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 organization 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: