

Representatives; one is appointed by the President pro tempore of the Senate after consultation with the minority leader of the Senate, and 16 are appointed by the Secretary of Health and Human Services.

Dated: March 1, 1999.

Margaret A. Hamburg

Dated: March 12, 1999.

John M. Eisenberg,

Cochairpersons, HHS Data Council.

[FR Doc. 99-6945 Filed 3-22-99; 8:45 am]

BILLING CODE 4151-04-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-1265]

Federal/State Memorandum of Understanding on Interstate Distribution of Compounded Drug Products; Draft; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to June 1, 1999, the comment period for the draft standard memorandum of understanding entitled "Memorandum of Understanding on Interstate Distribution of Compounded Drug Products" (draft standard MOU) that States may enter into with FDA. FDA published a notice of availability of the draft standard MOU in the **Federal Register** of January 21, 1999 (64 FR 3301). The agency is taking this action in response to a request for an extension.

DATES: Written comments on the draft standard MOU may be submitted by June 1, 1999.

ADDRESSES: Copies of the draft standard MOU are available on the Internet at "http://www.fda.gov/cder/pharmcomp/default.htm". Submit written requests for single copies of the draft standard MOU entitled "Memorandum of Understanding on Interstate Distribution of Compounded Drug Products" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments to the Dockets Management Branch (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Fred Richman, Center for Drug Evaluation and Research (HFD-332), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855-2737, 301-827-7292.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 21, 1999 (64 FR 3301), FDA published a notice announcing the availability of a draft standard MOU that States may enter into with FDA. The draft standard MOU describes the responsibilities of the States and FDA in investigating and responding to complaints related to compounded drug products distributed interstate and addresses the interstate distribution of inordinate amounts of compounded drug products. FDA has developed this MOU in consultation with the National Association of Boards of Pharmacy, under provisions of the Food and Drug Administration Modernization Act of 1997. Interested persons were given until March 22, 1999, to submit written comments on the draft standard MOU.

FDA received a letter dated February 12, 1999, from the South Carolina Board of Pharmacy (the Board) requesting that the agency extend the comment period on the draft standard MOU by 60 to 120 days to allow the Board time to finalize and submit its comments and for other State boards of pharmacy to respond to those comments.

In response to this request, FDA has decided to extend the comment period on the draft standard MOU to June 1, 1999.

Interested persons may, on or before June 1, 1999, submit to the Dockets Management Branch (address above) written comments on the draft standard MOU. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The draft standard MOU and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 17, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-7056 Filed 3-22-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-R-10 & HCFA-1513]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Information Collection Requirements Contained in BDP-718: Advanced Directives (Medicare and Medicaid) and Supporting Regulations in 42 CFR 417.436, 417.801, 422.128, 430.12, 431.20, 431.107, 434.28, 483.10, 484.10, 489.102;

Form No.: HCFA-R-10 (OMB# 0938-0610);

Use: Certain Medicare and Medicaid organizations are responsible for collecting and documenting, in medical records, whether or not an individual has executed an advanced directive. This document indicates the individual's preference if he/she is incapacitated;

Frequency: On occasion;

Affected Public: Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government;

Number of Respondents: 35,905;

Total Annual Responses: 35,905;

Total Annual Hours: 908,250.

(2) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Disclosure of Ownership and Financial Control Interest Statement and

Supporting Regulations in 42 CFR 420.200–420.206, 455.100–455.106;

Form No.: HCFA–1513 (OMB# 0938–0086);

Use: The Medicare/Medicaid Disclosure of Ownership and Control Interest Statement must be used by State agencies and HCFA regional offices to determine whether providers meet the eligibility requirements for Titles 18 and 19 (Medicare and Medicaid) and for grants under Titles V and XX. Review of ownership and control is particularly necessary to prohibit ownership and control for individuals excluded under Federal fraud statutes;

Frequency: Other (every 1 to 3 years);

Affected Public: Business or other for-profit, and Not-for-profit institutions;

Number of Respondents: 125,000;

Total Annual Responses: 125,000;

Total Annual Hours: 62,500.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address:

OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: February 25, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–6968 Filed 3–22–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1100–N]

RIN 0938–AJ49

Medicare Program; Medicare Coordinated Care Demonstration Project and Request for Information on Potential Best Practices of Coordinated Care

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

ACTION: Solicitation of information.

SUMMARY: This notice announces our intent to conduct the Medicare Coordinated Care Demonstration. It informs interested parties of the opportunity to submit information on examples of best practices of coordinated care, as well as comment on potential aspects of the overall Medicare Coordinated Care demonstration.

Section 4016 of the Balanced Budget Act of 1997 requires a review of best practices and, following this assessment, a Medicare Coordinated Care Demonstration to be launched by August 1999.

The purpose of the demonstration is to evaluate models of coordinated care that improve the quality of services furnished to specific beneficiaries and reduce expenditures under Parts A and B of the Medicare program.

EFFECTIVE DATE: Information and comments will be considered if we receive them at the address provided below, no later than 5 p.m., June 21, 1999.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Mathematica Policy Research, Inc., Attn: Ms. Kristin LaBounty, P.O. Box 2393, Princeton, NJ 08543–2393.

Comments may also be submitted electronically to Ms. LaBounty's e-mail address (Klabounty@mathematica-mpr.com). Electronically submitted comments should not include attachments.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1100–N.

FOR FURTHER INFORMATION CONTACT: Kathy Headen, Acting HCFA Project Officer, (410) 786–9253 or Kristin LaBounty, (609) 275–2263.

SUPPLEMENTARY INFORMATION:

I. Background

Section 4016 of the Balanced Budget Act of 1997 (Public Law 105–33) requires the Secretary of Health and Human Services (the Secretary) to evaluate best practices in the private sector for methods of coordinated care. The statute also directs the Secretary to design demonstration projects for the Medicare fee-for-service population based on the evaluation. The purpose of the demonstration is to evaluate models of coordinated care that improve the quality of services provided to specific beneficiaries who have a chronic illness and reduce expenditures under Parts A and B of the Medicare program.

We competitively awarded a task order for conducting a review of best practices in coordinated care and for

providing a recommendation of demonstration design options to Mathematica Policy Research, Inc. (MPR). We will perform the final assessment of best practices and select the demonstration design.

II. Provisions of This Notice

This notice announces our intent to conduct the Medicare Coordinated Care Demonstration and informs interested parties of the opportunity to submit information on potential best practices of coordinated care. In addition, this notice also requests comments on potential aspects of the overall demonstration. We are looking for information on successful models of coordinated care, disease management, or case management that are appropriate for the Medicare fee-for-service population.

Information about, and evidence of, successful models can be found in published literature; however, published literature is likely to be a limited resource and successful programs may not have been documented. Therefore, we would like to give interested parties the opportunity to submit information about models of coordinated care that are known to have achieved measurable success but may not have been discussed in published literature.

We anticipate this information will complement the review being conducted by MPR. Additional information regarding MPR's review can be found on their website (www.mathematica-mpr.com/projects/bestpractices).

Any person or organization may submit information about successful programs; however, the information must provide evidence of success in sufficient detail to be useful. Therefore, operators of programs may be in the best position to submit information regarding their approach. The following items of information should be submitted:

- The name and address of the program.
- The name, address, telephone number, facsimile number, and e-mail address of a contact person.
- Background on the program (including goals, history, relationship to larger organization(s), number of clients served, and length of time the program has been in operation).
- Special or innovative features of the program.
- Size and composition of the staff (number of RNs and number of social workers performing case management).