meetings, CMS reimburses travel, meals, lodging, and related expenses in accordance with standard Government travel regulations.

CMS has a special interest in attempting to ensure, while taking into account the nominee pool, that the Panel is diverse in all respects of the following: Geography; rural or urban practice; race, ethnicity, sex, and disability; medical or technical specialty; and type of hospital, hospital health system, or other Medicare provider subject to the OPPS.

Based upon either self-nominations or nominations submitted by providers or interested organizations, the Secretary, or his designee, appoints new members to the Panel from among those candidates determined to have the required expertise. New appointments are made in a manner that ensures a balanced membership under the guidelines of the Federal Advisory Committee Act.

II. Criteria for Nominees

The Panel must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed. The Panel shall consist of up to 15 members who are representatives of providers. Each Panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPS. All members must have technical expertise to enable them to participate fully in the Panel's work. The expertise encompasses hospital payment systems; hospital medical care delivery systems; provider billing systems; APC groups; Current Procedural Terminology codes; and alpha-numeric Health Care Common Procedure Coding System codes; and the use of, and payment for, drugs, medical devices, and other services in the outpatient setting, as well as other forms of relevant expertise.

It is not necessary for a nominee to possess expertise in all of the areas listed, but each must have a minimum of 5 years experience and currently have full-time employment in his or her area of expertise. Members of the Panel serve overlapping terms up to 4 years, based on the needs of the Panel and contingent upon the rechartering of the Panel.

Any interested person or organization may nominate one or more qualified individuals. Self-nominations will also be accepted. Each nomination must include the following:

- Letter of Nomination;
- Curriculum Vita of the nominee; and
- Written statement from the nominee that the nominee is willing to serve on the Panel under the conditions described in this notice and further specified in the Charter.

III. Copies of the Charter

To obtain a copy of the Panel's Charter, submit a written request to the DFO at the address provided in the **ADDRESSES** section or by e-mail at *CMS APCPanel@cms.hhs.gov*, or call 410–786–4474.

Copies of the Charter are also available on the Internet at the following: *http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage*.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare-Supplementary Medical Insurance Program).

Dated: December 11, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–30454 Filed 12–19–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2283–N]

RIN 0938–AP20

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Permit-Holding Laboratories in the State of New York

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

ACTION: Notice.

SUMMARY: This notice announces that CMS has granted exemption from CLIA requirements to laboratories located within the State of New York that possess a valid permit under Article Five of Title V of the Public Health Law of the State of New York and its implementing regulations at 10 N.Y. Comp. Codes R. & Regs., Title V, Part 58.

DATES: *Effective Date:* The exemption granted by this notice is effective, unless revoked, for 6 years from the date of publication of this notice.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. Federal Law

Section 353 of the Public Health Service Act (the Act), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. 263a) generally requires any laboratory that performs tests on human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or assessment of the health of human beings to possess a certificate to perform that category of tests issued by the Secretary of the Department of Health and Human Services (HHS). Under sections 1861(s) of the Social Security Act, the Medicare program will only pay for laboratory services if the laboratory meets the certification requirements under section 353 of the Public Health Service Act. Section 1902(a)(9)(C) of the Social Security Act requires that State Medicaid plans pay only for laboratory services furnished by laboratories in compliance with section 353 of the Act. Subject to specified exceptions, laboratories therefore must have a current and valid CLIA certificate to be eligible for payment from the Medicare or Medicaid programs. Regulations implementing section 353 of the Act are contained in 42 CFR part 493.

Section 353(p) of the PHS Act provides for the exemption of laboratories from CLIA requirements in States that enact legal requirements that are equal to or more stringent than CLIA's statutory and regulatory requirements.

Section 353(p) of the Act is implemented in subpart E of regulations at 42 CFR part 493. Sections 493.551 and 493.553 provide that we may exempt from CLIA requirements, for a period not to exceed 6 years, State licensed or approved laboratories in a State if the State licensure program meets specified conditions. Section 493.559 provides that we will publish a notice in the **Federal Register** when we grant approval to an approved State laboratory licensure program. It also provides that the notice will include the following:

- The basis for granting the exemption.
- A description of how the laboratory requirements are equal to or more stringent than those of CLIA.
- The term of approval, not to exceed 6 years.

B. New York State Law

This title is generally applicable to all clinical laboratories operating within the state of New York except those operated by the Federal Government and those operated by a licensed

physician, osteopath, dentist, midwife, nurse practitioner or podiatrist who performs laboratory tests or procedures, personally or through his or her employees, solely as an adjunct to the treatment of his or her own patients. This notice is a repeat of New York State's laboratory licensure program's CMS approval under CLIA, and announces the beginning of a new period of exemption for its permitted laboratories.

