DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3307-FN]

Medicare and Medicaid Programs; Continued Approval of The Joint Commission's Hospice Accreditation Program.

AGENCY: Centers for Medicare & 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 hospices that wish to participate in the Medicare or Medicaid programs. A hospice that participates in Medicaid must also meet the Medicare Conditions of Participation (CoPs).

DATES: This final notice is effective June 18, 2015 through June 18, 2021.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice provided certain requirements are met by the hospice. Section 1861(dd) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a hospice. 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 418 specify the conditions that a hospice must meet in order to

participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for hospices.

Generally, to enter into an agreement, a hospice must first be certified as complying with the conditions set forth in part 418 and recommended to the Center for Medicare & Medicaid (CMS) for participation by a state survey agency. Thereafter, the hospice 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 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, CMS 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 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 §488.4 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 CMS. The Joint Commission's (TJC's) current term of approval for its hospice accreditation program expires June 18, 2015.

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 December 19, 2014 **Federal Register** (79 FR 75817), we published a proposed notice announcing TJC's request for continued approval of its Medicare hospice accreditation program. In the December 19, 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 hospice 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 hospice surveyors; (4) ability to investigate and respond appropriately to complaints against accredited hospices; and (5) survey review and decision-making process for accreditation.

- The comparison of TJC's Medicare hospice accreditation program standards to our current Medicare hospice CoPs.

• 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 we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited hospices.

++ Evaluate TJC's procedures for monitoring hospices 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 hospice and respond to the hospice'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 December 19, 2014 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoPs for hospices. No comments were received in response to 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 hospice accreditation requirements and survey process with the Medicare CoPs of part 418, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's hospice 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 to meet the requirements at:

- §418.52(a)(1), to ensure hospices' provide verbal notification of the patient's rights and responsibilities.

- §418.52(b)(4)(i), to ensure all alleged violations of mistreatment are immediately reported to the hospice administrator.

- §418.54(c)(6) and §418.54(c)(6)(v), to ensure the patient's prescriptions, over the counter drugs, including herbal remedies and other alternative treatments, and drug therapy associated with laboratory monitoring are reviewed when completing the comprehensive assessment.

- §418.58(d)(1), to ensure that the number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, reflect the scope, complexity, and past performance of the hospice's operations.

- §418.58(e)(1), to ensure the ongoing quality improvement and patient safety program is evaluated annually.

- §418.64(d)(3)(iv), to ensure the family is advised of the availability of spiritual

counseling services.

- §418.76(c)(4), to ensure the direct supervision of the hospice aide training is completed by a registered nurse.

- §418.76(g)(1), to ensure written patient care instructions for the hospice aide are prepared by a registered nurse who is responsible for the supervision of the hospice aide.

- §418.76(h)(1)(i), to ensure the registered nurse's supervision of the hospice aide includes an assessment of the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs.

- §418.78(a), to ensure the hospice maintains, documents, and provides volunteer orientation and training that is consistent with hospice industry standards.

- §418.104(a)(2), to address the requirement that hospices include a signed copy of the election statement in the patient's clinical record.

- §418.106(a)(1), to ensure the interdisciplinary group "confers" with an individual with education and training in drug management to make sure drugs and biologicals meet the patient's needs.

- §418.106(e)(2)(i)(B), to address the requirement for the hospice to educate the patient, or representative and the family on the safe use and disposal of controlled drugs "in a language and manner that they understand."

- §418.106(e)(3)(i), to address the requirement that only personnel authorized to administer controlled drugs have access to the locked compartments.

- §418.108(c)(5), to address when inpatient care is provided under arrangement, that the hospice retains a description of the training provided and documents the names of those giving the training.

- §418.110(d), to ensure the Life Safety Code (LSC) requirements apply to all certified

in-patient hospice facilities regardless of the number of certified beds.

- §418.110(f)(3)(vi), to ensure patient rooms are equipped with an easily-activated, functioning and accessible device that is used for calling for assistance.

- §418.110(m), to ensure all patients have the right to be free from physical or mental abuse and corporal punishment.

- §418.110(m)(7)(ii), to address that each order for restraint used ensures the physical safety of the non-violent or non-self-destructive patients.

- §418.114(d)(1), to address the requirement that all contracted entities obtain criminal background checks on contracted employees who have direct patient contact or access to patient records.

- §488.4(a)(3)(ii), to ensure compliance with its own policies related to the minimum number of medical records reviewed while conducting an onsite hospice survey.

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

- §488.4(a)(4)(ii) through (v), to ensure its surveyors are appropriately qualified, trained, and evaluated.

- §488.4(a)(6), to ensure the minimum number of medical records are reviewed for complaint surveys.

- §488.8(a)(2)(v), to ensure data reported to CMS is accurate and complete.

- §488.26(b), to improve surveyors' abilities to--

    ++ Accurately and completely document instances of non-compliance at the appropriate level of citation (condition versus standard level citations).

    ++ Ensure that all instances of observed non-compliance are documented in the survey report.

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 hospices that request participation in the Medicare program, effective June 18, 2015 through June 18, 2021.

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. 35).

CMS-3307-FN

Dated: May 5, 2015

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Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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