

the 180-day probationary period, we may remove recognition of deemed authority for its ASC program effective 30 days after the date we provide written notice to AAAASF that its ASC deeming authority will be removed.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that AAAASF's accreditation program for ASCs requires further revision and subsequent review. We are confident that with additional time, AAAASF will make the necessary revisions to ensure AAAASF's accreditation program for ASCs meets or exceeds the Medicare requirements as stated at 42 CFR part 416. Therefore, we conditionally approve AAAASF as a national accreditation organization for ASCs that request participation in the Medicare program, effective November 27, 2009 through November 27, 2012, with a 180-day probationary period beginning November 27, 2009 through May 26, 2010.

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).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 29, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2302-FN]

Medicare and Medicaid Programs; Approval of the Application by the Joint Commission for Continued Deeming Authority for Hospitals

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

ACTION: Final notice.

SUMMARY: This final notice announces the approval of a deeming application from the Joint Commission for continued recognition as a national accreditation program for hospitals that request participation in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective July 15, 2010 through July 15, 2014.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786-0310. Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital, provided certain requirements are met. The regulations specifying the Medicare conditions of participation (CoPs) for hospitals are located at 42 CFR part 482. These CoPs implement section 1861(e) of the Social Security Act (the Act), which specifies services covered as hospital care and the conditions that a hospital program must meet in order to participate in the Medicare program. Regulations concerning provider agreements are located at 42 CFR part 489 and regulations pertaining to the survey and certification of facilities are located at 42 CFR part 488.

Generally, in order to enter into a provider agreement, a hospital must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 482 of our regulations. Then, the hospital is subject to routine surveys by a State survey agency to determine whether it continues to meet the Medicare requirements. There is, however, an alternative to State compliance surveys.

Section 1865(a)(1) of the Act (as redesignated under section 125 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275)) provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we would “deem” those provider entities as having met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, a provider entity accredited by the national accreditation body's approved

program would be deemed to meet the Medicare conditions. A national accreditation organization applying for deeming authority under part 488, subpart A, must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the re-approval of accreditation organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accreditation organizations to reapply for continued deeming authority every 6 years or as we determine.

In July 2008, section 125 of MIPPA revoked the Joint Commission's statutorily-guaranteed deeming authority for their hospital program and required the Joint Commission subsequently to be recognized as a national accreditation body for hospitals only after applying to CMS, subject to terms and conditions required by the Secretary. These terms and conditions are set out at 42 CFR part 488, subpart A, as described above. Based on the 24-month transition period allowed by section 125 of MIPPA, the Joint Commission's term of approval as a recognized accreditation program for hospitals expires July 15, 2010.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for deeming authority is conducted in a timely manner. We must complete our review of an accreditation organization's application within 210 calendar days after the date of receipt of the completed application (including all documentation necessary to make a determination). Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accreditation 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 and Response to Comments

On June 26, 2009, we published a proposed notice in the **Federal Register** (74 FR 30588) announcing the Joint Commission's request for re-approval as a deeming organization for hospitals. In that notice, we specified in detail our evaluation criteria. Under section 1865(a)(2) of the Act and in our

regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of the Joint Commission's application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of the Joint Commission's—(1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.

- A comparison of the Joint Commission's hospital accreditation standards to our current Medicare hospital CoPs.

- A documentation review of the Joint Commission's survey processes to—

- + Determine the composition of the survey team, surveyor qualifications, and the Joint Commission's ability to provide continuing surveyor training.
- + Compare the Joint Commission's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- + Evaluate the Joint Commission's procedures for monitoring providers or suppliers found to be out of compliance with the Joint Commission program requirements. The monitoring procedures are used only when the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).

- + Assess the Joint Commission's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- + Establish the Joint Commission's ability to provide us with electronic data and reports necessary for effective validation and assessment of the Joint Commission's survey process.

- + Determine the adequacy of staff and other resources.

- + Review the Joint Commission's ability to provide adequate funding for performing required surveys.

- + Confirm the Joint Commission's policies with respect to whether surveys are announced or unannounced.

- + Obtain the Joint Commission'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 June 26, 2009 proposed notice also solicited public comments regarding whether the Joint Commission's requirements met or exceeded the Medicare CoPs for hospitals. We received 4 comments in response to our proposed notice. Below are the comments received and our responses to these comments.

