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Center for Clinical Standards and Quality /Survey & Certification Group

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DATE: **March 15, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: AHRQ Common Formats - Information for Hospitals and State Survey Agencies (SAs) - Comprehensive Patient Safety Reporting Using AHRQ Common Formats

Memorandum Summary

Hospitals are Required to Track Adverse Events: The Condition of Participation (CoP) for Quality Assessment and Performance Improvement (QAPI) at 42 CFR 482.21(a)(2) requires hospitals to track adverse patient events. However, several recent reports completed by the Department of Health and Human Services Office of the Inspector General (OIG) indicated that hospitals fail to identify most adverse events.

Use of the Common Formats May Help Hospitals Improve Tracking. The OIG suggested staff failure to understand what events need to be reported to the hospital's QAPI program contributes to the problems with internal tracking systems. The OIG recommended that the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS) could help hospitals improve their ability to track adverse patient safety events by disseminating information on AHRQ's Common Formats. The Common Formats define a systematic process for reporting adverse events, near misses, and unsafe conditions, and allow a hospital to report harm from all causes. Hospital use of the AHRQ Common Formats is voluntary, but a hospital that uses them and is adept at the analysis that they permit will be in a better position to meet the CMS QAPI requirements. Common Formats version 1.2 can be accessed at www.psoppc.org

Surveyors Should be Familiar with the Common Formats: Surveyors may increasingly encounter use of the Common Formats in hospital QAPI programs. We encourage all surveyors to develop a general understanding of this tool, and become knowledgeable regarding how providers may access the relevant information about Common Formats.

Background

Despite substantial progress over the past decade in patient safety event reporting, two interrelated obstacles limit the effectiveness of current hospital practices in identifying adverse events: 1) widespread variation in reporting systems with respect to events identified for reporting as well as their clinical definitions, and 2) underreporting of a significant number of adverse events. The

Institute of Medicine, in a series of reports issued between 2000 and 2004, articulated the need for comprehensive patient safety event reporting to address the alarmingly high incidence of adverse events occurring in hospitals[1,2]. The findings of these reports provided impetus for the passage of the Patient Safety and Quality Improvement Act of 2005 (PSQIA). The PSQIA required AHRQ to develop and promulgate common definitions and reporting formats (Common Formats) to standardize the reporting (both internal and external) of patient safety events, both clinically and electronically. AHRQ has developed Common Formats for hospitals in collaboration with an interagency Federal Patient Safety Workgroup (PSWG), the National Quality Forum (NQF), and the public. Common Formats for nursing homes are under development.

A recent series of U.S. Department of Health and Human Services Office of Inspector General (OIG) reports has documented both the persistence, and underreporting, of a significant number of adverse events in hospitals. To address this problem, the November 2010 OIG report, "*Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*," recommended that AHRQ and the Centers for Medicare and Medicaid Services (CMS) encourage internal hospital reporting of all adverse events, whether or not preventable and whether or not caused by an identifiable process failure or error ("all cause harm").[3] In the OIG's view, reporting of adverse events should not be limited to a small, narrow subset (e.g., NQF Serious Reportable Events, CMS's Hospital Acquired Conditions (HACs)), as the vast majority of adverse events that occur to patients are not found on these lists.

The January 2012 OIG report "*Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*," found that staff of hospitals surveyed did not report 86% of adverse events to their hospitals' internal incident reporting systems.[4] The report further noted that in those States that require hospitals to report certain types of adverse events externally to the State, serious underreporting occurs, and most of the events that States required to be reported, but that hospitals did not report, were not identified by the hospitals' internal incident reporting systems. This inconsistent identification of adverse events was largely attributed by the OIG to confusion among front-line staff regarding what events they need to report internally.

The OIG stated that hospitals should strive to report all adverse events, or "all cause harm" – any event during the care process that results in harm to a patient, regardless of cause. The OIG report identified the Common Formats as providing a systematic method for collection of all types of adverse events and recommended that AHRQ and CMS promote more widespread use of the Formats. The OIG also observed that the Common Formats by themselves were not sufficient to promote a broader understanding of the types of occurrences that resulted in adverse events. To promote such understanding, the OIG subsequently recommended that AHRQ and CMS create and promote a list of patient safety event types that would address "the full range of harm" and could guide hospital internal reporting.[5]

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1 To err is human: building a safer health system. Kohn LT**,** Corrigan JM, Donaldson MS (Institute of Medicine). Washington, DC: National Academy Press, 2000.