II. Notice of Approval of CLIA Exemption to the New York State Laboratories

By this notice, we grant CLIA exemption to all laboratories located in the State of New York that possess a valid and appropriate permit to perform laboratory testing under New York's ''Clinical Laboratory Evaluation Program.''

III. Evaluation of the New York Laboratory Licensure (Permit) Program, the Clinical Laboratory Evaluation Program (CLEP)

The State of New York applied for exemption of its CLEP permit holding laboratories from CLIA program requirements. The State of New York submitted all of the applicable information and attestations required by § 493.551, § 493.553, and § 493.557 for State licensure programs seeking exemption of their licensed laboratories from CLIA program requirements. Examples of the documents and information that were submitted and reviewed are: A comparison of its laboratory licensure requirements with comparable CLIA condition-level requirements and descriptions of its: inspection and proficiency testing monitoring processes, data management and analysis system, investigative and response procedures for complaints received against laboratories, and policies regarding inspections.

IV. CMS and the Centers for Disease Control and Prevention (CDC) Analysis of New York's Application and Supporting Documentation

In order to determine whether we should grant a CLIA exemption to laboratories licensed by a State, we, with staff from CDC, review the application and additional documentation that the State submits to CMS and conducted a detailed and in-depth comparison of the CLEP State licensure (permit) program and CLIA requirements to determine whether the State program meets or exceeds the requirements at subpart E of part 493.

In summary, the State generally must demonstrate that its State licensure program meets the following requirements:

- Has State laws in effect that provide for laboratory licensure/permit program with requirements that are equal to or more stringent than CLIA condition-level requirements for laboratories.
- Has a State licensure program with requirements that are equal to or more stringent than the CLIA condition-level requirements such that a State program licensed laboratory would meet the CLIA condition-level requirements if it were inspected against those requirements.
- Is shown to meet the requirements of § 493.553, § 493.555, and § 493.557(b) and is approved by CMS under § 493.551. For example, among other things, a program would need to:

—Demonstrate that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.
—Permit CMS or CMS agents to inspect laboratories within the State.
—Require laboratories within the State to submit to inspections by CMS or CMS agents as a condition of licensure.
—Agree to pay the cost of the validation program administered by CMS and the cost of the State's pro rata share of the general overhead to develop and implement CLIA as specified in § 493.645(a), § 493.646(b), and § 493.557(b).
—Take appropriate enforcement action against laboratories found by CMS or CMS agents not to be in compliance with requirements comparable to condition-level requirements, as specified in § 493.557(b).

As specified in our regulations at § 493.555 and § 493.557(b), our review of a State laboratory program includes (but is not necessarily limited to) an evaluation of the following:

- Whether the State's requirements for laboratories are equal to or more stringent than the CLIA condition-level requirements.
- The State's inspection process requirements to determine the following:

—The comparability of the full inspection and complaint inspection procedures to those of CMS.
—The State's enforcement authority and procedures for laboratories found to be out of compliance with its requirements.
—The State's ability to electronically provide CMS with reports and data about adverse actions and corrective actions resulting from unsuccessful proficiency testing participation and with other data we determine to be necessary for validation review and assessment of the State's inspection process requirements.

- The State's agreement with CMS to ensure that the agreement obligates the State to do the following:

—Notify CMS within 30 days of the action taken against any CLIA-exempt laboratory that has had its licensure or approval withdrawn or revoked or been in any way sanctioned.
—Notify CMS within 10 days of any deficiency identified in a CLIA-exempt laboratory in cases when the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.
—Notify each laboratory licensed by the State within 10 days of CMS' withdrawal of the exemption.
—Provide CMS with written notification of any changes in its licensure (or approval) and inspection requirements.
—Disclose to CMS or a CMS agent any laboratory's PT results in accordance with a State's confidentiality requirements.
—Take the appropriate enforcement action against laboratories found by CMS not to be in compliance with CLIA condition-level requirements in a validation survey and report these enforcement actions to CMS.
—Notify CMS of all newly licensed laboratories, including changes in the specialties and subspecialties for which any laboratory performs testing, within 30 days.
—Provide CMS, as requested, inspection schedules for validation purposes.

In keeping with the process described above, CMS, with the assistance of CDC, reviewed and evaluated the application and supporting materials that were submitted by CLEP to verify that the CLEP permit holding laboratories will meet or exceed the requirements of the following subparts of part 493: Subpart H, Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing; Subpart J, Facility Administration for Nonwaived Testing; Subpart K, Quality Systems for Nonwaived Testing, Subpart M, Personnel for Nonwaived Testing; Subpart Q, Inspection; and Subpart R, Enforcement Procedures.

We found that the CLEP requirements mapped to all the applicable CLIA condition-level requirements. The New York State licensure program's inspection process and proficiency testing monitoring processes are equal to or more stringent than those of the CLIA program. Other materials that were submitted demonstrated compliance with the other above-

referenced requirements of subpart E of Part 493. As a result, CMS concluded that the submitted documents supported exempting permit holding laboratories under the CLEP from the CLIA program requirements. Furthermore, a review of CMS' validation inspections conducted by the CMS Regional Office in New York, New York supported that conclusion.

The Federal validation inspections of CLEP permit holding laboratories, as specified in § 493.563, were conducted on a representative sample basis as well as in response to any substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections has been and will continue to be CMS' principal tool for verifying that the laboratories located within the State that hold valid permits are in compliance with CLIA requirements.

The CMS Regional Office in New York has conducted validation inspections of a representative sample (approximately 5 percent) of the laboratories inspected by the New York State Office of Laboratory Quality Assurance (LQA). For some of these validation inspections, CMS surveyors simply accompanied New York State's inspectors, each inspecting against his or her agency's respective regulations. Analysis of the validation data revealed no significant differences between the State and Federal findings. The validation surveys verified that the CLEP inspection process covers all CLIA conditions applicable to each laboratory being inspected, and also verified that the CLEP licensure (permit) requirements meet or exceed CLIA condition-level requirements. The CMS validation surveys found the State inspectors highly skilled and qualified. The CLEP inspected laboratories in timely fashion, that is, all laboratories were inspected within the required 24-month cycle. All parameters monitored by CMS' New York Regional Office to date indicate that the State of New York is meeting all requirements for approval of CLIA exemption.

This Federal monitoring will continue as an on-going process.

V. Conclusion

Based on review of the documents submitted by the New York State laboratory licensure program, CLEP, pursuant to the requirements of subpart E of part 493, as well as the outcome of the validation inspections conducted by the CMS Regional Office in New York, we find that the State of New York laboratory licensure program meets the requirements of 42 CFR 493.551(a), and that as a result, we may exempt from CLIA program requirements all State licensed (permitted) or approved laboratories.

Approval of the CLIA exemption for laboratories located within and permitted by the State of New York is subject to removal if we determine that the outcome of a comparability review or a validation review inspection is not acceptable, as described under § 493.573 and § 493.575, or if the State of New York fails to pay the required fee every 2 years as required under § 493.646.

VI. Laboratory Data

In accordance with our regulations at § 493.557(b)(8), the State of New York will continue to agree to provide us with changes to a laboratory's specialties or subspecialties based on the State's survey. The State of New York also will provide us with changes in a laboratory's certification status.

VII. Required Administrative Actions

CLIA is a user-fee funded program. The registration fee paid by laboratories is intended to cover the cost of the development and administration of the program. However, when a State's application for exemption is approved, we do not charge a fee to laboratories in the State. The State's share of the costs associated with CLIA must be collected from the State, as specified in § 493.645.

Accordingly, the State of New York must pay for the following:

- Costs of Federal inspection of laboratories in the State to verify that New York State's CLEP requirements are enforced in an appropriate manner. The average Federal hourly rate is multiplied by the total hours required to perform Federal validation surveys within the State.
- Costs incurred for Federal investigations and surveys triggered by complaints that are substantiated. We will bill the State of New York on a semiannual basis.
- The State of New York's proportionate share of the costs associated with establishing, maintaining, and improving the CLIA computer system, a portion of those services from which the State of New York received direct benefit or contributed to the CLIA program in the State. Thus, the State of New York is being charged for a portion of CMS' direct and indirect costs as well as a portion of the costs incurred by the CDC and the Food and Drug Administration (FDA) in carrying out their responsibilities under CLIA.

In order to estimate the State of New York's proportionate share of the general overhead costs to develop and implement CLIA, we determined the ratio of laboratories in the State to the total number of laboratories nationally. Approximately 1.5 percent of the registered laboratories are in the State of New York. We determined that a corresponding percentage of the applicable CDC, FDA, and CMS costs should be borne by the State of New York.

The State of New York has agreed to pay us the State's pro rata share of the overhead costs and anticipated costs of actual validation and complaint investigation surveys. A final reconciliation for all laboratories and all expenses will be made. We will reimburse the State for any overpayment or bill it for any balance.

VIII. Approval

In light of the foregoing, CMS grants approval of the State of New York's laboratory licensure program (CLEP) under Subpart E. All laboratories located within the State of New York and hold valid CLEP permits are CLIA-exempt for all specialties and subspecialties.

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

Dated: November 7, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–30452 Filed 12–19–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Proposed Projects

Title: Hispanic Healthy Marriage Initiative Grantee Implementation Evaluation.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), in partnership with the Office of the Assistant Secretary for Planning, Research and Evaluation (ASPE), U.S. Department of Health and Human Services, is proposing an information collection activity as part of the Hispanic Healthy Marriage Initiative (HHMI) Grantee Implementation Evaluation study. The proposed information collection consists of two components: (1) Semistructured interviews with key respondents involved with selected marriage education programs serving Hispanic couples and individuals; and (2) focus