Dated: November 13, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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

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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

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 TJC's requirements met or exceeded the Medicare CfCs for ASCs. We received no comments in response to our proposed notice.

IV. Provisions of the Final Notice

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

We compared TJC's ASC accreditation requirements and survey process with the Medicare CfCs of part 416, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's ASC application was conducted as described in section III of this final notice. As of the date of this notice, TJC is in the process of or has completed revising its standards and certification processes in order to meet the following requirements:

- Section 416.41, to address the ASC's Governing Body's responsibility for oversight and accountability for determining, implementing, and monitoring policies governing the ASC's total operation.
- Section 416.41(b)(1), to ensure the ASC is required to have an effective procedure for the immediate transfer to a hospital and patients requiring emergency medical care beyond the capabilities of the ASC.
- Section 416.41(b)(2), to address the requirement that the hospital be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2.
- Section 416.41(b)(3)(i), to ensure the ASC has a written transfer agreement with a hospital that meets the requirements at § 416.41(b)(2).
- Section 416.41(b)(3)(ii), to address the requirement that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements at § 416.41(b)(2).
- Section 416.42(c)(1) and § 416.42(c)(2), to address State exemption from the requirement for physician supervision of a certified registered nurse anesthetist.
- Section 416.43(a)(1), to address the requirement that the program demonstrate measurable improvements in health outcomes and improves patient safety by the identification and reduction of medical errors.
- Section 416.43(c)(1)(ii), to address requirements related to the setting of priorities for ASC performance improvement activities.
- Section 416.43(e)(1), to ensure the Governing Body takes responsibility and is involved in the operation of the ASCs [Quality Assessment Performance Improvement (QAPI) Program.
- Section 416.43(e)(2), to include the requirement that the Governing Body is responsible for addressing the ASC's priorities and that all improvements are evaluated for effectiveness.
- Section 416.43(e)(4), to ensure that the ASC clearly establishes its expectations for safety.
- Section 416.44(a), to ensure ASCs maintain equipment in accordance with manufacturer requirements or other Federal or State requirements.
- Section 416.44(a)(1), to ensure operating rooms are designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.
- Section 416.44(b)(1), to include the provisions required under the 2000 edition of the Life Safety Code of the National Fire Protection Association.
- Section 416.44(b)(2), to address requirements related to life safety code waivers.
- Section 416.44(c), to address the requirement that the ASC medical staff and governing body coordinate, develop and revise ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room.
- Section 416.45(c), to include a provision that should the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures approved by the governing body for overseeing and evaluating their clinical activities.
- Section 416.47(b), to address the timeframe within which the pre-operative diagnostic studies must be present in the medical record.
- Section 416.48(a), to address the preparation of drugs.
- Section 416.49(a), to include the requirement that the ASC must have procedures for obtaining routine and emergency laboratory services from a certified laboratory when the ASC does not provide its own laboratory services.
- Section 416.49(b)(2), to include the requirement that radiologic services must meet the hospital conditions of participation for radiologic services specified in § 482.26.
- Section 416.50, to update the Medicare regulatory language on its standards crosswalk.
- Section 416.50(c)(3), to address the requirement that the ASC document in a prominent part of the medical record whether or not the individual has executed an advance directive.
- Section 416.50(g), to ensure the ASC complies with the Department of Health and Human Services (the Department) rules for the privacy and security of individually identifiable health information
- Section 416.51(a), to ensure the ASC provides a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.
- Section 416.51(b), to address the requirement that the ASC infection control and prevention program include documentation that the ASC has considered, selected, and implemented nationally recognized infection control program guidelines.
- Section 416.52(b)(1), to address the requirement related to whom may document that the patient has met discharge criteria.
- Section 416.52(c)(2), to address the requirement that each patient has a discharge order signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.
- Section 488.4(a)(4), to clarify the minimum composition of its survey team for its Medicare ASC accreditation program.
- Section 488.4(a)(4)(ii) through (v), to ensure compliance with its own policies that require evidence that its surveyors are appropriately qualified, trained, and evaluated.
- Section 488.4(a)(6), to ensure compliance with its own policies that require requests for a plan of correction (PoC) be timely, follow-up surveys for immediate threat to life (ITL) situations to be conducted timely, and that findings are accurately reported to CMS via the Accrediting Organization System for Storing User Recorded Experiences (ASSURE) database system.
- Section 488.4(b)(3)(iii) and § 488.8(d), to ensure CMS is notified of any proposed changes in its CMS-approved Medicare ASC accreditation program 30 days prior to implementation of such changes, and to confirm that it will not implement changes CMS have disapproved or required to be modified.
- Section 488.8, to provide CMS with data that ensures the following information is accurately reported: the date of a complaint receipt; determination of complaints as substantiated or unsubstantiated;

determinations of ITL situations; and surveyor documentation that includes a detailed deficiency statement that clearly supports the determination of manner and degree of non-compliance and the appropriate level of citation.

