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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3357-FN]

Medicare and Medicaid Program; Application from DNV GL—Healthcare (DNV GL) for Continued Approval of its Hospital Accreditation Program

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the DNV GL-- Healthcare for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: This decision is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] through September 26, 2022.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital, provided that certain requirements are met. Section 1861(e) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as a hospital. 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

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part 482 specify the minimum conditions that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 482 of our regulations. Thereafter, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, 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 may 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 the Department 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 may be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide the Centers for Medicare and Medicaid Services (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 its accreditation program every 6

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years or sooner as determined by CMS. DNV GL's current term of approval for their hospital accreditation program expires September 26, 2018.

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

In the April 17, 2018 **Federal Register** (83 FR 16862), we published a proposed notice announcing DNV GL's request for continued approval of its Medicare 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 GL's Medicare hospital accreditation renewal application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of DNV GL's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its hospital surveyors; (4) ability to investigate and respond

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appropriately to complaints against accredited hospitals; and, (5) survey review and decision-making process for accreditation.

- The comparison of DNV GL's Medicare hospital accreditation program standards to our current Medicare hospitals Conditions of Participation (CoPs).

- A documentation review of hospital's survey process to:

- ++ Determine the composition of the survey team, surveyor qualifications, and DNV GL's ability to provide continuing surveyor training.

- ++ Compare DNV GL's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited hospitals.

- ++ Evaluate DNV GL's procedures for monitoring hospitals it has found to be out of compliance with DNV GL's program requirements. (This pertains only to monitoring procedures when DNV GL identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at §488.9(c)).

- ++ Assess DNV GL's ability to report deficiencies to the surveyed hospital and respond to the hospital's plan of correction in a timely manner.

- ++ Establish DNV GL's ability to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ Determine the adequacy of DNV GL's staff and other resources.

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

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++ Confirm DNV GL's policies with respect to surveys being unannounced.

++ Obtain DNV GL'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.

In accordance with section 1865(a)(3)(A) of the Act, the April 17, 2018 proposed notice also solicited public comments regarding whether DNV GL's requirements met or exceeded the Medicare CoPs for hospitals. We received two comments in response to our proposed notice. All of the comments received expressed unanimous support for DNV GL's hospital accreditation program.

IV. Provisions of the Final Notice

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

We compared DNV GL's hospital accreditation program requirements and survey process with the Medicare CoPs at 42 CFR Part 482, and the survey and certification process requirements of Parts 488 and 489. Our review and evaluation of DNV GL's hospital application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, DNV GL has revised its standards and certification processes in order to meet the requirements at:

- Section 482.11 through 482.58, to ensure its standards replace the use of the word "shall" to "must" in all situations where CMS regulations use the word "must" or, clarify in DNV's glossary the intended definition of the word "shall" means "must."
- State Operations Manual, Section 3012, to ensure that DNV GL's policies related

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to the timeframe(s) for follow-up activities, including follow-up surveys, for facilities that have previously demonstrated non-compliance at the condition level.

- Section 488.5(a)(4)(iv), to ensure that the hospital and provider-based locations (or a sample when allowed) are included in the hospital survey and deficiencies cited under the appropriate CoPs.

- Section 488.5(a)(11)(ii), to ensure that the data submitted in to CMS is timely, complete and accurate.

- Section 488.5(a)(12), to ensure a clearly defined complaint investigation process is in place that meets the requirements in the State Operations Manual Chapter 5 Section 5010 and Chapter 5 Section 5075.2 that includes the following:

- ++ Complete and accurate tracking of complaints as well as a process for maintaining a documented record of contacts made (for example, phone, email and United States mail) with the complainant, and others, if applicable;

- ++ Define the number of contact attempts required before closing out a complaint, if the complainant does not respond;

- ++ Educate DNV GL complaint intake staff that when complaint allegations could potentially result in condition-level non-compliance affecting the health and safety of patients, a survey is to be considered regardless if the allegation also involves payment related allegations; and,

- ++ The complaint must be investigated onsite within an appropriate timeframe.

- Section 488.26(b), to ensure that DNV GL survey documentation includes a detailed deficiency statement that clearly supports the manner and degree of non-compliance and

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that all observed non-compliance is cited at the appropriate level (condition verses standard level).

- Section 488.26(c)(4), to ensure that DNV GL surveyors review a sufficient number of inpatient and outpatient medical records during the survey process; the appropriate number of documents, logs, personnel and credentialing files are reviewed during the survey process; the document sources are clearly identified in the survey file; and that DNV GL surveyors have been appropriately trained and determined by DNV GL to be competent in identifying Immediate Jeopardy (IJ) situations and appropriateness of facility actions to mitigate IJ risk factors prior to the exit of the survey team.

- Section 488.28(a), to ensure that the corrective action plan submitted by hospitals fully addresses the deficiencies cited and that the hospital's corrective actions are hospital wide and not focused solely on the area in which the deficiency was identified.

- Section 488.28(d), to ensure that all corrective action plans contain an expected correction completion date, consistent with CMS requirements.

- Section 488.18(a), to ensure all observations of non-compliance are adequately documented in the survey report and ensure corrective action is required by the hospital.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve DNV GL as a national accreditation organization for hospitals that request participation in the Medicare program, effective [Insert date of publication in the **Federal Register**] through September 26, 2022.

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To verify DNV GL's continued compliance with the provisions of this final notice, CMS will conduct a follow-up corporate on-site visit and survey observation within 18 months of the publication date of this notice.

V. 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.).

Dated: August 6, 2018.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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