for-profits, not-for-profit institutions; State, Local or Tribal Governments; and Federal Government. *Number of Respondents:* 21,000; *Total Annual Responses:* 10,500; *Total Annual Hours:* 5,248.

4. *Type of Information Collection Request:* New collection; *Title of Information Collection:* State Plan Amendment template for 1915(i) State Plan Home and Community-Based Services (HCBS) Benefit; *Use:* Section 6086 of the Deficit Reduction Act (DRA), expanded access to HCBS for the elderly and disabled and added a new section 1915(i) to the Social Security Act. Under 1915(i), States can amend their State plans to add these services. The template includes the information needed by CMS to determine whether the State's services will meet the requirements under 1915(i). *Form Number:* CMS–10259 (OMB# 0938–NEW); *Frequency:* Once; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 3; *Total Annual Hours:* 240.

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Disproportionate Share Hospital Annual Reporting; *Use:* Section 1923(j)(i) of the Social Security Act requires States to submit an annual report that identifies each disproportionate share hospital (DSH) that received a DSH payment under the State's Medicaid program in the preceding fiscal year and the amount of DSH payments paid to that hospital in the same year and such other information as the Secretary determines necessary to ensure the appropriateness of DSH payments. The information supplied will satisfy the requirements under section 1923(a)(2)(D) of the Act as well. *Form Number:* CMS–R–266 (OMB# 0938–0746); *Frequency:* Yearly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 52; *Total Annual Responses:* 52; *Total Annual Hours:* 1976.

6. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities (PRTFs) for Individuals Under Age 21; *Use:* PRTFs are required to report deaths, serious injuries and attempted suicides to the State Medicaid Agency and the Protection and Advocacy Organization. They are also required to provide residents the restraint and seclusion policy in writing, and to document in the residents' records all activities involving the use of restraint and seclusion. *Form Number:* CMS–R–306 (OMB# 0938–0833); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 500; *Total Annual Responses:* 329,500; *Total Annual Hours:* 501,750.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on June 23, 2008: OMB Human Resources and Housing Branch, Attention: Carolyn Raffaelli, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: May 14, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–11397 Filed 5–22–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2896–PN]

Medicare and Medicaid Programs; The Joint Commission for Continued Deeming Authority for Critical Access Hospitals

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice with comment period acknowledges the receipt of a deeming application from the Joint Commission for continued recognition as a national accrediting organization for critical access hospitals (CAHs) that wish to participate in the Medicare or Medicaid programs. Section 1865(b)(3)(A) of the Social Security Act requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides 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 June 23, 2008.

ADDRESSES: In commenting, please refer to file code CMS–2896–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically*. You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov*. Follow the instructions for ''Comment of Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail*. You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2896–PN, P.O. Box , 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 (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2896–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 (one original and two copies) before the close of the comment period to one of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the HHH 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.)

If you intend to deliver your comments to the Baltimore address, please call (410) 786–7195 in advance to schedule your arrival with one of our staff members.

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

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: Cindy Melanson, (410) 786–0310. 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 in a 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. 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 485, subpart F specify the conditions that a CAH must meet in order to participate in the Medicare program, and the scope of covered services. The conditions for Medicare payment for CAHs are set out at § 413.70.

Generally, in order 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 part 482 and part 485, subpart F of CMS regulations. Thereafter, the CAH 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(b)(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, CMS shall 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 provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for deeming authority under part 488, subpart A, must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the reapproval of accrediting organizations are set forth at §§ 488.4 and 488.8(d)(3). The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued deeming authority every 6 years or sooner as determined by CMS.

The Joint Commission's term of approval as a recognized accreditation program for CAHs expires November 21, 2008.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and reapproval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's: Requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(b)(3)(A) of the Act further 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. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the Joint Commission's request for continued deeming authority for CAHs. This notice also solicits public comment on whether the Joint Commission's requirements meet or exceed the Medicare conditions for participation for CAHs.

III. Evaluation of Deeming Authority Request

The Joint Commission submitted all the necessary materials to enable us to make a determination concerning its request for reapproval as a deeming organization for CAHs. This application was determined to be complete on March 28, 2008. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of the Joint Commission will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of the Joint Commission's standards for a CAH as compared with CMS' CAH conditions of participation.
- The Joint Commission's survey process to determine the following:

—The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

—The comparability of the Joint Commission's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

—The Joint Commission's processes and procedures for monitoring CAHs found out of compliance with the Joint Commission's program requirements. These monitoring procedures are used only when the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.7(d).

—The Joint Commission's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

—The Joint Commission's capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.

—The adequacy of the Joint Commission's staff and other resources, and its financial viability.

—The Joint Commission's capacity to adequately fund required surveys.

—The Joint Commission's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.
—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).

IV. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

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).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866 (September 1993, Regulatory Planning and Review, the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354)), the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or tribal governments.

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—Supplementary Medical Insurance Program)

Dated: May 1, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–10776 Filed 5–22–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2224–N]

RIN 0938–ZA98

Medicare, Medicaid, and CLIA Programs; Continuing Approval of AABB (Formerly the American Association of Blood Banks as a CLIA Accreditation Organization

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

ACTION: Notice.

SUMMARY: In this notice, we reapprove and grant AABB (formerly known as the American Association of Blood Banks) deeming authority as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. This deeming authority is granted to AABB for the Blood Bank and Transfusion Service (BB/TS) accreditation program and the Immunohematology Reference Laboratory (IRL) Program.

DATES: *Effective Date:* This notice is effective from May 23, 2008 to May 23, 2014.

FOR FURTHER INFORMATION CONTACT: Daralyn Hassan, (410) 786–9360.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100–578. CLIA replaced in its entirety, section 353(e)(2) of the Public Health Service Act, as enacted by the Clinical Laboratory Improvement Act of 1967. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under the CLIA program, CMS may grant deeming authority to an accreditation organization that accredits clinical laboratories if the organization meets certain requirements. An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). The regulations in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specify the requirements an accreditation organization must meet to be an approved accreditation organization. We approve an accreditation organization for a period not to exceed 6 years.

In general, the approved accreditation organization must:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories at the frequency determined by CMS.
- Apply standards and criteria that are equal to, or more stringent than, those condition-level requirements established by CMS.
- Assure that laboratories accredited by the accreditation organization continually meet these standards and criteria.
- Provide us with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action taken.
- Notify us at least 30 days before implementing any proposed changes in its standards.
- If we withdraw our approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal.

CLIA requires that we perform an annual evaluation of approved accreditation organizations by inspecting a representative sample of laboratories accredited by an approved accreditation organization as well as by any other means that we determine to be appropriate.

II. Notice of Approval of AABB as an Accreditation Organization

In this notice, we approve AABB as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements. We have examined the AABB application and all subsequent submissions to determine equivalency with our requirements under subpart E of part 493 that an accreditation organization must meet to be approved under CLIA. We have determined that AABB complies with the applicable CLIA requirements and grant AABB approval as an accreditation organization under subpart E, as for the period stated in the ''Effective Date'' section of this notice for the following specialty and subspecialty areas:

- Microbiology, including Bacteriology, Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry, Urinalysis, Toxicology.
- Hematology.
- Immunohematology, including ABO Group and Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.