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.

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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