FOR FURTHER INFORMATION CONTACT: Kathleen Todd, (410) 597–5906.

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 of the Public Health Service Act (PHSA), as enacted by the Clinical Laboratories Improvement Act of 1967, and made every laboratory in the United States and its territories that tests human specimens for health reasons subject to the requirements established by HHS, whether or not it participates in the Medicare or Medicaid programs. New section 353 requires HHS to establish certification requirements for any laboratory that performs tests on human specimens and certify through issuance of a certificate that a laboratory meets those certification requirements.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101–239, amended the Social Security Act (the Act) to require that a laboratory participating in the Medicare program meet the certification requirements of section 353 of the PHSA. Subject to specified exceptions, a laboratory must have a current unrevoked and unsuspended certificate to be eligible to participate in the Medicare or Medicaid programs or both. A laboratory that is accredited by an accreditation organization approved under section 353 of the PHSA is automatically eligible for Medicare and Medicaid participation as long as it meets applicable State licensure requirements.

Several additional rules have been published since the Congress enacted the CLIA requirements. Many of these rules gave non-Federal organizations the authority to act as an accrediting body to assure that a laboratory meets conditions required by Federal law and regulations. On February 28, 1992, we published several final rules in the **Federal Register** (57 FR 7002–7243) that implemented the amendments to section 353 of the PHSA. Specifically, regulations were established at 42 CFR part 493 that set forth the following:

- Require laboratories to pay fees for issuance of registration certificates, certificates of waiver, certificates of accreditation, or other applicable certificates and to fund activities to determine compliance with our performance requirements. (In a subsequent rule published January 19, 1993, 58 FR 5215, we added ''certificate for physician-performed microscopy procedures.'')
- Specify the performance requirements that apply to laboratories subject to CLIA (some of which were amended by the January 19, 1993 rule) and list requirements for laboratories performing certain limited testing to be eligible for a certificate of waiver.
- Set forth the rules for the enforcement of CLIA requirements on laboratories that are found not to meet Federal requirements.

On July 31, 1992, we issued a final rule (57 FR 33992), under the authority found in section 353(e)(2) of the PHSA, that permits us to approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if that organization's requirements for its accredited laboratories are equal to or more stringent than the applicable CLIA program requirements established at part 493 of our regulations. Under § 493.501(d)(4) of our regulations, the approval period may not exceed 6 years.

In general, the accreditation organization must meet the following requirements that are set forth in part 493:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HHS.
- Apply standards and criteria that are equal to or more stringent than those CLIA condition-level requirements for laboratories established by HHS when taken as a whole.
- Provide reasonable assurance that its standards and criteria are continually met by its accredited laboratories.
- Provide HHS with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited or revoked. HHS must receive this notification within 30 days of any adverse action against a laboratory.
- Notify HHS at least 30 days before the effective date of any proposed change in its standards.
- If HHS withdraws its approval for the organization to accredit laboratories, notify its accredited laboratories of the withdrawal within 10 days of the withdrawal.

Along with requiring us to publish criteria for approving an accreditation organization and for withdrawing the approval, CLIA requires HHS to annually evaluate the performance of the approved accreditation organization for compliance with the CLIA requirements by inspecting a sufficient number of laboratories accredited by the approved accreditation organization as well as by any other means that HHS determines appropriate. Under section 353(o) of the PHSA, HHS may, by agreement, use the services or facilities of any other Federal, State, or local public agency, or any private, nonprofit organization to conduct inspections of laboratories performing clinical testing on human specimens in the United States and its territories for the purpose of determining compliance with CLIA requirements.

II. Notice of Approval of AOA as an Accrediting Organization

This notice announces our decision to approve AOA as an organization that may accredit a laboratory for purposes of establishing its compliance with CLIA requirements for all specialty/subspecialty areas. We are approving AOA as an accreditation organization for the period July 21, 1995 through July 21, 1997.

AOA accredits laboratories for a 2-year period beginning with the date of the certification. Any laboratory that is accredited by AOA during this time period is deemed to meet the CLIA requirements 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 that we perform, or any other Federal, State, or local public agency or nonprofit private organization performs, which acts in conformance with an agreement with HHS.

III. Evaluation of the AOA Request for Approval as an Accreditation Organization under CLIA

AOA formally applied to us for approval as an accreditation organization under CLIA for all specialties and subspecialties. We evaluated the AOA application to determine equivalency with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules at 42 CFR part 493.

We also verified the organization's assurance that it requires the laboratories it accredits to be, and that the organization is, in compliance with the following subparts of 42 CFR part 493 as explained below:

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

AOA submitted a list of the specialties and subspecialties that it would accredit; a comparison of individual accreditation and condition-level requirements; a description of its