at 42 CFR part 485, subpart H specify the minimum conditions that an OPT must meet to participate in the Medicare program.

Generally, to enter into an agreement, an OPT must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 485, subpart H of our Medicare regulations. Thereafter, the OPT 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 a CMS-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 (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 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 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 § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF's) current term of approval for their OPT accreditation program expires April 22, 2015.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.8(a) 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, 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 AAAASF's request for continued approval of its OPT accreditation program. This notice also solicits public comment on whether AAAASF's requirements meet or exceed the Medicare conditions of participation (CoPs) for OPTs.

III. Evaluation of Deeming Authority Request

AAAASF submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its OPT accreditation program. This application was determined to be complete on September 29, 2014. Under Section 1865(a)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of AAAASF will be conducted in accordance with, but not necessarily limited to, the following factors:

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

—AAAASF's processes and procedures for monitoring a OPT found out of compliance with AAAASF's program requirements. These monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state survey agency monitors corrections as specified at § 488.7(d).

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

—AAAASF'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 AAAASF's staff and other resources, and its financial viability.

—AAAASF's capacity to adequately fund required surveys.

—AAAASF's policies to assure that surveys are unannounced.

—AAAASF's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey that CMS may request (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.

V. Response to Public 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.

Dated: November 5, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27649 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3301–FN]

Medicare and Medicaid Programs; Continued Approval of DNV GL—Healthcare (DNV GL) Critical Access Hospital (CAH) Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve DNV GL—Healthcare (DNV GL) [1] for continued recognition as a national accrediting organization (AO) for critical access hospitals (CAH) that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective December 23, 2014 through December 23, 2020.

FOR FURTHER INFORMATION CONTACT: Barbara Easterling, (410) 786–0482, Lillian Williams, 410–786–8636, Cindy Melanson, (410) 786–0310, or Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a Critical Access Hospital (CAH) provided certain requirements are met. 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. The regulations at 42 CFR part 485, subpart F, specify the conditions that a CAH must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for CAHs.

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, 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 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 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 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 § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require an AO to reapply for continued approval of its accreditation program every 6 years or sooner as determined by us. The DNV GL's current term of approval for their CAH accreditation program expires December 23, 2014.

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 with 210 calendar 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 27, 2014, we published a proposed notice in the **Federal Register** (79 FR 36521) announcing DNV GL's request for approval of its CAH accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 and § 488.8, we conducted a review of DNV GL's 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 surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and, (5) survey review and decision-making process for accreditation.
- The comparison of DNV GL's accreditation to our current Medicare CAH conditions of participation (CoPs).
- A documentation review of DNV GL'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 of state survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ Evaluate DNV GL's procedures for monitoring CAHs out of compliance with DNV GL's program requirements. The monitoring procedures are used only when DNV GL identifies noncompliance. If noncompliance is identified through validation reviews, the state survey agency monitors corrections as specified at § 488.7(d).

++ Assess DNV GL's ability to report deficiencies to the surveyed facilities and respond to the facility'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 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 whether surveys are announced or 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 June 27, 2014 proposed notice also solicited public comments regarding whether DNV GL's requirements met or exceeded the Medicare conditions of participation for CAHs. We received no comments in response to our proposed notice.

IV. Provisions of the Final Notice

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

We compared DNV GL's CAH requirements and survey process with the Medicare conditions of participation and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of DNV GL's

[1] Formerly known as Det Norske Veritas Healthcare, Inc. (DNVHC).

