DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Office of the Secretary

Information Collection Activity Under Emergency Review by the Office of Management and Budget (OMB)

Title: Survey of Biomedical Equipment Manufacturers for Year 2000 Compliance

Paperwork Reduction Act Requirements

We are required to solicit public comments under section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. Specifically, comments are invited on (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; (4) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. We are seeking emergency OMB approval for this collection of information.

Description

The Deputy Secretary of the Department of Health and Human Services, on behalf of the government-wide Biomedical Equipment Subgroup of the CIO Council's Year 2000 Subcommittee, is surveying manufacturers of biomedical equipment about the Year 2000 compliance of their products. The existence of a Year 2000 date problem in biomedical equipment could pose potentially serious health and safety consequences.

Manufacturers are requested to post information about noncompliance products on a web site and link this to a government web site on biomedical equipment. If all of a manufacturer's products are compliant, they are requested to provide notice of total product compliance. Manufacturers have the option to mail the information to the Department of Health and Human Services for posting on the government web site. All information collected will be available to the public through the government web site.

To be Year 2000 compliant, a product must be able to accurately process date information in the Year 2000 and between the twentieth and twenty-first centuries, including leap year calculations. Medical devices and scientific laboratory equipment may experience problems beginning January 1, 2000 if the computer systems, software applications, or embedded chips used in these devices and equipment contain two-digit fields for year representation.

The Food and Drug Administration (FDA) regulates medical devices and needs information regarding the Year 2000 compliance of these products. Under a previous Good Manufacturing Practices regulation and the current Quality System Regulation, effective June 1, 1997, manufacturers must investigate and correct problems with medical devices that present a significant risk to public health. This includes devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations. Also, section 518 of the Food, Drug and Cosmetic Act requires notification of users or purchasers when a device presents a reasonable risk of substantial harm to public health. These regulations, however, do not apply to all biomedical equipment, such as scientific laboratory equipment, but only to medical devices. Therefore, a proactive collection of Year 2000 compliance information of all biomedical equipment is necessary to prevent a Year 2000 date problem from causing any public health risk in the patient care services and health research initiatives of the next century.

Burden Information

Respondents: Biomedical Equipment Manufacturers.

Estimated Number of Potentially Noncompliant Products: 20,500.

Estimated Percentage of Responses Collected Electronically: 75%.

Estimated Response Time to Post One Noncompliant Product: 5 minutes.

Estimated Percentage of Written Responses: 25%.

Estimated Written Response Time for One Noncompliant Product: 20 minutes.

Estimated Total Annual Burden: 2989 hours.

Additional Information

HHS is requesting that OMB grant a seven day approval under procedures for emergency processing.

Questions about this information collection can be directed to the Project Coordinator, Gayle Finch, Director, Office of Information Technology Planning and Investment, Humphrey Building, 200 Independent Avenue, S.W., Washington, D.C. 20201, phone 202–690–5515 or fax 202–690–8715.

Written comments about the information collection described above can be directed to Wendy Taylor, OMB Desk Officer, Office of Management and Budget, 725 17th Street, N.W., Room 10235, Washington, D.C. 20503, or fax 202–395–6974.

Dated: December 15, 1997.

Tom Joyce,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Population-Specific Issues.

Times and Dates: 10:00 a.m.–5:00 p.m., January 12, 1998; 10:00 a.m.–4:00 p.m., January 13, 1998.

Place: Room 303A, Hubert H. Humphrey Building, 200 Independence Avenue S.W., Washington D.C. 20201.

Status: Open.

Purpose: The Subcommittee will discuss data needs and issues associated with Medicaid managed care. Presentations will be made by representatives of federal, State and local agencies, providers, plans, and patient advocacy groups who will describe their data needs and issues relating to Medicaid managed care. The Subcommittee also will plan site visits to selected States to assess data issues in Medicaid managed care.

Contact Person for More Information: Substantive program information as well as a roster of committee members may be obtained from James Scanlon, NCVHS Executive Staff Director, Office of the Assistant Secretary for Planning and Evaluation, DHHS, Room 440–D, Humphrey Building, 200 Independence Avenue S.W., Washington D.C. 20201, telephone (202) 690–7100, or Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050. Additional information about the full Committee is available on the NCVHS website, where the tentative agenda for the Subcommittee meeting will also be posted when available: http://aspe.os.dhhs.gov/ncvhs

Dated: December 17, 1997.

James Scanlon,

Director, Division of Data Policy.

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