Comment: One commenter expressed support for the Joint Commission's continued deeming authority for hospitals. This commenter stated the Joint Commission's accreditation and survey process has improved the safety and quality of healthcare with its rigorous evaluation system combined with mentoring and seeking solutions that take a systems approach.

Response: We appreciate the commenter's support. The Joint Commission has been approved for continued deeming authority as a national accreditation program.

Comment: One commenter agrees that it is a good idea to have options for accreditation. However, the commenter believes that a single, standardized, regulatory approach to healthcare is necessary.

Response: The Medicare CoPs are the minimum health and safety requirements that all hospitals must meet to participate in the Medicare program and serve as a single standardized Federal regulatory approach. We recognize only those accreditation programs that meet or exceed Medicare requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation. A hospital may opt for routine surveys by a State survey agency to determine whether it meets the Medicare requirements.

Comment: One commenter requested that the Joint Commission correct a patient safety deficiency in its standards by requiring all hospitals to be smoke free with no exceptions for special circumstances.

Response: The commenter's request is not directly related to this application for continued deeming authority for hospitals. All deeming applications are reviewed in accordance with the requirements at § 488.4 and § 488.8 to ensure that the applicant accreditation program meets or exceeds Medicare requirements. We recommend the commenter discuss this recommendation directly with the Joint Commission.

Comment: One commenter expressed concerns about the Joint Commission's

continued deeming authority for hospitals. The commenter stated that the Joint Commission's standards are not focused on the CMS CoPs and that the National Patient Safety Goals are not evidence-based. In addition, the commenter stated that the Joint Commission's standards are ever changing and confusing. The commenter further stated that organizations spend inordinate time and resources preparing for the Joint Commission surveys and that these resources should be more focused on the CMS CoPs and other important quality initiatives.

Response: On July 15, 2008, Congress enacted the Medicare Improvement for Patients and Providers Act (MIPPA). Section 125 of MIPPA revoked the Joint Commission's previously guaranteed statutory deeming authority for hospitals, and included a 24-month transition period. Effective July 15, 2010, the Secretary may recognize the Joint Commission as a national accreditation body for hospitals based on the terms and conditions, and upon submission of such information, as the Secretary may require. On May 1, 2009, the Joint Commission submitted a complete application for renewal of hospital deeming authority in accordance with the requirements at § 488.4. We have reviewed the application and have concluded that the Joint Commission's accreditation program for hospitals meets or exceeds Medicare requirements.

IV. Provision of the Final Notice

A. Differences Between the Joint Commission's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the Joint Commission's hospital accreditation requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of the Joint Commission's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 482.12(a)(2) and § 482.22(c)(4), the Joint Commission revised its elements of performance (EPs) to require that all licensed independent practitioners who provide for the patient's care, treatment, and services in an accredited hospital via telemedicine are credentialed and privileged at the originating site. If the distant site is a Medicare-participating hospital, the originating site's medical staff may use a copy of the distant site's

credentialing packet for privileging purposes. This packet includes all credentialing documents, a list of all privileges granted to the licensed independent practitioner by the distant site, and an attestation signed by an appropriate official of the distant-site hospital, indicating that the packet is complete, accurate, and up-to-date.

- To meet the requirements at § 482.12(a)(7), the Joint Commission added a note to its EPs to clarify that an accredited hospital's staff membership and/or professional privileges are not dependent solely upon certification, fellowship, or membership in a specialty board or society.

- To meet the requirements at § 482.12(c)(4), the Joint Commission revised its EPs to require that in all accredited hospitals, a doctor of medicine or osteopathy is responsible for the care of each Medicare patient's medical or psychiatric problem.

- To meet the requirements at § 482.12(e), the Joint Commission revised its EPs to require that an accredited hospital's governing body be responsible for the oversight of contracted services.

- To meet the requirements at § 482.12(f)(1), the Joint Commission revised its EPs to ensure emergency services provided at an accredited hospital comply with CMS requirements set out at § 482.55.

- To meet the requirements at § 482.13(a)(1), the Joint Commission revised its EPs to address an accredited hospital's responsibility to notify patients of their rights.

- To meet the requirements at § 482.13(a)(2)(iii), the Joint Commission revised its EPs to require the written notice provided by accredited hospitals to patients in the grievance process contain the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance, and the date of completion.