CAH accreditation program application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 412.25(d), DNV GL revised its standards to address the number of excluded units permitted.
- To meet the requirements at § 412.27(c)(2)(vii), DNV GL revised its standards to include the requirement for an inventory of the inpatient's assets in a descriptive fashion and ensured that consistent language is used in the crosswalk and manual.
- To meet the requirements at § 412.27(d)(3), DNV GL revised its standards to more fully address nursing services requirements.
- To meet the requirements § 412.27(d)(4), DNV GL revised its standards to address ''service objectives'' for psychological services.
- To meet the requirements at § 412.27(d)(6)(ii), DNV GL revised its standards to address the number of ''qualified therapists, support personnel and consultants'' needed to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.
- To meet the requirements at § 412.29(h), DNV GL revised its standards to ensure a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.
- To meet the requirements at § 482.12(c)(1)(iv), DNV GL revised its standards related to a doctor of optometry.
- To meet the requirements at § 482.12(c)(2), DNV GL revised its standards to address the regulatory language, ''patients are admitted to the hospital only on the recommendation of a licensed practitioner.''
- To meet the requirements at § 482.13(h)(1), DNV GL revised its standards to more fully address the requirement to inform each patient (or ''support person, where appropriate'') of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her rights under this section, and ensured consistent language is used in its manual and crosswalk.
- To meet the requirements at § 482.21(e)(1), DNV GL revised its standards to ensure that an ongoing quality assurance performance improvement program is ''maintained.''
- To meet the requirements at § 482.22(c)(5)(i) through (ii), DNV GL revised its standards to ensure that a medical history and physical is conducted, completed, and updated in accordance with ''hospital policy.''
- To meet the requirements at § 482.25(b)(2)(i), DNV GL revised its crosswalk to address the requirement that all drugs and biologicals must be kept in a secure area, and locked when appropriate.
- To meet the requirements at § 482.27(b)(3)(i), DNV GL revised its standards to more fully address the regulatory language related to HIV testing of blood and blood components from a blood donor who tested negative at the time of donation, but tests reactive for evidence of HIV or HCV infection on a later donation, ''or who is at increased risk for transmitting HIV or HCV infection.''
- To meet the requirements at § 482.30(f), DNV GL revised its crosswalk to address review of professional services.
- To meet the requirements at § 482.41(b)(6), DNV GL revised its standards to include a requirement for the proper routine storage and prompt disposal of all trash.
- To meet the requirements at § 482.41(b)(7), DNV GL revised its standards to address the evacuation and relocation plan requirement, periodic instruction for employees and a readily available plan in the telephone operator's position at the security center.
- To meet the requirements at § 483.12(a)(8), DNV GL revised its standards to address written advance notice of facility closure.
- To meet the requirements at § 483.15(f)(2)(i), DNV GL revised its standards to address this requirement for a qualified therapeutic recreational specialist or an activities professional.
- To meet the requirements at § 483.15(f)(2)(i), DNV GL revised its standards to include standards requiring a qualified therapeutic recreation specialist.
- To meet the requirements at § 483.55(a)(1), DNV GL revised its standards to address the requirement that the facility provide or obtain from an outside resource, routine and emergency dental services to meet the needs of each resident.
- To meet the requirements at § 485.604(c)(3), DNV GL revised its standards to include the requirement that physician assistants must have been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.
- To meet the requirements at § 485.604(b)(3), DNV GL revised its standards and crosswalk to address the requirement that the nurse practitioner must have ''been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.''
- To meet the requirements at § 485.604(c)(2)(ii), DNV GL revised its standards to more fully address physician assistant supervised clinical practice and classroom instruction program requirements.
- To meet the requirements at § 485.606, DNV GL revised its referenced standard and crosswalk to address how DNV GL determines that the appropriate CAH designations and certifications have been made by CMS and/or the state agency.
- To meet the requirements at § 485.608, DNV GL revised its standards to include compliance with federal, state and local CAH laws and regulations and to reconcile the inconsistent language between the manual and crosswalk.
- To meet the requirements at § 485.608(a), DNV GL revised its standards to address the requirement that the CAH must be licensed in accordance with federal ''regulations.''
- To meet the requirements at § 485.608(b), DNV GL revised its standards and crosswalk to address the requirement that all patient services are furnished in accordance with applicable ''local'' laws, and to address furnishing patient care services in accordance with state and local ''regulations.''
- To meet the requirements at § 485.608(c), DNV GL revised its standards to address the requirement that the CAH is licensed in accordance with applicable federal, state, and local ''regulations.''
- To meet the requirements at § 485.608(d), DNV GL revised its standards to address the requirement that staff of the CAH are ''licensed, certified, or registered in accordance with applicable federal, state, and local regulations.''
- To meet the requirements at § 485.612, DNV GL revised its standards to ensure the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.
- To meet the requirements at § 485.616(a), DNV GL revised its standards and crosswalk to address agreements with network hospitals.
- To meet the requirements at § 485.616(b), DNV GL revised its standards and crosswalk to address agreements for credentialing and quality assurance.
- To meet the requirements at § 485.616(c) through (c)(1)(ii), DNV GL

revised its standards to address agreements for credentialing and privileging of telemedicine physicians and practitioners.