[2] Patient safety: achieving a new standard for care. Committee on Data Standards for Patient Safety, Board on Health Care Services. Washington, DC. National Academies Press, 2004.

[3] http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf

[4] http://oig.hhs.gov/oei/reports/oei-06-09-00091.asp

[5] http://oig.hhs.gov/oei/reports/oei-06-09-00091.asp

Relationship to CMS Conditions of Participation

The CMS hospital Condition of Participation (CoP) for Quality Assessment and Performance Improvement (QAPI) at 42 CFR 482.21(a)(2) requires hospitals to track adverse patient events. Further, hospitals are obliged to use the data to monitor the effectiveness and safety of services (42 CFR 482.21(b), analyze the causes of adverse patient events, and implement actions and mechanisms to prevent recurrence (42 CFR 482.21(c)(2).

An internal hospital reporting system therefore represents a foundational capability that can determine whether or not the hospital can maintain compliance with key Conditions of Participation. Without an effective internal hospital reporting and feedback system, important patient events are less likely to be raised to the level where systemic improvements can be made, key adverse events are not tracked, the events are less likely to be analyzed or used to prevent recurrence, patients are at higher risk of adverse events, and the hospital is at higher risk of being cited for deficiencies and terminated from Medicare participation. These are compelling reasons to bolster hospital reporting systems, and ensure that they are integrated into the hospital's QAPI system.

Use of the AHRQ Common Formats by hospitals is not required under the QAPI CoP. We suggest, however, that a hospital that uses the Common Formats and is adept at the analysis that this structured system permits, will be in a better position to meet the CMS QAPI requirements.

Below we further describe the types of patient safety concerns that can be submitted to hospitals' internal incident reporting systems using the AHRQ Common Formats.

AHRQ Common Formats

AHRQ Common Formats represent a comprehensive and flexible tool for reporting all patient safety concerns: incidents, near misses, and unsafe conditions. They specify clinical definitions, data elements, and reporting formats that allow healthcare providers to collect and submit information regarding patient safety events in a standardized fashion. The Common Formats represent a standardized taxonomy by which a healthcare organization may identify and communicate events that are relevant to patient safety to both the hospital's internal reporting system and, when required, external entities (e.g., state patient safety reporting systems, FDA, etc.).

AHRQ has established a process to develop Common Formats that is:

1) Evidence-based;
2) Designed to allow harmonization of existing external reporting requirements across Federal and State health agencies;
3) Informed by feedback from the private sector, including professional associations/organizations, those who use the formats, and the public; and
4) Current, by timely updating of clinically-sensitive formats as clinical knowledge advances and experience with their use is gained.

The Common Formats allow for identification and reporting of ***any*** adverse event, including those that are rare, such as many of the National Quality Forum's Serious Reportable Events, and those that are common, such as falls or medication adverse events. The Common Formats are designed to

be used at the point of care, where events occur and where initial information should be collected as soon after an event as possible.

Common Formats are a Practical and Useful Tool for Hospital Adverse Event Tracking

The Common Formats support ongoing, data-driven quality assessment, regardless of hospital complexity, organization or services provided. They can be used for reporting patient safety concerns in all departments of the hospital, including general medical floors, surgery, ICUs, diagnostic and treatment centers (radiology, physical therapy, etc). The Common Formats support standardized information about the nature and frequency of events and support initial causal analysis and root cause analyses by capturing information about contributing factors (e.g., communication, handoffs, missing information, and stress/fatigue). Importantly, the Common Formats provide a harm scale for identifying and focusing on serious adverse events that may be preventable. The AHRQ harm scale standardizes evaluation of level of harm across different event types.

The Common Formats are a no-cost, publicly available taxonomy that has widespread use and is increasingly harmonized with other state and Federal reporting systems. The Common Formats have been implemented at hospitals and into patient safety and quality reporting software systems. The Common Formats (versions 1.1 and 1.2), including sample aggregate reports, technical specifications, other supporting materials, are available at www.psoppc.org, Attached is a more detailed discussion of the Common Formats.

Implications for Surveyors

Surveyors may increasingly encounter use of the Common Formats in hospital QAPI programs. We encourage all surveyors to develop a general understanding of this tool, and become knowledgeable regarding how providers may access the relevant information about Common Formats.

CMS wishes to acknowledge the support of AHRQ in developing this memorandum.

Questions about this memorandum should be sent to hospitalscg@cms.hhs.gov.

Effective Date: Not applicable. This memorandum is for information only.

Training: This information should be communicated to all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachment: (1)

cc: Survey and Certification Regional Office Management

Attachment
AHRQ's Common Formats

Concepts to Assist Reporting of Harm from All Causes ("All Cause Harm")

The U.S. Department of Health and Human Services Office of the Inspector General (OIG) noted that underreporting of adverse events by hospital staff can be attributed to misperceptions about what constitutes patient harm and to a lack of clarity regarding what types of patient safety concerns should be reported.[6] Variation in reporting practices both within different departments of a hospital and across hospitals further contributes to confusion and misunderstandings. The OIG reports were limited to considerations of events that reached the patient and caused harm ("harm incidents"). AHRQ's Common Formats expand the area of inquiry to apply to all patient safety concerns, including harm and no harm incidents, near misses, and unsafe conditions.

There is a broad range of potential patient safety concerns that occur in hospitals and a variety of ways in how these concerns may be recognized. The intent of this supplement is to provide more information on the characteristics of patient safety concerns, *with particular emphasis on harm incidents,* and provide examples of different types of incidents that might not be considered for reporting by hospital staff. Information is also provided on the modular construction of the AHRQ Common Formats.

Incidents vs. Near Misses vs. Unsafe Conditions

In order to reduce risk and harm to patients, it is important to understand and examine the full range of actual harm and potential threats to patient safety. Patient safety concerns comprise the following types (note that these AHRQ Common Formats terms differ from those found in the QAPI regulation and guidance, but are conceptually consistent with them):

- An incident is a patient safety event that reaches the patient, whether or not the patient was harmed
- A near miss (or close call) is a patient safety event that does not reach the patient
- An unsafe condition is neither an incident nor a near miss but is a circumstance that make the occurrence of such an event more likely

Incidents

Incidents can be considered in terms of the: 1) level of harm and 2) preventability.

Level of harm

Incidents can include both those where the patient is harmed and those that result in no harm to the patient. It is important to report "no harm" as well as "harm" incidents, because in either case, mechanisms for preventing the event from reaching the patient have failed and may fail again in the future.

For incidents that result in harm, the level of harm can range from minimal harm to death. AHRQ has developed a harm scale that can be used to document the degree of harm that

[6] http://oig.hhs.gov/oei/reports/oei-06-09-00091.asp

results from different types of patient safety incidents, and to measure an incident's impact on a patient's functional ability, including quality of life. The scale permits aggregating data about harm over all types of incidents. It is intended that harm assessment will be made only after efforts are made, if any, to prevent, reduce, or halt the progression of harm caused by a specific incident.

Hospital staff should be encouraged to report harm from all causes. As noted in the OIG report, there are a variety of events types that are currently overlooked but should be considered for reporting to the hospital's internal event reporting system. The table below, derived from observations in the OIG reports, sets out a few illustrative event categories and provides examples of types of events that, while sometimes overlooked, should be reported.

Event Category[7]	**Examples of event occurrences**
Event was an expected outcome or side effect	Thrush
Event caused little harm and/or harm was ameliorated	Hypoglycemia treated with orange juice (glucose)
Event was not on the hospital mandatory reporting list	Patient given wrong medication, but no harm; Reporting of Stage 2 pressure ulcers is not mandated in some states.
Event occurs frequently in hospitals	Medication given late; falls
Event symptoms became apparent after discharge	VTE diagnosed 10 days after discharge; Surgical Site infection 3 weeks after pacemaker implant.
Event occurred in a patient with a history of similar events	Falls, Stage 1 or 2 pressure ulcers
Events not caused by a perceptible error	Postoperative illeus (severe, lasting more than six days) Constipation after narcotics Adverse reaction (rash) to a medication the patient was not known to be allergic to

Preventable vs. Non-preventable

Incidents are not always preventable, as they do not necessarily reflect an error in care, negligence, or poor quality. Non-preventable incidents can occur despite proper assessment and treatment. A patient may have been highly susceptible to an event because of her health status, a complex diagnosis, or lack of available information.[8] In some situations, harm from treatment may have been anticipated, but the risk of harm was considered more acceptable than risk of failing to treat.

