DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3354–N]

Medicare Program; Announcement of the Reapproval 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 reapproval 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 reapproval and grant the Joint Commission deeming authority for a period of 6 years.

DATES: *Effective Date:* This notice is effective from May 25, 2018 to May 28, 2024.

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 (Pub. L. 100–578) (CLIA). 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 Reapproval of the Joint Commission as an Accreditation Organization

In this notice, we reapprove 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 reapproval 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 reapproval 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 Reapproval as an Accreditation Organization Under CLIA

The following describes the process we used to determine that the Joint Commission accreditation program meets the necessary requirements to be approved by CMS and that, as such, we may approve Joint Commission as an accreditation program with deeming authority under the CLIA program. Joint Commission formally applied to CMS for reapproval as an accreditation organization under CLIA for all specialties and subspecialties under CLIA on 14 September 2017. 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 a description of its mechanisms for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its client laboratories and the expiration date of their accreditations, and a detailed comparison of the Joint Commission's individual accreditation requirements with the comparable condition-level requirements. We determined that the Joint Commission's policies and procedures for oversight of laboratory testing for all CLIA specialties and subspecialties with respect to inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available, are equivalent to those of CMS. The Joint Commission also submitted descriptions of its infrastructure and procedures for monitoring and inspecting laboratories in the areas of data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. We have determined that the requirements of the Joint Commission accreditation program are equal to or more stringent than the requirements of the CLIA regulations.

Our evaluation determined that Joint Commission requirements regarding waived testing are more stringent than the CLIA requirements set out at Part 493, subpart B. 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.

Our CLIA regulations at § 493.15(e) require that a laboratory 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's requirements are equivalent to the CLIA requirements at §§ 493.801 through 493.865.

C. Subpart J—Facility Administration for Nonwaived Testing

The Joint Commission's 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 as 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 equivalent 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 equivalent 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 us 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 as 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 the approval period. 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 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 reapproval 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.

Dated: May 16, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0438]

Agency Information Collection Activities; Proposed Collection; Comment Request; Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's procedures for early food safety evaluation of new non-pesticidal proteins produced by new plant varieties intended for food use, including bioengineered food plants.

DATES: Submit either electronic or written comments on the collection of information by July 24, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 24, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 24, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way: