

confidence of unbiased decisions in formulary development? How can FDA protect scientific-exchange between the pharmaceutical company and the target audience while protecting the audience from false and misleading pharmaceutical promotion? How should FDA address methods employed by pharmaceutical manufacturers to "switch" patients from one drug therapy to another similar product? How should FDA address communications from the PBM's to the target audience? What specific types of information and services do managed health care organizations commonly request from the pharmaceutical industry? Examples of such services may include provider/patient education or formulary coordination between organizations ("pull-through").

III. Notice of Hearing under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner of Food and Drugs or his designee. The presiding officer will be accompanied by a panel of Public Health Service employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written notice of participation with the Dockets Management Branch (address above) by September 15, 1995. To ensure timely handling, any outer envelope should be clearly marked with docket number 95N-0228 and the statement "Pharmaceutical Marketing and Information Exchange in Managed Care Environments." Groups should submit two copies of materials. The notice of participation should contain the speaker's name, address, telephone number, affiliation, if any, brief summary of the presentation, and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. FDA will allocate the time available for the hearing among the persons who file notices of participation as described above. If time permits, FDA may allow interested persons attending the hearing who did not submit a written notice of participation in advance to make an oral presentation at the conclusion of the hearing.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the

person and the approximate time the person's oral presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing, the hearing schedule will be placed on file in the Dockets Management Branch under docket number 95N-0228.

Under § 15.30(f) (21 CFR 15.30(f)), the hearing is informal and the rules of evidence do not apply. The presiding officer and any panel members may question any person during or at the conclusion of their presentation. No other person attending the hearing may question a person making a presentation or interrupt the presentation of a participant.

Public hearings under part 15 are subject to FDA's guideline (21 CFR part 10, subpart C) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings. Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as required by § 15.30(b). Orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (address above).

Any handicapped person requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until December 29, 1995.

Dated: August 7, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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BILLING CODE 4160-01-F

Health Care Financing Administration [OPL-006-N]

Medicare Program; September 11, 1995 Meeting of the Practicing Physicians Advisory Council

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

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for September 11, 1995, from 8 a.m. until 4 p.m. e.d.t. An additional meeting is tentatively scheduled for December 11, 1995.

ADDRESSES: The meeting will be held in Room 800, 8th Floor, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Dr. Samuel Shekar, Executive Director, Practicing Physicians Advisory Council, Room 425-H, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, (202) 260-5463.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act as added by section 4112 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508, enacted on November 5, 1990), to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and under served urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term.

The Council held its first meeting on May 11, 1992.

The current members are: Richard Bronfman, DPM., Gary C. Dennis, M.D., Catalina E. Garcia, M.D., Harvey P. Hanlen, O.D., Kenneth D. Hansen, M.D., Ardis Hoven, M.D., Sandral Hullett, M.D., Jerilynn S. Kaibel, D.C., Marie G. Kuffner, M.D., Marc Lowe, M.D., Katherine L. Markette, M.D., Isadore Rosenfeld, M.D., Richard B. Tompkins, M.D., Kenneth M. Viste, Jr., and James C. Waites, M.D. The chairperson is Kenneth M. Viste, Jr. M.D.

The next meeting of the Council will be held on September 11, 1995. The Council agenda will provide for discussion and comment on two items:

- 1996 Physician fee schedule update.
- Notifying beneficiaries of the disposition of provider complaint investigations.

Those individuals or organizations who wish to make 5-minute oral presentations on the above issues should contact the Executive Director by 12:00 noon, August 25, 1995, to be scheduled. A written copy of the oral remarks should be submitted to the Executive Director no later than 12:00 noon, August 25, 1995. For the name, address, and telephone number of the Executive Director, see the **FOR FURTHER INFORMATION CONTACT** section at the beginning of this notice. The number of oral presentations may be limited by the time available.

