent Accrediting Organizations To Participate in the Home Infusion Therapy Supplier Accreditation Program'' (84 FR 7057). This notice informed national AOs that accredit HIT suppliers of an opportunity to submit applications to participate in the HIT supplier accreditation program. We stated that complete applications would be considered for the January 1, 2021 designation deadline if received by February 1, 2020.

Regulations for the approval and oversight of AOs for HIT organizations are located at 42 CFR part 488, subpart L. The requirements for HIT suppliers are located at 42 CFR part 486, subpart I.

II. Approval of Accreditation Organizations

Section 1834(u)(5) of the Act and the regulations at § 488.1010 require that our findings concerning review and approval of a national 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.

Section 488.1020(a) requires that we publish, after 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. In accordance with § 488.1010(d), 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 proposed notice is to inform the public of Community Health Accreditation Partner (CHAP) initial request for CMS's approval of its HIT accreditation program. This notice also solicits public comment on whether CHAP's requirements meet or exceed the Medicare conditions of participation for HIT services.

III. Evaluation of Deeming Authority Request

CHAP submitted all the necessary materials to enable us to make a determination concerning its request for initial approval of its HIT accreditation program. This application was determined to be complete on February 27, 2020. Under section 1834(u)(5) of the Act and § 488.1010 (Application and re-application procedures for national HIT AOs), our review and evaluation of CHAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of CHAP's standards for HIT as compared with CMS' HIT conditions for certification.
- CHAP'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 CHAP's to CMS standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ CHAP's processes and procedures for monitoring a HIT supplier found out of compliance with CHAP's program requirements.

++ CHAP's capacity to report deficiencies to the surveyed supplier and respond to the suppliers' plan of correction in a timely manner.

++ CHAP's capacity to provide CMS with electronic data and reports necessary for effective assessment and interpretation of the organization's survey process.

++ The adequacy of CHAP's staff and other resources, and its financial viability.

++ CHAP's capacity to adequately fund required surveys.

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

++ CHAP'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).

- CHAP's agreement or policies for voluntary and involuntary termination of suppliers.
- CHAP agreement or policies for voluntary and involuntary termination of the HIT AO program.
- CHAP's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

IV. Collection of Information Requirements

This document does not impose information collection and 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.

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.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 14, 2020.

Evell J. Barco Holland,

Federal Register Liaison, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0892]

Prospective Grant of an Exclusive Patent License: Development, Production, and Commercialization of a Seasonal Influenza Vaccine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to Sciogen Inc. located in San Jose, California.

DATES: Only written comments and/or complete applications for a license which are received by the FDA Technology Transfer Program within 15 days from the date of publication of this notice in the **Federal Register** will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, including inquiries concerning license applications, and comments and objections relating to the contemplated Exclusive Patent License should be directed to William Ronnenberg, Lead Patent Advisor, Technology Transfer Program, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; *FDAInventionLicensing@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: William Ronnenberg, Lead Patent Advisor, Technology Transfer Program, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; 240–402–4561, *FDAInventionLicensing@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Patent No. 9,163,068 issued October 20, 2015, entitled, ''Influenza Virus Recombinant Proteins'' (FDA Ref. No. E–2010–004/US–03).

2. U.S. Patent No. 9,896,484 issued February 20, 2018, entitled, ''Influenza Virus Recombinant Proteins'' (FDA Ref. No. E–2010–004/US–04).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States.

The prospective exclusive license territory may be limited to the United States for certain of the rights, or