



This document is scheduled to be published in the Federal Register on 06/27/2014 and available online at <http://federalregister.gov/a/2014-15103>, and on FDsys.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3290-FN]

Medicare and Medicaid Programs; Continued Approval of The Joint Commission's (TJC's) Hospital 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 hospitals that wish to participate in the Medicare or Medicaid programs. A hospital that participates in Medicaid must also meet the Medicare conditions of participation (CoPs) as required under section 1905(a) of the Social Security Act ("Act") and 42 CFR § 482.1(a)(5). This approval is effective July 15, 2014 through July 15, 2020.

DATES: This final notice is effective July 15, 2014 through July 15, 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 a hospital provided certain requirements are met. Section 1861(e) of the Social Security Act (the Act) establishes criteria for providers seeking participation as a hospital. 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 part 488. The regulations at part 482 specify the specific conditions that a provider must meet to participate in the Medicare program as a hospital.

Generally, to enter into a Medicare hospital provider agreement, a facility must first be certified as complying with the conditions set forth in part 482 and recommended to us for participation by a state survey agency. Thereafter, the hospital is subject to periodic surveys by a state survey agency to determine whether it continues to meet these conditions. However, there is an alternative to certification surveys by state agencies. Accreditation by a nationally recognized Medicare accreditation program approved by us may substitute for both initial and ongoing state review.

Section 1865(a)(1) of the Act provides that, if 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 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 determined by us. TJC’s current term of approval as a recognized Medicare accreditation program for hospitals expires July 15, 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 January 29, 2014 **Federal Register** (79 FR 4727), we published a proposed notice announcing TJC's request for continued approval of its Medicare hospital accreditation program. In the January 29, 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 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 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.

- The comparison of TJC's Medicare accreditation program standards to our current Medicare hospital CoPs.
- A documentation review of TJC's survey process to determine 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 hospitals.
 - ++ Evaluate TJC's procedures for monitoring hospitals 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 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 hospitals and respond to the hospital's plan of correction in a timely manner.
 - ++ Establish TJC'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 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 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 January 29, 2014 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoPs for hospitals. We received two unrelated 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 hospital accreditation requirements and survey process with the Medicare CoPs of 42 CFR Part 482, and the survey and certification process requirements of Parts 488 and 489. Our review and evaluation of TJC's 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, TJC is in the process of or has completed revising its standards and certification processes in order to meet the requirements at:

- §482.12(a)(1), to address the hospital's responsibility to determine which categories of practitioners are eligible candidates for appointment to the medical staff.
- §482.12(a)(2), to ensure recommendations of the existing members of the medical staff are considered by the governing body during the medical staff appointment process.
- §482.12(c)(2), to include the requirement that patients are admitted to the hospital only on the recommendation of a licensed practitioner.
- §482.13(a)(1), to ensure hospitals inform each patient or patient's representative of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.
- §482.13(b)(4), to address the patient's right to have a family member or representative of his or her choice notified promptly of the patient's admission to the hospital.

- §482.13(h) and §482.13(h)(1), to include the provisions that require hospitals inform each patient of his or her visitation rights and address the requirement for hospitals to have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinical restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.
- To meet the requirements at §482.13(h)(2), TJC revised its standards to include the requirement that the hospital must inform each patient of their right to receive designated visitors.
- §482.13(h)(4), to ensure all visitors enjoy full and equal visitation privileges consistent with patient preferences.
- §482.21, to address the hospital governing body's responsibility for maintaining an ongoing quality assessment and performance improvement (QAPI) program that includes services provided under arrangement; maintenance and demonstration of evidence of its QAPI program for review by us; and that the QAPI program is developed and executed in a manner that reflects the complexity of the hospital scope and focus.
- §482.22(a), to indicate that the medical staff may also include other categories of non-physician practitioners as eligible for appointment by the governing body.
- §482.23(b)(3), to require that a registered nurse must supervise the nursing care of each patient.
- §482.23(b)(5), to ensure a registered nurse assigns the nursing care of each patient to other nursing personnel.
- §482.23(c)(6)(i)(A) and §482.23(c)(6)(ii)(A), to require a written order permitting patient self-administration of hospital issued medications and the patient's own medications

brought to the hospital.

- §482.23(c)(6)(ii)(B), to include a provision for assessing the patient's capacity to self-administer medications and determining if the patient needs instruction in the safe and accurate administration of medications.
- §482.24(a), to ensure the organization of the medical record service is appropriate to the scope and complexity of the services performed.
- §482.24(b), related to the form and retention of the medical record.
- §482.24(b)(2), to include a provision that hospitals have a system that allows for timely retrieval by diagnosis and procedure, in order to support medical care evaluation and studies.
- §482.24(c)(2), to require all orders, including verbal orders, be dated, timed, and authenticated promptly by the ordering practitioner or another practitioner who is responsible for the care of the patient.
- §482.24(c)(4)(iv), to require documentation of complications, hospital-acquired infections, and unfavorable reactions to drugs and anesthesia.
- §482.25(a), to include the requirement that the pharmacy or drug storage area must be administered in accordance with accepted professional principles.
- §482.26, to include therapeutic radiologic services and the requirement that radiologic services must meet professionally approved standards for safety and personnel qualifications.
- §482.26 (b)(3), to require radiation workers be checked periodically for amounts of radiation exposure.
- §482.27, to require that the hospital maintain, or have available, adequate laboratory services to meet the needs of its patients and that such services are performed in a facility certified in accordance with part 493 of this chapter.

