AHRQ Common Formats Supplemental Details – November 2017

The Agency for Healthcare Research and Quality (AHRQ) coordinates the development of common definitions and reporting formats (Common Formats) for reporting and analysis of health care quality and patient safety Common Formats for reporting and analysis of patient safety data. This activity is authorized by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule).

The Patient Safety Act (at 42 U.S.C. 299b-24(b)(1)(F)) requires PSOs to collect information from providers in a standardized manner that permits valid comparisons of similar cases among similar providers, to the extent practical and appropriate. As explained in the Patient Safety Rule, 42 CFR 3.102(b)(2)(iii)(A)(1), one option for a PSO to satisfy this requirement is by certifying that it is using the Secretary's published guidance for Common Formats and definitions in its collection of information from health.

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 through the formation of patient safety organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery.

The Common Formats ensure that data collected by PSOs and other entities have comparable clinical meaning through the establishment a Network of Patient Safety Databases (NPSD) to aggregate and analyze patient safety data.

Information on the AHRQ Common Formats is available on the AHRQ PSO website at www.pso.arq.gov.

Scope of the Common Formats

The term Common Formats refers to the common definitions and reporting formats, specified by AHRQ, that allow healthcare providers to collect and submit standardized information regarding patient safety events. 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 Common Formats include:

- A common set of definitions of patient safety concerns that may give rise to patient harm;
- Examples of patient safety sample reports;
- Paper forms(for versions prior to Hospital Version 2.0) to guide development of data collection instruments;
- A Users Guide which describes how to use the Common Formats; and
- A meta-data registry with data element attributes and technical specifications for use by developers.

The formats include data elements that are structured and narrative:

> *Structured data* elements permit sorting of patient safety incidents and near misses for event analysis, as well as for pattern and trending analysis at all levels of the healthcare system. Structured data encompasses important descriptors, known risk factors, and the use of established risk reduction methods to permit efficient analysis of incidents and patterns of patient safety events. Structured data can be aggregated within and across provider organizations, as well as for national reports.

> *Narrative data elements* cannot be aggregated, but provide the necessary details about an individual event or condition needed to understand patient safety concerns at the provider and/or PSO levels. The narrative information may also assist with how the provider and/or PSO can act to reduce risk to patients.

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 healthcare providers to report information that is standardized both clinically and electronically.

AHRQ Common Formats Development

In anticipation of the need for Common Formats, AHRQ began its development by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provides an evidence base that informed construction of the Common Formats. The inventory includes many systems from the private sector, including 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).

Beginning in February 2005, AHRQ convened the Patient Safety Work Group (PSWG) as needed to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS—CDC, Centers for Medicare and 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.

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 for patient safety.

AHRQ Common Formats Releases

Currently, AHRQ has released Common Formats for three settings of care - hospitals, community pharmacies and nursing homes.

Common Formats for Hospitals

There are currently three types of Hospital Common Formats: Hospital Common Formats for Event Reporting, Hospital Common Formats for Readmissions, and Hospital Common Formats for Surveillance. After

completing a review of the existing patient safety reporting systems from a variety of health care organizations, AHRQ developed, piloted, drafted, and released Version 0.1 Beta of the Common Formats for Event Reporting in August 2008.

AHRQ further collaborated with NQF to solicit feedback on Version 0.1 Beta from private sector organizations and individuals. Based on the NQF's feedback, AHRQ in conjunction with PSWG further revised the Hospital Common Formats and released Version 1.0 in September 2009.

The review process was repeated to refine the Hospital Common Formats and incorporate public comments on Version 1.0, prior to finalizing the technical specifications for electronic implementation. Those modified formats for acute care hospitals were made available as Common Formats for Event Reporting - Hospital Version 1.1 in March of 2010 and included the event-specific modules of Blood or Blood Product; Device or Medical/Surgical Supply; Fall; Healthcare-associated Infection (HAI), Medication or Other Substance; Perinatal; Pressure Ulcer; and Surgery or Anesthesia. This version was retired with the release of Version 1.2.

In April 2012, AHRQ rolled out Common Formats for Event Reporting - Hospital Version 1.2, which featured the new event-specific module Venous Thromboembolism (VTE) and revised the Device or Medical/Surgical Supply module to capture patient safety concerns associated with Health Information Technology (HIT) devices. These formats include the event descriptions, sample reports, and forms for both generic and event-specific categories. The Generic Hospital Common Formats forms include the Healthcare Event Reporting Form (HERF), Patient Information Form (PIF), and Summary of Initial Report (SIR), and specify information that is to be collected pertaining to all patient safety concerns.

The event-specific categories for Hospital Common Formats Version 1.2, allow the collection of structured information for the following patient safety concerns: Blood or Blood Product; Device or Medical/Surgical Supply, including HIT; Fall; Healthcare-associated Infection (HAI); Medication or Other Substance; Perinatal; Pressure Ulcer; Surgery or Anesthesia; and VTE.

Common Formats for Event Reporting - Hospital Version 2.0 constitutes a major release of the AHRQ Common Formats. Version 2.0 incorporates new and modified content and technical specifications revised since the release of Hospital Version 1.2 in April 2012. Version 2.0 represents an overall decrease in scale from Version 1.2 to reduce reporting burden.

Version 2.0 consolidates the Healthcare Event Reporting Form (HERF), Patient Information Form (PIF), and Summary of Initial Report (SIR) into one module, called the Generic module. This version also eliminates paper forms to encourage electronic reporting of patient safety concerns, and designates a set of Core content required for event reporting, by providers to PSOs and by PSOs to the PSOPPC for national aggregation and analysis.

In July 2012, Common Formats - Readmissions - Version 0.1 Beta was released to allow hospitals to aggregate data and analyze readmission attributes. The Readmissions module is primarily designed for use in the acute care hospital environment to gain enhanced understanding about the circumstances surrounding readmissions. These formats can be used within a hospital or healthcare system and may assist hospitals in response to the Affordable Care Act Hospital Readmissions Reduction Program.

In February 2014, AHRQ released Common Formats for Surveillance - Hospital Version - 0.1 Beta, which also includes both generic and event-specific categories. The event-specific categories for patient safety surveillance included in the Beta version are Blood or Blood Product; Delivery-Maternal; Delivery-Neonatal; Device or Medical/Surgical Supply, including HIT; Fall; Medication; Pressure Ulcer; Readmission; Surgery or Anesthesia; VTE, and Other Outcomes of Interest. Common Formats for Surveillance - Hospital are designed to provide through retrospective review of medical records, information that is complementary to that derived

from event reporting systems. These formats facilitate improved detection of events and calculation of adverse event rates in populations reviewed.

Common Formats for Nursing Homes

AHRQ released the Common Formats - Nursing Home Version 0.1 Beta in March 2011, including event descriptions, sample reports, and forms for generic and event-specific categories. The generic categories of the Common Formats - Nursing Home include the HERF, PIF, and SIR, which pertain to all patient safety concerns. The event-specific categories for the Nursing Home Common Formats are the Device or Supply, including HIT; Fall; HAI; Pressure Ulcer; and Medication or Other Substance modules.

Common Formats for Community Pharmacies

AHRQ released the Common Formats - Retail Pharmacy Version 0.1 Beta in October 2015. AHRQ worked with the NQF based on the public review and comment received, and developed and released the Common Formats - Community Pharmacy Version 1.0 in December 2016. The Community Pharmacy Version 1.0 module is designed for use in the community pharmacy environment to gain enhanced understanding about the circumstances surrounding patient safety data in the community pharmacy setting. This module is self-contained, covering everything necessary to report patient safety data in the Community Pharmacy event-specific category.