

concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Annual Survey of the National Breast and Cervical Cancer Early Detection

Program (NBCCEDP) Grantees—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

To improve access to cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Pub. L. 101-354) which directed CDC to create the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). Currently, the NBCCEDP funds 67 grantees including all 50 states, the District of Columbia, 5 U.S. territories, and 11 American Indian/Alaska Native tribes or tribal organizations. Grantees provide screening services for breast and cervical cancer to low-income, uninsured, and underinsured women who otherwise would not have access to screening.

The NBCCEDP is shifting from a focus on direct service provision to implementation of expanded evidence-based activities intended to increase rates of breast and cervical cancer screening at the population level. Though NBCCEDP grantees continue to provide breast and cervical cancer screening for un- and underinsured women, CDC is encouraging the implementation of strategies to increase screening rates beyond that of program-eligible women. This data collection is being proposed in order to assess program implementation, particularly related to these expanded population-based efforts. A survey of NBCCEDP grantees was originally fielded in Fall/

Winter 2013–2014 and cleared under 0920–0879 as “Assess Breast and Cervical Cancer Screening Program Activities to Expand Access to Screening”. The survey was found to be useful by CDC and the awardees (which received feedback reports). For example, after the initial implementation of last year’s survey, CDC was able to tailor sessions at the Program Director’s meeting to the needs of grantees that had been expressed during last year’s information collection. DCPC has decided to continue the data collection as an annual survey. Questions are of various types including dichotomous and multiple response.

This assessment will enable CDC to gauge its progress in meeting NBCCEDP program goals, identify implementation activities, monitor program transition to efforts aimed at impacting population-based screening, identify technical assistance needs of state, tribe and territorial health department cancer control programs, and identify implementation models with potential to expand and transition to new settings to increase program impact and reach. The assessment will identify successful activities that should be maintained, replicated, or expanded as well as provide insight into areas that need improvement.

OMB approval is requested for three years. Participation is voluntary for NBCCEDP awardees and there are no costs to respondents other than their time. The estimated burden per response is 40 minutes and the total estimated annualized burden hours are 45.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) |
|---|--|-----------------------|------------------------------------|---------------------------------------|
| Breast and Cervical Cancer Program Directors. | Annual Survey of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Grantees’ Program Implementation. | 67 | 1 | 40/60 |

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

Breast and Cervical Cancer Early Detection and Control Advisory Committee (BCCEDCAC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC),

announces the following meeting of the aforementioned committee:

Times and Dates: 9:00 a.m.–5:00 p.m., EST, November 6, 2014. 9:00 a.m.–12:30 p.m. EST, November 7, 2014.

Place: CDC, 2900 Woodcock Boulevard, University Office Park, Columbia Building, Room 1064/1065, Atlanta, Georgia 30341.

Teleconference login information is as follows:

For Participants:
TOLL-FREE PHONE #: 800-988-9707.
Participant passcode: 4798.
For Participants:

URL: <https://www.mymeetings.com/nc/join/>.

Conference number: PW8992754.

Audience passcode: 4798.

Participants can join the event directly at: <https://www.mymeetings.com/nc/join.php?i=PW8992754&p=4798&t=c>.

There is also a toll number for anyone outside of the USA:

TOLL PHONE #: 1 (312) 470-7387.

Participant passcode: 4798.

Status: Open to the public, limited only by space and net conference and audio phone lines available.

Purpose: The committee is charged with advising the Secretary, Department of Health and Human Services, and the Director, CDC, regarding the early detection and control of breast and cervical cancer. The committee makes recommendations regarding national program goals and objectives; implementation strategies; and program priorities including surveillance, epidemiologic investigations, education and training, information, dissemination, professional interactions and collaborations, and policy.

Matters for Discussion: The agenda will include: (1) Discussing the impact of implementation of the Affordable Care Act on the National Breast and Cervical Cancer Early Detection Program (NBCCEDP); (2) assessing the needs of the public and impact to the NBCCEDP; (3) population-based activities to increase appropriate screening; (4) screening communication tools; (5) provider risk assessments.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Jameka R. Blackmon, MBA, CMP, Designated Federal Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway NE., Mailstop F76, Atlanta, Georgia 30341, Telephone (770) 488-4880.

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.

Claudette Grant,

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-N-1491]

Agency Information Collection Activities: Proposed Collection; Comment Request; Survey of Pharmacists and Patients; Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with a survey of pharmacists and patients about their experiences resulting from changes in generic drug pill appearance.

DATES: Submit either electronic or written comments on the collection of information by December 15, 2014.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey of Pharmacists and Patients: Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions—(OMB Control Number 0910-NEW)

Generic drugs make up approximately 85 percent of all human prescription drugs prescribed in the United States. While generic drugs are required to be pharmaceutically equivalent and bioequivalent to their brand-name counterparts, generics made by different manufacturers may differ substantially from their brand-name therapeutic equivalents and from each other in their physical appearance (e.g., color, shape, or size of pills). When pharmacists switch generic drug suppliers, patients refilling their generic prescriptions may therefore experience changes in their drugs' appearances. These changes may result in patient confusion and concerns about the safety and effectiveness of the generic drug products. Studies indicate that patients are more likely to stop taking their generic medications when they experience a change in their drugs' physical appearances, leading to harmful clinical and public health consequences as well as increased health care costs from avoidable morbidity and mortality.

To provide additional information that may help guide regulatory policy or pharmacy business practices, we intend to conduct surveys of pharmacists and patients about their perceptions about and experiences with generic drug