- To meet the requirements at § 482.13(b)(2), the Joint Commission revised its EPs to include the requirement that patients in accredited hospitals have the right to make informed decisions about their care; however, this right is not to be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

- To meet the requirement at § 482.13(b)(4), the Joint Commission revised its EPs to include the requirement that the patient in an accredited hospital has the right to have a family member or representative of his or her choice and his or her own

physician notified promptly of his or her admission to the hospital.

- To meet the requirements at § 482.21, the Joint Commission revised its EPs to require that an accredited hospital develop and maintain an on-going quality assessment and performance improvement program.

- To meet the requirements at § 482.21(b)(3), the Joint Commission revised its EPs to require an accredited hospital's governing body to specify the frequency and detail of data collection.

- To meet the requirements at § 482.21(c)(2), the Joint Commission revised its EPs to require that an accredited hospital's performance improvement activities improve patient safety.

- To meet the requirements at § 482.21(d)(3), the Joint Commission amended its survey process activities to include review of the hospital's performance improvement projects.

- To meet the requirements at § 482.21(e)(5), the Joint Commission revised its EPs to require that an accredited hospital's governing body determine the number of distinct improvement projects conducted annually.

- To meet the requirements at § 482.22, the Joint Commission added a new EP to require that an accredited hospital have a single organized medical staff.

- To meet the requirements at § 482.22(c)(6), the Joint Commission revised its EPs to require that an accredited hospital's bylaws include criteria for determining when privileges are to be granted to individual practitioners.

- To meet the requirements at § 482.23(c)(4), the Joint Commission revised its EPs to require that accredited hospitals have a procedure for reporting transfusion reactions.

- To meet the requirements at § 482.24(b), the Joint Commission revised its EPs to require an accredited hospital to maintain a complete and accurate medical record for each individual patient.

- To meet the requirements at § 482.24(b)(1), the Joint Commission revised its EPs to require accredited hospitals to retain medical records in their original or legally reproduced form for a period of at least 5 years.

- To meet the requirements at § 482.24(c)(2)(i)(A), the Joint Commission revised its EPs to require that accredited hospitals complete and document a medical history and physical examination no more than 30 days before or 24 hours after a patient's admission or registration.

- To meet the requirements at § 482.24(c)(2)(vii), the Joint Commission revised its EPs to require the final progress note for each patient include the outcome of hospitalization, disposition of the case, and provisions for follow-up care.

- To meet the requirements at § 482.25, the Joint Commission revised its EPs to require that an accredited hospital's medical staff develop policies and procedures that minimize drug errors.

- To meet the requirements at § 482.25(a)(1), the Joint Commission added a new EP to require that an accredited hospital retain a full-time, part-time, or consulting pharmacist to develop, supervise, and coordinate all the activities of the pharmacy department or pharmacy service.

- To meet the requirements at § 482.25(b)(6), the Joint Commission revised its EPs to ensure that drug administration errors, adverse drug reactions and incompatibilities are reported to the hospital-wide quality assurance program as appropriate.

- To meet the requirements at § 482.25(b)(7), the Joint Commission revised its EPs to require that an accredited hospital report abuses and losses of controlled substances to the chief executive as appropriate.

- To meet the requirements at § 482.26(b)(3), the Joint Commission revised its survey process to include observation and interview of staff in radiation areas for utilization of exposure meters and exposure meter data.

- To meet the requirements at § 482.26(c)(2), the Joint Commission added a new EP to require an accredited hospital's medical staff to determine the qualifications of the radiology staff.

- To meet the requirements at § 482.28(a)(1)(i), the Joint Commission added a note to its EPs to clarify that the director of dietetic services in an accredited hospital must be a full-time employee responsible for the daily management of dietary services.

- To meet the requirements at § 482.28(b)(3), the Joint Commission added a new EP to require that an accredited hospital make available to all medical, nursing, and food service staff a current therapeutic diet manual approved by the dietician and medical staff.

- To meet the requirements at § 482.42(a), the Joint Commission added a new EP to require that each accredited hospital have an infection control officer responsible for developing and implementing policies governing the control of infections and communicable diseases.

- To meet the requirements at § 482.42(b)(1), the Joint Commission added a new EP to require that an accredited hospital delineate the responsibilities of the chief medical officer, medical staff, and director of nursing, to ensure that problems identified by the infection control officer are addressed and that corrective action plans are successfully implemented.

