

and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1175.

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**Registration to Attend the Workshop and Requests to Participate in Open Public Hearing:** As part of the public workshop, an open public hearing will be held between 10:15 a.m. and 11:15 a.m. on July 29, 2013. If you wish to attend the public workshop or provide testimony for the open public hearing, please email your registration to: *IssuesWithOpioids@fda.hhs.gov* by July 15, 2013. Those without email access may register by contacting one of the persons listed in the *Contact Persons* section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number.

For those interested in providing testimony for the Open Public Hearing, please also provide a short abstract of your remarks by July 15, 2013. We will try to accommodate all persons who wish to testify; however, the duration of each speaker's testimony during this open public hearing may be limited by time constraints.

Registration for the public workshop is free and will be on a first-come, first-served basis. Early registration is recommended, because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm340470.htm>.

**Comments:** Submit either electronic or written comments by August 29, 2013. 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, and will be posted to the docket at <http://www.regulations.gov>.

If you need special accommodations due to a disability, please contact Elizabeth Giaquinto or Lisa Basham (see

*Contact Persons*) at least 7 days in advance of the public workshop.

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Introduction**

FDA is announcing this workshop to address public health concerns associated with the inclusion of equianalgesic opioid conversion tables in opioid product labels. Use of these conversion tables, intended for safe conversion between opioid products, has resulted in prescribing errors, serious adverse events, and deaths. While FDA will be giving a brief presentation on the use of conversion tables in the current product labels, we are holding this scientific workshop to bring the academic experts together to achieve consensus on what does or does not need to be done to improve how opioids are converted in clinical practice.

During the public workshop participants will do the following:

1. Review the data available supporting the basis of equianalgesic opioid conversion tables.
2. Review the problems associated with the use of equianalgesic opioid conversion tables, including prescribing errors and the occurrence of serious adverse events and deaths, with emphasis on the risks associated with extended-release opioids.
3. Review clinical strategies used for converting patients from one opioid product to another opioid product and the data to support the safety of those strategies.
4. Discuss gaps in the existing knowledge regarding equianalgesic opioid analgesic doses and opioid conversion in clinical practice.
5. Develop a research agenda to address those gaps.
6. Discuss the mechanisms for communicating about safe opioid analgesic conversion strategies to prescribers.

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm340470.htm>.

#### **II. Transcripts**

Please be advised that approximately 30 days after the public workshop, a transcript will be available. It will be accessible at <http://www.regulations.gov>, and may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information

(ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: May 21, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

#### **Agency Information Collection Activities; Proposed Collection; Public Comment Request**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this Information Collection Request must be received within 60 days of this notice.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Children's Hospital Graduate Medical Education Payment Program (CHGME PP) Annual Report OMB No. 0915-0313—Extension

*Abstract:* The CHGME Payment Program was enacted by Public Law 106-129 to provide Federal support for

graduate medical education (GME) to freestanding children's hospitals, similar to Medicare GME support received by other, non-children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

The CHGME Payment Program statute Public Law 109-307 requires that CHGME-participating hospitals provide information about their residency training programs in an annual report to HRSA that will be an addendum to the hospitals' annual applications for funds. Data are required to be collected on (1) the types of training programs that the hospital provided for residents such as

general pediatrics, internal medicine/pediatrics, and pediatric subspecialties including both medical subspecialties certified and non-medical subspecialties; (2) the number of training positions for residents, the number of such positions recruited to fill, and the number of positions filled; (3) the types of training that the hospital provided for residents related to the health care needs of different populations such as children who are underserved for reasons of family income or geographic location, including rural and urban areas; (4) changes in residency training including: (i) Changes in curricula, training experiences, and types of training programs, and benefits that have resulted from such changes, and (ii) changes for purposes of training residents in the measurement and improvement of the quality and safety of patient care; and (5) the numbers of residents (disaggregated by specialty and subspecialty) who completed their training at the end of the academic year

and care for children within the borders of the service area of the hospital or within the borders of the State in which the hospital is located.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Screening Instrument (HRSA 100-1) .....	56	1	56	9.2	515.2
Annual Report: Hospital and Program-Level Information (HRSA 100-2 and 3) .....	56	1	56	78.7	4,407.2
Total .....	56	.....	.....	.....	4,922.4

HRSA specifically requests comments on (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.

Dated: May 21, 2013.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request: National Institute of Mental Health Data Access Request and Use Certification**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Mental Health (NIMH), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the

agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301-443-4335 or Email your request, including your address to: [kshropsh@mail.nih.gov](mailto:kshropsh@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.