- §482.28, to address the hospital's responsibility to have a dietitian who serves the hospital on a full-time, part-time, or consultant basis either directly or through a contractual arrangement.
- §482.28(a)(1), to require that hospitals have a full-time employee responsible for the food and dietetic service.
- §482.41, to address the hospital's responsibility to provide facilities for special services appropriate to the needs of the community.
- §482.41(a)(1), to address the requirement for emergency power and lighting in intensive care and emergency rooms.
- §482.41(b)(1)(i) and chapters 18/19.7.1.2 and 18/19.7.1.3 of the Life Safety Code (LSC), to address various fire drill requirements that include transmission of a fire alarm signal, simulation of emergency fire conditions, varying conditions, and employees being instructed in life safety procedures and devices.
- §482.41(b)(2), to require submission of an equivalency or waiver request, including the supporting documentation along with TJC's recommendation for approval, to the applicable CMS Regional Office for processing.
- §482.41(b)(6), to address the proper routine storage and prompt disposal of trash.
- §482.41(b)(7), to include the requirement that the fire control plan must contain provisions for the prompt reporting of fires.
- §482.43(c)(4), to address the hospital's responsibility to reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.
- §482.43(c)(6), to include the requirement that a home health agency (HHA) must

request to be included on the list of HHAs a hospital provides to patients as part of their discharge plan.

- §482.51(a)(4), to include a requirement for surgical services to maintain a roster of practitioners, specifying the surgical privileges of each practitioner.
- §482.51(b)(2), to include a requirement that a properly executed informed consent for an operation must be in the patient's chart before surgery, except in emergencies.
- §482.52(a)(5), to include a requirement that the supervising anesthesiologist for an anesthesiologist's assistant be immediately available if needed.
- §482.53(b)(3), to ensure laboratory tests performed in the nuclear medicine service meet the applicable requirement for laboratory services specified in §482.27.
- §482.53(d)(3), to require the hospital maintain records of the disposition of radiopharmaceuticals.
- §482.55, to require the hospital to meet the emergency needs of patients in accordance with acceptable standards of practice.
- §482.56(a)(2), to ensure physical therapy, occupational therapy, speech-language pathology, and audiology services are provided by qualified therapists, as defined in 42 CFR part 484.
- §482.56(b)(2), to require the personnel qualifications of those providing care must be in accordance with nationally accepted standards of practice and meet the requirements at §409.17.
- §482.57(b)(2), to require blood gases or other laboratory tests performed in the respiratory care unit to meet the applicable requirements for laboratory services specified in §482.27.

- §488.3(a), to ensure that all services, including physician and ambulatory care services, which are furnished under the hospital's Medicare provider agreement are surveyed for compliance with TJC's CMS-approved Medicare hospital accreditation program.

- §488.4(a)(4), to clarify the minimum composition of its survey team for its Medicare hospital accreditation program.

- §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.

- §488.4(a)(6), to ensure compliance with its own policies that require plan of correction requests to be timely, follow-up surveys for ITL situations to be conducted timely, and that findings are accurately reported to us via the ASSURE database system.

- §488.4(b)(3)(iii) and §488.8(d), to ensure we are notified of any proposed changes in its CMS-approved Medicare hospital accreditation program prior to implementation of such changes within 30 days, and to confirm that it will not implement changes we have disapproved or required to be modified.

- §488.8, to provide us 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; final accreditation decisions for surveys where no deficiencies are found; 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.

- To ensure comparability with the survey process requirements at §488.26(d), TJC:

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

++ Updated its accreditation process policies to ensure all required follow-up surveys for its Medicare hospital 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 (ITL) is identified.

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

- ++ Updated its accreditation process policies to ensure its definition of a small hospital is consistent across its policies.

- §488.28(a), to include all documented observations of non-compliance and all internal, uncompleted Plans for Improvement (PFI) listed in the accredited hospital’s “Statement of Condition (SOC) to correct Life Safety Code Deficiencies” into the survey report.

- §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 survey process and effective date of accreditation when deficiencies have been identified are consistent with the regulatory requirements.

- 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 us for approval , as appropriate.

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 hospitals that request participation in the Medicare program, effective July 15, 2014 through July 15, 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 notice.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping 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).

CMS-3280-FN

Dated:

June 16, 2014.

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

BILLING CODE: 4120-01-P

[FR Doc. 2014-15103 Filed 06/26/2014 at 8:45 am; Publication Date: 06/27/2014]