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 **[insert date of publication in Federal Register]** 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.

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