

other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Evaluation of the MassHealth Insurance Partnership; *Form No.:* CMS-10051 (OMB# 0938-NEW); *Use:* This collection will be used to evaluate the Massachusetts' 1115 Waiver Demonstration, including Insurance Partnership program, offering subsidies to small employers to encourage them to offer health insurance coverage to employees. The purpose of the survey is to determine the factors influencing an employer's decision to participate or not, in the IP program and their respective characteristics.; *Frequency:* Other: One-time; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Farms; *Number of Respondents:* 2,016; *Total Annual Responses:* 2,016; *Total Annual Hours:* 336.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS'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 CMS 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 CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Dawn Willingham, CMS-10051, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: October 17, 2001.

John P. Burke III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10048]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as 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:* Health Insurance Flexibility and Accountability Section 1115 Model Waiver; *Form No.:* CMS-10048 (OMB# 0938-0848); *Use:* This Health Insurance Flexibility and Accountability (HIFA) Section 1115 Model Demonstration will enable states to use Medicaid and SCHIP funds in concert with private health insurance options to expand coverage to low-income uninsured individuals, with a focus on those with income at or below 200 percent of the Federal poverty level. The model demonstration application will facilitate State efforts in designing programs to cover the uninsured; *Frequency:* Other: 5 years after initial submission; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 25; *Total Annual Responses:* 25; *Total Annual Hours:* 250.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS'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 CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Julie Brown, CMS-10048, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: October 17, 2001.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0476]

Electronic Interchange Standard for Digital ECG and Similar Data; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to collect information regarding the content and format of electrocardiographic (ECG) data to be submitted to the agency in support of applications. The agency is interested in obtaining ECG waveform data in digital format from the full spectrum of ECG devices (i.e., standard 12-lead ECGs, Holter monitors, transtelephonic monitors, and implanted devices) along with annotations for events (e.g., standard ECG interval measurements, arrhythmic events).

DATES: The public meeting will be held on November 19, 2001, from 10 a.m. to 4 p.m. Submit registration requests by November 6, 2001. Written or electronic comments on ECG data standards are welcome at any time.

ADDRESSES: The public meeting will be held at FDA's Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Norman L. Stockbridge, Center for Drug

Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5329, e-mail: stockbridgen@cder.fda.gov; or Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, e-mail: levinr@cder.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is holding a public meeting to discuss potential data standards for digital ECG waveform data to be submitted in support of applications to FDA. Topics for discussion will include: (1) Scope of ECG datasets (i.e., what information should be included); (2) logical organization of a dataset supporting multiple recording sessions, multiple recording epochs within a session, and multiple leads; (3) logical organization supporting the annotation of data in one or more leads with the submitter’s assessment of the locations of events of interest, including standard ECG intervals, arrhythmic events, and other information; and (4) realization of the data in extensible markup language (XML) or other open formats.

Although the agency is considering updating guidance documents on related drug evaluation standards (i.e., arrhythmic potential, electronic submission of clinical trial data, including electronic ECG data), the use of ECG data in support of applications will not be the topic for this meeting. The purpose of this meeting is to get public input on the following questions related to the technical issues of transmitting digital ECG data:

- What information is needed to make ECG datasets easy to interpret?
- Is the data structure complex enough that the standard should be implemented in XML or some other format?
- Are the datasets so large that the data standards should be implemented in binary format?
- What tools can be used to review digital ECG data?

An agenda and other materials, including a proposed data standard, will be available on the Internet at <http://www.fda.gov/cder/regulatory/ersr/default.htm> before the meeting. Although there is no registration fee, preregistration by November 6, 2001, is recommended for those individuals who wish to attend this meeting. Participation is limited to the first 100

registrants. To accommodate the greatest number of interested parties, registration is limited to people outside FDA, and no more than two individuals from a company should attend. To register, send an e-mail message to Wendy Lail (lailw@cder.fda.gov) with the names of one or two individuals who wish to attend and the name of their company.

The location of the meeting is 5630 Fishers Lane, Rockville, MD (next to the Parklawn Bldg). Registrants should use the lower entrance, which faces Parklawn Dr. Visitors’ badges will be held at the guards’ station at the entrance to the building, and participants will need picture identification to pick up their badges. Public parking is not available at the 5630 Fishers Lane location. A public parking lot (for a fee) is available on Fishers Lane across from the Parklawn Bldg. Additional public parking (for a fee) is available at the Twinbrook Metro Station, which is located several blocks west of the meeting location.

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments on standards for digital ECG data. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 19, 2001.
Margaret M. Dotzel,
Associate Commissioner for Policy.
[FR Doc. 01–26821 Filed 10–19–01; 4:12 pm]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration

(SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Voluntary Customer Satisfaction Surveys to Implement Executive Order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)

OMB No. 0930–0197; Extension—Executive order 12862 directs agencies that “provide significant services directly to the public” to “survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.” SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse agencies, through a range of mechanisms, including publications, technical assistance and web sites. Many of these services are focused on information dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act (GPRA). Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances. The estimated annual hour burden is as follows:

Type of data collection	Number of respondents	Responses/Respondent	Hours/re-sponse	Total hours
Focus group	150	1	2.50	375