ascertain whether there have been any adverse events or medication errors associated with the doxycycline hyclate tablet emergency kit. If any such adverse events or medication errors have not previously been reported to FDA as outlined in paragraph H, they must be reported within 15 days to FDA. FDA has authorized ASPR's Form entitled ''Questions to Determine Status of Your Household Antibiotic Kit (HAK)'' (Kit Status form). Any revision of the Kit Status form is subject to FDA's prior approval. USPS, in conjunction with appropriate local public health authorities, will be responsible for ensuring that completed Kit Status forms are maintained until notified by FDA. A report summarizing the information collected on Kit Status forms under this paragraph will be submitted to FDA within 30 days of gathering such information. Associated records will be made available to FDA for inspection upon request.

L. USPS will be responsible for collecting any expired doxycycline hyclate tablet emergency kits and turning them over to the participating public health authority(ies). The participating public health authority(ies) will be responsible for disposing of expired doxycycline hyclate tablet emergency kits as instructed by ASPR at that time. The participating public health authority(ies) will ensure that drug accountability records are maintained and reconciled. Such records shall be made available to FDA for inspection upon request.

M. USPS and the participating public health authority(ies) will be responsible for ensuring that completed Health Assessment Forms, Healthcare Provider Quality Checklists, and any other records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

N. As a condition of this EUA, all advertising and promotional descriptive printed matter relating to the use of doxycycline hyclate tablet emergency kits authorized under this EUA shall be consistent with the Fact Sheets, home preparation instructions, and placard information, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

O. Upon termination of the declaration of emergency under section 564(b)(2) of the Act or upon revocation of this EUA under section 564(g) of the Act, USPS will be responsible for collecting all doxycycline hyclate tablet emergency kits and turning them over to the participating public health authority(ies). The participating public health authority(ies) will dispose of doxycycline hyclate emergency kits as instructed by ASPR at that time. The participating public health authority(ies) will ensure that drug accountability records are maintained and reconciled. Such records will be made available to FDA for inspection upon request.

P. HHS will notify FDA of its decision to add a CRI location and its decision to initiate distribution of doxycycline hyclate tablet emergency kits under this EUA to particular CRI locations.

The emergency use of doxycycline hyclate tablet emergency kits as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

Dated: June 17, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–15044 Filed 6–25–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2896–FN2]

Medicare and Medicaid Programs; Approval of the Joint Commission's Continued Deeming Authority for Critical Access Hospitals

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

ACTION: Final Notice of Removal of Conditional Probationary Status.

SUMMARY: Based on our review and observations, we have determined that the Joint Commission's accreditation standards for critical access hospitals (CAHs) meet or exceed our requirements. Therefore, this final notice announces our decision to approve without condition the Joint Commission's request for continued recognition as a national accreditation program for CAHs seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice of approval is effective November 21, 2008 through November 21, 2011.

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 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. Under this authority, the minimum requirements that a CAH must meet to participate in Medicare are set forth in regulations at 42 CFR part 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)) which determine the basis and scope of CAH covered services. Conditions for Medicare payment for CAHs are set forth at § 413.70. Applicable regulations concerning provider agreements are located in 42 CFR part 489 (Provider Agreements and Supplier Approval) and those pertaining to facility survey and certification are located in 42 CFR part 488, subparts A and B.

In general, we approve a CAH for participation in the Medicare program if it is participating as a hospital at the time it applies for CAH designation, and it is in compliance with part 482 (Conditions of Participation for Hospitals) and part 485, subpart F (*Conditions of Participation:* Critical Access Hospital (CAHs)).

For a CAH to enter into a provider agreement, a State survey agency must certify that the CAH is in compliance with the conditions or standards set forth in section 1820 of the Act and part 485 of our regulations. Thereafter, the CAH is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. There is, however, an alternative to State compliance surveys. Accreditation by a nationally-recognized accreditation program can substitute for ongoing State review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation 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.

