

Research Centers Network, SIP12-056, and Managing Epilepsy Well (MEW) Collaborating Center for Epilepsy Self-Management Intervention Research, SIP12-057, Panel E, initial review.”

*Contact Person for More Information:* M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F-46, Atlanta, Georgia 30341, Telephone: (770) 488-3585, [EEO6@cdc.gov](mailto:EEO6@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 17, 2012.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2012-12730 Filed 5-24-12; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS)

Notice of Cancellation: This notice was published in the **Federal Register** on April 13, 2012, Volume 77, Number 72, page 22326. This meeting scheduled to convene on May 17 and May 18, 2012, is cancelled due to lack of a quorum. Notice will be provided when the meeting is rescheduled in accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463).

*Contact Person for More Information:* Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7208, Hyattsville, Maryland 20782, Telephone (301) 458-4500, Fax (301) 458-4020, Email: [vcain@cdc.gov](mailto:vcain@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 15, 2012.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3257-N]

#### Medicare and Medicaid Programs; Announcement of the Re-Approval of the Joint Commission as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the application of the Joint Commission for re-approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for all specialty and subspecialty areas under CLIA. We have determined that the Joint Commission meets or exceeds the applicable CLIA requirements. We are announcing the re-approval and granting the Joint Commission deeming authority for a period of 6 years.

**DATES:** This notice is effective from May 25, 2012 to May 25, 2018.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Todd, (410) 786-3385.

#### SUPPLEMENTARY INFORMATION:

##### I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

## II. Notice of Approval of the Joint Commission as an Accreditation Organization

In this notice, we approve the Joint Commission as an organization that may accredit laboratories for purposes of establishing its compliance with CLIA requirements for all specialty and subspecialty areas under CLIA. We have examined the initial Joint Commission application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that the Joint Commission meets or exceeds the applicable CLIA requirements. We have also determined that the Joint Commission will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant the Joint Commission approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for all specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by the Joint Commission during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

## III. Evaluation of the Joint Commission Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the Joint Commission accreditation program meets the necessary requirements to be approved by CMS and that, as such, CMS may approve the Joint Commission as an accreditation program with deeming authority under the CLIA program. The Joint Commission formally applied to CMS for approval as an accreditation organization under CLIA for all specialties and subspecialties under CLIA. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

*A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program*

The Joint Commission submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. The Joint Commission policies and procedures for oversight of laboratories performing laboratory testing for all CLIA specialties and subspecialties are equivalent to those of CLIA in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. The Joint Commission's submitted requirements for monitoring and inspecting laboratories in the areas of accreditation organization, data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. The requirements of the accreditation programs submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

Our evaluation identified Joint Commission requirements pertaining to waived testing that are more stringent than the CLIA requirements. The Joint Commission waived testing requirements include the following:

- Defining the extent that waived test results are used in patient care.
- Identifying the personnel responsible for performing and supervising waived testing.
- Assuring that personnel performing waived testing have adequate, specific training and orientation to perform the testing and can demonstrate satisfactory levels of performance.
- Making certain that policies and procedures governing waived testing-related procedures are current and readily available.
- Conducting defined quality control checks.
- Maintaining quality control and test records.

The CLIA requirements at § 493.15 only require that a laboratory performing waived testing follow the manufacturer's instructions and obtain a certificate of waiver.

*B. Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing*

The Joint Commission requirements are equal to the CLIA requirements at § 493.801 through § 493.865.

*C. Subpart J—Facility Administration for Nonwaived Testing*

The Joint Commission requirements are equal to the CLIA requirements at § 493.1100 through § 493.1105.

*D. Subpart K—Quality System for Nonwaived Testing*

The Joint Commission requirements are equal to or more stringent than the CLIA requirements at § 493.1200 through § 493.1299. For instance, the Joint Commission has control procedure requirements for all waived complexity testing performed.

*E. Subpart M—Personnel for Nonwaived Testing*

We have determined that Joint Commission requirements are equal to the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing.

*F. Subpart Q—Inspections*

We have determined that the Joint Commission requirements are equal to the CLIA requirements at § 493.1771 through § 493.1780.

*G. Subpart R—Enforcement Procedures*

The Joint Commission meets the requirements of subpart R to the extent that it applies to accreditation organizations. The Joint Commission policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the Joint Commission will deny, suspend, or revoke accreditation in a laboratory accredited by the Joint Commission and report that action to CMS within 30 days. The Joint Commission also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the Joint Commission laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

**IV. Federal Validation Inspections and Continuing Oversight**

The Federal validation inspections of laboratories accredited by the Joint Commission may be conducted on a representative sample basis or in

response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the Joint Commission remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

**V. Removal of Approval as an Accrediting Organization**

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the Joint Commission, for cause, before the end of the effective date of approval. If we determine that the Joint Commission has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the Joint Commission would be allowed to address any identified issues. Should the Joint Commission be unable to address the identified issues within that timeframe, we may, in accordance with the applicable regulations, revoke the Joint Commission's deeming authority under CLIA.

Should circumstances result in our withdrawal of the Joint Commission's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

**VI. Collection of Information Requirements**

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938-0686.

**VII. Executive Order 12866 Statement**

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

**Authority:** Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: May 18, 2012.

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2012-12639 Filed 5-24-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3264-PN]

#### Medicare and Medicaid Programs; Application by American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) for Continuing CMS-Approval of its Ambulatory Surgery Center (ASC) Accreditation Program

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

**ACTION:** Proposed notice.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) for continued recognition as a national accrediting organization for ambulatory surgery centers (ASCs) that wish to participate in the Medicare or Medicaid programs.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 25, 2012.

**ADDRESSES:** In commenting, refer to file code CMS-3264-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

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-3264-PN, P.O. Box 8016, 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-3264-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments before only to 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, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously 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 section entitled **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Barbara Easterling, (410) 786-0416, Patricia Chmielewski, (410) 786-6899 or Cindy Melanson, (410) 786-0310.

**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

Section 1865(a)(3)(A) of the Social Security Act (the 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. Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of 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 an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416. 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 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 approval of its accreditation program under part 488, subpart A, must provide us with reasonable assurance that the