DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3388–FN]

Medicare and Medicaid Programs; Application From DNV GL Healthcare USA Inc. for Initial CMS Approval of Its Psychiatric Hospital Accreditation Program

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve DNV GL Healthcare USA Inc. (DNV GL) for initial recognition as a national accrediting organization for psychiatric hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this final notice is effective July 30, 2020 through July 30, 2024.

FOR FURTHER INFORMATION CONTACT: Joann Fitzell, (410) 786–4280. Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a psychiatric hospital provided certain requirements established by the Secretary of the Department of Health and Human Services (the Secretary) are met. Section 1861(f) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a psychiatric hospital under Medicare. Regulations concerning provider agreements and supplier approval 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 482 subparts A, B, C and E specify the minimum conditions that a psychiatric hospital must meet to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for psychiatric hospitals.

Generally, to enter into a provider agreement with the Medicare program, a psychiatric hospital must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 482 subpart A, B, C and E of Centers for Medicare & Medicaid Services (CMS) regulations. Thereafter, the psychiatric hospital is subject to regular surveys by a state survey agency to determine whether it continues to meet the Medicare 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 may treat the provider entity as having met those conditions, that is, we may deem the provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by CMS 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 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 § 488.5. The regulations at § 488.5(e)(2)(i) require the AO to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

II. Application Approval Process

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that findings concerning review and approval of an 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 that were 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 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 CMS 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, CMS 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, CMS must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On March 2, 2020 **Federal Register** (85 FR 12306), we published a proposed notice announcing DNV GL Healthcare USA Inc. (DNV GL) request for approval of its Medicare psychiatric 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 psychiatric hospital accreditation 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 psychiatric hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited psychiatric hospitals; and, (5) survey review and decision-making process for accreditation.
- The comparison of DNV GL's Medicare psychiatric hospital accreditation program standards to our current Medicare hospitals Conditions of Participation (CoPs) and psychiatric hospital special CoPs.
- A documentation review of DNV GL's psychiatric hospital survey process to do the following:

++ 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 re-survey and the ability to investigate and respond appropriately to complaints against accredited psychiatric hospitals.

++ Evaluate DNV GL's procedures for monitoring psychiatric 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 as 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)(1)).

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

++ Establish DNV GL'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 DNV GL's staff and other resources.

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

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

++ Confirm DNV GL'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.

++ Obtain DNV GL'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.

++ As authorized under § 488.8(h), CMS reserves the right to conduct onsite observations of accrediting organization's operations at any time as part of the ongoing review and continuing oversight of an AO's performance.

In accordance with section 1865(a)(3)(A) of the Act, the March 2, 2020 proposed notice also solicited public comments regarding whether DNV GL's requirements met or exceeded the Medicare CoPs for psychiatric hospitals. We received 4 comments in response to our proposed notice. We thank the commenters for their support. We agreed with the commenters that a new psychiatric hospital accreditation organization would provide hospitals further options in regards to accreditation. Based on our comprehensive review of their program, we have approved DNV GL as such a 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 psychiatric 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 psychiatric 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 482.41(c)(1):* DNV GL revised its standards to not require the hospitals to adopt Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code.
- *Section 482.61(a) through (a)(3):* DNV GL revised its standards to require a diagnosis for all patients.
- *Section 482.61(b):* DNV GL revised its standards to require a record of mental status.
- *State Operations Manual Chapter 3 Section 3012:* DNV GL revised its materials to reflect its 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)(12):* DNV GL revised its policies 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.

++ Defining the number of contact attempts required before closing out a complaint if the complainant does not respond.

++ Educating 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.

++ Investigating complaints onsite within an appropriate timeframe.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that DNV GL's psychiatric hospital accreditation program requirements meet or exceed our requirements, and its survey processes are also comparable. Therefore, we approve DNV GL as a national AO for psychiatric hospitals that request participation in the Medicare program, effective July 30, 2020 through July 30, 2024.

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.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 24, 2020.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1339]

Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff; 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 final guidance entitled ''Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff.'' This final guidance provides FDA's regulatory approach for device products with multiple functions including at least one device function and includes such device products that are part of combination products, in accordance with the 21st Century Cures Act (Cures Act).

DATES: The announcement of the guidance is published in the **Federal Register** on July 29, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a