days. The A series of worksheets collects the provider's trial balance of expenses for overhead costs, direct patient care services, and non-revenue generating cost centers. The B series of worksheets allocates the overhead costs to the direct patient care and non-revenue generating cost centers using functional statistical bases. The Worksheet C computes the apportionment of costs between Medicare beneficiaries and other patients. The D series of worksheets are Medicare specific and calculate the reimbursement settlement for services rendered to Medicare beneficiaries. The Worksheet F collects the provider's revenues and expenses data from the provider's income statement. *Form Number:* CMS–2088–17 (OMB control number: 0938–0378); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 191; *Total Annual Responses:* 191; *Total Annual Hours:* 17,190. (For policy questions regarding this collection contact Jill Keplinger at 410–786–4550.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–21055 Filed 9–16–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3465–PN]

Medicare and Medicaid Programs; Application From the Accreditation Commission for Health Care, Inc. (ACHC) for Continued Approval of Its Home Health Agency Accreditation Program

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

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of an application from the Accreditation Commission for Health Care, Inc. (ACHC) for continued recognition as a national accrediting organization for home health agencies (HHAs) 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, the Centers for Medicare & Medicaid Services (CMS) must 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, no later than 5 p.m. on October 17, 2024.

ADDRESSES: In commenting, refer to file code CMS–3465–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–3465–PN, P.O. Box 8013, Baltimore, MD 21244–8013.

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–3465–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:

Erin Imhoff (410) 786–2337.

Lillian Williams (410) 786–8636.

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. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues 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

Under the Medicare program, eligible beneficiaries may receive covered services from a home health agency (HHA), provided 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 surveys by state agencies. 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 the 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. The regulations at § 488.5(e)(2)(i) require accrediting organizations to reapply for continued approval of their accreditation program every 6 years or sooner as determined by CMS.

Accreditation Commission for Health Care, Incorporated's (ACHC's) term of approval for their HHA 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 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 us 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, a description of the nature of the request, and provision of 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 ACHC's request for continued CMS approval of its HHA accreditation program. This notice also solicits public comment on whether ACHC's requirements meet or exceed the Medicare conditions of participation (CoPs) for HHAs.

III. Evaluation of Deeming Authority Request

ACHC submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its HHA accreditation program. This application was determined to be complete on July 29, 2024. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of ACHC will be conducted in accordance with, but not necessarily limited to, the following factors:

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

++ ACHC's processes and procedures for monitoring HHAs found out of compliance with ACHC's program requirements. These monitoring procedures are used only when ACHC identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state survey agency monitors corrections as specified at § 488.9(c).

++ ACHC's capacity to report deficiencies to the surveyed HHAs and respond to the HHA's plan of correction in a timely manner.

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

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

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

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

++ 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.

++ ACHC's agreement to provide us 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 Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

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 notice. Upon completion of our evaluation, including evaluation of comments received because of this notice, we will publish a final notice in the **Federal Register** summarizing our response to comments and announcing the result of our evaluation.

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. 2024–21014 Filed 9–16–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1492]

Chemistry, Manufacturing, and Controls Technical Section Filing Strategies; Draft 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 draft guidance for industry (GFI) #227 entitled ''Chemistry, Manufacturing, and Controls (CMC) Technical Section Filing Strategies.'' This draft guidance provides recommendations to sponsors submitting CMC data submissions to new animal drug applications. This guidance describes the options for soliciting early input from the Center for Veterinary Medicine (CVM) and the process for submission of components of the CMC technical section.

DATES: Submit either electronic or written comments on the draft guidance by November 18, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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,