[7] This selection of event categories is excerpted from Table 2 in the OIG report *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*, page 13, http://oig.hhs.gov/oei/reports/oei-06-09-00091.asp

[8] OIG, *Adverse Events in Hospitals: national Incidence Among Medicare Beneficiaries*, Table F-2, page 48, http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf

However, a significant number of harm events (44% of adverse and temporary harm events[9]) are considered to be preventable. These incidents are related to errors in medical judgment or skill, provision of substandard care, and inadequate monitoring or assessment of monitoring or assessing patients. Examples include prescribing the wrong medication for the condition, or delay in treatment due to failure to recognize and monitor signs and symptoms related to early infection or shock. Other types of preventable incidents have been caused by a failure to provide necessary treatment, poor communication among caregivers, inadequate or flawed patient safety policies and procedures, and breakdowns in the hospital environment.

Hospital staff that complete initial adverse event reports for submission to a hospital incident reporting system should not be expected to make determinations regarding whether the incident that occurred was preventable. These judgments are more appropriately made subsequent to the initial report of an adverse event, after follow-up investigation.

Near Miss: A near miss is a potential harm event that did not reach a patient. Examples include discovery of a dispensing error by a nurse prior to administration of a potential overdose and discovery that a laboratory specimen was mislabeled prior to the results being entered into the wrong patient's record.

For example, if a nurse notices that the medicine that she is about to administer to the patient is wrong for the patient (so that she does not administer it), the result is a near-miss. The process failure may have originated upstream in the hospital pharmacy but it was blocked in a clinical direct care process.

A practitioner or health worker who catches or observes a production problem before it impacts a patient may not appreciate its potential to harm the patient, but the worker should still be encouraged to report the event. Subsequent investigation may allow the production process to be improved and similar problems to be avoided in the future. Since near misses are not usually reported in a patient's medical record, the event reporting system may be the only place where information about the problematic process will be recorded.

Unsafe condition: An unsafe condition is a patient safety hazard – a circumstance that increases the risk or probability of a future patient safety event. An unsafe condition exists until it is eliminated. Generally, it is the result of design or set-up flaws and/or steps in a production process. An unsafe condition does not involve an identifiable patient. Unsafe conditions may exist in direct clinical care or indirect care processes or the care environment. Examples of unsafe conditions include out-of-date medicines in inventory ready to be administered to patients, storing "look alike" medications in close proximity to each other, unreasonable staffing patterns, etc. All types of unsafe conditions may be reported in the internal hospital patient safety reporting system.

Modular Construction

AHRQ developed the Common Formats in modules for conceptual clarity, ease of use, and consistent maintenance. There are two types of Common Format modules: generic and event-specific. Generic Common Format modules contain data elements that may apply to any patient safety concern being reported. Such information might include the location of an event or condition

[9] OIG, *Adverse Events in Hospitals: national Incidence Among Medicare Beneficiaries*, http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf

within the facility, the role of the person submitting the report and whether, in the case of an incident, harm resulted. For a number of the most commonly-occurring types of patient safety events, event-specific modules with more granular structured information supplement that collected with generic modules. Event-specific modules allow for the reporting of contributing factors and are unique to the event type. Additional structured information is collected about the event itself, as well as information about the use or employment of measures designed to prevent the occurrence of the event.

The most recent version of the Common Formats (Hospital v1.2) contains nine event specific modules:

1. Blood or Blood Product
2. Device or Medical/Surgical Supply, including Health Information Technology (HIT)
3. Fall
4. Healthcare-associated Infection
5. Medication or Other Substance
6. Perinatal
7. Pressure Ulcer
8. Surgery or Anesthesia
9. Venous Thromboembolism
10. Other (allows collection of information on all other types of events)