DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2019–0094]

CDC Recommendations for Hepatitis C Screening Among Adults—United States, 2020

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces the availability of the final *CDC Recommendations for Hepatitis C Screening Among Adults—United States, 2020.*

DATES: The final document was published as an *MMWR Reports & Recommendations* on April 10, 2020.

ADDRESSES: The document may be found in the docket at *www.regulations.gov,* Docket No. CDC–2019–0084 and at *https://www.cdc.gov/mmwr/volumes/69/rr/rr6902a1.htm?s_cid=rr6902a1_w.*

FOR FURTHER INFORMATION CONTACT: CDR Sarah Schillie, MD, MPH, MBA, Centers for Disease Control and Prevention, 1600 Clifton Rd., NE U12–3, Atlanta, GA 30329. Telephone: (404) 639–8000; email: *DVHpolicy@cdc.gov.*

SUPPLEMENTARY INFORMATION: In 2019, CDC determined that *CDC Recommendations for Hepatitis C Screening Among Adults—United States, 2020* constituted influential scientific information (ISI) that will have a clear and substantial impact on important public policies and private sector decisions. Under the Information Quality Act, Public Law 106–554, agencies are required to conduct peer review of the information by specialists in the field who were not involved in the development of these recommendations. CDC solicited nominations for reviewers from the American Association for the Study of Liver Diseases (AASLD), Infectious Diseases Society of America (IDSA) and the American College of Obstetricians and Gynecologists (ACOG). Six clinicians with expertise in hepatology, gastroenterology, internal medicine, infectious diseases and/or obstetrics and gynecology provided structured peer reviews. Peer reviewers were supportive of the recommendations and raised comments about the benefit of screening pregnant women and inclusion of a prevalence threshold. Feedback obtained during the peer review process was carefully reviewed and considered by CDC. Ultimately no changes to the recommendation statement were made; however, additional references and justification for the recommendation to screen during every pregnancy and maintaining the prevalence threshold were added to the document. A summary of the peer review comments, CDC's response, and changes made to the document in response to the comments can be found in the Supporting Materials tab of the docket and at *https://www.cdc.gov/hepatitis/policy/isireview/PeerReviewCR.htm.*

In addition, on October 28, 2019, CDC published a notice in the **Federal Register** (84 FR 57733) announcing the opening of a docket to obtain public comment on the draft recommendations for hepatitis C screening among adults. The comment period closed December 27, 2019. CDC received response from 69 commenters on the draft recommendations document. Public commenters included those from academia, professional organizations, industry, and the public.

Many of the comments from the public were in support of the recommendations. For those comments that proposed changes, the majority related to removing the recommendation to screen for hepatitis C in every pregnancy or removing the prevalence threshold for universal screening. Feedback obtained during both the peer review process and the public comment period was carefully reviewed and considered by CDC. Ultimately no changes to the recommendation statement were made; however, additional references and justification for the recommendation to screen during every pregnancy and maintaining the prevalence threshold were added to the document. A summary of public comments and CDC's response is found in the Supporting Materials tab of the docket.

Dated: April 23, 2020.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2020–08960 Filed 4–27–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3396–PN]

Medicare Program; Application From National Association of Boards of Pharmacy for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Notice with comment period.

SUMMARY: This proposed notice acknowledges the receipt of an application from National Association of Boards of Pharmacy 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) publishes 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 June 26, 2020.

ADDRESSES: In commenting, please refer to file code CMS–3396–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–3396–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–3396–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.

Our regulations at 42 CFR 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 National Association of Boards of Pharmacy's (NABP's) initial request for CMS's approval of its HIT accreditation program. This notice also solicits public comment on whether NABP's requirements meet or exceed the Medicare conditions of participation for HIT services.

III. Evaluation of Deeming Authority Request

NABP 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 28, 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 NABP will be conducted in accordance with, but not necessarily limited to, the following factors:

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

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

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

++ NABP'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 NABP's staff and other resources, and its financial viability.

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

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

++ NABP'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).

- NABP's agreement or policies for voluntary and involuntary termination of suppliers.

• NABP agreement or policies for voluntary and involuntary termination of the HIT AO program.

• NABP'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.

[FR Doc. 2020–08990 Filed 4–27–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3657]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Accreditation Scheme for Conformity Assessment Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 28, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

OMB Control Number 0910–NEW

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d(d)) by adding a new subsection (d) entitled ''Pilot Accreditation Scheme for Conformity Assessment. [1] Section 514(d) of the FD&C Act requires FDA to establish a pilot program under which testing laboratories may be accredited, by accreditation bodies meeting criteria specified by FDA, to assess the conformance of a device within certain FDA-recognized standards. Determinations by testing laboratories so accredited that a device conforms with an eligible standard included as part of the ASCA Pilot Program shall be accepted by FDA for the purposes of demonstrating such conformity, unless FDA finds that a particular such determination shall not be so accepted.[2]

The statute provides that FDA may review determinations by accredited testing laboratories, including by conducting periodic audits of such determinations or processes of accreditation bodies or testing laboratories.[3] Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device assessed by an accredited testing laboratory, FDA may take additional measures as determined appropriate, including suspension or withdrawal of ASCA Accreditation of a testing laboratory or a request for additional information regarding a specific device.[4]

FDA intends to issue guidance regarding the goals and implementation of the voluntary Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program (hereafter referred to as the ASCA Pilot) in accordance with amendments made to section 514 of the FD&C Act [5] by FDARA, and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV).[6]

The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Pilot supports the Agency's continued efforts to use its scientific resources effectively and efficiently to protect and promote public health. FDA believes the voluntary ASCA Pilot may further encourage international harmonization of medical device regulation because it incorporates elements, where appropriate, from a well-established set of international conformity assessment practices and standards (*e.g.,* ISO/IEC 17000 series). The voluntary ASCA Pilot does not supplant or alter any other existing statutory or regulatory requirements governing the decision-

[1] See Pub. L. 115–52, section 205.

[2] See section 514(d)(1)(B) of the FD&C Act.

[3] See section 514(d)(2)(A) of the FD&C Act.

[4] See section 514(d)(2)(A) and (B) of the FD&C Act.

[5] See section 514(d)(3)(B) of the FD&C Act.

[6] See also MDUFA IV Commitment Letter: *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf.*