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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3390–FN]

Medicare Program; Approval of Application by the Accreditation Commission for Healthcare 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 Accreditation Commission for Healthcare 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 April 23, 2020 through April 23, 2024.

FOR FURTHER INFORMATION CONTACT: Christina Mister-Ward, (410) 786–2441. Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION:

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 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. 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 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.

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 approve or deny the application.

III. Provisions of the Proposed Notice

In the November 25, 2019 **Federal Register** (84 FR 64904), we published a proposed notice announcing Accreditation Commission for Health Care's (ACHC's) request for initial approval of its Medicare HIT accreditation program. In the November 25, 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 ACHC 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 ACHC'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 an ACHC to conduct timely review of accreditation applications.
- The ability of an ACHC to take into account the capacities of suppliers located in a rural area.
- The comparison of an ACHC's Medicare home infusion therapy accreditation program standards to our current Medicare home infusion therapy conditions for coverage (CfCs).
- ACHC's survey process to determine the following:

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

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

++ Evaluate ACHC's procedures for monitoring home infusion therapies it has found to be out of compliance with ACHC's program requirements.

++ Assess ACHC'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 ACHC'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 ACHC's staff and other resources.

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

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

++ Review ACHC'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 ACHC'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 November 25, 2019 proposed notice also solicited public comments regarding whether ACHC'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 ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared ACHC'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 ACHC'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, ACHC has completed revising its standards and certification processes in order to meet the condition at:

- § 486.520(c), to address the requirement of the plan of care must be periodically reviewed by the physician.
- § 486.525(a)(3), to address the requirement of remote monitoring for the provision of home infusion therapy.
- § 488.1010(a)(6)(iv), to revise ACHC's survey procedures for surveys.
- § 488.1010(a)(6)(v), to revise ACHC'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 ACHC's procedures and timelines for monitoring the home infusion therapy supplier's correction of identified non-compliance with the accreditation program's standards.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that ACHC's requirements for HITs meet or exceed our requirements. Therefore, we approve ACHC as a national accreditation organization for HITs that request participation in the Medicare program, effective April 23, 2020 through April 23, 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, 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–1987–P–0074]

Canned Pacific Salmon Deviating From Identity Standard; Amendment of Temporary Marketing Permit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending Bumble Bee Seafoods Inc.'s temporary permit to market test canned skinless and boneless chunk salmon packed in water that contains sodium tripolyphosphate to inhibit protein curd formation during retorting. The temporary permit is amended to allow for the canned skinless and boneless chunk salmon packed in water with or without sodium tripolyphosphate and to update the manufacturing location. This amendment will allow the applicant to continue to test market the test product and collect data on consumer acceptance of the test product.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 13, 1987 (52 FR 26186), we issued a notice announcing that we had issued a temporary permit to Bumble Bee Seafoods, Inc., San Diego, CA 92123, to market test products identified as canned skinless and boneless chunk salmon packed in water and containing added sodium tripolyphosphate to inhibit protein curd formation during retorting. The permit allowed for the test product to be manufactured at a plant located in Petersburg, AK. We issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for canned Pacific salmon in 21 CFR 161.170, which were issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

In the **Federal Register** of April 8, 1988 (53 FR 11710), we issued a notice announcing that we had amended the temporary permit to permit the test product be manufactured at one additional plant, Chugach Alaska Fisheries, Inc., Ocean Dock Rd., Cordova, AK 99574. In the **Federal Register** of September 6, 1988 (53 FR 34354), we issued another notice announcing that we were extending the expiration date of the permit to either the effective date of a final rule for any proposal to amend the standard of identity for canned Pacific salmon that may result from the National Food Processors Association's petition, submitted on behalf of Bumble Bee Seafoods, Inc., and other salmon packers holding temporary permits, or 30 days after termination of such proposal.

Under our regulations at 21 CFR 130.17(f), we are amending the temporary permit issued to Bumble Bee Seafoods, Inc., to allow for the canned skinless and boneless chunk salmon packed in water with or without sodium tripolyphosphate and to allow the test product to be manufactured only at one