IV. Provisions of the Final Notice

A. Differences Between URAC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

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

- § 486.520(a), to address the requirement stating all patients must be under the care of an applicable provider.
- § 488.1010(a)(5), to provide a detailed crosswalk identifying the exact language of the organization's comparable accreditation requirements and standards.
- § 488.1010(a)(6)(ix), to revise URAC's procedures for ''immediate jeopardy'' situations.
- § 488.1010(a)(6)(iv), to revise URAC's survey procedures for surveys.
- § 488.1010(a)(6)(v), to revise URAC's procedures and timelines for notifying a surveyed or audited home infusion therapy supplier of non-compliance with the home infusion therapy accreditation program's standards.
- § 488.1010(a)(6)(vi), to revise URAC's procedures and timelines for monitoring the home infusion therapy supplier's correction of identified non-compliance with the accreditation program's standards.
- § 489.13, to reflect our policies regarding when the effective period of an accreditation begins and ends

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that URAC's requirements for HITs meet or exceed our requirements. Therefore, we approve URAC as a national accreditation organization for HITs that request participation in the Medicare program, effective March 27, 2020 through March 27, 2024.

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).

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

Dated: March 26, 2020.

Evell J. Barco Holland,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–06795 Filed 3–31–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3384–FN]

Medicare and Medicaid Programs; Application From the Joint Commission (TJC) for Continued Approval of Its Home Health Agency Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve The Joint Commission (TJC) for continued recognition as a national accrediting organization for home health agencies (HHAs) that wish to participate in the Medicare or Medicaid programs. A HHA that participates in Medicaid must also meet the Medicare conditions of participation (CoPs).

DATES: The decision announced in this final notice is effective March 31, 2020 through March 31, 2026.

FOR FURTHER INFORMATION CONTACT:
Sharon Lash (410) 786–9457.
Caecilia Blondiaux (410) 786–2190.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a home health agency (HHA), provided that certain requirements are met. Sections 1861(m) and (o), 1891 and 1895 of the Social Security Act (the Act) establish distinct criteria for an entity seeking designation as an HHA. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities and other entities are at 42 CFR part 488. The regulations at 42 CFR parts 409 and 484 specify the conditions that an HHA must meet to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for home health care.

Generally, to enter into a provider agreement with the Medicare program, an HHA must first be certified by a state survey agency as complying with the conditions or requirements set forth in 42 CFR part 484 of our regulations. Thereafter, the HHA is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. However, there is an alternative to certification surveys by state agencies. Accreditation by a nationally recognized Medicare accreditation program approved by CMS may substitute for both initial and ongoing state review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met our requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for CMS approval of their accreditation program under 42 CFR part 488, subpart A must provide CMS with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.5. Section 488.5(e)(2)(i) requires accrediting organizations to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS.

The Joint Commission's (TJC's) term of approval for their HHA accreditation program expires March 31, 2020.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-

approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

In the October 24, 2019 **Federal Register** (84 FR 57026), we published a proposed notice announcing TJC's request for continued approval of its Medicare HHA accreditation program. In the October 24, 2019 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of TJC's Medicare HHA accreditation application in accordance with the criteria specified by our regulations, which include, 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 HHA surveyors; (4) ability to investigate and respond appropriately to complaints against accredited HHAs; and (5) survey review and decision-making process for accreditation.
- The comparison of TJC's Medicare HHA accreditation program standards to our current Medicare HHA CoPs.
- A documentation review of TJC's survey process to do the following:

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

++ Compare TJC's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited HHAs.

++ Evaluate TJC's procedures for monitoring HHAs it has found to be out of compliance with TJC's program requirements. (This pertains only to monitoring procedures when TJC identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c)).

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

++ Establish TJC's ability to provide CMS 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 with respect to surveys being unannounced.

