DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3397–FN]

Medicare and Medicaid Programs; Application From The Joint Commission for Continued Approval of Its Ambulatory Surgical Center (ASC) Accreditation Program

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve The Joint Commission for continued recognition as a national accrediting organization for Ambulatory Surgical Centers that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is effective on December 20, 2020 through December 20, 2024.

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I. Background

Ambulatory Surgical Centers (ASCs) are distinct entities that operate exclusively for the purpose of furnishing outpatient surgical services to patients. Under the Medicare program, eligible beneficiaries may receive covered services from an ASC provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for a facility seeking designation as an ASC. 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 416 specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ASCs.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency (SA) as complying with the conditions or requirements set forth in part 416 of our Medicare regulations. Thereafter, the ASC is subject to regular surveys by an SA to determine whether it continues to meet these requirements.

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 conditions are met or exceeded, we may deem that 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 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. The 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 Joint Commission's (TJC's) current term of approval for its ASC program expires December 20, 2020.

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 May 26, 2020 we published a proposed notice in the **Federal Register** (85 FR 31511), announcing TJC's request for continued approval of its Medicare ASC accreditation program. In the May 26, 2020 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 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 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 ASC accreditation program standards to our current Medicare ASC conditions for coverage (CfCs).

- A documentation review of TJC's survey process to do the following:

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

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

++ Evaluate TJC's procedures for monitoring accredited ASCs it has 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 SA through a validation survey, the SA monitors corrections as specified at § 488.9(c)).

++ Assess TJC's ability to report deficiencies to the surveyed ASCs and respond to the ASCs' plans 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.

++ Confirm TJC'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 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.

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

In accordance with section 1865(a)(3)(A) of the Act, the May 26, 2020 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CfCs for ASCs. No comments were received in response to our proposed notice.

V. 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 parts 416, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's ASC 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, TJC has completed revising its standards and certification processes in order to do all of the following:

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

++ Section 416.2, to include the regulatory definition of an ASC as a comparable TJC standard instead of a glossary definition.

++ Section 416.43(c)(2), to address the broad requirement under the quality improvement program to track adverse patient events.

++ Section 416.44(c), to include reference to the Health Care Facilities Code (HCFC) of the National Fire Protection Association (NFPA) 99 (2012 edition).

++ Section 416.45(a), to include adequate review of credential and personnel files during survey activity.

++ Section 416.48(a), to include policies regarding the administration of drugs be in accordance with acceptable standards of practice.

++ Section 416.50(a), to provide the correct regulatory citation reference to the CMS standard, ''Condition for Coverage—Patient Rights; Notice of Rights.''

++ Section 488.5(a)(4)(iv), to include the requirement that all comparable Medicare CfC citations be included in the findings sections of TJC's survey reports.

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

++ Modifying TJC's accreditation award letter to facilities to remove the term ''lengthen'' to eliminate potential conflict as it relates to survey cycle length not to exceed 36 months, as survey cycles for deeming purposes do not exceed this timeframe.

++ Adding references to the HCFC of the NFPA 99 (2012 edition). (NFPA 99) within its Accreditation Process and Surveyor Activity Guide.

++ Providing clarification to its Surveyor Activity Guide indicating that the 2012 edition of the NFPA Life Safety Code and NFPA 99 applies to ASCs, regardless of the number of patients served.

++ Clarifying the process for TJC's performance of on-site Evidence of Standard Compliance (ESC) processes, including what it means to provide coaching and guidance as part of TJC's ESC survey activities.

B. Term of Approval

Based on our review described in section III. and section V. of this final notice, we approve TJC as a national accreditation organization for ASCs that request participation in the Medicare program. The decision announced in this final notice is effective December 20, 2020 through December 20, 2024. In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years. Due to travel restrictions and the reprioritization of survey activities brought on by the 2019 Novel Coronavirus Disease (COVID–19) Public Health Emergency (PHE), CMS was unable to observe an ASC survey completed by TJC surveyors as part of the application review process, which is one component of the comparability evaluation. Therefore, we are providing TJC with a shorter period of approval. Based on our discussions with TJC and the information provided in its application, we are confident that TJC will continue to ensure that its accredited ASCs will continue to meet or exceed Medicare standards. While TJC has taken actions based on the findings annotated in section V.A., of this final notice, (Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements) as authorized under § 488.8, we will continue ongoing review of TJC's ASC survey processes and will conduct a survey observation once the COVID–19 PHE has expired. In keeping with CMS's initiative to increase AO oversight broadly, and ensure that our requested revisions by TJC are completed, CMS expects more frequent review of TJC's activities in the future.

VI. Collection of Information and Regulatory Impact Statement

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: October 8, 2020.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10752, CMS–10137, CMS–R–262 and CMS–10549]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and