

questions about the caseload for the registry (the number of new cancer cases reported annually), the sources of case information, whether case information is collected utilizing manual or electronic methods, and the type of software employed for electronic collection. Because many tasks can be performed manually or using electronic methods, and because cancer coding systems are frequently revised to reflect changes in cancer diagnosis and care, the WLM survey asks registry managers to identify training needs that would improve registry productivity, and to provide comments about other resource needs and management issues.

The web-based WLM Survey will also collect information about the total amount of time dedicated by registry staff to specific activities such as case finding, records abstraction, follow-up, quality assurance, professional

development, travel, and death clearances. In order to complete this section of the WLM survey, detailed information will be collected from registry staff. An average of eight registrars in each registry will be asked to maintain a paper Work Activities Journal for a one-week period. Each registrar will record the number of hours and minutes dedicated to case finding, records abstraction, follow-up, and quality assurance, and where applicable, indicate whether tasks were conducted manually or electronically. In addition, each registrar will estimate the amount of time dedicated to auditing, database management, professional development, travel, and death clearances on a monthly or annual basis. At the end of the one-week data collection period, the registry manager will compile information from all of the Work Activities Journals completed by

the registry's staff. The aggregate information will be reported to CDC through the WLM Survey. The individual Work Activities Journals will not be submitted to CDC.

Findings from the WLM survey will enable CDC to assess the workforce necessary for meeting data reporting requirements and to estimate the impact of planned changes to surveillance data reporting. CDC plans to develop guidance so that cancer registry managers can more effectively measure workload, evaluate the need for staff and staff credentials, and advocate for adequate staffing.

OMB approval is requested for one year. Participation in the survey is voluntary. There are no costs to respondents other than their time. The total estimated annualized burden hours are 921.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
NPCR managers	Workload and Time Management Survey	46	1	4
	Telephone Reminder	15	1	3/60
NPCR Staff Registrars	Work Activities Journal	368	1	2

Dated: August 23, 2010.

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Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-10-10AK]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to 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

National Notifiable Condition Messaging Support Strategy—New—Public Health Surveillance Program Office (PHSPO); Office of Surveillance, Epidemiology, and Laboratory Services (OSELs), Centers for Disease Control and Prevention, (CDC).

Background and Brief Description

The Public Health Services Act (42 U.S.C. 241) authorizes CDC to disseminate nationally notifiable condition information. CDC's *Morbidity and Mortality Weekly Report* publishes incidence tables for nationally notifiable conditions reported through the National Electronic Disease Surveillance System (NEDSS) and other surveillance data sources to the National Notifiable Diseases Surveillance System (NNDSS).

NEDSS (OMB 0920-0728, expiration date: 2/28/2010) is an internet-based infrastructure for public health surveillance data exchange that uses specific Public Health Information Network (PHIN) and NEDSS electronic data and information standards to advance the development of efficient, integrated, and interoperable surveillance systems at federal, state and local levels. CDC's proposed Public Health Surveillance Program Office

(PHSPO) is responsible for establishing and managing the national reporting system of epidemiologic data for notifiable conditions (diseases) via NEDSS.

Case notification messaging for most of the nationally notifiable conditions (77 infectious conditions as of August 2009) will eventually be supported by the standard Health Level 7 v2.5 (HL7) message format. The HL7 message format requires a Message Mapping Guide (MMG)—developed by the NEDSS and NNDSS programs, in collaboration with state and federal subject matter experts—to implement case notification to CDC via NEDSS. At present, seven MMGs are available for implementation by jurisdictions, and current NEDSS resources support the development of three new MMGs per year. A jurisdiction's implementation of a MMG requires an average of four months per MMG, and a jurisdiction could potentially implement up to three MMGs a year. In most instances, National Center for Public Health Informatics' (NCPHI) programmatic and technical expertise is required to support this process at the jurisdictional level.

The National Notifiable Condition Messaging Support Strategy

Questionnaire has been developed by the NEDSS program to gather information needed for formulating a technical and project management support strategy for 57 reporting jurisdictions (i.e., 50 states, 5 territories, and 2 cities (New York City, NY and Washington, DC)) as they implement NEDSS messaging using MMGs. A jurisdiction's response to the questionnaire will be used by the NEDSS implementation and management teams to assess the jurisdiction's IT system environment and capacity and help determine the

project schedule and level of human and technical support needed to complete the jurisdiction's implementation of a nationally notifiable condition message. NEDSS infrastructure implementation support includes, but is not limited to implementing NEDSS Message Subscription Service (MSS) and NEDSS Messaging Solution (NMS) software in requesting jurisdictions; providing MSS and NMS software training and ongoing technical support; and distributing funding via the CDC Epidemiology and

Laboratory Capacity cooperative agreement.

Questionnaires will be distributed to jurisdictions that initiate MMG implementation for a condition; therefore, the maximum annual frequency of responses per jurisdiction is three. The NEDSS team will request the jurisdiction to voluntarily complete the questionnaire, but a response is not a pre-requisite for support.

There is no cost to respondents other than their time to participate in the survey. The total estimated annual burden hours are 114.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State, Territory and Local Public Health Department.	National Notifiable Condition Messaging Support Strategy Questionnaire.	57	3	40/60

Dated: August 23, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0258]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission Using Food and Drug Administration Form 3503

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 29, 2010.

ADDRESSES: To ensure that comments on the information collection are received,

OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0016. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission Using FDA Form 3503—21 CFR 70.25, 71.1, 170.35, 171.1, 172, 173, 179, and 180 (OMB Control Number 0910-0016)—Revision

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) The additive and its use, or intended use, are in conformity with a regulation issued under section 409 of the FD&C Act that describes the condition(s) under which the additive may be safely used; (2) the additive and

its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) of the FD&C Act is effective. Food additive petitions (FAPs) are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 179, and 180 (21 CFR parts 172, 173, 179, and 180) contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the FD&C Act. Color additive petitions (CAPs) are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 of the agency's regulations (21 CFR 71.1) specifies the information that a