FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–5496.

Dated: October 23, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–27835 Filed 10–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2118–N]

Medicare, Medicaid, and CLIA Programs; Continuance of the Approval of COLA as a CLIA Accreditation Organization

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the continued approval of COLA (formerly the Commission on Office Laboratory Accreditation) as an accreditation organization for 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 CLIA law and regulations. Consequently, laboratories that voluntarily become accredited by COLA in lieu of direct Federal oversight and continue to meet COLA 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 CLIA requirements. They are, however, subject to Federal validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective for the period October 31, 2000, through December 31, 2002.

FOR FURTHER INFORMATION CONTACT: Val Coppola, (410) 786–3531.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On July 31, 1992, HCFA issued a final rule (57 FR 33992). Under section 353(e)(2) of the Public Health Service Act (PHSA), HCFA may approve a private, nonprofit organization to accredit clinical laboratories (an ''approved accreditation organization'') under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program if the organization meets certain requirements. An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 Code of Federal Regulations (CFR), part 493 (Laboratory Requirements). Therefore, a laboratory accredited by an approved accreditation organization that meets and continues to meet all of the accreditation organization's requirements would be considered to meet CLIA condition level requirements if it were inspected against CLIA regulations. The regulations listed in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) of part 493 specify the requirements an accreditation organization must meet to be an approved accreditation organization. HCFA approves an accreditation organization for a period not to exceed 6 years.

In general, the approved accreditation organization must among other conditions and requirements:

- 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 HCFA when taken as a whole.
- Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories;
- Provide HCFA with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action taken.
- Notify HCFA in writing at least 30 days before the effective date of any proposed changes in its standards.
- If HCFA withdraws its approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal. A laboratory can be accredited if, among other things, it meets the standards of an approved accreditation organization 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 the accreditation body and for withdrawing this approval, CLIA requires 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.

II. Notice of Continued Approval of COLA as an Accreditation Organization

In this notice, we approve COLA as an organization that may continue to accredit laboratories for purposes of establishing their compliance with CLIA requirements. HCFA and Centers for Disease Control and Prevention (CDC) have examined the COLA application and all subsequent submissions to determine equivalency with HCFA requirements under subpart E of part 493 that an accreditation organization must meet to be granted approved status under CLIA. We have determined that COLA has complied with the applicable CLIA requirements as of October 31, 2000, and grant COLA approval as an accreditation organization under subpart E, through August 31, 2002, for the following specialty/subspecialty areas:

- Bacteriology.
- Mycobacteriology.
- Mycology.
- Parasitology.
- Virology.
- Syphilis Serology.
- General Immunology.
- Routine Chemistry.
- Endocrinology.
- Toxicology.
- Urinalysis.
- Hematology.
- Immunohematology.

As a result of this determination, any laboratory that is accredited by COLA during this time period for an approved specialty/subspecialty (listed above) is deemed to meet the applicable CLIA condition level requirements for the laboratories found in part 493 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 under an agreement with the Secretary.

III. Evaluation of COLA

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

A. Requirements for Approving an Accreditation Organization Under CLIA

To determine whether we should grant approved status to COLA as a private, nonprofit organization for accrediting laboratories under CLIA for the specific specialty or subspecialty areas of human specimen testing it requested, we conducted a detailed and in-depth comparison of COLA's requirements for its laboratories to those of CLIA. In summary, we evaluated whether COLA meets the following requirements:

• 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 (for the requested specialties/subspecialties) 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.

• Meets the applicable requirements of Subpart E.

As specified in the regulations of subpart E, HCFA review of a private, nonprofit accreditation organization seeking approved status under CLIA includes, but is not limited to, an evaluation of the following:

• 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 requirements to the Federal requirements 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 testing.

—The adequacy of the numbers of staff and other resources.

—The organization's ability to provide adequate funding for performing the required inspections.

• The organization's agreement with HCFA that requires it, among other things, to meet the following requirements:

—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 if 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 approval of the organization.

—Provide HCFA with inspection schedules, as requested, for the purpose of conducting onsite validation inspections.

—Provide HCFA or our agent, or the State survey agency with any facility-specific data that includes, but is not limited to, PT results that constitute unsuccessful participation in an approved PT program 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.

—Provide upon the request by any person, on a reasonable basis (under State confidentiality and disclosure requirements, if applicable), any laboratory's PT results with the explanatory information needed to assist in the interpretation of the results.

