the current NIOSH Strategic Plan: FYs 2019–2023.

*Information Needs:* NIOSH seeks comments on the following: (1) Does the draft plan address the research that is most critical for understanding and reducing work-related motor vehicle crashes and injuries? If not, please provide details on research topics that are also critical and should therefore be added to the plan. (2) Are there research topics in the draft plan that are low-priority or are already being adequately addressed by others, which therefore should not be included in the plan? If so, please identify these topics and explain why they should not be included.

To view the notice and related materials, visit *https://www.regulations.gov* and enter CDC–2019–0107 in the search field and click ''Search.''

**John J. Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

[FR Doc. 2019–26999 Filed 12–13–19; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–3381–FN]**

### Medicare Program; Application From the Joint Commission for Initial CMS-Approval of its Home Infusion Therapy Accreditation Program

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

**ACTION:** Final notice.

**SUMMARY:** This final notice announces our decision to approve The Joint Commission (TJC) for initial recognition as a national accrediting organization for home infusion therapy (HIT) suppliers that wish to participate in the Medicare program. An HIT supplier that participates must meet the Medicare conditions for coverage (CfCs).

**DATES:** The approval announced in this final notice is effective December 15, 2019 through December 15, 2023.

**FOR FURTHER INFORMATION CONTACT:**

Christina Mister-Ward, (410)786–2441.

Lillian Williams, (410)786–8636.

## 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 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 HIT 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. HIT 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)(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 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) of the Act defines ''qualified HIT suppliers'' as being accredited by a CMS-approved AO.

In the March 1, 2019 **Federal Register**, 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. Complete applications will 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 part 488, subpart L. The requirements for HIT suppliers are located at part 486, subpart I.

## II. Approval of Accreditation Organizations

Section 1834(u)(5) of the Act and the regulations at 42 CFR 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 us with the necessary data.

Our regulations at § 488.1020(a) require 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.

## III. Provisions of the Proposed Notice

In the July 16, 2019 **Federal Register** (84 FR 33944), we published a proposed notice announcing TJC's request for initial approval of its Medicare HIT accreditation program. In the July 16, 2019 proposed notice, we detailed our evaluation criteria. Under section of 1834(u)(5) the Act and in our regulations at § 488.1010, we conducted a review of TJC Medicare home infusion accreditation application in accordance with the criteria specified by our regulations, which included, but are not limited to the following:

- An onsite administrative review of TJC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its HIT surveyors; (4) ability to investigate and respond appropriately to complaints against accredited HITs; and (5) survey review and decision-making process for accreditation.
- The ability for TJC to conduct timely review of accreditation applications.

• The ability of TJC to take into account the capacities of suppliers located in a rural area.

• The comparison of TJC's Medicare HIT accreditation program standards to our current Medicare HIT CfCs.

• A documentation review of TJC's survey process to—

++ Determine the composition of the survey team, surveyor qualifications, and TJC's ability to provide continuing surveyor training.

++ Compare TJC's processes, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited HITs.

++ Evaluate TJC's procedures for monitoring HITs it has found to be out of compliance with TJC's program requirements.

++ Assess TJC's ability to report deficiencies to the surveyed HIT and respond to the HIT's plan of correction in a timely manner.

++ Establish TJC's ability to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of TJC's staff and other resources.

++ Confirm TJC's ability to provide adequate funding for performing required surveys.

++ Confirm TJC's policies for surveys being unannounced.

++ TJC'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.

++ Obtain TJC's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1834(u)(5) of the Act, the July 16, 2019 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CfCs for HIT. No comments were received in response to our proposed notice.

## IV. Provisions of the Final Notice

### *A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements*

We compared TJC's HIT accreditation requirements and survey process with the Medicare CfCs of 42 CFR part 486, and the survey and certification process requirements of part 488. Our review and evaluation of TJC's HIT application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, TJC has completed revising its standards and certification processes to meet the conditions at:

• § 486.520 (b), to address the requirement that the plan of care must be established by a physician prescribing the type, amount and duration for HIT.

• § 486.520 (c), to address the requirement that the plan of care must be periodically reviewed by the physician.

• § 486.525 (a), to address the requirement that the HIT suppliers to be available 7 days a week, 24 hours a day.

• § 486.525 (a)(1), to address the requirement of all professional services, including nursing services, to be available to the home infusion patient.

• § 486.525 (a)(2), to address the requirement for patient education and training to be available for patients on a 7 day a week, 24 hour a day basis.

• § 486.525 (a)(3), to address the requirement of remote monitoring for the provision of HIT.

• § 488.1010 (a)(6)(ii), to ensure surveyors are educated on TJC survey policies and survey process for patient and record selection.

### *B. Term of Approval*

Based on the review and observations described in section III. of this final notice, we have determined that TJC's requirements for HITs meet or exceed our requirements. Therefore, we approve TJC as a national accreditation organization for HITs that request participation in the Medicare program, effective December 15, 2019 through December 15, 2023.

## 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. chapter 35).

Dated: December 2, 2019.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2019–26954 Filed 12–13–19; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–D–0529]**

## Qualification Process for Drug Development Tools; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) are announcing the availability of a draft guidance for industry and FDA staff entitled ''Qualification Process for Drug Development Tools.'' Under the 21st Century Cures Act (Cures Act), enacted on December 13, 2016, a new section was added to the Federal Food, Drug, and Cosmetic Act (FD&C Act), which defined a three-stage qualification process for drug development tools (DDTs). This guidance meets the Cures Act's mandate to issue guidance on this qualification process and related Prescription Drug User Fee Act (PDUFA) VI commitments. It elaborates on the new qualification process and transparency requirements and discusses the taxonomy for biomarkers and other DDTs, and the draft guidance of the same name issued January 7, 2014, is withdrawn.

**DATES:** Submit either electronic or written comments on the draft guidance by February 14, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact