during this time period meets the CLIA requirements for 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 HCFA, or by any other Federal or State or local public agency or nonprofit private organization which acts in comformance to an agreement with the Secretary.

III. Evaluation of CAP

The following describes the process used to determine that CAP, as a private, nonprofit organization, provides reasonable assurance that those laboratories it accredits will meet the applicable requirements of the Federal law and regulations.

A. Requirements for Approving an Accreditation Organization Under CLIA

To determine whether HCFA should grant approval to CAP as a private, nonprofit organization for accrediting laboratories under CLIA, HCFA and CDC conducted a detailed and in-depth comparison of CAP's requirements for its laboratories to those of CLIA and evaluated whether CAP's standards are at least as stringent as the requirements of 42 CFR part 493 when taken as a whole. In summary, we evaluated whether CAP:

- Provides reasonable assurance to us that it requires the laboratories it accredits to meet requirements that are equal to or more stringent than the CLIA condition level requirements and would, therefore, meet the condition level requirements of CLIA if those laboratories had not been granted deemed status and had been inspected against condition level requirements; and
- Meets the requirements of § 493.506, which specify the Federal review and approval requirements of private, nonprofit accreditation organizations.

As specified in the regulations at § 493.506, our review of a private, nonprofit accreditation organization seeking deemed status under CLIA includes, but is not limited to, an evaluation of:

- Whether the organization's requirements for its accredited laboratories are equal to or more stringent than the condition level requirements of the CLIA regulations;
- The organization's inspection process to determine:

—The composition of the inspection teams, qualifications of the inspectors, and the ability of the organization to provide continuing education and training to all of its inspectors;
—The comparability of the organization's full inspection and complaint inspection processes to those of HCFA, including but not limited to inspection frequency, and the ability to investigate and respond to complaints against its accredited laboratories;
—The organization's procedures for monitoring laboratories that it has found to be out of compliance with its requirements;
—The ability of the organization to provide HCFA with electronic data and reports that are necessary for effective validation and assessment of the organization's inspection process;
—The ability of the organization to provide HCFA with electronic data, related to the adverse actions resulting from unsuccessful proficiency testing (PT) participation in HCFA approved PT programs, as well as data related to the PT failures, within 30 days of the initiation of the action;
—The ability of the organization to provide HCFA with electronic data for all its accredited laboratories and the areas of specialty and subspecialty of testing;
—The adequacy of numbers of staff and other resources; and
—The organization's ability to provide adequate funding for performing the required inspections.

- The organization's agreement with HCFA that requires it to:

—Notify HCFA of any laboratory that has had its accreditation denied, limited, suspended, withdrawn, or revoked by the accreditation organization, or that has had any other adverse action taken against it by the accreditation organization within 30 days of the action taken;
—Notify HCFA within 10 days of a deficiency identified in an accredited laboratory where the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public;
—Notify HCFA of all newly accredited laboratories, or laboratories whose areas of specialty or subspecialty are revised, within 30 days;
—Notify each laboratory accredited by the organization within 10 days of HCFA's withdrawal of recognition of the organization's approval as an accrediting organization under CLIA;
—Provide HCFA with inspection schedules, as requested, for the purpose of conducting onsite validation inspections;
—Provide HCFA, the State survey agency or other HCFA agent with any facility-specific data that includes, but is not limited to, PT results that constitute unsuccessful participation in HCFA approved PT programs and notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation;
—Provide HCFA with written notification at least 30 days in advance of the effective date of any proposed changes in its requirements; and
—Make available, on a reasonable basis, any laboratory's PT results upon the request by any person, with such explanatory information needed to assist in the interpretation of the results.

Laboratories that are accredited by a HCFA approved accreditation organization must:

- Authorize the organization to release to HCFA all records and information required by HCFA as required at § 493.501;
- Permit inspections as required by the CLIA regulations at 42 CFR part 493, subpart Q;
- Obtain a certificate of accreditation as required by § 493.632; and
- Pay the applicable fees as required by §§ 493.638 and 493.645.

B. Evaluation of the CAP Request for Approval as an Accreditation Organization Under CLIA

CAP has formally applied to HCFA for approval as an accreditation organization under CLIA for all specialties and subspecialties. We have evaluated the CAP application to determine equivalency with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules. 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

CAP has submitted a list of all specialties and subspecialties that it would accredit, a comparison of individual accreditation and condition level requirements, a description of its inspection process, PT monitoring process, and its data management and analysis system, a listing of the size, composition, education and experience of its inspection teams, its investigative