DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3460–PN]

Medicare and Medicaid Programs: Application by the DNV Healthcare USA, Inc. for Continued CMS-Approval of Its Critical Access Hospital 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 DNV Healthcare USA, Inc. for continued recognition as a national accrediting organization for critical access hospitals 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 15, 2024.

ADDRESSES: In commenting, please refer to file code CMS–3460–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–3460–PN, P.O. Box 8010, 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–3460–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: Caecilia Andrews, (410) 786–2190.

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 critical access hospital (CAH), provided that certain requirements are met by the CAH. Section 1861(mm) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as a CAH. 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 485, subpart F specify the conditions that a CAH must meet to participate in the Medicare program.

Generally, to enter into an agreement, a CAH must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 485 of our regulations. Thereafter, the CAH 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 states, if a provider entity demonstrates through accreditation by an 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 Centers for Medicare & Medicaid Services (CMS) 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 us 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 § 488.5. The regulations at § 488.5(e)(2)(i) require an AO to reapply for continued approval of its accreditation program every 6 years or as determined by CMS.

The DNV Healthcare USA, Inc.'s (DNV's) current term of approval for their critical access hospital accreditation program expires December 23, 2024.

II. Approval of Accreditation 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 DNV's request for continued approval of its CAH accreditation program. This notice also solicits public comment on whether the DNV requirements meet or exceed the Medicare conditions of participation (CoPs) for CAHs.

III. Evaluation of Deeming Authority Request

DNV submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its CAH accreditation program. This application was determined to be complete on March 1, 2024. Under 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 the DNV CAH accreditation program will be conducted in accordance with, but not necessarily limited to, the following factors:

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

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

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

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

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

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

++ DNV'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.

++ DNV'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. Chapter 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 for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10398]

Agency Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice of request for reinstatement of a previously approved information collection.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the ''generic'' clearance process. Generally, this is an expedited clearance process by which agencies may obtain OMB's approval of collection of information requests that are ''usually voluntary, low-burden, and uncontroversial,'' do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that may be submitted under that umbrella. This notice is intended to advise the public of our intent to reinstate OMB's approval of our generic umbrella (CMS–10398, OMB control number 0938–1148) and all of the individual generic collection of information requests that fall under that umbrella. This notice also provides the public with general instructions for obtaining documents that are associated with such collections and for submitting comments.

DATES: Comments must be received by August 12, 2024.

ADDRESSES:

Submitting comments: When commenting, please reference the applicable collection's CMS ID number and/or the OMB control number (both numbers are listed below under the **SUPPLEMENTARY INFORMATION** caption). To be assured consideration, comments and recommendations must be submitted in any one of the following ways and by the applicable due date:

1. *Electronically.* We encourage you to submit comments through the Federal eRulemaking portal at the applicable web address listed below under the **SUPPLEMENTARY INFORMATION** caption under ''Docket Information.'' If needed, instructions for submitting such comments can be found on that website.

2. *By regular mail.* Alternatively, you can submit written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs (OSORA), Division of Regulations Development, Attention: CMS–10398/OMB 0938–1148, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Obtaining documents: To obtain copies of supporting statements and any related forms and supporting documents for the collections listed in this notice, we encourage you to access the Federal eRulemaking portal at the applicable web address listed below under the **SUPPLEMENTARY INFORMATION** caption under ''*Docket Information*'' and ''Docket Web Address.'' If needed, follow the online instructions for accessing the applicable docket and the documents contained therein.

FOR FURTHER INFORMATION CONTACT: For general information contact William N. Parham at 410–786–4669. For policy related questions contact the individual listed below under the **SUPPLEMENTARY INFORMATION** caption under ''*Docket Information.*''

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information that they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). Generally, it applies to voluntary and mandatory requirements that are related to any one or more of the following activities: the collection of information, the reporting of information, the disclose of information to a third-party, and/or recordkeeping.

While there are some exceptions (such as collections having non-substantive changes and collections requesting emergency approval) section