In addition, Council members will receive a legislative update and be briefed on the Medicaid statewide health care reform demonstrations under section 1115 of the Social Security Act, automated multi-channel laboratory testing, and recent regulatory reforms.

Individuals or organizations may submit written comments on any of the above listed issues to the Executive Director by 12:00 noon, September 1, 1995. The meeting is open to the public, but attendance is limited to the space available on a first-come basis.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92-463 (5 U.S.C. App. 2, section 10(a)); 45 CFR Part 11)

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

Dated: August 7, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95-19995 Filed 8-11-95; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. FR-3946-D-01]

Redelegation of Authority

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of redelegation of authority.

SUMMARY: The General Deputy Assistant Secretary for Community Planning and Development is redelegating to the Director, Office of Technical Assistance and Management, the authority to impose sanctions pursuant to 24 CFR Part 24, as to certain enumerated programs.

EFFECTIVE DATE: August 4, 1995.

FOR FURTHER INFORMATION CONTACT:

Georjan D. Overman, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street, SW., Room 10251, Washington, DC 20410, telephone (202) 708-4248. A telecommunications device for the hearing-impaired (TDD) is available at (202) 708-0850. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: By delegations of authority dated October 23, 1983 (48 FR 49384), September 4, 1987 (52 FR 33793), June 3, 1988 (53 FR 20563) and August 22, 1994 (59 FR 43132), the Secretary of Housing and Urban Development has delegated to the Assistant Secretary and General Deputy Assistant Secretary for Community Planning and Development the power and authority of the Secretary with respect to certain enumerated programs. This authority includes the authority to impose sanctions on contractors and participants in those programs, pursuant to the provisions of 24 CFR Part 24. See 53 FR 39535 (October 7, 1988) (delegating to all the Assistant Secretaries of HUD the authority to impose sanctions pursuant to 24 CFR Part 24.) In this notice, the General Deputy Assistant Secretary for Community Planning and Development redelegates this authority to impose sanctions pursuant to 24 CFR Part 24, with respect to certain enumerated programs, to the Director, Office of Technical Assistance and Management.

Section A. Authority Redelegated

The General Deputy Assistant Secretary for Community Planning and Development redelegates to the Director,

Office of Technical Assistance and Management, Office of Community Planning and Development, the authority to impose sanctions on contractors and participants, pursuant to the provisions of 24 CFR Part 24, for those programs and matters listed below:

1. Title of the Housing and Community Development Act of 1974 (42 U.S.C. 5301), excluding the Work Study Program, under Section 107(c), and the Joint Community Development Program, under Section 107(b)(5).
2. The Urban Homesteading Program under section 810(b), (c), (d), (e), (g) and (h) of the Housing and Community Development Act of 1974 (12 U.S.C. 1706e), excluding the responsibilities delegated specifically to the Assistant Secretary for Housing.
3. The Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. 4601.)
4. The Rehabilitation Loan Program under section 312 of the Housing Act of 1964 (42 U.S.C. 1452b), excluding the exercise of powers under section 402(a) of the Housing Act of 1950 (12 U.S.C. 1749(a)), and excluding the responsibilities delegated specifically to the Assistant Secretary for Housing.
5. Community Planning and Development programs no longer authorized for funding until all Departmental responsibilities associated with them are discharged and finally terminated.
6. The Rental Rehabilitation Program under Section 17 of the Housing Act of 1937 (42 U.S.C. 1437o.)
7. The Comprehensive Homeless Assistance Plan, as authorized by Subtitle A of Title IV of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11301 note.)
8. The Emergency Shelter Grants Program as authorized by Subtitle B of Title IV of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11301 note.)
9. Enterprize Zone development as authorized by Title VII of the Housing and Community Development Act of 1987 (42 U.S.C. 11501-11505.)

Section B. No Further Redelegation

The authority redelegated to the Director, Office of Technical Assistance and Management may not be further redelegated pursuant to this delegation.

Authority: Sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).