ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden (in hours) per response	Total burden hours
Focus Group	General Public	621	1	1.5	932
Focus Group screening	General Public	5544	1	10/60	924
Web usability testing	General Public	144	1	1.5	216
Web usability screening	General Public	2160	1	10/60	360
Self-Administered Surveys	General Public	2000	1	15/60	500
Self-Administered survey screening	General Public	8000	1	10/60	1333
Omnibus Surveys	General Public	2000	1	10/60	333
Cognitive testing	General Public	25	1	2	50
Focus Group	Health Professional	288	1	1.5	432
Screening	Health Professional	4320	1	10/60	720
Web usability testing	Health Professional	144	1	1.5	216
Screening	Health Professional	2160	1	10/60	360
Self-Administered Surveys	Health Professional	2000	1	15/60	500
Screening	Health Professional	8000	1	10/60	1333
Omnibus Surveys	Health Professional	2000	1	10/60	333
In-Depth Interviews	Health Professional	100	1	45/60	75
Screening	Health Professional	1000	1	10/60	167
Total (Overall)		40,506			8,784

Keith A. Tucker,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

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BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Patient Safety Data Collection and Event Reporting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Availability—New Common Format.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) provides for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Act (at 42 U.S.C. 299b–23) authorizes the collection of this information in a standardized manner, as explained in the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008: 73 FR 70731–70814. AHRQ coordinates the development of a set of common definitions and reporting formats (Common Formats) that allow health care providers to voluntarily collect and submit standardized information regarding patient safety events. The purpose of this notice is to announce the availability of a new beta version Common Format for Venous Thromboembolism (VTE) for public review and comment.

DATES: Ongoing public input.

ADDRESSES: The new beta version of the Common Format for Venous Thromboembolism (VTE), version dated October 2011, and the remaining Common Formats, can be accessed electronically at the following HHS Web site: *http://www.PSO.AHRQ.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Susan Grinder, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *PSO@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other health care providers may voluntarily report information regarding patient safety events and quality of care. Both the Patient Safety Act and Patient Safety Rule, including any relevant guidance, can be accessed electronically at: *http://www.PSO.AHRQ.gov/regulations/regulations.htm.*

AHRQ develops and maintains the Common Formats in order to facilitate standardized data collection and improve the safety and quality of health care delivery. Since the initial release of the Common Formats in August 2008, AHRQ regularly revises the formats based upon public comment. Earlier this year, AHRQ released the beta version of the Skilled Nursing Facilities format, as announced in the **Federal Register** on March 7, 2011: 76 FR 12358–12359. With this release, AHRQ had made available Common Formats for two settings of care—acute care hospitals and skilled nursing facilities. The new beta version of the Common Format for Venous Thromboembolism (VTE), which includes Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), will apply to both settings of care.

Definition of Common Formats

The term ''Common Formats'' refers to the common definitions and reporting formats that allow health care providers to collect and submit standardized information regarding patient safety events. The Common Formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/recording system; rather the formats are intended to enhance the ability of health care providers to report information that is standardized both clinically and electronically.

The scope of Common Formats applies to all patient safety concerns including:

- Incidents—patient safety events that reached the patient, whether or not there was harm,

• 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*.

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 pre-test: (1) Data collection from hospital ambulatory departments including emergency departments (ED), outpatient departments (OPD), and ambulatory surgery locations (ASLs) through the