''Guidance on Medical Device Patient Labeling.'' This draft guidance is not final nor is it in effect at this time. This draft guidance describes how to make medical device patient labeling understandable to and usable by patients (or family members or other lay persons caring for patients). It is intended to assist manufacturers in their development and reviewers in their review and evaluation of medical device patient labeling. This draft guidance is designed to help assure safe and effective use of medical devices through medical device patient labeling that informs patients or their lay caregivers about proper use, risks, and benefits of the device in language they can understand.

DATES: Submit written comments on this draft guidance by June 2, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Guidance on Medical Device Patient Labeling'' to the Division of Small Manufacturers Assistance (DSMA) (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Paula G. Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–1217.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance provides information on the content, format, and organization of information that patients need to use medical devices safely and effectively. It also gives principles for writing and presenting patient information in a manner most understandable and usable to patients and their lay caregivers. With an increase in patient use of complex medical devices previously used primarily by skilled and knowledgeable health-care professionals, effective medical device patient labeling has become increasingly important in helping to assure the safe and effective use of devices.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on medical device patient labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance on Medical Device Patient Labeling'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1128) followed by the pound sign (#). Then 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 Intenet. Updated on a regular basis, the CDRH home page includes the Medical Device Patient Labeling, 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. The document entitled ''Guidance on Medical Device Patient Labeling'' will be available at http://www.fda.gov/cdrh/HumanFactors.html.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by June 2, 2000. 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 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: February 28, 2000.

Linda S. Kahan,

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

[FR Doc. 00–5086 Filed 2–28–00; 4:36 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–197]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration. 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: Maximizing the Effective Use of Telemedicine: A Study of the Effects, Cost Effectiveness and Utilization Patterns of Consultations via Telemedicine.

Form No.: HCFA–R–197 (OMB# 0938–0705).

Use: This study deals with several issues of importance to HCFA regarding the recent proliferation of Telemedicine programs. The primary goal of this study is to develop policy recommendations for Medicare concerning utilization review and

payment methods for Telemedicine services. The major objective is to evaluate the use of interactive video Telemedicine consultation. Recommendations will be based on analysis of the use of Telemedicine for such medical consultation.

Frequency: Other: periodically.

Affected Public: Individuals or households, Business or other for-profit, and Not-for-profit institutions.

Number of Respondents: 1,450.

Total Annual Responses: 84,235.

Total Annual Hours: 360.

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 Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 24, 2000.

John P. Burke III,

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

[FR Doc. 00–5106 Filed 3–2–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0280]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS. 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 Request: Extension of a currently approved collection.

Title of Information Collection: Medigap Compare.

HCFA Form Number: HCFA–R–0280 (OMB approval #:0938–0767).

Use: HCFA collects plan-specific Medigap data, including but not limited to premiums charged and additional benefits offered, from each insurer offering Medigap plans. The data collection occurs electronically. The data are provided on www.medicare.gov to assist beneficiaries in obtaining accurate information on all their health care coverage options.

Frequency: Annually, and semi-annually if needed.

Affected Public: Business or other for-profit, Federal Government, State, Local, or Tribal Government, not-for-profit institutions.

Number of Respondents: 300.

Total Annual Responses: 450.

Total Annual Burden Hours: 75.

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: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 17, 2000.

John P. Burke III,

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

[FR Doc. 00–5108 Filed 3–2–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–43]

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: Application for Health Insurance Benefits Under Medicare For Individuals With Chronic Renal Disease and Supporting Regulations in 42 CFR 406.13.

Form No.: HCFA–0043 (OMB #0938–0080).

Use: This form is used as a standard method of eliciting information necessary to determine entitlement to Medicare under the end stage renal disease provision of the law. This form was developed to satisfy the requirements of law and regulations and provide a form for eligible individuals to apply for Medicare entitlement.

Frequency: Other; one time only.

Affected Public: Individuals or households, Federal Government, and State, Local or Tribal Government.

Number of Respondents: 60,000.