DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2159–N]

RIN 0938–ZA34

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Continuance of Approval of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as an Accrediting Organization

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the continued approval of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by JCAHO meet the conditions required by the CLIA statute and its implementing regulations. Consequently, laboratories that voluntarily become accredited by JCAHO, in lieu of direct Federal oversight, and continue to meet JCAHO 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. These laboratories are, however, subject to Federal validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective for the period October 25, 2002, through October 25, 2005.

FOR FURTHER INFORMATION CONTACT: Kathleen Todd, (410) 786–3385.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100–578. CLIA replaced in its entirety section 353(e)(2) of the Public Health Service Act, as enacted by the Clinical Laboratories Improvement Act of 1967. On July 31, 1992, we published a final rule in the **Federal Register** (57 FR 33992) implementing the accreditation provisions of CLIA. Under this rule, we may approve a private, nonprofit organization as an approved accreditation organization to accredit clinical laboratories under the CLIA program if the organization meets certain requirements. An organization's requirements for accrediting a laboratory must be equal to, or more stringent than, the applicable CLIA program requirements in 42 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 in 42 CFR part 493, subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specify the requirements an accreditation organization must meet to be an approved accreditation organization. We approve an accreditation organization for a period not to exceed 6 years.

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

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by us.
- Apply standards and criteria that are equal to, or more stringent than, those condition level requirements established by us when taken as a whole.
- Provide reasonable assurance that these standards and criteria are continuously met by its accredited laboratories.
- Provide us 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 us at least 30 days before implementing any proposed changes in its standards.
- If we withdraw our approval, we will notify the accredited laboratory of the withdrawal within 10 days of the withdrawal. A laboratory can be accredited if, among other conditions and requirements, it meets the standards of an approved accreditation organization and authorizes the accreditation organization to submit records and other information to us as required.

In addition to requiring the publication of criteria for approving an accreditation organization and withdrawing this approval, CLIA regulations require us 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 we determine appropriate.

II. Notice of Continued Approval of the Joint Commission on Accreditation of Healthcare Organizations as an Accreditation Organization

In this notice, we approve JCAHO as an organization that may continue to accredit laboratories for purposes of establishing their compliance with CLIA. The Centers for Disease Control and Prevention (CDC) and CMS have examined the JCAHO application and all subsequent submissions to determine equivalency with the requirements under 42 CFR part 493, subpart E that an accreditation organization must meet to be granted approved status under CLIA. We have determined that JCAHO complied with the applicable CLIA requirements and grant JCAHO approval as an accreditation organization under 42 CFR part 493, subpart E, as of October 25, 2002, through October 25, 2005, for all specialty and subspecialty areas under CLIA.

As a result of this determination, any laboratory that is accredited by JCAHO during this time period for an approved specialty or subspecialty is deemed to meet the applicable CLIA condition level requirements for the laboratories found in 42 CFR 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 us, or by any other Federal, State, or local public agency, or nonprofit organization under an agreement with the Secretary.

III. Evaluation of Joint Commission on Accreditation of Healthcare Organizations

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

A. Requirements for Approving an Accreditation Organization Under Clinical Laboratory Improvement Amendments of 1988

To determine whether we should grant approved status to JCAHO as a private, nonprofit organization for accrediting laboratories under CLIA for all specialty or subspecialty areas of human specimen testing it requested, we conducted a detailed and in-depth comparison of JCAHO's requirements

for its laboratories to those of CLIA. In summary, we evaluated whether JCAHO 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 and 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 42 CFR part 493, subpart E.

As specified in the regulations of 42 CFR part 493, subpart E, the 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 following:

—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 finds out of compliance with its requirements.

—The ability of the organization to provide us 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 us with electronic data related to the adverse actions resulting from unsuccessful proficiency testing (PT) participation in CMS-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 us with electronic data for all its accredited laboratories and the area 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.