A national AO applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions of participation. Our regulations concerning re-approval of AOs are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require AOs to reapply for continued approval of deeming authority every 6 years, or sooner as we determine. The regulations at § 488.8(f)(3)(i) provide CMS the authority to grant conditional approval of an AO's deeming authority, with a 180-day probationary period, if the AO has not adopted comparable standards during the reapplication process.

We received a complete application from the Joint Commission for continued recognition as a national accrediting organization for CAHs on March 28, 2008. In accordance with the

requirements at § 488.4 and § 488.8(d)(3), we published a proposed notice on May 23, 2008 (73 FR 30107) and a final notice announcing our decision approving deeming authority subject to probationary conditions on October 24, 2008 (73 FR 63480). This final notice is in response to the conditional approval with a 180-day probationary period granted to the Joint Commission on October 24, 2008. The Joint Commission did not adopt comparable standards to meet the requirements for distinct part units (DPU) in CAHs during its reapplication for renewal of deeming authority. This final notice is required to be published no later than July 19, 2009.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of a complete application to conduct our survey activities and application review process. Within 60 days of 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 an approval or denial of the application. In accordance with § 488.8(f)(2), if CMS determines, following the deeming authority review that the organization has failed to adopt requirements comparable to CMS requirements, the AO may be given a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements. Within 60 days after the end of this period, we must make a final determination as to whether or not the Joint Commission's CAH DPU accreditation requirements are comparable to CMS requirements and issue an appropriate notice that includes the reasons for our determination.

III. Provisions of the October 23, 2008 Final Notice

We revised the CAH requirements on August 11, 2004 (69 FR 49272) to include a new condition at § 485.647. This condition of participation (CoP) outlines the eligibility requirements for CAHs that wish to have a psychiatric or rehabilitation DPU. Under this condition, a CAH can provide inpatient psychiatric or rehabilitation services in a DPU so long as the services furnished in the DPU comply with the general hospital requirements specified at part 482, the requirements for excluded hospital units at § 412.25, and the additional requirements at § 412.27 for excluded psychiatric units; and § 412.29 and § 412.30 for excluded rehabilitation units as applicable. As a result, the Joint Commission had to address all of the DPU requirements set out at § 485.647, including a crosswalk addressing the Medicare hospital CoPs at part 482, as part of its application for renewal of CAH deeming authority. Review of the Joint Commission's accreditation standards during the reapplication submitted for renewal of deeming authority revealed significant gaps between the Joint Commission's standards and the Medicare CoPs. On October 24, 2008, we conditionally approved the Joint Commission's accreditation program for CAHs that request participation in the Medicare program with a 180 day probationary period. Under section 1865(a)(2) of the Act and our regulations at § 488.4 and § 488.8, we conducted a comparability review of the Joint Commission's CAH DPU standards to CMS hospital standards in part 482 and appropriate provisions of part 412 in order to determine compliance with the CAH DPU requirements at § 485.647.

IV. Provisions of the Final Notice

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

During the 180-day probationary period, we conducted a comparison of the Joint Commission's CAH DPU accreditation standards to our current Medicare CAH CoPs as outlined in the State Operations Manual. We also conducted a survey observation to validate proper application of the standards. Our review and evaluation of the Joint Commission's CAH DPU standards yielded the following:

