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 a new Common Format—Readmissions Version 0.1 Beta for public review and comment.

DATES: Ongoing public input.

ADDRESSES: The new Common Format—Readmissions Version 0.1 Beta, version dated July 2012—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: Cathryn Niane, 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 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. This collection 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).

Since the initial release of the Common Formats in August 2008, AHRQ has regularly revised the formats based upon public comment. Most recently, AHRQ and the PSWG developed Common Format—Readmissions Version 0.1 Beta to allow hospitals to aggregate data that describe circumstances associated with the readmission of patients. These factors include actions taken at the index hospitalization to prevent a readmission, risk factors for readmission, length of stay, presence of an adverse event, location of discharge setting, as well as other attributes. Using this standardized method of review, hospitals can identify factors associated with unnecessary readmissions. In addition, hospitals can compare their data to others and analyze trends on a community, regional, and national level. The Common Format—Readmissions Version 0.1 Beta, dated July 2012, 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 Format—Readmissions Version 0.1 Beta

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 Format—Readmissions Version 0.1 Beta to guide the improvement of the formats. Information on how to comment and provide feedback on the Common Format—Readmissions Version 0.1 Beta 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: July 13, 2012.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Delisting for Cause for The Steward Group PSO

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

ACTION: Notice of delisting.

SUMMARY: AHRQ has delisted The Steward Group PSO as a Patient Safety Organization (PSO) due to its failure to correct a deficiency. The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is to conduct activities to improve patient safety and the quality of health care delivery. HHS issued the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on June 19, 2012.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: *http://www.PSO.AHRQ.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, 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, Public Law 109–41, 42 U.S.C. 299b–21—b–26, provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Rule, 42 CFR part 3, authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found no longer to meet the requirements of the Patient Safety Act and Patient Safety Rule. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

The Steward Group PSO failed to respond to a Notice of Preliminary Finding of Deficiency sent by AHRQ pursuant to 42 CFR 3.108(a)(2) and a Notice of Proposed Revocation and Delisting sent by AHRQ pursuant to 42 CFR 3.108(a)(3)(iii)(C) which found that The Steward Group PSO failed to have, within every 24-month period following the PSO's date of initial listing, at least two bona fide contracts with different providers for the purpose of receiving and reviewing patient safety work product, and to notify AHRQ no later than 45 calendar days prior to the last day of the pertinent 24-month period that the PSO has met this requirement. The Steward Group PSO did not exercise its opportunity to be heard in writing to respond to the deficiencies specified in the notices, and has not provided any evidence of a good faith effort to correct the deficiency.

Accordingly, AHRQ has revoked the listing of The Steward Group PSO, PSO number P0088, a component entity of The Steward Group, Inc., effective at 12:00 Midnight ET (2400) on June 19, 2012.

More information on PSOs can be obtained through AHRQ's PSO Web site at *http://www.PSO.AHRQ.gov/index.html.*

Dated: July 3, 2012.

Carolyn M. Clancy,

Director.

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