• Whether the organization has an agreement with us that requires it, among other conditions and requirements, to meet the following:

—Notify us 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 date the action is taken.

—Notify us 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 us 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 our withdrawal of approval of the organization as an accreditation organization.

—Provide us with inspection schedules, on request, for the purpose of conducting onsite validation inspections.

—Provide our agent, the State survey agency, or us 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 us 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 conditions and requirements, meet the following requirements:

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

• Permit inspections as required by the CLIA regulations at 42 CFR part 493, subpart Q (Inspection).

• Obtain a certificate of accreditation under § 493.55 (Application for registration certificate and certificate of accreditation).

B. Evaluation of the Joint Commission on Accreditation of Healthcare Organizations Request for Continued Approval as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

We have examined JCAHO'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:

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

JCAHO has requested continued approval to accredit all specialties and subspecialties and has submitted the following:

• Description of its PT monitoring process, inspection process, policies, and data management and analysis system.

• List of its inspection team size, composition, and education and experience.

• Investigative and complaint response procedures.

• Our notification agreements.

• Procedures for the removal or withdrawal of accreditation from a laboratory.

• Current list of accredited laboratories with an announced or unannounced inspection process.

We have determined that JCAHO has complied with the requirements under CLIA for approval as an accreditation organization under this subpart.

Our evaluation identified JCAHO requirements pertaining to waived testing that are more stringent than the CLIA requirements. The JCAHO waived testing requirements include the following:

• Defining the extent that waived test results are used in patient care.

• Identifying the personnel responsible for performing and supervising waived testing.

• Assuring that personnel performing waived testing have adequate, specific training and orientation to perform the testing and can demonstrate satisfactory levels of performance.

• Making certain that policies and procedures governing waived testing-related processes are current and readily available.

• Conducting defined quality control checks.

• Maintaining quality control and test records.

The CLIA requirements at § 493.15 only require that a laboratory follow

manufacturer's instructions and obtain a certificate of waiver.

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

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

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

JCAHO's requirements in Patient Test Management are equivalent to those of CLIA.

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

The quality control (QC) requirements of JCAHO have been evaluated against the applicable requirements of CLIA and its implementing regulations. We have determined that JCAHO's requirements, when taken as a whole, are more stringent than the CLIA requirements. The specific areas that are more stringent are the following:

- Requirements that laboratories must meet JCAHO's QC requirements for all waived testing performed.
- A requirement for mycobacteriology that laboratories perform daily QC of flourochrome acid-fast stains.
- Specific requirements for embryo laboratories that include standards for cryopreservation of specimens, embryo transfer procedures, and QC of the culture media used.
- Requirements for autopsy pathology that include appropriate refrigeration for cadaver storage when a delay occurs in performing an autopsy and requiring that provisional anatomic diagnoses are recorded in the clinical record within 3 days after the autopsy is performed.

5. Subpart M—Personnel for Moderate and High Complexity Testing

We have found that JCAHO's personnel requirements, when taken as a whole, are equal to the CLIA requirements.

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

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

7. Subpart Q—Inspections

JCAHO will continue to perform on-site inspections on a biennial basis. Therefore, we have determined that JCAHO's inspections are equivalent to CLIA.

8. Subpart R—Enforcement Procedures for Laboratories

JCAHO meets the requirements of subpart R to the extent that it applies to accreditation organizations. JCAHO policy stipulates the action it takes when laboratories it accredits do not comply with its requirements. JCAHO will deny, revoke, or limit accreditation of a laboratory as appropriate and report the action to us within 30 days. JCAHO also provides an appeal process for laboratories that have had accreditation denied, revoked, suspended, or limited.

We have determined that JCAHO's laboratory enforcement and appeal 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 JCAHO 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 our agent, or the State survey agency, or us, will be our principal means for verifying that the laboratories accredited by JCAHO remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide, in part, that we may remove the approval of an accreditation organization, such as that of JCAHO, 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 programs), we will conduct a review of an approved accreditation organization's program. In addition, we will conduct a review, when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2), indicate widespread or systemic problems in the organization's accreditation 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 validation inspection results over a 1-year period indicate a rate of disparity of 20 percent or more between the findings of the organization and those of CMS, we will conduct a review under § 493.575(a)(4).