- To meet the requirements at § 482.12(b), the Joint Commission added an element of performance (EP) to affirm that only one individual or designee may be the chief executive officer.
- To meet the requirements at § 482.12(e)(2), the Joint Commission added a new EP to require hospitals to maintain a list of all contracted services.
- To meet the requirements at § 482.12(f)(2), the Joint Commission added a new EP to require that the medical staff have written policies and procedures for on-campus and off-campus locations appraising emergencies, providing initial treatment, and for referring and transferring patients.
- To meet the requirements at § 482.13(e)(1)(i),the Joint Commission revised its EPs to include a definition of restraints.
- To meet the requirements at § 482.13(e)(1)(ii), the Joint Commission revised its EPs to include a definition of seclusion.
- To meet the requirements at § 482.13(e)(5), § 482.13(e)(8)(ii), § 482.23(c), and § 482.23(c)(2), the Joint Commission revised its EPs to include the reference ''as specified under § 482.12(c),'' which addresses the care of the patient.
- To meet the requirements at § 482.13(e)(10), the Joint Commission revised its EP to address the staff training requirements of individuals that monitor patients in restraints and seclusion.
- To meet the requirements at § 482.11(e)(11), the Joint Commission revised its EPs to require physicians and other licensed independent practitioners authorized to order restraints and seclusion have a working knowledge of hospital policy regarding the use of restraint and seclusion.
- To meet the requirements at § 482.13(f)(2), the Joint Commission revised its EPs to address the components of training, education, and demonstrated knowledge on restraint and seclusion.
- To meet the requirements at § 482.22(c)(5)(i), the Joint Commission revised its EP to include ''as defined in section 1861(r) of the Social Security Act,'' which contains the definition of a physician.
- To meet the requirements at § 482.23(b), the Joint Commission revised its EP to address the nurse staffing requirements, supervisory personnel, and immediate availability of a registered nurse for bedside care.
- To meet the requirements at § 482.23(c)(2), the Joint Commission revised its EP to address the requirements related to orders for drugs and biologicals.
- To meet the requirements at § 482.23(c)(2)(ii), the Joint Commission revised its EPs to address the requirement that hospitals have policies and procedures on who is authorized to accept verbal orders.
- To meet the requirements at § 482.23(c)(3), the Joint Commission added a new EP to require special training for staff members administering blood transfusions.
- To meet the requirements at § 482.24, the Joint Commission revised its EPs to include medical records as an essential service.

• To meet the requirements at § 482.24(a), the Joint Commission added a new EP that states the hospital must be able to ensure prompt completion, filing, and retrieval of records.

• To meet the requirements at 482.24(c)(1), the Joint Commission added a new EP that requires all patient medical records entries be timed.

• To meet the requirements at 482.24(c)(1)(i), the Joint Commission revised its EP to address ''all orders.''

• To meet the requirements at § 482.24(c)(1)(iii), the Joint Commission added a new EP to address the timeframe requirement for verbal order authentication.

• To meet the requirements at § 482.25, the Joint Commission revised its EP to include a requirement that the pharmacy must be directed by a registered pharmacist.

• To meet the requirements at § 482.25(b)(1), the Joint Commission revised its EP to require a pharmacist supervise all compounding, packing, and dispensing of drugs and biologicals.

• To meet the requirements at § 482.25(b)(2)(ii), the Joint Commission revised its EP to require all controlled substances included in Schedules II, III, IV, and V of the Comprehensive Drug Abuse and Prevention and Control Act be locked and secure.

• To meet the requirements at § 482.25(b)(6), the Joint Commission revised its EP to address the requirement, if necessary, to report drug administration errors, adverse drug reactions and incompatibilities to the hospital-wide quality assurance program.

• To meet the requirements at § 482.26(c)(1), the Joint Commission revised its EPs to state that a radiologist is a doctor of medicine or osteopathy.

• To meet the requirements at § 482.27(a), the Joint Commission revised its EP to include a statement that hospitals must provide laboratory services with a certified laboratory that meet the requirements of part 493 of title 42 of the Code of Federal Regulations.

• To meet the requirements at § 482.27(a)(1), the Joint Commission added a new EP requiring laboratory services be available 24 hours a day.

• To meet the requirements at § 482.27(a)(4), the Joint Commission added a new EP to require the medical staff and pathologist establish which tissue specimens require macroscopic and microscopic examinations.

• To meet the requirements at § 482.27(b), the Joint Commission added new EPs associated with potentially infectious blood and blood components.

• To meet the requirements at § 482.27(b)(5)(ii), the Joint Commission revised its EP to include the requirement that the plan to transfer medical records must be ''fully funded.''

