DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Impact Studies of the Health Professions Opportunity Grants.

OMB No.: New Collection.

Description

The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing data collection activities as part of the Impact Studies of the Health Professions Opportunity Grants (HPOG-Impact). The goal of HPOG-Impact is to evaluate the effectiveness of approaches HPOG grantees use to provide Temporary Assistance for Needy Families (TANF) recipients and other low-income individuals with opportunities for education, training and advancement within the health care field. HPOG-Impact also is intended to evaluate variation in participant impact that may be attributable to different HPOG program components and models. The impact study design is a classic experiment in which eligible applicants for HPOG program services will be randomly assigned to a treatment group offered participation in HPOG and a control group not offered the opportunity to enroll in HPOG.

To achieve these goals, it is necessary to collect data about both treatment group and control group sample members. It also is necessary to collect data about implementation from program operators (site managers and staff) and from employers involved in programs. This 60-day notice describes the universe of data collection efforts for this study. However, this information request is limited to the baseline surveys and the program implementation data collection activities, which are described under 1, 2, 3, and 4 below. As part of this submission, we are also requesting permission to waive 60-day notices necessary for the follow-up surveys (described under 5 and 6 below).

The universe of information collection proposed for HPOG-Impact includes:

1. Brief baseline survey of eligible applicants to HPOG programs. This survey will augment data already collected about eligible program applicants through the Performance Reporting System (PRS) that currently is being used in the Implementation, Systems and Outcome Evaluation of the Tribal and Low-Income Health Profession Opportunity Grants (OMB Control No. 0970–0394). To reduce burden to the extent possible, HPOG-Impact will use data from the PRS. The 15-minute ''supplemental survey'' will collect any additional information necessary for HPOG-Impact and will be administered prior to random assignment.

2. In-person interviews with HPOG site managers. The site manager protocol will collect data about program design and content and will provide information about the grantees' rationale for applying for HPOG funding, about administrative challenges and about challenges implementing programs as planned.

3. In-person interviews with HPOG site staff. The protocol for site staff will include questions about staff roles and responsibilities and perceptions of the program.

4. In-person interviews with partnering employer(s). The protocol for employers will include questions about employers' rationale for participating in the effort, their perceptions of program strengths and challenges, and their role in program design and implementation. At each site, evaluators will conduct one meeting with an average of two employers.

5. A follow-up survey of both treatment and control group members. This survey will be administered approximately 12 months after baseline. It will be administered by phone with field back-up. It will collect data about program experiences and outcomes of interest, including certifications and educational achievements, job placement, wages, and benefits. It also will collect some information about participants' tenure and experience in HPOG programming.

6. A second follow-up survey of both treatment and control group members. This survey will be administered approximately 30 months after baseline and will be administered by phone with field back-up. It will collect updated information about outcomes of interest, including certifications and educational achievements, job placement, wages, and benefits.

Respondents

Individuals enrolled in HPOG interventions; control group members; HPOG program managers; HPOG program staff, including program designers, instructors, case managers; employers.

ANNUAL RESPONSE BURDEN ESTIMATES

[These data collection activities will occur over a two-year period]

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
1. Brief baseline survey of eligible applicants to HPOG programs	4000	1	.25	1000
2. In-person interviews with HPOG site managers	50	1	3	150
3. In-person interviews with HPOG site staff	200	1	1	200
4. In-person interviews with partnering employer(s)	25	1	1	25

Estimated Annual Response Burden Hours: 1,375.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families (ACF), Department of Health and Human Services, is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded in writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 30, 2012.

Steven M. Hanmer,

Reports Clearance, Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0084]

Submission of Extended Digital Electrocardiogram Waveform Data; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to consider changes in how digital electrocardiogram (ECG) data gathered to assess a drug's adverse effects on heart function should be submitted for review. At the meeting, an extension of the Health Level-7 (HL7) Annotated ECG standard data format—used by the ECG warehouse—will be presented. The new data format is intended to facilitate electronic submission and sharing of ECG data from continuous recordings. We encourage device manufacturers, ECG laboratories, investigators, industry, and academic researchers to offer advice on the proposed format and perspective on the collection, analysis, submission, and review of data from long-term continuous ECG recordings for assessing the safety of investigational drugs.

Date and Time: The public meeting will be held on Wednesday, March 14, 2012, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, rm. 2031, Silver Spring, MD 20993.

Contact Person: Devi Kozeli, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4183, Silver Spring, MD 20993–0002, (301) 796–1128, FAX: (301) 796–9841, email: *Devi.Kozeli@fda.hhs.gov.*

Attendance and Registration: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Therefore, early arrival is encouraged. There is no fee to attend the meeting, and attendees who do not wish to make an oral presentation do not need to register. Seating will be on a first-come, first-served basis.

If you would like to make an oral presentation during the meeting, you must register by sending an email to *devi.kozeli@fda.hhs.gov* by February 14, 2012. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, and phone number. We will try to accommodate all persons who wish to make a presentation. Registrants will receive confirmation after they have been selected. Persons registered to make an oral presentation should check in before the meeting. If you need special accommodations because of a disability, please contact Devi Kozeli (see *Contact Person*) at least 7 days before the meeting.

Comments: Interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. To ensure consideration, all comments must be received by March 28, 2012.

SUPPLEMENTARY INFORMATION:

I. Background

Some drugs are known to interfere with the electrical function of the heart by delaying cardiac repolarization, and this delay may be associated with serious and sometimes fatal adverse events. Delay in cardiac repolarization can be assessed with an ECG, a recording of the cyclical changes in the heart's electrical activity. The delay is quantified as the increase in the Q wave and T wave (QT) interval, the length of time corresponding to the start of the Q wave and the end of the T wave on the ECG tracing. In 2005, FDA issued a guidance that was developed within the Expert Working Group of the International Conference on Harmonization of Technical Requirements (ICH) that made recommendations for the gathering and submission of ECG data, the clinical evaluation of the QT interval, and reporting of adverse events.

In responding to this guidance (ICH E–14), investigators of the efficacy and safety of drugs typically submit digitized 10-second ECGs taken at key protocol time points to FDA's ECG Warehouse. These ECGs are often extracted from continuous ECG recordings collected on Holter, Telemetry, and other long-term monitoring devices. ECG information submitted through the ECG warehouse should be in a format that was jointly developed by FDA, sponsors, core laboratories, and device manufactures under the auspices of HL7, an international organization of information scientists who collaborate to create standards for the exchange of electronic healthcare information.

Because effects on heart function that are only apparent in long-term ECG data from continuous recordings have been shown to be important in the evaluation of drug efficacy and safety, FDA plans to request these data whenever they are collected in clinical trials. This will necessitate changes in the HL7 Annotated ECG.

II. Purpose and Scope of the Meeting

The HL7 Annotated ECG data format will be discussed, and changes to it for handling long-term ECG data from continuous recordings will be proposed. The revised format is expected to proceed through the standard approval processes of HL7. Needed expansions to the hardware and software resources of FDA's ECG Warehouse and modifications to the upload process for ECG data are underway. FDA is interested in the perspective of manufacturers, ECG laboratories, investigators, industry, and academic researchers as it seeks to improve the collection, analysis, submission, and review of continuous ECG recordings for purposes of assessing drug safety.

Dated: February 2, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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