++ Confirm 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 CMS 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 1865(a)(3)(A) of the Act, the October 24, 2019 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoPs for HHA. 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 HHA accreditation requirements and survey process with the Medicare CoPs of parts 409 and 484, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's HHA 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 in order to do all of the following:

- Meet the requirements of all of the following regulations:

++ Section 484.45 to address that HHAs must electronically report all OASIS data collected in accordance with § 484.55.

++ Section 484.50 to include language referencing patient representatives, to be included within the ''Patient Rights'' condition of participation.

++ Section 484.50(a)(1)(i) to incorporate language related to the right of persons who have limited English proficiency and individuals with disabilities to receive understandable, accessible communications.

++ Section 484.50(c)(11) to include the patient's rights to voice grievances to an outside entity.

++ Section 484.50(d)(1) to address safe and appropriate transfer of patients.

++ Section 484.50(e)(2) to include reporting of injuries of unknown source, or misappropriation of patient property.

++ Section 484.60 to address ''individualized'' and ''patient-specific'' plans of care, specifically that the individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care.

++ Section 484.60(b)(4) to address that stamped signatures are not acceptable unless used in a case of an author with a physical disability that can provide proof to a CMS contractor of his/her inability to sign their signature due to their disability (Rehabilitation Act of 1973).

++ Section 484.80(g)(1) to include professions of physical therapist, speech-language pathologist, or occupational therapist professions in any of their standards where ''appropriate skilled professional'' is found in the regulatory language.

++ Section 484.105(h)(2)(i) and 484.105(h)(2)(ii)(B) to include that transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing and to include section 1122 of the Act (42 U.S.C. 1320a–1) and implementing regulations.

++ Section 484.115(a)(1) to address citable standards to this CoP regarding HHA administrators.

- Provide clarifications and training to surveyors related to the verification of written documentation of the facility's emergency preparedness program as required under § 484.102.
- Provide training to TJC surveyors related to report gathering, specifically the requirements for CASPER and OASIS reports.
- Make changes to the amount of detail provided to the facility during TJC's daily briefing to ensure tracer methodology does not change the integrity of the survey process.
- Remove previous references to the educational and consultative nature of TJC's services when TJC is conducting

surveys, particularly during communications with the facility. Accrediting organization survey processes should emphasize facility compliance with Medicare's health and safety standards, rather than any educational function.

B. Term of Approval

Based on our review and observations described in section III. of this final notice, we approve TJC as a national accreditation organization for HHAs that request participation in the Medicare program. The decision announced in this final notice is effective March 31, 2020 through March 31, 2026.

V. 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.*).

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

Dated: March 26, 2020.

Evell J. Barco Holland,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–06792 Filed 3–31–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1057]

Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.'' Due to the Coronavirus Disease 2019 (COVID–19) pandemic, FDA has been closely monitoring the medical product supply chain with the expectation that it may be impacted by the COVID–19 outbreak, potentially leading to supply disruptions or shortages of drug and biological products in the United States. The guidance is intended to assist applicants and manufacturers in providing FDA timely, informative notifications about changes in the production of certain drugs and biological products that will, in turn, help the Agency in its efforts to prevent or mitigate shortages of such products. Given the public health emergency presented by COVID–19, this guidance document is being implemented without prior public comment because FDA has determined that prior public participation is not feasible or appropriate, but it remains subject to comment in accordance with the Agency's good guidance practices. In addition, this guidance is intended to remain in effect for the duration of the public health emergency related to COVID–19 declared by the Department of Health and Human Services (HHS). However, the recommendations and processes described in the guidance are expected to assist the Agency more broadly in its efforts to prevent and mitigate shortages, including under circumstances outside of the COVID–19 public health emergency and reflect the Agency's current thinking on this issue. Therefore, within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with any appropriate changes following the public health emergency and in consideration of comments received on this guidance and the Agency's experience with implementation.

DATES: The announcement of the guidance is published in the **Federal Register** on April 1, 2020. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

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 information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–1057 for ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on