## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–10117, 10118, 10119, 10135, 10136 and CMS–R–138]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Advantage Application for Coordinated Care, Private Fee-for-Service, Regional Preferred Provider Organization, Service Area Expansion for Coordinated Care and Private Fee-for-Service Plans, Medical Savings Account Plans; *Form Nos.:* CMS–10117, 10118, 10119, 10135, 10136 (OMB # 0938–0935); *Use:* Health plans must meet certain regulatory requirements to enter into a contract with CMS to provide health benefits to Medicare beneficiaries. These applications are the collection forms to obtain the information from a health plan that will allow CMS staff to determine compliance with the regulations; *Frequency:* Other—one-time submission; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 420; *Total Annual Responses:* 520; *Total Annual Hours:* 20,100.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Geographic Classification Review Board (MGCRB) Procedures and Supporting Regulations in 42 CFR Sections 412.256 and 412.230; *Form Nos.:* CMS–R–138 (OMB #0938–0573); *Use:* Section 1886(d)(10) of the Social Security Act established the Medicare Geographic Classification Review Board (MGCRB), an entity with the authority to accept short-term hospital inpatient prospective payment system applications from hospitals requesting geographic reclassification for wage index or standardized payment amounts and to issue decisions on these requests. This regulation sets up the application process for prospective payment system hospitals that choose to appeal their geographic status to the MGCRB. This regulation also establishes procedural guidelines for the MGCRB; *Frequency:* Reporting—Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 500.

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/regulations/pra/*, 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 within 60 days of this notice to the address below:CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development,Attention: Melissa Musotto, PRA Specialist,Room C4–26–05,7500 Security Boulevard,Baltimore, Maryland 21244–1850.

Dated: April 22, 2005.

**Michelle Shortt,**

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

[FR Doc. 05–8713 Filed 4–28–05; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–2207–N]**

### Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988; Continuance of 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 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 (RCW), continue to be exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) until April 30, 2007.

**DATES:** The continuance granted by this notice is effective until April 30, 2007.

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

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Section 353 of the Public Health Service Act (PHS Act), as amended by the Clinical Laboratory Improvement Amendments of 1988, Pub. L. 100–578 (CLIA), provides that no laboratory may perform tests on human specimens unless it has a certificate to perform these tests issued by the Secretary of the Department of Health and Human Services (HHS). Under section 1861(s) of the Social Security Act, the Medicare program will pay for laboratory services only if the laboratory has a CLIA certificate. Section 1902(a)(9)(C) of the Social Security Act requires that State Medicaid plans pay only for laboratory services furnished by CLIA-certified laboratories. Thus, although subject to specified exemptions, laboratories generally must have a current and valid CLIA certificate to test human specimens and to be eligible for payment 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 a State that applies requirements that are equal to or more stringent than those of CLIA.

Regulations in 42 CFR part 493 subpart E implement section 353(p) of

the PHS Act. 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 specified conditions. Section 493.559 provides that we will publish a notice in the **Federal Register** when we grant exemption to a 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, and the term of approval, not to exceed 6 years.

On July 1, 1997 (62 FR 35513), we published a notice in the **Federal Register** announcing that the State of Washington had applied for exemption of its laboratories from CLIA requirements; that the evaluation of this application demonstrated that all requirements for exemption were met; and that the Washington State Laboratory licensure program was granted an approval of CLIA exemption for laboratories in its program.

## II. Requirements for Granting CLIA Exemption

In order to determine whether we should grant or continue an approval of an existing CLIA exemption to laboratories licensed by a State, we conduct a detailed and in-depth comparison of State licensure program and CLIA requirements to determine whether the State program meets the requirements at § 493.551 and § 493.553. In summary, the State must—

- Have laws in effect that provide for requirements that are equal to or more stringent than CLIA requirements;
- Have a State licensure program that licenses or approves laboratories that meet State requirements that meet or exceed CLIA requirements, and, therefore, meet the condition-level requirements of the CLIA regulations;
- Meet the requirements and be approved in accordance with § 493.555 and § 493.557(b);
- 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); and
- 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—

- 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 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; and
  - —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 us to ensure that the agreement obligates the State to—
  - —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 requirements comparable to CLIA condition-level requirements 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; and
  - —Provide CMS, as requested, inspection schedules for validation purposes.

## III. Evaluation of Washington's Request for Continued CLIA Exemption of Its Laboratories

Washington has applied for continued exemption of its laboratories from CLIA program requirements.

We evaluated the application to verify Washington's assurance of continued compliance with 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.

The Washington State Laboratory Licensure Program was found to continue to meet the requirements of subparts H, J, K, M, Q, and R.

We also verified the State of Washington's assurance that it requires the laboratories it licenses to meet the requirements for 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*

The State of Washington submitted 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 complaint response procedures; its current list of licensed laboratories; and its policy regarding announcement and unannouncement of inspections. We have determined that the State of Washington has complied with the requirements under subpart E of part 493 and that the requirements of its laboratory licensure program are equal to the condition-level requirements in subparts H, J, K, M, Q, and R of part 493.

*Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing*

The Washington State program's requirements are equal to the CLIA

requirements at § 493.801 through § 493.865.

*Subpart J—Facility Administration for Nonwaived Testing*

The Washington State Program's requirements are equal to the CLIA requirements at § 493.1100 through § 493.1105.

*Subpart K—Quality System for Nonwaived Testing*

The Quality Control (QC) requirements of the Washington State Laboratory Licensure Program have been evaluated against the requirements of the CLIA regulations. The Washington State Program has modified its survey process and made revisions to its requirements encompassing general QC as well as specialty and subspecialty QC requirements in order to reflect the new QC requirements of the CLIA regulations. As such, we have determined that the Washington State Program's requirements are equal to the requirements of the CLIA regulations.

*Subpart M—Personnel for Nonwaived Testing*

The Washington State Program requirements are equal to the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing.

*Subpart Q—Inspections*

The Washington State Laboratory Licensure Program requires laboratories to comply with the inspection requirements of § 493.1773 and § 493.1780 of this subpart, as applicable. Thus, we have determined that the Washington State Program's requirements are equal to the requirements of the CLIA regulations.

*Subpart R—Enforcement Procedures*

The Washington State Program meets the requirements of subpart R to the extent that subpart R applies to State laboratory licensure programs. Accordingly, we have determined that the Washington State Program's enforcement and appeal policies are equal to the requirements of the CLIA regulations.

**IV. Validation Inspections**

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.

Staff in the CMS Regional Office in Seattle, Washington have 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'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 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 survey staff 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 staff to date indicate that Washington is meeting all requirements for approval of CLIA exemption. This Federal monitoring will continue as an on-going process.

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

**V. Laboratory Data**

In accordance with § 493.557(b)(8), Washington will continue to agree to provide us with changes to a laboratory's specialties or subspecialties based on the State's survey. 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.

**VI. Required Administrative Actions**

CLIA is a totally 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.

Washington must pay for the following:

- Costs of Federal inspection of laboratories in the State to verify that Washington'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 Washington on a semiannual basis.
- Washington's proportionate share of the costs associated with establishing, maintaining, and improving the CLIA computer system, a portion of those services from which Washington received direct benefit or contributed to the CLIA program in the State. Thus, 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).

In order to estimate 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 1.6 percent of the registered laboratories are in Washington. We determined that 1.6 percent of the applicable CDC and CMS costs should be borne by Washington.

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.

**VII. Approval**

CMS grants continued approval of the CLIA exemption for all laboratory specialties and subspecialties to all laboratories located in and licensed by the State of Washington effective April 30, 2001 to April 30, 2007.

The State of Washington applied timely for re-approval, that is, to continue approval for exemption beyond the period ending April 30, 2001. Review of the application for continued approval, and evaluation of the outcomes of the validation inspections indicated that continued approval for 6 more years was in order. The actual publication of the continued approval was delayed, however, due to the timing of the publication of changes to the CLIA regulations, and subsequently the time period necessary

for the State of Washington to publish corresponding changes to the Washington State Medical Test Site Rules, which were effective March 19, 2005.

### VIII. Collection of Information Requirements

This document does not impose information collection, and recordkeeping requirements, which are subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 35). Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the PRA.

### VIX. Regulatory Impact Statement

This notice announces the continuance of the exemption of laboratories licensed by the State of Washington from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The State has established that the quality of laboratory services required under its Laboratory licensure program continues to be equal or more stringent than those required by the CLIA program. Washington also has established that it has a comparable program to monitor and evaluate compliance with its laboratory licensure program requirements. The effect of the continued exemption from CLIA requirements is that laboratories will remain under State, rather than Federal, regulation, with no discernible difference in the operations of the programs. Consequently, we anticipate that our continued approval of Washington's CLIA exemption will not affect the laboratories or the quality and availability of services provided.

We have examined the impact of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 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). This notice does not reach the economic threshold and thus is not considered a major rule.

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 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a notice 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. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

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. This notice will have no 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. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

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

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 8, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 05–8286 Filed 4–22–05; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–5033–N4]**

### Medicare Program; Meeting of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease Services—May 24, 2005

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the second public meeting of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease (ESRD) Services. Notice of this meeting is required by the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). The Advisory Board will provide advice and recommendations with respect to the establishment and operation of the demonstration mandated by section 623(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

**DATES:** The meeting is on May 24, 2005 from 9 a.m. to 5 p.m., eastern standard time.

*Special Accomodations:* Persons attending the meeting, who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify Pamela Kelly by May 17, 2005 by e-mail at *ESRDAdvisoryBoard@cms.hhs.gov* or by telephone at (410) 786–2461.

**ADDRESSES:** The meeting will be held at the Holiday Inn—BWI Airport, 890 Elkridge Landing Rd., Linthicum, MD 21090.

Attendance is limited to the space available, so seating will be on a first come, first served basis.

Web site: Up-to-date information on this meeting is located at *http://www.cms.hhs.gov/faca/esrd.*

Hotline: Up-to-date information on this meeting is located on the CMS Advisory Committee Hotline at 1 (877)