- To meet the requirements at § 482.45(b)(2), the Joint Commission added the definition of “organ” to its glossary.

- To meet the requirements at § 482.51(a)(4), the Joint Commission added a new EP to address the hospital’s responsibility to maintain a roster of practitioners specifying the surgical privileges of each practitioner.

- To meet the requirements at § 482.51(b)(2), the Joint Commission revised its EPs to require an accredited hospital to place a properly executed informed consent form in each patient’s chart before surgery, except in emergencies.

- To meet the requirements at § 482.51(b)(3), the Joint Commission added a note to its standards to clarify that the hospital must have the necessary resuscitation equipment available in the operating room.

- To meet the requirements at § 482.52(a), the Joint Commission added a new EP to include the requirements for individuals qualified to administer anesthesia in an accredited hospital.

- To meet the requirements at § 482.52(c), the Joint Commission added a new EP to incorporate the permissive exemption from physician supervision of certified registered nurse anesthetists.

- To meet the requirements at § 482.53(a)(2), the Joint Commission added a new EP to require that an accredited hospital’s service director and medical staff approve the qualifications, training, functions, and responsibilities of nuclear medicine personnel.

- To meet the requirements at § 482.53(c)(2), the Joint Commission revised its EPs to require an accredited hospital to inspect, test, and calibrate nuclear medicine equipment annually.

- To meet the requirements at § 482.53(d)(3), the Joint Commission added the definition “radiopharmaceuticals” to its glossary.

- To meet the requirements at § 482.54(b)(1), the Joint Commission added a new EP to require that an accredited hospital assign responsibility for outpatient services to one individual.

- To meet the requirements at § 488.55(a)(1) and § 482.55(b)(1), the

Joint Commission added a new EP to require an accredited hospital’s emergency services to be directed and supervised by a qualified member of the medical staff.

- To meet the requirements at § 482.56(a)(2), the Joint Commission revised its EPs to include qualifications for physical therapy, occupational therapy, speech-language pathology, and audiology services when these services are provided by accredited hospitals.

- To render a decision regarding the deemed status of an accredited hospital, The Joint Commission revised its accreditation decision letters to ensure that they are accurate and contain all the required elements for the CMS Regional Office.

- To meet the requirements at § 488.28(a), the Joint Commission updated its guidelines for submission of Evidence of Standards Compliance (ESC) to emphasize that the person responsible for implementation of corrective action and assessment of ongoing compliance must be documented in the ESC.

- To clearly identify whether an identified deficient practice represented condition-level or standard-level noncompliance, the Joint Commission modified its survey report.

- To meet the requirements of section 2728 of the SOM, the Joint Commission modified its policies regarding timeframes for sending an ESC.

- To meet the requirements at section 5075.9 of the SOM, the Joint Commission revised its policies to ensure complaint surveys triaged as non-immediate jeopardy (IJ) high and non-IJ medium are conducted within 45 calendar days.

- To meet the survey process requirements in Appendix A of the SOM, the Joint Commission developed a policy outlining the minimum number of inpatient records required for review during a certification survey.

- To meet the requirements at § 488.3(a), section 2026A of the SOM and Appendix A, the Joint Commission developed a new policy to ensure all areas and locations receiving payment under the Medicare’s provider agreement are surveyed for compliance with the conditions of participation independently.

- To meet the requirements at section 2700A of the SOM, the Joint Commission revised its survey activity guide to ensure all deemed status surveys are unannounced.

- To meet the requirements at § 489.18 and section 3210 of the SOM, the Joint Commission revised its policies to state that if an organization

acquires a new service, program, or site which requires an extension survey, the survey will be conducted within 6 months, and the results of the survey will immediately impact the accreditation status of the acquiring organization.

To verify the Joint Commission’s continued compliance with the provisions of this final notice, we will conduct a follow-up corporate onsite visit and survey observation within 1 year of the effective date of this notice.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that the Joint Commission’s requirements for hospitals meet or exceed our requirements. Therefore, we approve the Joint Commission as a national accreditation organization for hospitals that request participation in the Medicare program, effective July 15, 2010 through July 15, 2014.

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).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 15, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2305–FN]

Medicare and Medicaid Programs; Approval of the Accreditation Commission for Health Care for Deeming Authority for Hospices

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the