

information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a voluntary consumer survey about food safety.

DATES: Submit written comments on the collection of information by July 3, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Safety Survey (OMB Control Number 0910-0345)—Extension

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. FDA is planning to conduct a consumer survey about food safety under this authority. The food safety survey will provide information about consumers' food safety awareness, knowledge, concerns, and practices. A nationally representative sample of 2,000 adults in

households with telephones and cooking facilities will be selected at random and interviewed by telephone. Participation will be voluntary. Detailed information will be obtained about risk perception, perceived sources of food contamination, knowledge of particular microorganisms, safe care label use, food handling practices, consumption of raw foods from animals, information sources, and perceived foodborne illness and food allergy experience.

Most of the questions to be asked are identical to ones asked in the 1998 Food Safety Survey. Because of recent national consumer education campaigns about food safety and the large amount of media attention to food safety issues in the past few years, consumer attitudes, knowledge, and practices are likely to have changed greatly since the 1998 survey. FDA needs current information to support consumer education programs and regulatory development. In addition, FDA needs information from the consumer perspective on several new areas related to food safety. New areas include attitudes toward genetically modified foods, irradiated foods, and organically grown foods; handling of leftovers and foods associated with *listeria monocytogenes* contamination; washing practices for fresh fruits and vegetables; reaction to warning statements on unpasteurized juice and to handling statements on eggs; disability status; and perceived food allergy.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
2,000	1	2,000	.5	1,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate is based on FDA's experience with the 1998 survey mentioned in the previous paragraph.

Dated: April 26, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-10839 Filed 5-1-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-2117-N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Removal of Exemption of Laboratories in the State of Oregon

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice removes the Clinical Laboratory Improvement Amendments of 1988 (CLIA) exemption previously granted to laboratories within the State of Oregon. Section 353(p) of the Public Health Service Act grants us the authority to exempt from CLIA clinical laboratories located in a State that enacts and implements laws with requirements equal to or more stringent than the CLIA requirements.

EFFECTIVE DATE: The provisions of this notice are effective on May 2, 2000.

FOR FURTHER INFORMATION CALL: Judith Yost, (410) 786-3531.

SUPPLEMENTARY INFORMATION:

I. Background

Section 353 of the Public Health Service Act (PHSA), as amended by the Clinical Laboratory Improvement Act of 1988 (CLIA), requires laboratories that perform tests on human specimens to meet the requirements we establish. Laboratories that also request to be paid for services furnished to Medicare beneficiaries must meet the requirements of section 353 of the PHSA, as stipulated in section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101-239. Subject to specific exceptions, laboratories must have a current and valid CLIA certificate to test human specimens to receive payment from the Medicare or Medicaid programs. Regulations implementing section 353 of the PHSA are contained in 42 CFR part 493 (Laboratory Requirements).

Section 353(p) of the PHSA authorizes us to exempt from the CLIA requirements laboratories located in a State that applies laboratory licensure requirements equal to or more stringent than those of CLIA. Part 493, subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) implements section 353(p) of the PHSA.

Section 493.553 sets forth the information that must be submitted with a State licensure program's application for CLIA approved status. 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 specific conditions. After that time, the State must re-apply to us for continued exemption. Section 493.575(f) provides that we will publish a notice in the **Federal Register** containing justification for removing the CLIA approved status of a State licensure program.

II. CLIA Exemption of Licensed Oregon State Laboratories

The State of Oregon's period of exemption began on June 13, 1996, with the publication of our notice entitled, "Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories in the State of Oregon," in the **Federal Register** (61 FR 30072). That exemption period expired December 31, 1999. The State of Oregon has formally notified us that it will not be re-applying for exemption of its licensed laboratories located within the State. Without an application for continued approval of Oregon's

licensure program, we cannot continue to exempt Oregon laboratories from the CLIA requirement.

III. Removal of CLIA Approval of the State of Oregon's Laboratory Licensure Program

The nearly 4½-year exemption period that we granted to laboratories in the State of Oregon expired on December 31, 1999. Therefore, we are removing the CLIA approved status of Oregon's licensure program effective May 2, 2000.

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

Dated: March 3, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00-10882 Filed 5-1-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1134-N]

Medicare Program; Open Public Meeting on May 18, 2000 to Discuss the Coverage of Drugs and Biologicals that Cannot be Self-Administered

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting to obtain input on the Medicare program policy for drugs and biologicals which cannot be self-administered and are furnished as an incident to a physician's professional service. The meeting will provide an opportunity for providers, suppliers, beneficiaries, beneficiary advocates, and other interested parties to furnish information and raise issues about the program's policy concerning the self-administration of drugs and biologicals.

DATES: The meeting is scheduled for May 18, 2000 from 9:30 a.m. until 3:30 p.m.

ADDRESSES: The meeting will be held at the Health Care Financing Administration headquarters, in the auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT: Heidi Adams, (410) 786-1620.

SUPPLEMENTARY INFORMATION:

Background

As suggested by the report language accompanying section 219 of the Department of Health and Human Services Appropriations Act, 2000

(Public Law 106-113), we are announcing the first of two "town hall" meetings to discuss our current policy regarding Medicare coverage of drugs and biologicals which cannot be self-administered and are furnished as an incident to a physician's professional service.

The purpose of the May 18th meeting is to obtain focused input on how this statutory provision should reasonably be interpreted; how the evolution of medical technology has affected physician practice in self-administration; how different interpretations of the provision might affect considerations of fairness and equity among beneficiary populations; and how physician practice may be affected by different interpretations. Due to time constraints and the need to focus on the above topics, the agency is unable to undertake a discussion of options or ideas that require a statutory change.

The format of the meeting will include an introduction and opening statements by the administration, followed by 15-minute presentations by panel members. These statements will discuss the historical development of the "self-administered" issue and will examine the current policy and information that has been gathered on the issue. Following the short presentations, the meeting will move to an open dialogue.

Individuals interested in making a presentation at the meeting or who need special arrangements should contact Heidi Adams at (410) 786-1620 or via e-mail at HAdams@hcfa.gov no later than May 7, 2000. Individuals should identify the topics they wish to discuss during their presentation. Because of time constraints, only a limited number of individuals will be able to make presentations. In an effort to assure that all viewpoints are represented, we will notify participants who are selected to make a presentation. We will not assign presentation times until after May 7, 2000.

While the meeting is open to the public, attendance is limited to space available. Individuals must register in advance as described below.

Registration

The Center for Health Plans and Providers will handle registration for the meeting. Individuals may register by sending a fax to the attention of Heidi Adams at (410) 786-0169. At the time of registration, please provide your name, address, telephone number, company name and fax number.

Receipt of your fax will constitute confirmation of your registration.