Another program modification addresses the gathering of information needed to investigate complaints. CAP has discontinued its practice of notifying the laboratory director of the specific reason for contact or inspection when a complaint investigation is in process.

The CAP will continue its policy of conducting announced biennial on-site inspections. An unannounced inspection would be performed when a complaint, lodged against a CAP accredited laboratory, indicates that severe and major problems exist within that laboratory that are likely to have serious and immediate effects on patient care.

Some areas of the CAP inspection process are more stringent that those of CLIA:

- CAP requires a mid-cycle selfinspection of all accredited laboratories. All requirements must be responded to in writing and the responses submitted to CAP within a specified timeframe; and
- A written evaluation of the inspection process and the inspectors must be completed after each on-site inspection of an accredited laboratory.
 The director of the inspected laboratory must submit this evaluation to the CAP within a specified timeframe.

Subpart R—Enforcement Procedures for Laboratories

CAP meets the requirements of subpart R to the extent that it applies to accreditation organizations. CAP policy stipulates the actions it takes when laboratories it accredits do not comply with its requirements and standards for accreditation. CAP will deny accreditation to a laboratory when appropriate and report the denial to HCFA within 30 days. CAP also provides an appeals process for laboratories that have had accreditation denied.

Some specific actions CAP takes in response to non-compliance or violation of its requirements or standards for accreditation include:

- When an accredited laboratory has been identified as having intentionally referred a PT specimen to another laboratory for analysis prior to the PT program end-date for receipt of results, the CAP laboratory will be denied accreditation and be ineligible for CAP accreditation for one year. This action is similar to the HCFA action of denial of certification for 1 year.
- When a CAP accredited laboratory participates unsuccessfully in PT for an analyte, subspecialty, and/or specialty, the laboratory must initiate corrective actions. It must submit to CAP

- documentation of a detailed investigation of the problem causing the unsuccessful performance with a corrective action plan within ten working days. Specific educational activity or the retention of the services of a consultant may also be imposed. Failure to bring PT performance into acceptable limits or failure to address the PT problem seriously would cause CAP to request the laboratory to cease testing for the procedure(s) in question or, if warranted, revoke the laboratory's accreditation. This action is equal to the actions that HCFA may take under this subsection.
- · When CAP becomes aware of a problem that is severe and extensive enough that it could cause a serious risk of harm (immediate jeopardy) situation in an accredited laboratory, an expedited evaluation is immediately undertaken by the Chair and Vice Chair of the Accreditation Committee, the regional Commissioner and the Director of the Laboratory Accreditation Program. If it is determined that an immediate jeopardy situation exists, the laboratory is required to remove the jeopardy situation immediately or accreditation would be revoked. An onsite focused re-inspection may be performed to verify that the immediate jeopardy no longer exists. These actions are similar to HCFA actions for immediate jeopardy.
- The CĂP requires its accredited laboratories to correct all deficiencies within 30 days. CLIA deficiencies that are not condition level must be corrected in a timeframe that is acceptable to HCFA, but no longer than 12 months. CLIA deficiencies that are condition level but are not instances of immediate jeopardy must be corrected in an acceptable timeframe; however, HCFA may impose one or more alternate sanctions or a principal sanction to motivate laboratories to correct these deficiencies. The CAP timeframe for correction of deficiencies, when taken as a whole, is more stringent than CLIA.

We have determined that CAP's laboratory enforcement and policies are equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of CAP accredited laboratories, as specified in § 493.507, may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (called complaint inspections). The outcome of those validation inspections, performed

by HCFA, the State survey agency, or a HCFA agent, will be HCFA's principal means for verifying that the laboratories accredited by CAP remain in compliance with CLIA requirements. This Federal monitoring is an on-going process.

V. Removal of Approval as an Accrediting Organization

Our regulations at § 493.511 provide that the approval of an accreditation organization, such as that of CAP, may be removed by HCFA for cause, prior to the end of the effective date of approval. If validation inspection outcomes and the comparability or validation review produce findings as described at § 493.509(a), HCFA will conduct a review of an accreditation organization's program. A review is also conducted when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2), indicate systemic problems in the organization's processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to the CLIA requirements, taken as a whole.

If it is determined that CAP has failed to adopt requirements that are equal to or more stringent than the CLIA requirements, or systemic problems exist in its inspection process, a probationary period, not to exceed one year, may be given to allow CAP to adopt comparable requirements. Based on an evaluation of any of the items stipulated at § 493.511(d), we will determine whether or not CAP retains its approved status as an accreditation organization under CLIA. If we deny approved status, an accreditation organization such as CAP may resubmit its application when it has revised its program to address the rationale for the denial, demonstrated that it can reasonably assure that its accredited laboratories meet CLIA condition level requirements, and resubmits its application for approval as an accreditation organization in its entirety. If, however, an accrediting organization requests reconsideration of an adverse determination in accordance with Subpart D of part 488 of our regulations, it may not submit a new application until a final reconsideration determination is issued.

Should circumstances result in CAP having its approval withdrawn, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.