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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3389-FN]

Medicare Program; Approval of Application by the Utilization Review Accreditation 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 Utilization Review Accreditation Commission (URAC) for initial recognition as a national accrediting organization for home infusion therapy suppliers that wish to participate in the Medicare program. A home infusion therapy supplier that participates must meet the Medicare conditions for coverage (CfCs).

DATES: The approval announced in this final notice is effective March 27, 2020 through March 27, 2024.

FOR FURTHER INFORMATION CONTACT:

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I. Background

Infusion therapy 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 Home Infusion Therapy (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
- 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 home infusion therapy 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 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 § 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 October 24, 2019 **Federal Register** (84 FR 57021), we published a proposed notice announcing URAC's request for initial approval of its Medicare HIT accreditation program. In the October 24, 2019 proposed notice, we detailed our evaluation criteria. Under section 1834(u)(5) the Act and in our regulations at § 488.1010, we conducted a review of URAC 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 URAC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its home infusion therapy surveyors; (4) ability to investigate and respond appropriately to complaints against accredited home infusion therapies; and (5) survey review and decision-making process for accreditation.

- The ability for URAC to conduct timely review of accreditation applications.

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

- The comparison of URAC's Medicare home infusion therapy accreditation program standards to our current Medicare home infusion therapy CfCs.

- A documentation review of URAC's survey process to--

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

++ Compare URAC's processes, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited home infusion therapies.

++ Evaluate URAC's procedures for monitoring home infusion therapies it has found to

be out of compliance with URAC's program requirements.

++ Assess URAC's ability to report deficiencies to the surveyed home infusion therapy and respond to the home infusion therapy's plan of correction in a timely manner.

++ Establish URAC'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 URAC's staff and other resources.

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

++ Confirm URAC's policies with respect to surveys being unannounced.

++ URAC'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 URAC'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.

The October 24, 2019 proposed notice also solicited public comments regarding whether URAC's requirements met or exceeded the Medicare CfCs for home infusion therapy. No comments were received in response to our proposed notice.

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.

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Evell J. Barco Holland,

Federal Register Liaison,

Department of Health and Human Services.

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