

- Near misses or close calls—patient safety events that did not reach the patient, and
- Unsafe conditions—circumstances that increase the probability of a patient safety event.

The Common Formats include two general types of formats, generic and event-specific. The generic Common Formats pertain to all patient safety concerns. The three generic formats are: Healthcare Event Reporting Form, Patient Information Form, and Summary of Initial Report. The event-specific Common Formats pertain to frequently-occurring and/or serious patient safety events. When used as designed, the Common Formats allow collection of information on all harms to patients: “All-cause harm.”

The VTE format includes a description of the patient safety events to be reported (event description), and a sample patient safety aggregate report. The Venous Thromboembolism (VTE) Common Format is available at the PSO Privacy Protection Center (PPC) Web site: <https://www.psoppc.org/web/patientsafety>.

#### **Commenting on Venous Thromboembolism (VTE) Common Format**

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the National Quality Forum (NQF), a non-profit organization focused on health care quality, to solicit comments and advice to guide the further refinement of the Common Formats. The NQF began this process with feedback on AHRQ's 0.1 Beta release of the Common Formats in 2008. Based upon the expert panel's feedback, AHRQ, in conjunction with an interagency Federal Patient Safety Work Group (PSWG), revises and refines the Common Formats.

The Agency is specifically interested in obtaining feedback from both the private and public sectors on this new beta VTE format to guide their improvement. Information on how to comment and provide feedback on the Common Formats, including the Venous Thromboembolism (VTE) beta version, is available at the National Quality Forum (NQF) Web site for Common Formats: <http://www.Quality.forum.org/projects/commonformats.aspx>.

#### **Common Formats Development**

In anticipation of the need for Common Formats, AHRQ began their development in 2005 by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provides an

evidence base that informs construction of the Common Formats. The inventory includes systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (e.g., the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems are included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has coordinated the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies and offices within the HHS—CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the National Library of Medicine, Office of Healthcare Quality, Office of the National Coordinator for Health Information Technology (ONC), the Office of Public Health and Science, the Substance Abuse and Mental Health Services Administration—as well as the DoD and the VA.

The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues. When developing Common Formats, AHRQ first reviews existing patient safety event reporting systems from a variety of health care organizations. Working with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment. To the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, framework, and definitions contained in their draft International Classification for Patient Safety (ICPS).

The process for updating and refining the formats will continue to be an iterative one. Future versions of the Common Formats will be developed for ambulatory settings, such as ambulatory surgery centers and physician and practitioner offices. More information on the Common Formats can be obtained through AHRQ's PSO Web site: <http://www.PSO.AHRQ.gov/index.html>.

Dated: October 20, 2011.

**Carolyn M. Clancy,**  
Director.

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

[60Day–12–12AL]

#### **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 the CDC Reports Clearance Officer at (404) 639-5960 or send comments to Daniel Holcomb, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto: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**

The National Hospital Care Survey (NHCS): Ambulatory Care Pretest—New—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

#### **Background and Brief Description**

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States. This one-year clearance request seeks approval to pretest: (1) Data collection from hospital ambulatory departments including emergency departments (ED), outpatient departments (OPD), and ambulatory surgery locations (ASLs) through the

National Hospital Care Survey (NHCS) (OMB No. 0920–0212); (2) new questions on drug-related ED visits; and (3) new questions on colorectal cancer screening in ambulatory surgery visits.

In 2012, a pretest of 30 hospitals will collect data using methods approved for the National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920–0278) data collection. The proposed pretest will test the data collection procedures involved in integrating the NHAMCS into the NHCS. NHAMCS has provided data annually since 1992 concerning the nation's use of hospital emergency and outpatient departments, and since 2009, on hospital-based ASLs. If the pretest is successful, NHAMCS will be integrated into NHCS in order to increase the wealth of data on health care utilization in hospitals across episodes of care and to allow for linkages to other data sources such as the National Death Index and data from Centers for Medicare and Medicaid Services (CMS).

The data items to be collected from the recruited hospitals in the pretest will include facility level data items such as visit volume, number of treatment areas, and information on electronic health record systems. Facility level data will be collected through in-person interviews and recorded on computerized survey

instruments, at the hospital-level and at the ambulatory unit level. It is anticipated that each hospital will have approximately four ambulatory units.

Patient level data items will include basic demographic information, name, address, social security number (if available), and medical record number (if available), and characteristics of the patients including admission and discharge dates, reason for visit, diagnoses, diagnostic services, procedures, medications, providers seen, and disposition. Patient visit data will be abstracted by field representatives of the data collection agent. A targeted number of patient visits will be sampled from each department depending on the type of department—approximately 100 across ambulatory units in the ED, 200 across ambulatory units in the OPD, and 100 across ambulatory units in ASLs.

Secondly, the pretest will collect specific information on drug-related visits to the ED. This endeavor, funded by the Center for Behavioral Health Statistics & Quality (CBHSQ) of the Substance Abuse & Mental Health Administration (SAMHSA), will assess the feasibility of integrating the Drug Abuse Warning Network (DAWN) (OMB No. 0930–0078) into the emergency department component of the NHCS. In each of the 30 pretest hospitals with an

emergency department, a sample of all patient visits will be abstracted; for each drug-related visit within this sample, additional drug-related data will be abstracted. The only burden to the respondent at the patient visit level will be due to pulling and refiling of approximately 133 medical records at each ambulatory unit.

Finally, the pretest will assess the feasibility of obtaining information on colorectal cancer screening during ambulatory surgery visits where a colonoscopy is performed. The endeavor is sponsored jointly by the National Center for Chronic Disease Prevention and Promotion (NCCDPHP) and the National Cancer Institute (NCI). The questions will be added to the Ambulatory Surgery Patient Record form and will be completed for patients that have a colonoscopy performed at the sampled visit.

Potential users of the NHCS ambulatory data include, but are not limited to CDC, Congressional Research Office, Office of the Assistant Secretary for Planning and Evaluation (ASPE), American Health Care Association, Centers for Medicare & Medicaid Services (CMS), Bureau of the Census, state and local governments, and nonprofit organizations. There is no cost to respondents other than their time to participate.

#### ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)	Total burden hours
Hospital Chief Executive Officer .....	Hospital Induction Interview .....	30	1	1	30
Ancillary Service Executive .....	Ambulatory Unit Induction .....	120	1	15/60	30
Medical Record Clerk .....	Pulling and Refiling Records .....	120	133	1/60	266
<b>Total</b> .....	.....	.....	.....	.....	<b>326</b>

Dated: October 26, 2011.

**Daniel Holcomb,**

*Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

##### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Emerging Infections Programs, Funding Opportunity Announcement (FOA) CK12–1202, initial review.

*Correction:* The notice was published in the **Federal Register** on September 13, 2011, Volume 76, Number 177, Page 56461. The place should read as follows:

*Place:* Sheraton Gateway Hotel Atlanta Airport, 1900 Sullivan Road, Atlanta, Georgia 30337, Telephone: (770) 997–1100.

*Contact Person For More Information:* Amy Yang, Ph.D., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 498–2733.

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.