

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration [HCFA-1141-N]

Medicare Program; Open Public Meeting on July 25, 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 second public meeting to obtain input on the Medicare program policy for drugs and biologicals that are furnished as an incident to a physician's professional service and which cannot be self-administered. This meeting follows the public meeting held on May 18, 2000 at the Health Care Financing Administration headquarters on the same subject. The meeting will provide an opportunity for providers, suppliers, beneficiaries, beneficiary advocates, and other interested parties to furnish information and to address issues about the Medicare program's policy concerning the self-administration of drugs and biologicals.

DATES: The meeting is scheduled for July 25, 2000 from 9:30 a.m. until 1:30 p.m.

ADDRESSES: The meeting will be held at the Hyatt Regency O'Hare, 9300 West Bryn Mawr, Rosemont, IL, 60018, located three miles from the airport in Chicago. Special arrangements have been made with the Hyatt Regency to hold a limited number of rooms for out of town guests interested in attending. To reserve your room, please call the Hyatt directly at (847) 696-1234. When calling to make a reservation reference the *Health Care Financing Administration Town Hall Meeting*.

FOR FURTHER INFORMATION CONTACT: Heidi Adams, (410) 786-1620 (telephone); (410) 786-0169 (fax); Hadams@hcfa.gov (e-mail). We will accept written comments at the following address: Health Care Financing Administration, Heidi Adams, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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 second of two town hall meetings to discuss our current policy

regarding Medicare coverage of drugs and biologicals that are furnished as an incident to a physician's professional service and which cannot be self-administered. The first meeting was held on May 18, 2000. It raised several issues, in addition to other policy considerations that we believe should be addressed.

The scope of benefits provided to Medicare beneficiaries who are eligible under the Supplemental Medical Insurance program (Part B) includes coverage for certain "medical and other health services." Among those services are two specific provisions that include limited coverage of drugs and biologicals. Sections 1861(s)(2)(A) and (B) provide, in pertinent part, that:

(A) services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;

(B) hospital services (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) incident to physicians' services rendered to outpatients * * *

Coverage of drugs and biologicals under these provisions are only covered in the context of items furnished "incident to a physician's service." Moreover, historically, the determination of whether a drug "cannot be self-administered" has been based on the characteristics of the drug itself and not the patient's capacity to self-administer.

When considering self-administration and its effect on the coverage of drugs under Medicare, compelling concerns about Medicare beneficiary access to needed drugs were raised by presenters during the town hall meeting held on May 18, 2000. A report of the May 18, 2000 meeting may be found on the HCFA website (www.hcfa.gov). In addition, other important policy issues including financial, equity, and ethical issues are implicated. Due to time constraints, however, it may not be possible to present all view points on each issue at the public meeting.

Equity

In the area of equity, the main question is around the limitations on coverage.

- If considering "usual medical practice" for specific drugs, then what percentage of patients should constitute a usual practice? Should the universe of patients that is considered be:

- + Every patient;

- + Every Medicare patient;
 - + Every patient in the carrier's area;
- or
- + Every Medicare patient in the carrier's area.

- Should coverage be limited to beneficiaries whose condition is such that they could not self-administer any drug; for example, the disabled and those with dementia?

- Is it appropriate to consider only the patient's ability to self-administer, exclusive of any other considerations, such as those in this list?

- Should there be information collected on certain drugs to estimate a percentage of patients who could self-administer or who actually self-administer?

- Should psychiatric drugs be considered under special criteria, since patient compliance may be particularly problematic?

- Should coverage be limited only to injectable drugs?

- Should the policy consider whether another person, who is not a health-care professional (for example, the patient's spouse) can administer the drug to the beneficiary?

- Should the policy consider whether the drug is used to treat an acute illness or injury as compared to a chronic condition that requires drug therapy over an extended period?

Ethical Concerns

The ethical issues raised related to dilemmas physicians face in determining treatment practices as they try to follow the Medicare practices and policies when treating their patients with drug therapies.

- In developing criteria for application of this policy, is there a way to address the physician's dilemma of administering medication based on Medicare coverage status versus the most appropriate medical treatment.

- If the criterion is solely that physicians monitor the effects of the drug, then on what basis would oral drugs be excluded? What meaning would "cannot be self-administered" have over and above the meaning for "incident to a physician's service"?

- Should the criterion be solely the method of administration? Or should the nature of the chemical compound and its possible side effects also be considered?

- If the criterion is safe self-administration, then safely by whom? Should this be determined on a patient-by-patient basis?

Financial

The financial issues vary from the stand point of the manufacturer, program, and patient.

- How to address possible incentives for drug manufacturers to make drugs only in the form that cannot be self-administered. How should oral versus injectable drugs be evaluated?

- Considering the marketplace, how should Medicare's policy concerning self-administered drugs take into account a possible competitive disadvantage for oral and subcutaneous drugs that are self-administrable?

The purpose of the meeting on July 25, 2000 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. We are holding the second meeting to allow the public to address in more detail the issues raised during the first meeting by way of panel presentations and discussion. Due to time constraints, and the need to focus on the above topics, we are unable to undertake a discussion of options or ideas that require a statutory change.

Format

We will begin the meeting with a brief summary of the first meeting and a brief exposition of policy concerns that should be considered when addressing the issue of drugs and biologicals that cannot be self-administered. This will be followed by 15-minute panel presentations by participants who submit a prior request to speak.

Panels will be organized in the following manner to address the general categories of policy concerns:

1. Financial, including incentives/marketplace advantage to manufacturers of non self-administrable forms of drugs.
2. Beneficiary equity.
3. Physicians' ethical dilemmas, including prescription of drugs based on coverage status versus the most appropriate medical treatment.

After the last panel has concluded its presentations the meeting will move to an open dialogue.

Presentations

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@hcfca.gov, no later than July 14, 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 July 14, 2000.

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 July 14, 2000 at the address noted above.

While the meeting is open to the public, attendance is limited to space available. Individuals must register in advance as described above. Individuals requiring sign language interpretation for the hearing impaired or other special accommodations should contact Heidi Adams at least 10 days before the meeting.

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302) and 5 CFR 1320.3(h)(4).

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

Dated: June 28, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Availability of Funds for Loan Repayment Program for Repayment of Health Professions Educational Loans

AGENCY: Indian Health Service, HHS.

ACTION: Revised notice of availability of funds for loan repayment program for repayment of health professions educational loans for Fiscal Year (FY) 2000.

SUMMARY: The announcement for FY 2000 Availability of Funds for Loan

Repayment Program for Repayment of Health Professions Educational Loans was announced in 64 FR 53681 on October 4, 1999. The Indian Health Service (IHS) is republishing the full notice, for the convenience of the public, and in order to add that the IHS Area Offices and Service Units may provide additional funding to make awards to participants in the Loan Repayment Program (LRP), and to describe the policy for administering these funds.

The Administration's budget request for fiscal year (FY) 2000 includes \$11,000,000 for the Indian Health Service Loan Repayment Program for health professionals educational loans (undergraduate and graduate) in return for full-time clinical service in Indian health programs. It is anticipated that \$11,000,000 will be available to support approximately 275 competing awards averaging \$40,000 per award.

This program announcement is subject to the appropriation of funds. This notice is being published early to coincide with the recruitment activity of the IHS, which competes with other Government and private health management organizations to employ qualified health professionals. Funds must be expended by September 30 of the fiscal year. This program is authorized by Section 108 of the Indian Health Care Improvement Act (IHCA) as amended, 25 U.S.C. 1601 et seq. The IHS invites potential applications to request an application for participation in the Loan Repayment Program.

DATES: Applications for the FY 2000 Loan Repayment Program will be accepted and evaluated monthly beginning January 14, 2000, and will continue to be accepted each month thereafter until all funds are exhausted. Subsequent monthly deadline dates are scheduled for Friday of the second full week of each month. Notice of awards will be mailed on the last working day of each month.

Applicants selected for participation in the FY 2000 program cycle will be expected to begin their service period no later than September 30, 2000.

Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date; or
2. Sent on or before the deadline date. (Applicants should request a legibly dated U.S. Postal Service post mark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks are not acceptable as proof of timely mailing.)

Applications received after the monthly closing date will be held for