conflicts of interest involving Medicare contractors' ownership of other entities in the health care industry. If a response has indicated that a potential conflict of interest exists, the contractor is contacted and asked to address how the conflict can be avoided or mitigated. *Form Number:* CMS–R–312 (OMB#: 0938–0795); *Frequency:* Reporting—Annually; *Affected Public:* Private Sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 37; *Total Annual Responses:* 37; *Total Annual Hours:* 11,100.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: September 21, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–19247 Filed 9–27–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2267–N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories Licensed by the State of Washington

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

ACTION: Notice.

SUMMARY: This notice announces that laboratories located in and licensed by the State of Washington that possess a valid license under the Medical Test Site Licensure Law, Chapter 70.42 of the Revised Code of Washington, are exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 until September 28, 2013.

EFFECTIVE DATES: The exemption granted by the notice is effective until September 28, 2013.

FOR FURTHER INFORMATION CONTACT: Sandra Farragut (410)786–3531.

SUPPLEMENTARY INFORMATION:

I. Background

Section 353 of the Public Health Service Act (PHSA), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578) enacted on October 31, 1988, generally provides that no laboratory may perform tests on human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or assessment of the health of human beings unless it has a certificate to perform that category of tests issued by the Secretary of the Department of Health and Human Services (HHS). Under section 1861(s) of the Social Security Act (the Act), the Medicare program will only pay for laboratory services if the laboratory has a CLIA certificate. Section 1902(a)(9)(C) of the Act requires that State Medicaid plans pay only for laboratory services furnished by CLIA-certified laboratories. Thus, although subject to specified exemptions and exceptions, laboratories generally must have a current and valid CLIA certificate to test human specimens for medical purposes noted above to be eligible for payment for those tests from the Medicare or Medicaid programs. Regulations implementing section 353 of the PHS 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 PHS 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, all State licensed or approved laboratories in a State if the State Licensure Program meets the specified conditions. Section 493.559 provides that we will publish a notice in the **Federal Register** when we grant exemption 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.

State of Washington's Application for CLIA Exemption of Its Laboratories

The State of Washington has applied for exemption of its laboratories from CLIA program requirements. The State of Washington 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 documents and information submitted are: A comparison of its laboratory licensure requirements with comparable CLIA condition-level requirements (that is, a crosswalk); a description of its inspection process; proficiency testing monitoring process; its data management and analysis system; its investigative and response procedures for complaints received against laboratories; and its policy regarding announcement and unannouncement of inspections.

CMS Analysis of Washington's Application and Supporting Documentation

In order to determine whether we should grant a CLIA exemption to laboratories licensed by a State, we review the application and additional documentation that the State submits to CMS and conduct a detailed and in-depth comparison of State licensure program and CLIA requirements to determine whether the State program meets the requirements at subpart E of part 493.

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

- Have State laws in effect that provide for laboratory requirements that are equal to or more stringent than CLIA condition-level requirements for laboratories.
- Have a State licensure program with requirements that are equal to or more stringent than the CLIA condition-level requirements such that the State program licenses 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, programs 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 procedures for laboratories found to be out of compliance with its requirements.
—The ability of the State to provide CMS with electronic data and reports with the adverse or corrective actions resulting from proficiency testing (PT) results that constitute unsuccessful participation in CMS-approved PT programs 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, we evaluated the application and supporting materials that were submitted by Washington State to verify that the laboratories licensed through their program 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 Washington State's laboratory licensure program requirements mapped to all the CLIA condition-level requirements. Its licensure program's inspection process and proficiency testing monitoring processes were adequate. 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 laboratories licensed under that program from the CLIA program requirements. Furthermore, a review of CMS' validation inspections conducted by the CMS office in Seattle, Washington, supported the conclusion.

The Federal validation inspections of CLIA-exempt 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 in and licensed by the State are in compliance with CLIA requirements.

The CMS Regional Office in Seattle, Washington has conducted validation inspections of a representative sample (approximately 5 percent) of the laboratories inspected by the Washington State Office of Laboratory Quality Assurance (LQA). The validation inspections were primarily of the concurrent type; that is, CMS surveyors accompanied Washington 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 State of Washington inspection process covers all CLIA conditions applicable to each laboratory being inspected, and also verified that the State laboratory licensure requirements meet or exceed CLIA condition-level requirements. The CMS validation surveys found the State inspectors highly skilled and qualified. The LQA inspected laboratories in timely fashion, that is, all laboratories were inspected within the required 24-month cycle. All parameters monitored by CMS' Seattle office to date indicate that the State of Washington is meeting all requirements for approval of CLIA exemption. This Federal monitoring will continue as an on-going process.

