

Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Many cancer-related deaths in women could be avoided by increased utilization of appropriate screening and early detection tests for breast and cervical cancer. Mammography is extremely valuable as an early detection tool because it can detect breast cancer well before the woman can feel the lump, when the cancer is still in an early and more treatable stage. Similarly, a substantial proportion of cervical cancer-related deaths could be prevented through the detection and treatment of precancerous lesions. The Papanicolaou (Pap) test is the primary method of detecting both precancerous cervical lesions as well as invasive cervical cancer. Mammography and Pap tests are underused by women who have no source or no regular source of health

care and women without health insurance.

The CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) provides screening services to underserved women through cooperative agreements with 50 States, the District of Columbia, 5 U.S. Territories, and 11 American Indian/Alaska Native tribal programs. The program was established in response to the Breast and Cervical Cancer Mortality Prevention Act of 1990. Screening services include clinical breast examinations, mammograms and Pap tests, as well as timely and adequate diagnostic testing for abnormal results, and referrals to treatment for cancers detected. NBCCEDP awardees collect patient-level screening and tracking data to manage the program and clinical services. A de-identified subset of data on patient demographics, screening tests and outcomes are reported by each awardee to CDC twice per year.

CDC is requesting OMB approval to collect MDE information for an additional three years. There are no changes to the currently approved minimum data elements, electronic data collection procedures, or the estimated burden. Because NBCCEDP awardees already collect and aggregate data at the state, territory and tribal level, the additional burden of submitting data to CDC will be modest. CDC will use the information to monitor and evaluate NBCCEDP awardees; improve the availability and quality of screening and diagnostic services for underserved women; develop outreach strategies for women who are never or rarely screened for breast and cervical cancer, and report program results to Congress and other legislative authorities.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 536.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
NBCCEDP Awardees	Minimum Data Elements	67	2	4

Leroy A. Richardson,
 Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff; Meeting

Name: ICD-10 Coordination and Maintenance (C&M) Committee meeting.
Times and Dates: 9 a.m.-5 p.m., September 22-23, 2015.
Place: Centers for Medicare and Medicaid Services (CMS) Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.
Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 240 people. We will be broadcasting the meeting live via Webcast at <http://www.cms.gov/live/>.
Security Considerations: Due to increased security requirements CMS has instituted stringent procedures for entrance into the building by non-government employees.

Attendees will need to present valid government-issued picture identification, and sign-in at the security desk upon entering the building.
 Attendees who wish to attend the September 22-23, 2015 ICD-10-CM C&M meeting must submit their name and organization by September 11, 2015 for inclusion on the visitor list. This visitor list will be maintained at the front desk of the CMS building and used by the guards to admit visitors to the meeting.
 Please register to attend the meeting on-line at: <http://www.cms.hhs.gov/apps/events/>. Please contact Mady Hue (410-786-4510 or Marilu.hue@cms.hhs.gov), for questions about the registration process.
 Participants who attended previous Coordination and Maintenance meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you wish attend.
 Purpose: The ICD-10 Coordination and Maintenance (C&M) Committee is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Tenth Revision, Clinical Modification and ICD-10 Procedure Coding System.
Matters To Be Discussed: Agenda items include:
September 22-23, 2015
 ICD-10-PCS Topics:
 Branched and Fenestrated Endograft Repair of Aortic Aneurysms

Cerebral Embolic Protection during Transcatheter Aortic Valve Replacement (TAVR)
 Endovascular Repair of Aortic Aneurysm via Entire Sac-Sealing
 Leadless Pacemakers
 Repair of Total Anomalous Pulmonary Venous Return (TAPVR) Addenda Updates
 ICD-10-CM Diagnosis Topics:
 Acute Kidney Injury (AKI)
 Amyotrophic Lateral Sclerosis (ALS)
 Amblyopia
 Asthma
 Blindness/Low vision
 Caries Risk Levels
 Chronic kidney disease (CKD)
 Epilepsy
 External cause codes for over exertion; repetitive motion
 Heart Failure
 Hypophosphatasia
 Lysosomal acid lipase
 Non-exudative AMD
 Prolapse vaginal vault
 ICD-10-CM Addendum
 Agenda items are subject to change as priorities dictate.
Note: CMS and NCHS no longer provide paper copies of handouts for the meeting. Electronic copies of all meeting materials will be posted on the CMS and NCHS Web sites prior to the meeting at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage and http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm.

Contact Persons For Additional Information: Donna Pickett, Medical Systems Administrator, Classifications and Public Health Data Standards Staff, NCHS, 3311 Toledo Road, Hyattsville, Maryland 20782, email dfp4@cdc.gov, telephone 301-458-4434 (diagnosis); Mady Hue, Health Insurance Specialist, Division of Acute Care, CMS, 7500 Security Boulevard, Baltimore, Maryland 21244, email marilu.hue@cms.hhs.gov, telephone 410-786-4510 (procedures).

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.

Catherine Ramadei,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0852]

Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled “Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products; Guidance for Industry.” The guidance document provides sponsors of virus or bacteria-based gene therapy products (VBGT products) and oncolytic viruses or bacteria (oncolytic products) with recommendations on how to conduct shedding studies during preclinical and clinical development. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2014.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. 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:

Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products; Guidance for Industry.” The guidance provides sponsors of VBGT and oncolytic products with recommendations on how to conduct shedding studies during preclinical and clinical development. VBGT and oncolytic products are derived from infectious viruses or bacteria. In general, these product-based viruses and bacteria are not as infectious or as virulent as the parent strain of virus or bacterium. Nonetheless, FDA is issuing this guidance because the possibility that infectious product-based viruses and bacteria may be shed by a patient raises safety concerns related to the risk of transmission to untreated individuals. To understand the risk associated with product shedding, sponsors should collect data in the target patient population in clinical trials before licensure.

In the **Federal Register** of July 9, 2014 (79 FR 38908), FDA announced the availability of the draft guidance of the same title. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes reorganization of and within certain sections of the guidance, and addition of new bullet points and information to address specific questions raised in the comments and at the November 6, 2014, meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee. In addition,

editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2014.

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 design and analysis of shedding studies for virus or bacteria-based gene therapy and oncolytic products. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 600 have been approved under OMB control number 0910-0308; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338; and the collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0755.

III. 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>.

IV. Electronic Access

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

Dated: August 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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