If we determine that JCAHO has failed to adopt or maintain requirements that are equal to or more stringent than the CLIA requirements, or systematic problems exist in its inspection process, a probationary period as determined by us, not to exceed 1 year, may be given to JCAHO to adopt equal or more stringent requirements. We will make a final determination as to whether or not JCAHO retains its approved status as an accreditation organization under CLIA.

If approved status is withdrawn, an accreditation organization such as JCAHO 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. However, if 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 we issue a final reconsideration determination.

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

VI. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Since this notice announces the continued approval of JCAHO as an accreditation organization for clinical laboratories under the CLIA program and has no economic impact

on the Medicare, Medicaid, and CLIA programs, we have determined this requirement does not apply to this notice.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 to $29 million in any 1 year. For purposes of the RFA, JCAHO, a private, nonprofit organization, is considered to be a small entity. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We have determined that this notice will not have a consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this notice will not have a substantial effect on State or local governments.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this notice will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

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

Dated: June 14, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–25947 Filed 10–24–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4038–N]

Medicare Program: Meeting of the Advisory Panel on Medicare Education—November 19, 2002

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, section 10(a) (Pub. L. 92–463), this notice announces a meeting of the Advisory Panel on Medicare Education (the Panel) on November 19, 2002. The Panel advises and makes recommendations to the Secretary of the Department of Health and Human Services (HHS) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public.

DATES: The meeting is scheduled for November 19, 2002, from 9 a.m. to 4 p.m., e.d.s.t. *Deadline for Presentations and Comments:* November 12, 2002, 12 noon, e.d.s.t.

ADDRESSES: The meeting will be held at the Holiday Inn on the Hill, 415 New Jersey Avenue, NW., Washington, DC, 20001, (202) 638–1616.

FOR FURTHER INFORMATION CONTACT: Nancy Caliman, Health Insurance Specialist, Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, S2–23–05, Baltimore, MD, 21244–1850, (410) 786–5052. Please refer to the CMS Advisory Committees Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (*http://www.cms.hhs.gov/faca/apme/default.asp*) for additional information and updates on committee activities, or contact Ms. Caliman via e-mail at *ncaliman@cms.hhs.gov.* Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, grants to the Secretary the authority to establish an advisory panel if the Secretary finds the panel necessary and in the public interest. The Secretary signed the charter establishing the Advisory Panel on Medicare Education (the Panel) on January 21, 1999 (64 FR 7849) and approved the renewal of the charter on January 18, 2001. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the Panel are as follows:

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Dr. Jane Delgado, Chief Executive Officer, National Alliance for Hispanic Health; Joyce Dubow, Senior Policy Advisor, Public Policy Institute, AARP; Timothy Fuller, Executive Director, National Gray Panthers; John Graham IV, Chief Executive Officer, American Diabetes Association; Dr. William Haggett, Senior Vice President, Government Programs, Independence Blue Cross; Thomas Hall, Chairman and Chief Executive Officer, Cardio-Kinetics, Inc.; David Knutson, Director, Health System Studies, Park Nicollet Institute for Research and Education; Brian Lindberg, Executive Director, Consumer Coalition for Quality Health Care; Katherine Metzger, Director, Medicare and Medicaid Programs, Fallon Community Health Plan; Dr. Laurie Powers, Co-Director, Center on Self-Determination, Oregon Health Sciences University; Dr. Marlon Priest, Professor of Emergency Medicine, University of Alabama at Birmingham; Dr. Susan Reinhard, Co-Director, Center for State Health Policy, Rutgers University and Chairperson of the Advisory Panel on Medicare Education; Dr. Everard