• To meet the requirements at § 482.27(b)(6)(ii), the Joint Commission revised its EPs to include the statement that if the hospital administered potentially HIV or HCV infectious blood or blood components and the physician is unavailable or declines to make the notification, the hospital must make reasonable attempts to give this notification to the patient, legal guardian, or relative.

• To meet the requirements at § 482.28(a)(1)(iii), the Joint Commission revised its EP to include that the full time director of food and dietetic services be qualified by experience or training.

• To meet the requirements at § 482.43, the Joint Commission added a new EP to require hospitals have a discharge planning process that applies to all patients.

• To meet the requirements at § 482.43(b)(2), the Joint Commission added a new EP to require RNs, social workers or other appropriately qualified personnel develop, or supervise the development of the evaluation.

• To meet the requirements at § 482.43(b)(6), the Joint Commission added a new EP to require the inclusion of a discharge planning evaluation in the medical record for use in establishing an appropriate discharge plan. The Joint Commission also requires the hospital to discuss the results of the discharge plan with the patient or individual acting on behalf of the patient.

• To meet the requirements at § 482.43(c), the Joint Commission added new EPs to address the discharge planning requirements.

• To meet the requirements at § 482.51(b)(1)(ii), the Joint Commission revised its EPs to include a requirement for an update within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.

• To meet the requirements at § 482.52(a)(5), the Joint Commission revised its EPs to include ''as defined in § 410.69(c),'' which provides the definition of an anesthesiologist assistant.

• To meet the requirements at § 482.52(b)(3), the Joint Commission added a new EP to address the requirements of the postanesthesia evaluation.

• To meet the requirements at § 482.53(a)(1), the Joint Commission added a new EP to identify the nuclear medicine services that must be supervised and administered by a doctor of medicine or osteopathy qualified in nuclear medicine.

• To meet the requirements at § 482.53(b)(1), the Joint Commission added a new EP to state that the ''in-house preparation'' of radiopharmaceuticals must be under the supervision of an ''appropriately trained registered pharmacist or a doctor of medicine or osteopathy.''

• To meet the requirements at § 482.55(a)(1), the Joint Commission added a new EP that requires a qualified member of the medical staff direct emergency services.

• To meet the requirements at § 482.55(a)(3), the Joint Commission added an EP to clarify that the policies and procedures governing medical care provided in the emergency department are established by and are a continuing responsibility of the medical staff.

• To meet the requirements at § 482.55(b)(1), the Joint Commission added a new EP to require a qualified member of the medical staff supervise emergency services.

• To meet the requirements at § 482.57(a)(1), the Joint Commission added a new EP to address the requirement that there must be a director of respiratory services who is a doctor of medicine or osteopathy.

• To meet the requirements at § 482.57(b)(3), the Joint Commission added new EPs to state respiratory services are provided only on and in accordance with, the orders of a doctor of medicine or osteopathy.

B. Term of Approval

Based on the review and observations, we have determined that the Joint Commission's accreditation standards for CAHs meet or exceed our requirements. Therefore, we approve the Joint Commission as a national accreditation organization for CAHs that request participation in the Medicare program, effective November 21, 2008 through November 21, 2011. Under § 488.8(f)(4), notice was given to the Joint Commission on October 24, 2008 (73 FR 63480) and this notice, although not required by our regulations is being published as a public service for informational purposes.

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).

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

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

Dated: May 7, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–14778 Filed 6–25–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2476–PN]

Medicare and Medicaid Programs; Application by the American Association for Accreditation of Ambulatory Surgery Facilities for Continued Deeming Authority for Ambulatory Surgical Centers

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

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of an application from the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) for continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to participate in the Medicare or Medicaid programs. The statute requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 27, 2009.

ADDRESSES: In commenting, please refer to file code CMS–2476–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''More Search Options'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2476–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2476–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786–8636. Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from an ambulatory surgical center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for facilities 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, in order to enter into a provider agreement with the Medicare program, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416 of our regulations. Thereafter, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any