organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have found that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by it meet the conditions required by Federal law and regulations. Consequently, laboratories that voluntarily become accredited by CAP in lieu of receiving direct Federal oversight and continue to meet CAP requirements would 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 validation and complaint investigation surveys. **EFFECTIVE DATE:** This notice is effective for the period February 9, 1995 through December 31, 1998.

FOR FURTHER INFORMATION CONTACT: Val Coppola (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 and Federal regulation whether or not it participates in the Medicare or Medicaid program and whether or not it tests specimens in interstate commerce. 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 those laboratories meet the certificate requirements established by HHS.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101–239, amended the Social Security Act (the Act) to require that laboratories participating in the Medicare program meet the certificate requirements of section 353 of the PHSA. Subject to specified exceptions, laboratories must have a current unrevoked and unsuspended certificate to be eligible for reimbursement in the Medicare or Medicaid programs or both. Laboratories that are accredited by a private nonprofit organization approved under section 353 of the PHSA will automatically be eligible for Medicare and Medicaid participation as long as they meet applicable State requirements.

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. The technical and scientific portions of these rules were crafted by The Centers for Disease Control and Prevention (CDC) of the Public Health Service (PHS). Specifically, regulations were established at 42 CFR part 493 that:

• Require laboratories to pay fees for issuance of registration certificates, certificates of waiver, certificates of accreditation, or other applicable certificates (in a subsequent rule published January 19, 1993, 58 FR 5215, we added "certificate for physician-performed microscopy procedures") and to fund activities to determine compliance with our performance requirements;

• 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; and

• Set forth the rules for the enforcement of CLIA requirements on laboratories that are found not to meet Federal requirements.

On July 31, 1992, HCFA issued additional final rules (57 FR 33992), under authority found in section 353(e)(2) of the PHSA, that establish that we may 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 of part 493 of our regulations. Therefore, a laboratory accredited by an approved organization that meets and continues to meet all of the accreditation organization's requirements would meet CLIA condition level requirements if it were inspected against CLIA regulations. The regulations listed in subpart E of part 493 specify the requirements an accreditation organization must meet in order to be approved. We may approve an accreditation organization under §493.501(d) of our regulations for a period not to exceed six years.

In general, the accreditation organization must:

• Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HCFA; • Apply standards and criteria that are equal to or more stringent than those condition level requirements established by HHS when taken as a whole:

• Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories;

• Provide HCFA, within 30 days, with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked;

• Notify HCFA at least 30 days prior to changing its standards; and

• If HCFA withdraws its approval, notify its accredited laboratories of the withdrawal within 10 days of the withdrawal. A laboratory can be accredited if it meets the standards of an approved accreditation body and authorizes the accreditation body to submit to HCFA records and other information HCFA may require.

Along with requiring the promulgation of criteria for approving an accreditation body and for withdrawing such approval, CLIA regulations require HCFA to 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 HCFA determines appropriate. Under section 353(o) of the PHSA, the Secretary 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 CAP as an Accrediting Organization

In this notice, we approve CAP as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements. HCFA has examined the CAP application, in which it requested deemed status for all specialties and subspecialties, and all subsequent submissions against the requirements under subpart E of part 493 that an accreditation organization must meet in order to be granted approved status under CLIA. We have determined that CAP has complied with the applicable CLIA requirements as of February 9, 1995 and grant CAP approval as an accreditation organization under this Subpart through December 31, 1998 for all specialty/subspecialty areas.

As a result of this determination, any laboratory that is accredited by CAP