Conclusion

Based on review of the documents submitted by the Washington State laboratory licensure program 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 Seattle, we find that the Washington State 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 or approved laboratories.

Approval of the CLIA exemption for laboratories located in and licensed by the State of Washington 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 Washington fails to pay the required fee every 2 years as required under § 493.646.

Laboratory Data

In accordance with our regulations at § 493.557(b)(8), the State of Washington 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 Washington also will provide us with changes in a laboratory's certification

status, such as a change from a regular certificate to a certificate of waiver.

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.

The State of Washington must pay for the following:

• Costs of Federal inspection of laboratories in the State to verify that Washington State's laboratory licensure program 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 Washington on a semiannual basis.

• The State of Washington'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 Washington received direct benefit or contributed to the CLIA program in the State. Thus, the State of Washington is being charged for a portion of CMS' direct and indirect costs as well as a portion of the costs incurred by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).

In order to estimate the State of Washington'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 Washington. We determined that a corresponding percentage of the applicable CDC, FDA, and CMS costs should be borne by the State of Washington.

The State of Washington 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.

II. Approval

In light of the foregoing, CMS grants approval of the State of Washington's laboratory licensure program under Subpart E. All laboratories located in and licensed by the State of Washington under the Medical Test Site Licensure Law, Chapter 70.42 of the Revised Code of Washington, are CLIA-exempt for all specialties and subspecialties until September 28, 2013.

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

Dated: July 20, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–18731 Filed 9–27–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Pennsylvania State Plan Amendment (SPA) 06–007

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

ACTION: Notice of Hearing.

SUMMARY: This notice announces an administrative hearing to be held on November 16, 2007, at Suite 216, The Public Ledger Building, 150 S. Independence Mall West, Conference Room 241, the Pennsylvania Room, Philadelphia, PA 19106, to reconsider CMS's decision to disapprove Pennsylvania SPA 06–007.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by October 15, 2007.

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, CMS, Lord Baltimore Drive, Mail Stop LB–23–20, Baltimore, MD 21244. Telephone: (410) 786–2055

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS's decision to disapprove Pennsylvania State plan amendment (SPA) 06–007 which was submitted on September 27, 2006. This SPA was disapproved on June 29, 2007.

Under this SPA, the State requested the addition of targeted case management services to low-income, first-time expectant mothers who have, or are at risk of having, a high incidence of medical or social problems. The new targeted case management services were to be provided through the Nurse Family Partnership Program. CMS made a Request for Additional Information on December 22, 2006, to which the State responded on April 2, 2007. The information provided confirmed that the targeted case management services proposed in SPA 06–007 are currently provided to all individuals without charge.

The amendment was disapproved because CMS found that the amendment violated the statute for reasons set forth in the disapproval letter. CMS consulted with the Secretary as required by Federal regulations at 42 CFR 430.15(c)(2).

Section 1902(a)(10) of the Social Security Act (the Act) requires that States make available medical assistance which is defined at section 1905(a) of the Act, and is limited to payment of medical costs for ''individuals whose income and resources are insufficient to meet all of such costs.'' The term ''medical assistance'' fundamentally excludes payment for medical services that are free to the general public, since where a service is provided without charge the individual is not in the circumstance of having insufficient income or resources to meet the cost of care. Hence, such services do not meet the definition of ''medical assistance.''

In addition, section 1902(a)(30) of the Act requires States to have methods and procedures in place to assure that payments are consistent with efficiency, economy, and quality of care. CMS did not find that Medicaid payments for case management for first-time expectant mothers were consistent with this requirement when these same services are available to non-Medicaid enrollees without charge. Furthermore, the State failed to provide documentation requested by CMS demonstrating that the rate methodology used to determine payments to service providers was consistent with section 1902(a)(30). The State also failed to provide documentation of the various cost elements used to determine a fee-schedule amount or to submit provider surveys conducted by the State to determine whether its proposed indirect cost rate should be applied to direct costs to calculate the final fee paid to providers.

Based on the above, and after consultation with the Secretary of the Department of Health and Human Services as required under Federal regulations at 42 CFR 430.15(c)(2), CMS disapproved Pennsylvania Medicaid SPA 06–007.

The issues to be decided at the hearing are:

• Whether Pennsylvania has demonstrated that its SPA 06–007