DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on July 30, 1998, 9:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Mary J. Cornelius, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194, ext. 118, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12523. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) Reclassification of extracorporeal shock wave lithotriptors indicated for the fragmentation of kidney and ureteral calculi, (2) revised clinical and preclinical performance testing requirements, and (3) labeling.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 23, 1998. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the FDA proposed reclassification before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 23, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

FDA regrets that it was unable to publish this notice 15 days prior to the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Dated: July 10, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–19175 Filed 7–17–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–P0015S]

Agency Information Collection Activities: Proposed Collection; 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, is publishing the following summary of proposed collections for public comment. 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: Revision of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey: National Baseline Medicare Beneficiary Knowledge Supplement; *Form No.:* HCFA–P–0015S; *Use:* This survey will establish baseline measures of Medicare beneficiary knowledge/understanding of the Medicare program, their new choices legislated under the Balanced Budget Act (BBA) which will allow HCFA to quantify current knowledge and attribute future changes in their understanding and knowledge to HCFA information and education initiatives. *Frequency:* Biennially; *Affected Public:* Business or other for-profit; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours:* 2,667.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, 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 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: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 9, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Security and Standards Group, Health Care Financing Administration.

[FR Doc. 98–19255 Filed 7–17–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–21, 21B, 21P, 21.11A, 21E]

Agency Information Collection Activities: Proposed Collection; 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, is publishing the following summary of proposed collections for public comment. 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: New Collection;

Title of Information Collection: Children's Health Insurance Program (CHIP) Budget and Expenditure System State Reporting Forms.

Form Nos.: HCFA–21, 21B, 21P, 21.11A, 21E;

Use: These forms will be used by State CHIP agencies to report CHIP program budget projections and actual CHIP program benefits and administrative expenditures, and the numbers of children being served in the CHIP program, to the Health Care Financing Administration (HCFA). The information provided by these new forms will be used by HCFA to prepare the grant awards to States for the CHIP, to ensure that the appropriate level of Federal payments for State expenditures under the CHIP are made in accordance with the CHIP-related BBA legislative provisions of 1997, and to track, monitor, and evaluate the numbers of children being served by the CHIP.

Note: at this time Form HCFA–21E of this package is for States to report the numbers of children, by service delivery system, that are served in the States' CHIPs based on age categories. However, we are continuing to work with the States to develop an appropriate format for States to report the numbers of children, by service delivery system, that are served in the CHIP based on Federal poverty income level categories and under the age categories previously requested. When this format is finalized it will be incorporated into Form HCFA–21E.

For a short description of the CHIP reporting forms, see below:

- Form HCFA–21 Summary Sheet. Quarterly Children's Health Insurance Program Statement of Expenditures for Title XXI Summary Sheet. This form summarizes the total expenditures in the State's CHIP reported by the State for the reporting quarter.
- Form HCFA–21. Children's Health Expenditures by Type of Service for the Title XXI Program, Expenditures in this Quarter. States use this form to report CHIP current quarter expenditures in accordance with services categories authorized under title XXI.
- Form HCFA–21B. Children's Health Insurance Program Budget Report for the Title XXI Program State Expenditure Plan. States use this form to report their budget projections each quarter for their Title XXI CHIPs for the current and budget Federal fiscal years and broken out by quarter.
- Form HCFA–21P. Children's Health Expenditures by Type of Service for the Title XXI Program, Prior Period Adjustments. States use this form to report CHIP prior period adjustment expenditures claimed in the submission quarter in accordance with services categories authorized under title XXI.
- Form HCFA–21.11A. Provider-Related Donations and Health Care Related Taxes, Fees, and Assessments Received Under Section 1903(w) for Title XXI. States use this form to report CHIP-related State receipts of provider related donations, and health care related taxes, fees, and assessments.
- Form HCFA–21E. Children's Health Insurance Program, Number of Children Served. States use this form to report the numbers of children, by service delivery system, that are served in the States' CHIPs based on age categories.

Note: HCFA is working with States to develop an appropriate format for States to report numbers of children, by service delivery system, that are served in the CHIP based on Federal poverty income level categories and under the age categories previously requested. When the format is finalized it will be incorporated into this form.

Frequency: Quarterly;

Affected Public: State and Federal government;

Number of Respondents: 56;

Total Annual Responses: 224;

Total Annual Hours: 7,840.

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 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: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 9, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Security and Standards Group, Health Care Financing Administration.

[FR Doc. 98–19256 Filed 7–17–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–P–11]

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 currently approved collection; *Title of Information Collection:* Medicare Home Health Quality Assurance Demonstration and Supporting Regulations 42 CFR 484.48; *Form No.:* HCFA—P–11, OMB # 0938–0519; *Use:* Do to the accelerated growth in the home health Care industry, the Health Care Financing Administration (HCFA) has identified a need to measure the effectiveness of home health services by analyzing patient outcomes. The Medicare Home Health Quality Assurance Demonstration will test the feasibility of collecting patient outcome data in Medicare-certified Home Health Agencies (HHAs) nationally. *Frequency:* On occasion; *Affected Public:* Not-for-profit institutions, business or other for-profit, and individuals or households; *Number of Respondents:* 35,905; *Total Annual Responses:* 99,825; *Total Annual Hours:* 7,697.