• Section 488.8(a)(2)(iv), to strengthen surveyor documentation to include sufficient detail to support the determination of the manner and degree of non-compliance and the appropriate level of deficiency citation.

• Section 489.13, related to the effective date of accreditation for facilities undergoing a survey for purposes of its initial participation in Medicare; to ensure the effective date of accreditation when deficiencies have been identified, and to ensure it is consistent with CMS regulatory requirements.

• To ensure comparability with the survey process requirements at § 488.26(d), TJC must have—

++ Updated its accreditation process policies to clarify that all surveys for TJC's Medicare ASC accreditation program are conducted unannounced.

++ Updated its accreditation process policies to ensure all required follow-up surveys for its Medicare ASC accreditation program meet the Medicare requirements.

++ Revised its accreditation process policies to clarify that the appropriate level of citation be made when an Immediate Threat to Health or Safety is identified.

++ Clarified its survey policies in the surveyor activity guide (SAG) to address how ''Special Issue Resolution'' is handled during surveys lasting only 1 day.

++ Updated its ASC accreditation process policies to clearly demonstrate that the policies are related to ASCs and not hospitals.

• Section 488.28(a), to include all documented observations of non-compliance and all internal, uncompleted Plans for Improvement (PFI) listed in the accredited ASC's ''Statement of Condition (SOC) to correct Life Safety Code Deficiencies'' into the survey report. In addition, TJC will provide CMS with rationale for each standard for which TJC has determined will not require a citation of non-compliance when a single observation has been made.

• Complied with section 1861(e)(9)(C) of the Act, to require that waiver and equivalency requests submitted by accredited organizations for Life Safety Code deficiencies that would result in unreasonable hardship for such a facility to resolve and would not jeopardize patient health or safety, be reviewed by TJC, and forwarded to CMS for approval, as appropriate.

• To demonstrate comparability with minimum eligibility requirements for Initial surveys, increased the minimum number of patients/volume of services from three patients served with one active at the time of survey, to ten patients served, with one active at the time of survey.

• To comply with TJS's own policies, TJS must—

++ Ensure its surveyors complete the ASC Infection Control Worksheet on every survey.

++ Ensure its surveyors observe at least one surgery during every survey.

++ Ensure that the minimum number of medical records have been reviewed on every survey.

++ Ensure that findings noted on the Infection Control Worksheet are integrated into the survey report findings.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve TJC as a national accreditation organization for ASCs that request participation in the Medicare program, effective December 20, 2014 through December 20, 2020.

To verify TJC's continued compliance with the provisions of this final notice, we will conduct a follow-up corporate on-site visit and survey observation within 18 months of the date of publication of this final 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. Chapter 35).

Dated: November 5, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6064–N]

Medicare Program; Prior Authorization of Non-Emergent Hyperbaric Oxygen (HBO) Therapy

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

ACTION: Notice.

SUMMARY: This notice announces a 3-year Medicare Prior Authorization model for non-emergent hyperbaric oxygen therapy services in the states of Illinois, Michigan, and New Jersey where there have been high incidences of improper payments for these services.

DATES: The model will begin on March 1, 2015 in Michigan, New Jersey, and Illinois.

FOR FURTHER INFORMATION CONTACT: Jennifer McMullen, (410) 786–7635.

Questions regarding the Medicare Prior Authorization Model for Non-Emergent Hyperbaric Oxygen (HBO) Therapy should be sent to *HBOPA@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Hyperbaric Oxygen (HBO) therapy is a modality used for treatment of wounds in which the entire body is exposed to oxygen under increased atmospheric pressure. HBO therapy is covered as adjunctive therapy only after there have been no measurable signs of healing during at least 30 consecutive days of treatment with standard wound therapy, and must be used in addition to standard wound care. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Medicare issued a National Coverage Determination (NCD) for HBO therapy in 2002, which lists clinical conditions for which HBO therapy is medically necessary and clinical conditions for which HBO therapy is not medically necessary, and therefore; not covered by Medicare. The NCD can be found in the Medicare National Coverage Determinations Manual (CMS Pub. No. 100–03), Chapter 1, Part 1, Section 20.29, and in the NCD database at *http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=37&bc=AiAAAAAAAgAAAA%3d%3d&*. In addition, some of