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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: As authorized by the Secretary of HHS, AHRQ coordinates the development of a set of common definitions and reporting formats (Common Formats) for reporting patient safety events to Patient Safety Organizations (PSOs). The purpose of this notice is to announce the availability of new Common Formats - Hospital Version 1.2 for public review and comment.

DATES: Ongoing public input.

ADDRESSES: The new Common Formats - Hospital Version 1.2, version dated April 2012, and the remaining Common Formats can be accessed electronically at the following HHS Web site: <http://www.PSO.AHRQ.gov/index.html>

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SUPPLEMENTARY INFORMATION:

Background

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 PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. The Patient Safety Act (at 42 U.S.C. 299b-23) authorizes healthcare providers to voluntarily collect and submit 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. The collection of patient safety work product allows the aggregation of sufficient data to identify and address underlying causal factors of patient safety problems.

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other healthcare providers may assemble information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs – called "patient safety work product" – is privileged and confidential. Patient safety work product is used to identify events, patterns of care, and unsafe conditions that increase risks and hazards to patients. Definitions and other details about PSOs and patient safety work product are included in the Patient Safety Act and Patient Safety Rule which can be accessed electronically at:
<http://www.PSO.AHRQ.gov/REGULATIONS/REGULATIONS.htm>.

Definition of Common Formats

The term "Common Formats" refers to the common definitions and reporting formats, specified by AHRQ, 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.

In collaboration with the interagency Federal Patient Safety Workgroup (PSWG), the National Quality Forum (NQF) and the public, AHRQ has developed Common Formats for two settings of care – acute care hospitals and skilled nursing facilities – in order to facilitate standardized data collection. 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.

AHRQ's Common Formats include:

- Event descriptions (descriptions of patient safety events and unsafe conditions to be reported);
- Specifications for patient safety aggregate reports and individual event summaries;
- Delineation of data elements to be collected for different types of events to populate the reports;
- A user's guide and quick guide, and
- Technical specifications for electronic data collection and reporting.

The technical specifications promote standardization of collected patient safety event information by specifying rules for data collection and submission, as well as by providing guidance for how and when to create data elements, their

valid values, conditional and go-to logic, and reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning. They also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PSOs, so that the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PPC) for data de-identification and transmission to the Network of Patient Safety Databases (NPSD).

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.

Since the initial release of the Common Formats in August 2008, AHRQ regularly revises the formats based upon public comment. The Common Formats – Hospital Version 1.2 features new content to incorporate the event specific formats entitled Venous Thromboembolism (VTE) and Device or Medical/Surgical Supply including Health Information Technology (HIT) Device. Common Formats – Hospital Version 1.2, which also includes minor changes to existing modules and technical specifications, is available at the PSO PPC Web site: <https://www.PSOPPC.ORG/web/patientsafety>.

Common Formats Development

In anticipation of the need for Common Formats, AHRQ began their development 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 many systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (e.g., from 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 convened the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS—CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration—as well as the DoD and VA.

When developing Common Formats, AHRQ first reviews existing patient safety event reporting systems from a variety of health care organizations. In collaboration with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment. The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues. 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).

Commenting on Common Formats Hospital 1.2

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the 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 then convenes an expert panel to review the comments received and provide feedback. 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 the PSWG, revises and refines the Common Formats.

The Agency is specifically interested in obtaining feedback from both the private and public sectors on the new Common Formats – Hospital Version 1.2 to guide the improvement of the formats. Information on how to comment and provide feedback on the Common Formats - Hospital Version 1.2, is available at the NQF Web site for Common Formats:
<http://www.Quality.forum.ORG/projects/commonformats.aspx>.

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: April 5, 2012

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Director