

such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/ohrms/dockets/default.htm>, or <http://www.fda.gov/cber/guidelines.htm>.

Dated: May 17, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-216]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

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, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Procedures for Advisory Opinions Concerning Physician Referrals and Supporting Regulations in 42 CFR 411.370 through 411.389; *Form No.:* HCFA-R-216 (OMB# 0938-0714); *Use:* Section 4314 of Public Law 105-33, in establishing section 1877(g)(6) of the Act, requires the Department to provide advisory opinions to the public regarding whether a physician's referrals for certain designated health services are prohibited under the other provisions in section 1877 of the Act. These regulations provide the procedures under which members of the public may request advisory opinions from HCFA. Because all requests for advisory opinions are purely voluntary, respondents will only be required to provide information to us that is relevant to their individual requests.; *Frequency:* On occasion; *Affected Public:* Not-for-profit institutions, Business or other for-profit, and Individuals and Households; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 2,000.

To obtain copies of the supporting statement and any related forms 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, phone number, OMB number, and HCFA document identifier, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, HCFA-R-216, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 17, 2001.

John P. Burke III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-224]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS. 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, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Collection of Managed Care Data Using the Uniform Institutional Providers Form (HCFA-1450/UB-92) and Supporting Statute section 1853(a)(3) of the Balanced Budget Act of 1997; *Form No.:* HCFA-R-224 (OMB No. 0938-0711); *Use:* Section 1853(a)(3) of the Balanced Budget Act (BBA) requires Medicare+Choice organizations, as well as eligible organizations with risk-sharing contracts under section 1876, to submit encounter data. Data regarding inpatient hospital services are required for periods beginning on or after July 1, 1997. These data may be collected starting January 1, 1998. Other data (as the Secretary deems necessary) may be required beginning July 1, 1998.

The BBA also requires the Secretary to implement a risk adjustment methodology that accounts for variation in per capita costs based on health status. This payment method must be implemented no later than January 1, 2000. The encounter data are necessary to implement a risk adjustment methodology.

HCFA continues to require hospital inpatient encounter data from Medicare+Choice organizations to