appropriate component office of the Commission.

The FMC will implement a new web portal, the FMC Assistance Center, available through the agency's website to collect this information from the public. The collected information will be internally routed to the appropriate component office for response. As this collection includes inquiries related to dispute resolution services, it also encompasses Forms FMC–32 (Dispute Resolution Service Request—Cruise) and FMC–33 (Dispute Resolution Service Request—Cargo). Forms FMC–32 and FMC 33 have been modified in the Affirmation section to remove a statement directing the public to a link on the agency web page and to add a statement that the matter will be closed if false statements and documents are provided. These forms and the Assistance Center screen mock-ups are included in this docket. The burden associated with these forms is included in this collection.

Current Actions: The information being submitted contains a new data collection.

Type of Review: New information collection.

Needs and Uses: The Commission will use the FMC Assistance Center (web portal) to receive requests from the public and ensure prompt response to the shipping public.

Frequency: This information will be collected when members of the public choose to submit it.

Type of Respondents: Individuals and establishments who wish to ask questions, express concerns, or submit complaints to the Federal Maritime Commission.

Number of Annual Respondents: The Commission estimates an annual respondent universe of 5,000. The Commission further estimates 300 of these responses will require attaching an FMC form related to dispute resolution services (FMC–32 or FMC–33).

Estimated Time per Response: The time per response is estimated at 6 minutes per response for submissions that do not involve attaching forms and 20 minutes for responses requiring attaching forms.

Total Annual Burden: Burden is calculated as 4,700 × 6 minutes = 470 hours per portal submission that does not also include a form and 300 × 20 minutes = 100 hours for a submission that also includes either FMC–32 or FMC–33. Total burden equals 570 hours.

Carl Savoy,

Federal Register Alternate Liaison Officer.

[FR Doc. 2023–24785 Filed 11–8–23; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS 3452–PN]

Medicare Program; Application by the Utilization Review Accreditation Commission (URAC) for Continued CMS Approval of Its Home Infusion Therapy (HIT) Accreditation Program

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

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from the Utilization Review Accreditation Commission (URAC) for continued approval by the Centers for Medicare & Medicaid Services (CMS) of URAC's national accrediting organization program for suppliers providing home infusion therapy (HIT) services and that wish to participate in the Medicare or Medicaid programs. The statute requires that within 60 days of receipt of an organization's complete application, CMS will publish 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, by December 11, 2023.

ADDRESSES: In commenting, refer to file code CMS–3452–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–3452–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–3452–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: 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. We will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. We continue to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other 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. 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)(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 Deeming Organization

Section 1834(u)(5) of the Act and regulations at 42 CFR 488.1010 require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization'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 rules at 42 CFR 488.1020(a) require that we publish, after receipt of an organization's complete application, 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. Pursuant to our rules at 42 CFR 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 of the Utilization Review Accreditation Commission (URAC) request for CMS' continued recognition of its HIT accreditation program. This notice also solicits public comment on whether URAC's requirements meet or exceed the Medicare requirements of participation for HIT services.

III. Evaluation of Deeming Authority Request

In the October 24, 2019, **Federal Register**, we published URAC's initial application for recognition as an accreditation organization for HIT (84 FR 57021). On April 1, 2020, we published notification of their approval as such an organization, effective March 27, 2020, through March 27, 2024 (84 FR 18243). URAC has since submitted all the necessary materials to enable us to make a determination concerning its request for continued recognition of its HIT accreditation program. This application was determined to be complete on August 30, 2023. Under section 1834(u)(5) of the Act and 42 CFR 488.1010 (Application and re-application procedures for national home infusion therapy accrediting organizations), our review and evaluation of URAC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of URAC's standards for HIT as compared with CMS' HIT requirements for participation in the Medicare program.
- URAC'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 URAC's to CMS' standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

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

++ URAC's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

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

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

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

++ 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 CMS may require (including corrective action plans).

++ URAC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions.

++ URAC's agreement or policies for voluntary and involuntary termination of HIT suppliers.

++ URAC's agreement or policies for voluntary and involuntary termination of the HIT AO program.

IV. 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.*).

V. Response to 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.

The Administrator of the Centers for Medicare & Medicaid Services (CMS),

Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–24850 Filed 11–8–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1716]

Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry and the public on the requirements related to cosmetic product facility registration and cosmetic product listing under the Federal Food, Drug, and Cosmetic Act (FD&C Act) entitled ''Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.'' This guidance announces FDA's intention to delay enforcement of the requirements related to cosmetic product facility registration and cosmetic product listing for an additional 6 months after the initial December 29, 2023, deadline.

DATES: The announcement of the guidance is published in the **Federal Register** on November 9, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2023–D–1716 for ''Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing; Guidance for Industry; Availability.'' 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, 240–402–7500.

- 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Jennifer Ross, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–4880 (this is not a toll-free number), email: *QuestionsAboutMoCRA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry and the public entitled ''Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.'' This guidance is intended to assist owners or operators of cosmetic product facilities that are subject to the requirements related to facility registration and responsible persons that are subject to the requirements related to cosmetic product listing under the FD&C Act. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public