DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2218–N]

RIN 0938–ZA99

Medicare, Medicaid, and CLIA Programs; Approval of the Joint Commission (Formerly the Joint Commission on Accreditation of Healthcare Organizations) as a CLIA Accreditation Organization

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

ACTION: Notice.

SUMMARY: This notice announces CMS' grant of deeming authority to the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the requirements of the Joint Commission accreditation process are equal to or more stringent than the CLIA condition level requirements, and that the Joint Commission has met the requirements of subpart E of 42 CFR part 493. Consequently, laboratories that are voluntarily accredited by the Joint Commission and continue to meet the Joint Commission requirements will be deemed to meet the CLIA condition level requirements for laboratories and therefore are not subject to routine inspection by State survey agencies to determine their compliance with Federal requirements. They are, however, subject to Federal validation and complaint investigation surveys conducted by us or our designee.

DATES: *Effective Date:* This notice is effective from February 23, 2007 to February 23, 2012.

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), Public Law 100–578. CLIA replaced in its entirety section 353(e)(2) of the Public Health Service Act, as enacted by the Clinical Laboratories 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 approves a grant of deeming authority to an accreditation organization to accredit 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 with the frequency determined by us.
- Apply standards and criteria that are equal to, or more stringent than those condition level requirements established by us.
- 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 by inspecting a sufficient number 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 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 their compliance with CLIA requirements. We have examined the Joint Commission 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 the Joint Commission complied with the applicable CLIA requirements and grant the Joint Commission deeming authority as an accreditation organization under subpart E, for the period stated in the ''Effective Date'' 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 effective time period for an approved specialty or subspecialty is deemed to meet the CLIA requirements for the laboratories found in part 493 of our regulations and, therefore, is not subject to routine inspection 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 us, or by any other validly authorized agent.

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

The following describes the process used to determine that requirements of the Joint Commission accreditation program are equal to or more stringent than the CLIA condition level requirements, and that the Joint Commission has met requirements of subpart E of 42 CFR part 493.

The Joint Commission formally reapplied to us for approval as an accreditation organization under CLIA for all specialties and subspecialties. We evaluated the Joint Commission application to determine compliance with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules.

We verified that the Joint Commission accreditation program requirements and methods require the laboratories it accredits to be, and that the organization meets or exceeds the following subparts of part 493 as explained below:

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

The Joint Commission submitted the specialties and subspecialties that it would accredit; a comparison of individual accreditation and condition level requirements; a description of its inspection process; proficiency testing (PT) monitoring process; its data management and analysis system; a listing of the size, composition, education and experience of its inspection teams; its investigative and complaint response procedures; its notification agreements with us; its removal or withdrawal of laboratory accreditation procedures; its current list

of accredited laboratories; and its announced or unannounced inspection process.

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 processes 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 follow manufacturer's instructions and obtain a certificate of waiver.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

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

Subpart J—Facility Administration for Nonwaived Testing

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

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. We have determined that Joint Commission's requirements, when taken as a whole, are more stringent than the CLIA requirements. For instance, the Joint Commission has control procedure requirements for all waived complexity testing performed.

Subpart M—Personnel for Nonwaived Testing

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

Subpart Q—Inspections

We have determined that the Joint Commission requirements are equal to or more stringent than the CLIA requirements at § 493.1771 through § 493.1780. The Joint Commission will continue to perform onsite inspections every 2 years.

Subpart R—Enforcement Procedures

The Joint Commssion 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 us within 30 days. The Joint Commission also provides an appeal process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the Joint Commission's 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 Joint Commission accredited laboratories 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 us 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 failed to adopt requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its inspection process, we may give it a probationary period, not to exceed 1 year to allow the Joint Commission to adopt comparable requirements.

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 Clinical Laboratory Improvement Amendments of 1988 (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: December 7, 2006.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1391–NC]

Medicare and Medicaid Programs; Announcement of an Application From a Hospital Requesting Waiver for Organ Procurement Service Area

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

ACTION: Notice with comment period.

SUMMARY: This notice announces a hospital's request for a waiver from entering into an agreement with its designated organ procurement organization (OPO), in accordance with section 1138(a)(2) of the Social Security Act (the Act). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

DATES: *Comment Date:* To be assured consideration, comments must be