- To meet the requirements at § 485.616(c)(2)(iv), DNV GL updated their Medicare cross-walk to include standards to address when telemedicine services are provided to the CAH's patients through an agreement with a distant site hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions of the distant site hospital.
- To meet the requirements at § 485.616(c)(3), DNV GL revised its standards to address the governing body of the CAH must ensure that telemedicine services are furnished in accordance with § 485.635(c)(4)(ii) and to ensure consistent language in its crosswalk.
- To meet the requirements at § 485.618(c), DNV GL revised its standards to address the requirement that the facility provide blood and blood products, either directly or under arrangement.
- To meet the requirements at § 485.618(c)(1), DNV GL revised its standards to address the requirement that the facility provide services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hour a day basis.
- To meet the requirements at § 485.618(c)(2), DNV GL revised its standards and crosswalk to address blood storage facilities.
- To meet the requirements at § 485.618(d)(1), DNV GL revised its standards to address personnel requirements and to ensure consistent language in its crosswalk.
- To meet the requirements at § 485.623, DNV GL revised its standards to address physical plant and environment and to ensure consistent language in its crosswalk.
- To meet the requirements at § 485.631(b)(1)(ii), DNV GL revised its standards to address written policies governing services the CAH furnishes.
- To meet the requirements at § 485.631(b)(1)(iii), DNV GL revised its standards to address the requirement for providing medical orders.
- To meet the requirements at § 485.631(b)(2), DNV GL revised its standards to address the requirement for providing medical care services.
- To meet the requirements at § 485.631(c)(1)(i), DNV GL revised its standards to address other CAH non-clinical written policies.
- To meet the requirements at § 485.635(a)(3)(ii), DNV GL revised its standards to address the requirement for emergency medical services policies and procedures.
- To meet the requirements at § 485.635(a)(3)(iii), DNV GL revised its standards to address ''the maintenance of health care records.''
- To meet the requirements at § 485.635(a)(3)(iv), DNV GL revised its standards to address the requirement that current and accurate records are kept of the receipt and disposition of all scheduled drugs.
- To meet the requirements at § 485.635(b)(1)(ii), DNV GL revised its standards to clarify how their surveyors determine that a CAH furnishes acute care inpatient services when no inpatients are present at the time of the survey.
- To meet the requirements at § 485.635(d)(1), DNV GL revised its standards to clarify under what authority nursing services may be provided or supervised by a Physician Assistant (PA) where permitted by state law.
- To meet the requirements at § 485.635(d)(4), DNV GL revised its standards and crosswalk to fully address the requirement that a nursing care plan must be developed and kept current for each patient.
- To meet the requirements at § 485.638(a)(4), DNV GL revised its standards to more fully address the requirement that the CAH maintains a medical record for each patient receiving health care services.
- To meet the requirements at § 485.638(a)(4)(iii), DNV GL revised its standards to fully address the requirement that the medical record contains ''reports of treatments and medications.''
- To meet the requirements at § 485.639(a), DNV GL revised its standards to fully address the requirement related to designation of qualified practitioners allowed to perform surgery ''in accordance with approved policies and procedures, and with state scope of practice laws.''
- To meet the requirements at § 485.639(b)(2) and (b)(3), DNV GL revised its standards to address the requirement to specify a ''qualified'' practitioner examine each patient before surgery to evaluate the risk of anesthesia.
- To meet the requirements at § 485.641(b)(5)(i), DNV GL revised its standards to fully address the requirement that the CAH consider the findings of the evaluations, ''including any findings or recommendations of the Quality Improvement Organization (QIO),'' and takes corrective action if necessary.
- To meet the requirements at § 485.645, DNV GL revised its standards to explain how it would determine that we have granted approval for the CAH to provide and be paid for post-hospital SNF level care as specified in 42 CFR 409.30.
- To meet the requirements § 488.28(a) and section 2728B of the State Operations Manual (SOM), DNV GL amended its policies to ensure that the accepted PoCs contains the elements comparable to those specified in the SOM, section 2728B.
- To meet the requirements at § 488.6, DNV GL provided a written plan to address the components of the CAH application for Distinct Part Units (DPUs) and swing beds, and to ensure that the surveys consistently document evaluation of the CAH's DPUs and swing beds, as applicable.
- To meet the requirements at § 488.8(a)(2)(iv), DNV GL developed an action plan designed to: Strengthen DNV GL surveyor documentation skills; consistently develop more detailed, quantifiable deficiency statements that contain all evidence collected by the survey team; and support the determination of the manner and degree of non-compliance and the appropriate level of citation.
- To meet the requirements at § 489.13(b), DNV GL revised its policy for determining the effective date of accreditation for an initial and re-accreditation survey.

