Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States.

The National Survey of Residential Care Facilities (NSRCF) is a new collection. It is designed to complement data collected by other federal surveys and to fill a significant data gap about a major portion of the long-term care population. Data from the NSRCF will provide a database on residential care facilities that researchers and policymakers can use to address a wide array of research and policy questions. The survey will utilize a computer-assisted personal interviewing (CAPI) system to collect information about facility and resident characteristics. This computerized system speeds the flow of data making it possible to release information on a more timely basis and makes it easier for respondents to participate in the survey.

A stratified random sample of residential care facilities across four strata (small, medium, large and extra large) will be selected to participate in the NSRCF. Within each facility a random sample of residents will be selected. To be eligible a facility must have four or more beds, be licensed, certified, or registered and provide or arrange for 24 hour supervision and personal care services for residents.

The facility questionnaire will collect data about facility characteristics (size, age, types of rooms), services offered, characteristics of the resident population, facility policies and services, costs of services, and background of the administrator. The Resident Questionnaire collects information on resident demographics, current living arrangements within the facility, involvement in activities, use of services, charges for care, health status, and cognitive and physical functioning.

In the pretest, 25 facility administrators, and 25 facility staff serving as respondents will be interviewed on an annualized basis. Residents themselves will not be interviewed. For the national survey, approximately 2,250 facilities will be surveyed for an annual average of 750. Information on 5 residents each will be collected from an annual average of 750 facility staff. Users of NSRCF data include, but are not limited to the CDC; the Congressional Research Office; the Bureau of Health Professions, Health Resources and Services Administration; the Office of the Assistant Secretary for Planning and Evaluation (ASPE); the Agency for Healthcare Research and Quality; the American Association of Homes and Services for the Aging; the National Hospice and Palliative Care Organization; American Health Care Association, Centers for Medicare and Medicaid Services (CMS), Bureau of the Census; and AARP. Other users of these data include universities, contract research organizations, many in the private sector, foundations, and a variety of users in the print media. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Facility Administrator (pretest)	25	1	1	25
Facility Staff (pretest)	25	5	30/60	63
Facility Administrator	750	1	1	750
Facility Staff	750	5	30/60	1,875
Total				2,713

Dated: September 24, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R–312]

Agency Information Collection Activities: Submission for OMB Review; 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), Department of Health and Human Services, 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 function; (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:* Conflict of Interest and Ownership and Control Information; *Use:* The Conflict of Interest and Ownership and Control Information Statement (COI Statement) is sent to all Medicare Fiscal Intermediaries (FIs) and Carriers to collect full and complete information on any entity's or individual's ownership interest (defined as a 5 per centum or more) in an organization that may present a potential conflict of interest in their role as a Medicare FI or Carrier.

The information gathered in the survey is used to ensure that all potential, apparent and actual conflicts of interest involving Medicare contractors are appropriately mitigated and that employees of the contractors, including officers, directors, trustees and members of their immediate families, do not utilize their positions with the contractor for their own private business interest to the detriment of the Medicare program. Information is also requested on potential organizational

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: