



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-3336-FN]**

### **Medicare and Medicaid Programs: Approval of an Application from the Joint Commission (TJC) for Continued CMS Approval of its Critical Access Hospital (CAH) 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 critical access hospitals (CAHs) that wish to participate in the Medicare or Medicaid programs.

**DATES:** This final notice is effective November 21, 2017 through November 21, 2023.

**FOR FURTHER INFORMATION CONTACT:** Monda Shaver, (410) 786-3410, Karena Meushaw, (410) 786-6609 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) and 1861(mm) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. The minimum requirements that a CAH must meet to participate in the Medicare Program are at 42 CFR part 485, subpart F. Conditions for Medicare payment for CAHs are at 42 CFR 413.70. Applicable regulations concerning provider agreements are at 42

CFR part 489 and those pertaining to facility survey and certification are at 42 CFR part 488, subparts A and B.

For a CAH to enter into a provider agreement with the Medicare program, a CAH must first be certified by a State survey agency as complying with the conditions or requirements set forth in section 1820 of the Act and our regulations at part 485. Subsequently, the CAH is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. However, there is an alternative to State compliance surveys. Certification by a nationally recognized accreditation program can substitute for 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 the Centers for Medicare & Medicaid Services (CMS) 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 §488.5. The regulations at §488.5(e)(2)(i) require an accrediting organization to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS. The Joint

Commission's (TJC's) term of approval as a recognized Medicare accreditation program for CAHs expires November 21, 2017.

## **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 19, 2017, we published a proposed notice in the **Federal Register** (82 FR 23004) announcing TJC's request for continued approval of its Medicare 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 §488.5, we conducted a review of TJC's Medicare CAH 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 hospital surveyors; (4) ability to investigate and respond

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

- A comparison of TJC's Medicare accreditation program standards to our current Medicare CAH Conditions of Participation (CoPs).
- 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 accredited CAHs.
  - ++ Evaluate TJC's procedures for monitoring CAHs found to be out of compliance with TJC's program requirements. (This pertains only to monitoring procedures when TJC identifies non-compliance. If non-compliance is identified by a State survey agency through a validation survey, the State survey agency monitors corrections as specified at §488.9(c).)
  - ++ Assess TJC's ability to report deficiencies to the surveyed hospitals and respond to the hospital'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 May 19, 2017 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoP for CAHs. There were two comments submitted, neither of which related to the content of the 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 CAH accreditation requirements and survey process with the Medicare CoPs at part 485, and the survey and certification process requirements of parts 488 and 489. TJC's standards and crosswalk were also examined to ensure that the appropriate CMS regulations would be included in citations as appropriate. We reviewed and evaluated TJC's CAH application, which was conducted as described in section III of this final notice. As a result TJC has revised the following standards and certification processes:

- Section 482.21(d)(2): Updated its standards and crosswalk to include a comparable standard to allow facilities to develop and implement an information technology system explicitly designed to improve patient safety and quality of care as part of its quality improvement program.
- Section 482.21(d)(4): Updated its standards and crosswalk to include a comparable standard that requires facilities that do not participate in a cooperative project to implement projects that are of comparable effort.
- Sections 482.22(b)(4)(iii) through (b)(4)(iv): Updated its standards and crosswalk to ensure that CAHs are not permitted to have a "unified and integrated medical staff."

- Section 482.28(b)(2): Updated its standards and crosswalk to include a comparable standard to require that all patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutritional professionals.
- Section 482.53(b): Updated its standards and crosswalk to include the “preparation” of radioactive materials.
- Section 485.618(d)(4): Updated its standards and crosswalk to address the withdrawal of a request for using Registered Nurses on a temporary basis as part of their State Rural Healthcare Plan with the State Boards of Medicine and Nursing.
- Sections 485.627(b)(1) through (b)(3): Updated its standards and crosswalk to include comparable standards to require disclosure of the names and addresses of the facility’s owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest.
- Section 485.645(a)(2): Updated its crosswalk to include the correct regulatory language to require that the facility limits inpatient beds to no more than 25 and is verified on all surveys.
- Section 488.5(a)(4)(vii): Updated its policies and review process to ensure that approved plans of correction fully address all non-compliant practices identified during the survey; that appropriate policy changes have been made to ensure compliance; and that plans of correction identify the responsible party for ensuring corrective actions are implemented within the CAH and contain a description of how the CAH will monitor and evaluate the effectiveness of the corrective actions, analyze the data, and report findings to the senior leadership and

governing body to ensure continued regulatory compliance.

- Section 488.5(a)(12): Provided CMS with assurance that its procedures for responding to, and investigating complaints against accredited facilities are fully implemented and followed.
- Section 488.26(b): Revised surveyor documentation to include appropriately detailed deficiency statements that clearly support the determination of noncompliance and appropriate level of deficiency.

TJC revised its survey policy and procedure to clearly delineate that a survey will not occur until after the applicable Regional Office has made a determination of the CAH's compliance with location and distance requirements.

#### **B. Term of Approval**

Based on our review and observations described in section III of this final notice, we have determined that TJC's CAH program requirements meet or exceed our requirements, and its survey processes are comparable to ours. Therefore, we approve TJC as a national accreditation organization for critical access hospitals that request participation in the Medicare program, effective November 21, 2017 through November 21, 2023.

#### **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: October 16, 2017.

**Seema Verma,**

Administrator,

Centers for Medicare & Medicaid Services.

**BILLING CODE 4120-01-P**

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