Laboratories that are accredited by an approved accreditation organization must, among other things, meet the following requirements:

• Authorize the organization to release to HCFA all records and information required.

• Permit inspections as required by the CLIA regulations in part 493, subpart Q (Inspection).

• Obtain a certificate of accreditation as required by § 493.55 (Application for registration certificate and certificate of accreditation).

B. Evaluation of the COLA Request for Continued Approval as an Accreditation Organization under CLIA

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

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

COLA has submitted a list of the specialties and subspecialties that it would continue to accredit, a description of its inspection process and guidelines, 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 and complaint response procedures, its notification agreements with HCFA, its removal or withdrawal of laboratory accreditation procedures, its current list of accredited laboratories, and its announced or unannounced inspection process. We have determined that COLA has complied with the requirements under CLIA for approval as an accreditation organization under this subpart.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both

COLA's requirements for PT are equivalent to those of CLIA.

Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both

COLA has revised its requirements to equal the CLIA requirements at §§ 493.1101 through 493.1111 on an overall basis.

Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both

The quality control (QC) requirements of COLA have been evaluated against the applicable requirements of CLIA and its implementing regulations. We have determined that COLA's requirements, when taken as a whole, are equal to or

more stringent than the CLIA requirements.

Subpart M—Personnel for Moderate and High Complexity Testing

We have found the COLA personnel requirements to be equal to the CLIA personnel requirements.

Subpart P—Quality Assurance for Moderate or High Complexity Testing or Both

We have determined that COLA's requirements are equal to the CLIA requirements of this subpart.

Subpart Q—Inspections

We have determined that COLA's inspection requirements are equal to the requirements of this subpart.

Subpart R—Enforcement Procedures for Laboratories

COLA meets the requirements of subpart R to the extent it applies to accreditation organizations. COLA policy stipulates the action it takes when laboratories it accredits do not comply with its requirements. COLA shall suspend, withdraw, revoke, or limit accreditation of a laboratory as appropriate and report the action to HCFA within 30 days. COLA also provides an appeals process for laboratories that have had accreditation denied.

We have determined that COLA's laboratory enforcement and appeal policies are essentially 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 COLA accredited laboratories may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections, performed by HCFA or our agent, or the State survey agency, will be HCFA's principal means for verifying that the laboratories accredited by COLA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may remove the approval of an accreditation organization, such as that of COLA, for cause, before the end of the effective date of approval. If validation inspection outcomes and the comparability or validation review produce findings as described in § 493.573 (Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure program), HCFA will conduct a review of an approved accreditation organization's program. We also conduct a review 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 HCFA determines that COLA has failed to adopt or maintain 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 1 year, may be given to COLA to adopt equal or more stringent requirements. HCFA will make a determination as to whether or not COLA retains its approved status as an accreditation organization under CLIA. If approved status is withdrawn, an accreditation organization such as COLA may resubmit its application if it revises its program to address the rationale for the denial, demonstrates 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 approved accreditation organization requests reconsideration of an adverse determination in accordance with subpart D (Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs) of part 488 (Survey, Certification, and Enforcement Procedures) of our regulations, it may not submit a new application until HCFA issues a final reconsideration determination.

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

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: September 18, 2000.

Nancy-Ann Min-DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–27956 Filed 10–30–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–4010–GNC]

RIN 0938–AK26

Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance During Fiscal Year 2001

AGENCY: Health Care Financing Administration (HCFA), Health and Human Services (HHS).

ACTION: General notice with comment period.

SUMMARY: This notice describes the criteria and standards to be used for evaluating the performance of fiscal intermediaries and carriers in the administration of the Medicare program beginning October 1, 2000. The results of these evaluations are considered whenever we enter into, renew, or terminate an intermediary agreement or carrier contract or take other contract actions, for example, assigning or reassigning providers or services to an intermediary or designating regional or national intermediaries. We are requesting public comment on these criteria and standards.

EFFECTIVE DATE: The criteria and standards are effective October 1, 2000.

COMMENTS: Comments will be considered if we receive them at the appropriate address as provided below no later than 5 p.m. (EDT) on November 30, 2000.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing, Administration, Department of Health and Human Services, Attention: HCFA–4010–GNC, P.O. Box 8016, Baltimore, MD 21244–8016.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, Maryland.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. When commenting, please refer to file code HCFA–4010–GNC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's office at 200 Independence Avenue,