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William N. Parham III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3460–FN]

Medicare and Medicaid Programs: Approval of 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.

SUMMARY: This notice acknowledges the approval of an application by 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.

FOR FURTHER INFORMATION CONTACT: Caecilia Andrews, (410) 786–2190.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a critical access hospital (CAH), provided that the facility meets certain requirements. Sections 1820(c)(2)(B), 1820(e), and 1861(mm)(1) of the Social Security Act (the Act) establish 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. Our regulations at 42 CFR part 485, subpart F specify the conditions of participation (CoPs) that a CAH must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for CAHs. The regulations at § 485.647 specify that a CAH's psychiatric or rehabilitation

distinct part unit (DPU), if any, must meet the hospital requirements specified in subparts A, B, C, and D of part 482 in order for the CAH DPU to participate in the Medicare program.

Prior to becoming a CAH, to enter into an agreement, a CAH must first be certified by a state survey agency as a hospital complying with the conditions of participation at 42 CFR part 482. It then can convert to a CAH by complying with the conditions or requirements at part 485, subpart F. 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. Certification by a nationally recognized accreditation program can substitute for ongoing state review.

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 requirements are met or exceeded, we will deem those provider entities as having met such 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 requirements. A national AO applying for approval of its accreditation program under 42 CFR 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 requirements.

Our regulations concerning the approval of AOs are at §§ 488.4 and 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 sooner, as determined by CMS. This notice is to announce our continued approval of the DNV Healthcare USA, Inc.'s (DNV's) CAH accreditation program for a period of 4 years.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with

any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On June 13, 2024, we published a proposed notice in the **Federal Register** (89 FR 50332), announcing DNV's request for continued approval of its Medicare critical hospital accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of DNV's Medicare CAH accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An administrative review of DNV's:
 - (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.
- A comparison of DNV's accreditation to our current Medicare CAH conditions of participation (CoPs).
- A documentation review of DNV's survey process to:
 - ++ Determine the composition of the survey team, surveyor qualifications, and DNV's ability to provide continuing surveyor training.
 - ++ Compare DNV's processes to those of state survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
 - ++ Evaluate DNV's procedures for monitoring CAHs out of compliance with DNV's program requirements. The monitoring procedures are used only when DNV identifies noncompliance. If noncompliance is identified through validation reviews, the state survey agency monitors corrections as specified at § 488.7(d).
 - ++ Assess DNV's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
 - ++ Establish DNV'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 staff and other resources.

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

++ Confirm DNV's policies with respect to whether surveys are unannounced.

++ Obtain 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. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the June 13, 2024 proposed notice also solicited public comments regarding whether DNV's requirements met or exceeded the Medicare CoPs for CAHs. We did not receive any comments.

V. Provisions of the Final Notice

A. Differences Between DNV's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared DNV's CAH requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of DNV's CAH application were conducted as described in section III. of this notice and has yielded the following areas where, as of the date of this notice, DNV's has completed revising its standards and certification processes in order to:

- Meet the standard's requirements of all of the following regulations:

++ Section 485.614, to incorporate language ensuring promotion and protection of each patient's rights.

++ Section 485.614(b)(4), to incorporate language ensuring the patient's family member or representative of their choice and their own physician are notified promptly of their admission to the hospital.

++ Section 485.614(d)(2), to incorporate language that the patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format.

++ Section 485.618(d)(1)(ii)(A), to add the definition of a CAH that is located in an area designated as a frontier area.

++ Section 485.625(d), to specify that the CAH must review and update its

emergency preparedness training program at least every two years.

++ Section 485.625(d)(1), to include language that training must include: prompt reporting and extinguishing of fires; protection and, where necessary, evacuation, of patients, personnel, and guests; fire prevention; and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

++ Section 485.625(d)(1)(iv), to specify that staff must be able to demonstrate knowledge of their role during an emergency.

++ Section 485.627(b), to include the requirement for addresses within the disclosure.

++ Section 485.631(a)(3), to clarify that staff is sufficient to provide the services essential to the operation of the CAH.

++ Section 485.638(b)(2), to provide additional language that there must be written policies and procedures that govern the use and removal of records from the CAH and the conditions for the release of information.

++ Section 485.639(c), to revise the language from "directing" to "administering" anesthesia.

++ Section 485.639(c)(2), to clarify the requirement surrounding a Certified Registered Nurse Anesthetist supervision requirements under the operating practitioner when administering anesthesia.

++ Section 485.640, to include that the CAH's infection prevention and control and antibiotic stewardship program is an active facility-wide program.

++ Section 485.645(d)(5), to encompass the notation of comprehensive assessment of a resident's needs, strengths, goals, life history and preferences.

++ Section 485.645(d)(8), to state "assisted nutrition and hydration."

In addition to the standards review, we also reviewed DNV's comparable survey processes, which were conducted as described in section III. of this notice, and yielded the following areas where, as of the date of this notice, DNV has completed revising its survey processes, in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- Revising DNV's complaint policy to reflect that any withdrawals from accreditation and deemed status, whether voluntary or involuntary, must be reported within three business days.

- Revising DNV's internal policies to ensure all surveyors are qualified.

- Providing training and education to surveyors to ensure records are reviewed and reported consistently on DNV's survey report.

- Developing a process to verify levels of deficiency citations for the physical environment and Life Safety Codes citations to ensure facilities are appropriately cited based on the potential for harm.

- Ensuring citations are closely aligned or cross-walked from DNV's standard to the Medicare condition(s).

- Developing process or policy to ensure swing beds are reviewed, when applicable, and providing education to surveyors to adequately annotate swing bed reviews in DNV's surveyor notes.

- Providing additional education to surveyors related to observations of care and patient interviews.

- Providing additional clarifications on the survey process for medical record reviews comparable to those in the SOM, Appendix W.

B. Term of Approval

Based on our review and observations described in section III. and section V. of this notice, we approve DNV as a national AO for CAHs that request participation in the Medicare program. The decision announced in this final notice is effective December 23, 2024 through December 23, 2028 (4 years).

VI. 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.*).

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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