

payers and providers regarding the value and challenges of P4Q programs in safety net settings. The P4Q evaluation is designed to assess whether P4Q programs in such settings appear to improve quality on the measures that are the focus of the programs and also whether the programs lead to unintended consequences. The P4Q evaluation will also seek to identify design and implementation practices that are likely to increase as well as decrease the risks of negative outcomes resulting from the implementation of P4Q programs in safety net settings.

Data collection in the P4Q evaluation will be approved by the Boston University's Medical Campus Institutional Review Board. It will be conducted in accordance with the

Health Insurance Protection and Portability Act (HIPAA) Privacy Rule and with the Protection of Human Subjects regulations, 45 CFR part 46. In addition, the identifiable data collected in this study about provider organizations and individuals will only be used for the above-stated purposes and will be protected in accordance with the AHRQ confidentiality statute, section 934(c) of the Public Health Service Act (42 U.S.C. 299c-3(c)).

**Methods of Collection**

The evaluation will use several methods to examine P4Q programs in safety net settings, including a survey and key informant interviews. Survey data will be obtained from physicians participating in P4Q programs using a

confidential mailed questionnaire. The key informant interviews will consist of 35-minute semi-structured interviews with physician organization executives, practice leaders, physicians, and other senior managers in each study setting regarding program design, implementation, and impact. The research project investigators will interview up to six informants at each site.

**Estimated Annual Respondent Burden**

The table below indicates that total time burden required to obtain all of the data required to meet the study's objectives. It does not include time required to analyze the data and prepare it for reporting and publication.

Type of respondent	Number of respondents	Number of responses per respondent	Estimated time per respondent (hours)	Estimated total burden (hours)	Estimated annual cost to the government
Physicians .....	216	1	0.25 hours (15 minutes) .....	54	\$5,322.12 to cover costs of responding to survey. \$841.35 to cover costs of participating in in-person interviews.
Practice executives and other senior managers.	24	1	0.58 hours (35 minutes) .....	14	
Total .....	.....	.....	.....	68	\$6,163.47

**Estimated Costs to the Federal Government**

The total cost to the government for this activity is estimated to be \$193,941. This funding will be used to support survey administration costs, salary and fringe benefits for the research team relating to the design and administration of the survey and informant interviews, and costs for two members of the research team to travel to each site for the informant interviews. The project will attempt to minimize burden to physician survey respondents by distributing surveys at medical staff meetings.

**Request for Comments**

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: October 10, 2006.

**Carolyn M. Clancy,**  
Director.

[FR Doc. 06-8831 Filed 10-23-06; 8:45am]

BILLING CODE 4160-90-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Statement of Organization, Functions, and Delegations of Authority**

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-72, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended

most recently at 71 FR 50065, dated August 24, 2006) is amended to reflect the establishment of the Statistical Support Most Efficient Organization within the Division of Surveillance, Hazard Evaluation, and Field Studies, National Institute for Occupational Safety and Health.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the functional statement for the *Division of Surveillance, Hazard Evaluation, and Field Studies (CCK)* and insert the following: (1) Develops and maintains a surveillance system of the Nation's work force and its environs to make an early detection and continuous assessment of the magnitude and extent of job-related illness, exposures, and hazardous agents; (2) conducts the legislatively mandated health hazard evaluation and industry-wide epidemiological research programs through longitudinal record studies and clinical/environmental field studies and surveys to identify the occupational causes of disease in the working population and their offspring, and to determine the incidence and prevalence of acute and chronic effects from work-related exposures to toxic and hazardous substances; (3) conducts epidemiological research for input to criteria for standards for the control of occupational health hazards; (4)

provides statistical support including the collection, processing, compilation, computation, analysis, editing, and/or presentation of statistical data to CDC; and provides, upon request and on a self-initiated basis, technical assistance, demonstrations, and consultation on technical matters pertaining to occupational safety and health to other Federal agencies, state, and local agencies, other agencies, other technical groups, unions, employers, and employees.

*Statistical Support Most Efficient Organization (CCKE).* (1) Provides statistical support including the collection, processing, compilation, computation, analysis, editing and/or presentation of statistical data; (2) provides technical statistical support to professionals as they analyze and prepare reports on statistical studies and surveys; (3) provides information, reference, and research services; and (4) provided administrative services related to statistical support.

Delete item (5) of the functional statement of the *Community Health and Program Services Branch (CUCEG), Division of Adult and Community Health (CUCE), National Center for Chronic Disease Prevention and Health Promotion (CUC), Coordinating Center for Health Promotion (CU)*, and insert the following: (5) provides professional statistical and programming services to the division, including assistance in design of data collection instruments, computer programming, and statistical analysis.

Delete item (1) of the functional statement for the *Information Technology, Statistics, and Surveillance Branch (CUC/D), Division of Reproductive Health (CUCJ)*, and insert the following: (1) Provides professional statistical and computer services to the division including statistical consultation, systems analysis, technical assistance, and resource identification.

Delete item (6) of the functional statement for the *Statistics and Data Management Branch (CVBCG), Division of Sexually Transmitted Disease Prevention (CVBC), National Center for HIV, STD, and TB Prevention (CVB), Coordinating Center for Infectious Diseases (CV)*, and insert the following: (6) provides data management and professional statistical services for STD surveillance and epidemiologic studies.

Delete item (3) of the functional statement for the *Statistics and Data Management Branch (CVBED), Division of HIV/AIDS Prevention-Surveillance and Epidemiology (CVBE)*, and insert the following: (3) provides data management and statistical services for HIV/AIDS surveillance, HIV

serosurveys, epidemiologic studies and other studies conducted within the division and DHAP/IRS.

Dated: October 4, 2006.

**William H. Gimson,**

*Chief Operating Officer, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 06-8839 Filed 10-23-06; 8:45 am]

**BILLING CODE 4160-18-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0333]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry: Emergency Use Authorization of Medical Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry: Emergency Use Authorization of Medical Products" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 18, 2006 (71 FR 40722), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0595. The approval expires on October 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 18, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-17718 Filed 10-23-06; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0021]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Request for Samples and Protocols

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Request for Samples and Protocols" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 29, 2006 (71 FR 37080), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0206. The approval expires on September 30, 2009. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 18, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-17720 Filed 10-23-06; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006P-0085]

#### Medical Devices; Exemptions From Premarket Notification; Class II Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing