performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Collection title: Recordkeeping and Disclosure Requirements Associated with CFPB's Regulation Z.

Collection identifier: FR Z.

OMB control number: 7100–0199.

General description of collection: The Truth in Lending Act (TILA) and Regulation Z require creditors to provide consumers with disclosures about the costs, terms, and related information regarding a wide range of credit products for personal, family, or household purposes. Depending on the credit product, required disclosures include information that must be provided at the time of the consumer's application for credit, at consummation (for closed-end credit) or account-opening (for open-end credit), and throughout the term of the loan. The TILA and Regulation Z also contain rules concerning recordkeeping and credit advertising.

The FR Z is the Board's information collection associated with the Consumer Financial Protection Bureau's (CFPB's) Regulation Z. FR Z is used to promote the informed use of credit by consumers for personal, family, or household purposes by requiring these disclosures about the terms and costs of these products, as well as ensuring that consumers are provided with timely information on the nature and costs of the residential real estate settlement process.

Frequency: Event-generated.

Respondents: State member banks with assets of $10 billion or less that are not affiliated with an insured depository institution with assets over $10 billion (irrespective of the consolidated assets of any holding company); non-depository affiliates of such state member banks; and non-depository affiliates of bank holding companies that are not affiliated with an insured depository institution with assets over $10 billion.

Total estimated number of respondents: 3,695.

Total estimated annual burden hours: 387,079.

Board of Governors of the Federal Reserve System, June 4, 2024.

Benjamin W. McDonough,

Deputy Secretary and Ombuds of the Board.

[FR Doc. 2024–12500 Filed 6–6–24; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3457–PN]

Medicare and Medicaid Programs: Application by the Community Health Accreditation Partner (CHAP) Inc. for Continued CMS-Approval of Its Hospice Accreditation Program

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

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from the Community Health Accreditation Partner for continued recognition as a national accrediting organization for hospices that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 8, 2024.

ADDRESSES: In commenting, refer to file code CMS–3457–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–3457–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–3457–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Lillian Williams, (410) 786–8636.

Erin Imhoff, (410) 786–2337.

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.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice, provided that certain requirements are met by the hospice. Section 1861(dd) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a hospice. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 418 specify the conditions that a hospice must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for hospice services.

Generally, to enter into an agreement, a hospice must first be certified by a State survey agency (SA) as complying with the conditions or requirements set forth in part 418. Thereafter, the hospice is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

However, section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national Accrediting Organization (AO) that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) 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 AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at §§ 488.4 and 488.5. The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

Community Health Accreditation Partner's (CHAP's) current term of approval for their hospice accreditation program expires February 24, 2025.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 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 for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of 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. 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 CHAP request for continued approval of its hospice accreditation program. This notice also solicits public comment on whether the CHAP's requirements meet or exceed the Medicare conditions of participation (CoPs) for hospices.

III. Evaluation of Deeming Authority Request

CHAP submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its hospice accreditation program. This application was determined to be complete on April 20, 2024. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national AO) our review and evaluation of CHAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of CHAP's standards for hospices as compared with CMS' hospice CoPs.
- CHAP'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 CHAP's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ CHAP's processes and procedures for monitoring hospices, which are found out of compliance with CHAP's program requirements. These monitoring procedures are used only when CHAP identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the SA monitors corrections as specified at § 488.9.

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

++ CHAP's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of CHAP's staff and other resources, and its financial viability.

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

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

++ CHAP'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.

++ CHAP'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).

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 Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document forpurposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–12495 Filed 6–6–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2390]

Proposal To Refuse To Approve a New Drug Application Supplement for HETLIOZ (Tasimelteon); Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Director of the Center for Drug Evaluation and Research (Center Director) at the Food and Drug Administration (FDA or Agency) is