

information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Generic Clearance for Questionnaire Testing and Methodological Research for the Medicare Current Beneficiary Survey (MCBS); *Use:* The purpose of this OMB clearance package is to clear a Generic Clearance to support an effort to evaluate the operations and content of the Medicare Current Beneficiary Survey (MCBS). The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries. The MCBS, which is sponsored by the Centers for Medicare & Medicaid Services (CMS), is the only comprehensive source of information on the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries.

The core of the MCBS is a series of interviews with a stratified random sample of the Medicare population, including aged and disabled enrollees, residing in the community or in institutions. Questions are asked about enrollees’ patterns of health care use, charges, insurance coverage, and payments over time. Respondents are asked about their sources of health care coverage and payment, their demographic characteristics, their health and work history, and their family living circumstances. In addition to collecting information through the core questionnaire, the MCBS collects information on special topics through supplements. For example, questions are asked about enrollees’ income and assets, access to health care, health and functional status and satisfaction with care. Special supplements also focus on emerging trends in health care. *Form Number:* CMS-10549 (OMB control

number 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 1,500; *Total Annual Responses:* 1,500; *Total Annual Hours:* 1,117. (For policy questions regarding this collection contact William Long at 410-786-7927.)

Dated: March 26, 2015.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015-07322 Filed 4-1-15; 8:45 am]

BILLING CODE CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Availability: Test Tools and Test Procedures Approved by the National Coordinator for the ONC HIT Certification Program

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the availability of test tools and test procedures approved by the National Coordinator for Health Information Technology (the National Coordinator) for the testing of EHR technology to two 2014 Edition Release 2 EHR certification criteria under the ONC HIT Certification Program. The approved test tools and test procedures for the “optional—transitions of care” certification criterion (§ 170.314(b)(8)) and the revised “view, download, and transmit to 3rd party” certification criterion (§ 170.314(e)(1)) are identified on the ONC Web site at: <http://healthit.gov/policy-researchers-implementers/testing-and-test-methods>. The test tools and test procedures for all the other 2014 Edition Release 2 EHR certification criteria were previously approved by the National Coordinator.

FOR FURTHER INFORMATION CONTACT: Alicia Morton, Director, Office of Certification, Office of the National Coordinator for Health Information Technology, 202-549-7851.

SUPPLEMENTARY INFORMATION: On January 7, 2011, the Department of Health and Human Services issued a final rule establishing a permanent certification program for the purposes of testing and certifying health information technology (“Establishment of the Permanent Certification Program for Health Information Technology,” 76 FR 1262) (Permanent Certification Program final rule). The permanent certification

program was renamed the “ONC HIT Certification Program” in a final rule published on September 4, 2012 (77 FR 54163) (“2014 Edition EHR Certification Criteria final rule”). In the preamble of the Permanent Certification Program final rule, we stated that when the National Coordinator had approved test tools and test procedures for certification criteria adopted by the Secretary ONC would publish a notice of availability in the **Federal Register** and identify the approved test tools and test procedures on the ONC Web site.

In the 2014 Edition Release 2 EHR Certification Criteria final rule the Secretary adopted additional and revised certification criteria as part of the 2014 Edition EHR certification criteria (79 FR 54430). The National Coordinator has approved test tools and test procedures for testing EHR technology for two 2014 Edition Release 2 EHR certification criteria under the ONC HIT Certification Program. These approved test tools and test procedures for the “optional—transitions of care” certification criterion (§ 170.314(b)(8)) and the revised “view, download, and transmit to 3rd party” certification criterion (§ 170.314(e)(1)) are identified on the ONC Web site at: <http://healthit.gov/policy-researchers-implementers/testing-and-test-methods>. The test tools and test procedures for all the other 2014 Edition Release 2 EHR certification criteria were previously approved by the National Coordinator (80 FR 4577) and are available for review at the Web site listed above.

Authority: 42 U.S.C. 300jj-11.

Dated: March 20, 2015.

Lisa Lewis,
Acting National Coordinator for Health Information Technology

[FR Doc. 2015-07572 Filed 4-1-15; 8:45 am]

BILLING CODE CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Advisory Council for the Elimination of Tuberculosis, Department of Health and Human Services, has been renewed for a 2-year period through March 15, 2017.

For information, contact Hazel Dean, Sc.D., M.P.H., Designated Federal Officer, Advisory Council for the

Elimination of Tuberculosis, Department of Health and Human Services, 1600 Clifton Road NE., Mailstop E-10, Atlanta, Georgia 30333, telephone 404/639-8000 or fax 404/639-8600.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015-07541 Filed 4-1-15; 8:45 am]

BILLING CODE CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0045]

Abuse-Deterrent Opioids—Evaluation and Labeling; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Abuse-Deterrent Opioids—Evaluation and Labeling”. This guidance explains FDA’s current thinking about the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties. This guidance also makes recommendations about how those studies should be performed and evaluated, and discusses how to describe those studies and their implications in product labeling. It is intended to assist sponsors who wish to develop opioid drug products with potentially abuse-deterrent properties and is not intended to apply to products that are not opioids or opioid products that do not have the potential for abuse.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-

0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT:

Brutrinia D. Cain, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4633, Brutrinia.Cain@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Abuse-Deterrent Opioids—Evaluation and Labeling.” Prescription opioid products are an important component of modern pain management. However, abuse and misuse of these products have created a serious and growing public health problem. One potentially important step towards the goal of creating safer opioid analgesics has been the development of opioids that are formulated with some properties intended to deter abuse. FDA considers development of these products a high public health priority.

The guidance is intended to provide industry with a framework for evaluating and labeling abuse-deterrent opioid products. The guidance discusses how the potentially abuse-deterrent properties of an opioid analgesic formulated to deter abuse should be studied, specifically addressing in vitro studies, pharmacokinetic studies, clinical abuse potential studies, and postmarket studies. The guidance also describes the types of information that may be suitable for inclusion in labeling.

Providing a clear framework for the evaluation and labeling of the abuse-deterrent properties of opioid analgesics intended to deter abuse should help to incentivize the development of safer, less abusable opioid analgesics, and should also facilitate the dissemination of fair and accurate information regarding such products.

In the **Federal Register** of January 14, 2013 (78 FR 2676), FDA announced the availability of a draft version of this guidance and provided interested parties an opportunity to submit comments. The Agency has carefully reviewed and considered the comments it received in developing this final

version of the guidance. The Agency has made revisions to the guidance as it deemed appropriate.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the evaluation and labeling of abuse-deterrent opioids. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-07562 Filed 4-1-15; 8:45 am]

BILLING CODE CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0005]

Agency Information Collection Activities: Application for Family Unity Benefits, Form I-817; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).

ACTION: 60-Day notice.

SUMMARY: DHS, USCIS invites the general public and other Federal agencies to comment upon this proposed revision of a currently