

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.

Meeting materials will be provided at the time of the meeting.

If you have questions regarding registration, please contact Heidi Adams. We will accept written comments, questions, or other materials specifically dealing with the issue that are received no later than 5 p.m. on May 7, 2000. Written submissions must be sent to: Health Care Financing Administration, ATTN: Heidi Adams, C4-07-07, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302). (Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 26, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00-10883 Filed 5-1-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Clarification—Fiscal Year (FY) 2000 Funding Opportunities Notice

AGENCY: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Clarification of a Notice of Funding Availability Regarding the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) PRC Implementation Program Funding Announcement.

SUMMARY: This notice is to inform the public that a statement in the SAMHSA/CSAT Guidance for Applicants No. TI 00-004 entitled, Cooperative Agreement to Bridge the Gap: Phase II Implementation of Community-Based Practice/Research Collaboratives (Short Title: PRC Implementation Program) has been clarified. The Notice of Funding Availability for the PRC Implementation Program was published in the **Federal Register** on March 28, 2000 (65 FR 16401-16403).

A sentence in the last paragraph of Section II—Program Description, subsection 3, Pilot and Knowledge Application Evaluation Studies, has been clarified by adding the words “per year.” The revised sentence reads: “No single Knowledge Application Evaluation Study should exceed

\$75,000 in direct costs per year.” The full Guidance for Applicants is available via the SAMHSA web site—www.samhsa.gov, or from the National Clearinghouse for Alcohol and Drug Information (Telephone: 800-729-6686).

Questions concerning the clarification or other program issues may be directed to: Frances Cotter, Project Director, Office of Managed Care, Center for Substance Abuse Treatment, SAMHSA, Rockwall II, Suite 740, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (301) 443-8796.

Dated: April 24, 2000.

Richard Kopanda,

Executive Office, Substance Abuse and Mental Health Services Administration.

[FR Doc. 00-10838 Filed 5-1-00; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of the Secretary

Working Groups of the Invasive Species Advisory Committee

AGENCY: Office of the Secretary, DOI.

ACTION: Establishment.

SUMMARY: This notice is published in accordance with the provisions of the Federal Advisory Committee Act (Pub. L. 92-463). Pursuant to Executive Order 13112, the National Invasive Species Council (Council) on behalf of the Invasive Species Advisory Committee (ISAC) is establishing working groups to assist preparation of a National Invasive Species Management Plan (Management Plan) and ongoing stakeholder input to assist ISAC and Council activities.

SUPPLEMENTARY INFORMATION:

Working Groups—Scope and Objectives

The purpose of the working groups is to provide the ISAC and the Council advice on a broad array of issues related to preventing the introduction of invasive species and providing for their control and minimizing the economic, ecological, and human health impacts that invasive species cause. Six working groups have been established as follows:

1. Communication, Outreach, and Education
2. International Activities and Cooperation
3. Policy and Regulation
4. Research, Information Sharing, Documentation and Monitoring
5. Risk Analysis and Prevention
6. Management (Control and Restoration)

The working groups will help maintain a regular dialogue with

stakeholders to provide national leadership regarding invasive species issues. They will assist the ISAC and the Council to (1) Prepare and issue a Management Plan; (2) encourage planning and action at local, tribal, State, regional and ecosystem-based levels to achieve the goals and objectives of the management plan; (3) develop recommendations for international cooperation in addressing invasive species; (4) develop, in consultation with the Council on Environmental Quality, guidance to Federal agencies pursuant to the National Environmental Policy Act on invasive species matters; (5) facilitate development of a coordinated network to document, evaluate, and monitor impacts from invasive species; (6) facilitate establishment of an information-sharing system on invasive species that utilizes, to the greatest extent practicable, the Internet; and (7) support long-term continuance and effective implementation of the Management Plan.

Working groups have been organized with federal and non-federal co-leaders. The groups will utilize electronic communications (email, listservers, and web-based postings) to accelerate development of Management Plan input. The vision or scoping statements developed by each working group will reflect a more specific refinement of the draft guiding principles now under development by the ISAC. Priority issues will be identified and the groups will develop draft responses or actions to be taken for consideration by the ISAC. As part of the management planning process, model projects will be identified which improve coordination and effectiveness and stimulate action.

The working groups will report to the ISAC at least twice before the Management Plan is due to be completed in August, 2000. After issuance of the plan, the working groups will help implement the plan and begin developing input for its biennial revision.

Members of the working groups serve without pay.

FOR FURTHER INFORMATION CONTACT:

Kelsey Passe, National Invasive Species Council Program Analyst, Department of the Interior; Email: kelsey_passe@ios.doi.gov; Phone: (202) 208-6336; Fax: (202) 208-1526.

Dated: April 26, 2000.

William Y. Brown,

Science Advisor to the Secretary.

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