B. Term of Approval

Based on our review and observations described in section IV of this final notice, we have determined that DNV GL's CAH accreditation program requirements meet or exceed our requirements. Therefore, we approve DNV GL as a national accreditation organization for CAHs that request participation in the Medicare program, effective December 23, 2014 through December 23, 2020.

V. Collection of Information Requirements

This document does not impose information collection, recordkeeping requirements or third party disclosure requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: November 13, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27576 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3297–FN]

Medicare and Medicaid Programs: Continued Approval of The Joint Commission's Ambulatory Surgical Center Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve The Joint Commission (TJC) for continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective December 20, 2014 through December 20, 2020.

FOR FURTHER INFORMATION CONTACT: Monda Shaver (410) 786–3410, Cindy Melanson, (410) 786–0310, or Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

A healthcare provider may enter into an agreement with Medicare to participate in the program as an Ambulatory Surgical Center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes criteria for providers seeking participation as an ASC. Regulations concerning Medicare provider agreements in general are at 42 CFR part 489 and those pertaining to the survey and certification for Medicare participation of providers and certain types of suppliers are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the specific conditions that a provider must meet to participate in the Medicare program as an ASC.

Generally, to enter into a Medicare provider agreement, a facility must first be certified as complying with the conditions set forth in part 416 and recommended to CMS for participation by a State survey agency. Thereafter, the ASC is subject to periodic surveys by a State survey agency to determine whether it continues to meet these conditions. Accreditation by a nationally recognized Medicare accreditation program approved by CMS may substitute for both initial and ongoing State review.

Section 1865(a)(1) of the Act provides that, if the Secretary of the Department of Health and Human Services (the Secretary) finds that accreditation of a provider entity by an approved national accrediting organization meets or exceeds all applicable Medicare conditions, we may treat the provider entity as having met those conditions, that is, we may ''deem'' the provider entity to be in compliance. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

Part 488, subpart A, implements the provisions of section 1865 of the Act and requires that a national accrediting organization applying for approval of its Medicare accreditation program must provide us with reasonable assurance that the accrediting organization requires its 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 § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require an accrediting organization to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as as determined by CMS. The Joint Commission (TJC's) current term of approval as a recognized Medicare accreditation program for ASCs expires December 20, 2014.

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 June 27, 2014 **Federal Register** (79 FR 36522), we published a proposed notice announcing TJC's request for continued approval of its Medicare ASC accreditation program. In the June 27, 2014 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 and § 488.8, we conducted a review of TJC's Medicare ASC 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 TJC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its ASC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ASCs; and (5) survey review and decision-making process for accreditation.
- The comparison of TJC's Medicare accreditation program standards to our current Medicare ASC conditions for coverage (CfCs).
- A documentation review of TJC's survey process to—

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

++ Compare TJC's processes to those CMS require of State survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited ASCs.

++ Evaluate TJC's procedures for monitoring ASCs found to be out of compliance with TJC's program requirements. (This pertains only to monitoring procedures when TJC 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 § 488.7(d).)

++ Assess TJC's ability to report deficiencies to the surveyed ASCs and respond to the ASC's plan of correction in a timely manner.

++ Establish TJC'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 TJC's staff and other resources.

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

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

++ Obtain TJC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey