

distribution. On the other hand, an action to replace software to correct a yet-to-be-manifested Y2K error in blood donor deferrals or in radiation dose calculations could be a market withdrawal, if that action is completed for all affected products in commercial distribution prior to the first date impacted by the Y2K failure.

For medical devices, if on or after May 18, 1998, (62 FR 27191 May 19, 1997) a manufacturer or importer initiates a correction or removal of medical devices to address a Y2K problem and that action is undertaken to reduce a risk to health, then the firm must report their action to FDA in accordance with the Corrections and Removals Regulation (21 CFR Part 806), regardless of whether or not there has been a malfunction related Y2K.

IV. Enforcement Discretion

The agency may exercise enforcement discretion and take into consideration any unusual or extenuating circumstance(s) that may have a bearing on a decision regarding enforcement action.

Regulatory Action Guidance:

I. Where regulated establishments and products are not compliant with laws and regulations administered by FDA because of Y2K computer issues, decisions on whether or not to pursue regulatory action should be based on an agency assessment of several factors including the following:

A. Products

1. Evaluate whether there is an existing or a potential risk to the public health (for example, specific patient populations or disease conditions) and the impact on product quality, intended purpose, function and/or use of the product. If it is a critical use or critical need product, assess its continued availability and whether there is/are the same or suitable substitute product(s) available to meet the anticipated need; and
2. Evaluate the firm's efforts to develop and initiate a Y2K contingency plan, implement suitable and timely risk assessment, prevention, and correction efforts, including efforts to inform potential users, re-label, return, reprocess, repair, or replace the product identified as Y2K non-compliant.

B. Establishments

In addition to the two items above (A1 and A2), where regulated establishments market violative products resulting from Y2K computer problems, determine responsibility to identify and correct Y2K problems prior to marketing the violative products.

II. District offices should consult with the respective center program monitor(s) (where appropriate) and/or center compliance officer(s) prior to recommending regulatory actions. District offices should obtain concurrence of the respective center program monitor(s) (where appropriate) and/or center compliance office(s) before issuing a warning letter regarding a Y2K computer problem.

Regulatory action with respect to product or process deficiencies caused by a Y2K computer problem must be based on applicable regulations and statutes. Therefore, regulatory citations should reference such regulations.

Dated: May 4, 1999.

Gary Dykstra,

Deputy Associate Commissioner for Regulatory Affairs.

[FR Doc. 99-12178 Filed 5-13-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1072-N]

Medicare Program; June 14, 1999, 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 June 14, 1999, from 8:30 a.m. until 5 p.m., e.s.t.

ADDRESSES: The meeting will be held in the Multipurpose Room/Auditorium, 1st Floor, Health Care Financing Administration Building, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Aron Primack, M.D., M.A., F.A.C.P., Executive Director, Practicing Physicians Advisory Council, Room 435-H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, (202) 690-7874. News media representatives should contact the HCFA Press Office, (202) 690-6145.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act 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, as 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 underserved 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—Jerold M. Aronson, M.D.; Richard Bronfman, D.P.M.; Wayne R. Carlsen, D.O.; Mary T. Herald, M.D.; Sandra Hullett, M.D.; Stephen A. Imbeau, M.D.; Jerilynn S. Kaibel, D.C.; Marie G. Kuffner, M.D.; Derrick K. Latos, M.D.; Dale Lervick, O.D.; Sandra B. Reed, M.D.; Susan Schooley, M.D.; Maisie Tam, M.D.; Victor Vela, M.D.; and Kenneth M. Viste, Jr., M.D. The Council chairperson is Marie G. Kuffner, M.D.

Council members will be updated on the following subjects—The acquisition of Provider Identification Numbers; Quality Improvement Activities as they relate to the Peer Review Organization Sixth Scope of Work; Managed Care Provider Protections under Medicare+Choice; Negotiated Rulemaking for Laboratories, and items and recommendations made at previous meetings.

The agenda will provide for discussion and comment on the following topics:

- Doctors' Readiness for Y2K. (How can HCFA reach and encourage practicing physicians to test their systems and equipment to be sure of their Y2K readiness?)
- HCFA's New Coverage Process.
- Requirements for Lead Screening.

Individual physicians or medical organizations that represent physicians that wish to make 5-minute oral presentations on the agenda issues should contact the Executive Director by 12 noon, May 21, 1999, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks should be submitted to the Executive Director no later than 12 noon, May 28, 1999, for distribution to Council members for review prior to the meeting. Physicians and organizations not scheduled to speak may also submit

written comments to the Executive Director and Council members. The meeting is open to the public, but attendance is limited to the space available.

(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 C.F.R. 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: May 10, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 99-12235 Filed 5-13-99; 8:45 am]

BILLING CODE 4120-01-U

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Renewal of Agency Information Collection for Indian Self-Determination and Education Assistance Contracts

AGENCIES: Bureau of Indian Affairs, Department of the Interior, and Indian Health Service, Department of Health and Human Services.

ACTION: Notice of request for comments.

SUMMARY: The Department of the Interior (DOI) and the Department of Health and Human Services (DHHS) announce a request for comments concerning renewal of 1076-0136, the Information Collection Request used for Indian Self-Determination and Education Assistance actions. The information collection will be used to process contracts, grants or cooperative agreements for award by the Bureau of Indian Affairs (Bureau) and the Indian Health Service (IHS) as authorized by the Indian Self-Determination and Education Assistance Act as amended and set forth in 25 CFR part 900. DOI and DHHS invite comment on the information collection described below. **DATES:** Interested persons are invited to submit comments on or before July 13, 1999.

ADDRESSES: If you wish to comment, you may submit your comments to James Thomas, Office of Tribal Services, Bureau of Indian Affairs, Department of the Interior, 1849 C Street NW, MS 4603 MIB, Washington, DC 20240. You may telefax comments on this information collection to (202) 208-5113. You may

also hand deliver written comments or view comments at the same address. You may obtain a copy of this information collection document at no charge by a written request to the same address, telefaxing a request to the above number, or by calling (202) 208-5727. Please identify the information collection by the number 1076-0136.

FOR FURTHER INFORMATION CONTACT: James Thomas, (202) 208-5727.

SUPPLEMENTARY INFORMATION: DOI and DHHS developed a joint rule, 25 CFR part 900, to implement section 107 of the Indian Self-Determination and Education Assistance Act, as amended, and Title I, Public Law 103-413, the Indian Self-Determination Contract Reform Act of 1994. Section 107(a)(2)(A)(ii) of the Indian Self-Determination Contract Reform Act requires the joint rule to permit contracts and grants be awarded to Indian tribes without the unnecessary burden or confusion associated with two sets of rules and information collection requirements when there is a single program legislation involved. The Bureau expects that the base burden hours established for this Information Collection Request, OMB 1076-0136, will be substantially reduced during the renewal process. The reduction in the number of base burden hours established for information collection requirements of 25 CFR part 900 is a result of three following factors:

(1) More tribes are contracting under 25 CFR 900.8 which permits tribes to contract several programs under a single contract;

(2) The number of self-governance tribes has increased. Self-governance tribes may combine all programs under a single self-governance compact;

(3) A moratorium on new and expanded self-determination contracting for FY 1999, which is expected to carry over into FY 2000, has prevented the tribes from requesting new contracts which have a higher burden than the recontracting proposals.

The information requirements for this joint rule represent significant differences from other agencies in several respects. Both the Bureau and IHS let contracts for multiple programs whereas other agencies usually award single grants to tribes. Under the Indian Self-Determination and Education Assistance Act, as amended, and the Indian Self-Determination Contract Reform Act of 1994, tribes are entitled to contract and may renew contracts annually where other agencies provide grants on a discretionary/competitive basis.

The proposal and other supporting documentation identified in this

information collection is used by the DOI and DHHS to determine applicant eligibility, evaluate applicant capabilities, protect the service population, safeguard Federal funds and other resources, and permit the Federal agencies to administer and evaluate contract programs. Tribal governments or tribal organizations provide the information by submitting Public Law 93-638 contract or grant proposals to the appropriate Federal agency. No third party notification or public disclosure burden is associated with this collection.

Request for Comments

DOI and DHHS request comments on this information collection particularly concerning:

(1) the necessity of the information collection for the proper performance of the agencies' functions;

(2) whether this information collection duplicates a collection elsewhere by the federal government;

(3) whether the burden estimate is accurate or could be reduced using technology available to all respondents;

(4) if the quality of the information requested ensures its usefulness to the agency(ies);

(5) if the instructions are clear and easily understood, leading to the least burden on the respondents.

Burden Statement

Each respondent is required to respond from 1 to 12 times per year, depending upon the number of programs they contract from the Bureau and IHS. In addition, each Subpart concerns different parts of the contracting process. For example, Subpart C relates to provisions of initial contract proposal contents. The burden associated with this would not be used when contracts are renewed. Subpart F describes minimum standards for the management systems used by Indian tribes or tribal organizations under these contracts. Subpart G addresses the negotiability of all reporting and data requirements in the contract.

Total annual burden: 299,552 hours.

Total number of respondents: 620.

Total number of responses: 6,880.

Dated: May 10, 1999.

Kevin Gover,

Assistant Secretary—Indian Affairs, Department of the Interior.

Dated: May 10, 1999.

Michel E. Lincoln,

Acting Director, Indian Health Service, Department of Health and Human Services.

[FR Doc. 99-12176 Filed 5-13-99; 8:45 am]

BILLING CODE 4310-02-P