

they must provide proof that the group health plan coverage is (or was) based on current employment status. This form is used by the Social Security Administration to obtain information from employers regarding whether a Medicare beneficiary's coverage under a group health plan is based on current employment status. *Form Number:* CMS-R-297 (OMB#: 0938-0787); *Frequency:* Once; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 5,000; *Total Annual Responses:* 5,000; *Total Annual Hours:* 1250. (For policy questions regarding this collection contact Kevin Simpson at 410-786-0017. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Chronic Care Improvement Program and Medicare Advantage Quality Improvement Project; *Use:* The Social Security Act, section 1852 e(1), (2) and (3)(a)(i), and CFR 42, 422.152 describe CMS' regulatory authority to require each Medicare Advantage Organization (other than Medicare Advantage (MA) private fee for service and MSA plans) that offers one or more MA plans to have an ongoing quality assessment and performance improvement program. This program must include measuring performance using standard measures required by CMS and report its performance to CMS. *Form Number:* CMS-10209 (OMB#: 0938-1023); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 394; *Total Annual Responses:* 788; *Total Annual Hours:* 18,912. (For policy questions regarding this collection contact Darlene Anderson at 410-786-9824. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on August 16, 2010.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, e-mail: OIRA_submission@omb.eop.gov.

Dated: June 28, 2010.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day-10-0753]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Evaluation of the Centers for Disease Control and Prevention's Consumer Response Service Center, CDC INFO. (OMB No. 0920-0753—Revision—Office of the Associate Director of Communication, Centers for Disease Control and Prevention (CDC).)

Background and Brief Description

In September 2005, the Centers for Disease Control and Prevention launched CDC-INFO, a consolidated, comprehensive effort to respond to consumer, provider and partner inquiries on a broad spectrum of public health topics by telephone, e-mail, fax, or postal mail. More than 40 nationwide public health hotlines and warm lines were consolidated into one central phone number using a phased approach from 2005 to 2008. Management of CDC-INFO services is increasingly guided by a comprehensive evaluation that includes point-of-service and follow-up customer satisfaction surveys. These surveys provide the public with ongoing opportunity to express their level of satisfaction and report how they have used this information. All members of the public, health care providers and businesses can contact CDC-INFO by phone, e-mail, or postal mail to request health information or order CDC publications.

CDC-INFO is a proactive, unified, and integrated approach to the delivery of public health information and is designed to contribute to improving the health and safety of the public. Customers are defined as any individual or group seeking health or public health information from CDC. This includes the public, media, medical and healthcare professionals, public health professionals, partner groups, businesses, researchers, and others. Customer interactions occur through multiple channels, e.g., telephone calls, e-mails, and postal mail. There are seven (7) potential evaluation points across three (3) major categories: consumer satisfaction, special event/outreach, and emergency response. All survey tools provide the participant an opportunity to decline and are available in English and Spanish.

These satisfaction surveys track the utility of CDC-INFO to the public at point of service and are integral for directing attention towards programs that are underperforming or receiving high endorsement, to understand the basis for disparity. Industry benchmarks for performance, including consumer satisfaction, were helpful for creating measures, and setting realistic expectations for performance. With the passage of time, the private sector has integrated new performance indicators for contact centers, and the suggested revisions reflect these innovations. These innovations and survey findings form the rationale for new question items and revised burden estimates. Minor changes were made to the research protocol to improve

recruitment, and are discussed throughout the application where there is any implication for information privacy.

These evaluations have provided volumes of data, reports, and presentations on the progression of CDC-INFO, an innovative, multi-million dollar, Federal public health

contact center. The outcome of this feedback is tangible, with the average number of incoming calls to CDC-INFO reaching new heights on an annual basis, and consumer satisfaction hovering around the best practice benchmark of 75 percent of callers participating in a satisfaction survey

endorsing the highest level of satisfaction—*very satisfied*.

Sample size, respondent burden, and intrusiveness have been minimized to be consistent with national evaluation objectives. There is no cost to the respondent, other than the amount of time required to respond to the survey.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hrs) | Total burden hours |
|---------------------------|---|-----------------------|------------------------------------|--------------------------------------|--------------------|
| General Callers | Satisfaction survey | 92,000 | 1 | 4/60 | 6,133 |
| Email Inquirers | Satisfaction survey | 1,460 | 1 | 3/60 | 73 |
| Callers (follow-up) | Follow-up survey | 5,290 | 1 | 9/60 | 794 |
| General Public | Special event/Outreach survey | 5,120 | 1 | 7/60 | 597 |
| Professionals | Special event/Outreach survey | 2,080 | 1 | 5/60 | 173 |
| General Public | Emergency response survey—Level 1 | 8,288 | 1 | 5/60 | 691 |
| Professionals | Emergency response survey—Level 1 | 1,658 | 1 | 5/60 | 138 |
| General Public | Emergency response survey—Level 2 | 8,637 | 1 | 5/60 | 720 |
| Professionals | Emergency response survey—Level 2 | 1,727 | 1 | 5/60 | 144 |
| General Public | Emergency response survey—Level 3 | 35,185 | 1 | 5/60 | 2,932 |
| Professional | Emergency response survey—Level 3 | 7,037 | 1 | 5/60 | 586 |
| General Public | Emergency response survey—Level 4 | 129,126 | 1 | 5/60 | 10,761 |
| Professional | Emergency response survey—Level 4 | 29,825 | 1 | 5/60 | 2,485 |
| Total Burden Hours | | | | | 26,227 |

Dated: June 24, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2010-M-0068, FDA-2010-M-0078, FDA-2010-M-0063, FDA-2010-M-0135, FDA-2010-M-0158]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and

effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the SUPPLEMENTARY INFORMATION section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d)

and 814.45(d) to discontinue individual publication of PMA approvals and denials in the Federal Register. Instead, the agency now posts this information on the Internet on FDA's home page at <http://www.fda.gov>. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the Federal Register, and FDA believes that the Internet is accessible to more people than the Federal Register.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that