

such approach satisfies the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document is issued as a Level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive "Pre-market Guidance: Reprocessing and Reuse of Single-Use Devices" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1331) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by August 30, 2001. Submit two copies of any comments, 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 The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 22, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01-13731 Filed 5-31-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-906]

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: Revision of a Currently Approved Collection; *Title of Information Collection:* The National Data Reporting Requirements (NDRR). We are requesting the name of the collection be changed to the Fiscal Soundness Reporting Requirements (FSRR) and Supporting Regulations in 42 CFR 417., .126.478., 162; *Form No.:* HCFA-906 (OMB# 0938-0469); *Use:* HCFA needs this information to establish an on-going fiscal soundness of the Managed Care Organizations in the Medicare+Choice Program; *Frequency:* Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 301.

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](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: Melissa Musotto, 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.

[FR Doc. 01-13762 Filed 5-31-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10008]

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.

Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired;

Title of Information Collection: Medical Equipment and Supplies Consumer Survey;

Form No.: 10008 (OMB# 0938-0807).

Use: This survey is necessary to collect access, quality, and diversity of product selection information from beneficiaries. These key elements of the evaluation cannot be thoroughly evaluated without a beneficiary survey. The information will be presented to HCFA and to Congress, who will use the results to determine whether the demonstration should be extended to other sites.

Frequency: Annually;

Affected Public: Individuals or households;

Number of Respondents: 2,500;

Total Annual Responses: 2,500;

Total Annual Hours: 725.

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: 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.

[FR Doc. 01-13760 Filed 5-31-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-2728]

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.

Type of Information Collection

Request: Extension of a previously approved collection;

Title of Information Collection: End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration and Supporting Regulations in 42 CFR, 405.2133;

Form No.: HCFA-2728 (OMB# 0938-0046);

Use: To capture the necessary medical information required to determine Medicare eligibility of an end stage renal disease claimant. It also captures the specific medical data required for research and policy decisions on this population as required by law;

Frequency: weekly, monthly, quarterly, semi-annually, and annually;

Affected Public: Individuals or households, business or other for profit, not-for-profit institutions;

Number of Respondents: 60,000;

Total Annual Responses: 60,000;

Total Annual Hours: 25,000.

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: 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.

[FR Doc. 01-13761 Filed 5-31-01; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-3071-N]

Medicare Program; Meeting of the Drugs, Biologics, and Therapeutics Panel of the Medicare Coverage Advisory Committee—June 20, 2001

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Drugs, Biologics, and Therapeutics Panel (the Panel) of the Medicare Coverage Advisory Committee. The Panel provides advice and recommendations to us about clinical issues. The Panel will hear and discuss presentations from interested persons regarding the use of levo-carnitine in end stage renal disease patients.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* June 20, 2001 from 8 a.m. until 4:30 p.m. E.D.T.

Deadline for Presentations and Comments: June 13, 2001, 5 p.m., E.D.T.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires other special assistance or accommodations, are asked to notify the Executive Secretary by June 6, 2001 (**see FOR FURTHER INFORMATION CONTACT**).

ADDRESSES: *The Meeting:* The meeting will be held at The Baltimore Convention Center, Rooms 321 and 322, One West Pratt Street, Baltimore, MD 21201.

Presentations and Comments: Submit formal presentations and written comments to Kimberly A. Long, Executive Secretary; Office of Clinical Standards and Quality; Health Care Financing Administration; 7500 Security Boulevard; Mail Stop S3-02-01; Baltimore, MD 21244.

Website: You may access up-to-date information about this meeting at www.hcfa.gov/coverage.

Hotline: You may access up-to-date information about this meeting on the HCFA Advisory Committee Information Hotline, 1-877-449-5659 (toll free) or in the Baltimore area (410) 786-9379.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Long, Executive Secretary, 410-786-5702.

SUPPLEMENTARY INFORMATION: On August 13, 1999, we published a notice (64 FR