

Message from the Chair

MAJOR CATALYSTS FOR IMPROVING U.S. HEALTHCARE

Two significant events are happening this fall and are worthy of discussion. On September 26, the *Federal Register* published a final notice from the Centers for Medicare and Medicaid Services (CMS) that gives deeming authority to DNV Healthcare to accredit our hospitals. DNV HC will utilize its National Integrated Accreditation for Healthcare Organizations (NIAHOSM) program, which combines ISO 9001 and the CMS conditions of participation for hospitals into a single survey process. This event will mark the first time in more than 40 years that a new hospital accreditation service has been approved by CMS, and it will provide competition in the marketplace. Hospitals choosing NIAHOSM accreditation will be required to comply with the ISO 9001 quality management system standards within 2 years.

The second important event is the final ruling on the Patient Safety and Quality

Improvement Act of 2005. This act was passed by Congress in 2005 to provide a way for healthcare providers to report and learn from medical errors they encounter. At present, the federal government is completing work on the final rule, which is being reviewed by the Agency for Healthcare Research and Quality (AHRQ) and Office of Civil Rights (OCR). The final rule establishes Patient Safety Organizations (PSOs) and describes the types of organizations eligible to become PSOs as well as their activities, reporting infrastructure, and data requirements. Douglas Dotan, immediate past chair of our Division, has written an accompanying article describing PSOs in more detail. We are confident that healthcare providers at all levels will participate in this new process in order to report patient safety events and learn from the information gathered.

There are several other topics of interest. Following a very successful program this year, we are currently in the planning stages for the Quality Institute for Healthcare, which will be held May 18 to 20, 2009, in conjunction with the ASQ World Congress in Minneapolis. The theme for the QIHC is *Building a Better Delivery System*, and we encourage you to put the dates on your calendars. Ray Zielke, marketing manager for our Division, is developing webinars on various topics in healthcare. He invites members to contribute content in areas of their expertise (rzielke@asq.org). We are also working to develop more content for our website. Please send ideas to Bill Dunwoody (amwhd@iioe.net).

James M. Levett, MD, FACS
Healthcare Division Chair
jmlevett@hotmail.com

EDITOR'S NOTES: HEALTHCARE COMMUNITY BUILDING: A TWO-PRONG APPROACH, NOW!

I second James Levett's observation about real changes happening. At the national level—the *first prong*—are the Patient Safety and Quality Improvement Act of 2005 and a new accreditation process. The act will change our healthcare landscape by allowing protected reporting and sharing of vital quality and safety information. The creation of PSO networks around the country is the most promising development in healthcare for a long time (OK, maybe after the global eradication of smallpox and polio). At the same time, Congress has given deemed status to DNV Healthcare to offer the NIAHOSM to accredit healthcare organizations. It is evident that we have reached critical mass to infuse innovative thinking and actions necessary for change and improvement.

While you may not be aware, the *second prong* for change is occurring without much fanfare and media attention—yet. A grassroots effort has begun to form and strengthen a coalition of individuals and organizations under the umbrella of the National Patient Safety Community. From individuals such as Lisa Lindell, the author who chronicled her observations of her husband's tenuous medical experience in her book, *108 Days*, to the organization *PULSE* (Persons United Limiting Substandards and Errors in Healthcare), a community partnership is taking shape to draw greater

attention to healthcare quality and safety, from the patient/consumer perspective. By the way, if you have been nodding off, we are now officially in the early phase of the “consumer-driven” healthcare system.

The ribbon's been cut, and the ground's now broken. A new healthcare community is gaining momentum. According to experts, the recent developments in healthcare are only indications of the nascent transformation of the system into a true “community,” one that would demonstrate patient-centeredness, high levels of quality, safety, and compassion. As a matter of fact, the term “community” is used by many industries as a metaphor for team, group, department, division, organization, and system. *Community* conveys the importance of belonging and working effectively and competently together—not a bad idea. So, how does ASQ HCD fit in this new healthcare community blueprint? How do YOU fit in as our system changes? How can we apply our leadership, knowledge, and wisdom individually and collectively to help shape this Community? Only time will tell.

Matthew Mireles, PhD, MPH
Newsletter Editor
mmireles@comofcom.com

UNDERSTANDING PATIENT SAFETY ORGANIZATIONS AND THE COMMON FORMATS

By Douglas B. Dotan, President, CRG Medical, Inc.; PSO Services Group

The IOM's 1999 landmark report, *To Err Is Human: Building a Safer Health System*, highlighted critical areas of research and activities basic to improving the safety and quality of healthcare delivery. One major, longstanding barrier to reporting, aggregating, and analyzing patient safety data was the fact that physicians and other clinicians feared legal liability, professional sanctions, or injury to their reputations. The format and content of reports allowing aggregation of data and sharing across different institutions were not standardized. Additionally, the low number of reports collected made it difficult to identify and mitigate underlying patterns of causal factors impacting overall patient safety.

What is a Patient Safety Organization?

Congress passed the Patient Safety and Quality Improvement Act of 2005 to create Patient Safety Organizations (PSOs) and encourage voluntary, confidential provider-driven reporting of data to improve the safety of healthcare. PSOs are designed to collect, analyze, and report data on the risks and hazards associated with patient care to identify and reduce risks and hazards and improve safety.

The privilege protections enforced by the judicial system allow reporting without fear of legal discovery and forbid the use of this information in criminal, civil, administrative, or other proceedings. AHRQ administers the provisions of the act dealing with PSO operations.

Public or private entities, profit or not-for-profit entities, provider entities such as hospital chains, and other entities that establish special components are eligible to become PSOs. Major advantages of PSOs are:

- Promote and enable wide sharing of findings that help identify solutions for risks and hazards thus increasing the pace of improvement.
- Provide the framework and methods to aggregate a sufficient number of events in a protected legal environment.
- Encourage organizations to work with clinicians and healthcare orga-

nizations to identify, analyze, and implement procedures and "best practices" to help improve patient safety and quality of care.

Who is responsible for PSOs?

The United States Department of Health and Human Services' Office of Civil Rights (OCR) is responsible for enforcing the confidentiality protections regarding patient safety work product that includes patient-, provider- and reporter-identifying information that is collected, created, or used by PSOs for patient safety activities. Civil money penalties may be imposed for knowing or impermissible disclosures of patient safety work product.

What are Common Formats for reporting, and how were they created?

The Common Formats developed by AHRQ describe the technical requirements and reporting specifications that allow healthcare providers to collect and submit standardized information describing patient safety events or incidents that reached the patient, data elements describing whether or not there was harm, near misses or close calls (patient safety events that did not reach the patient), and unsafe conditions.

The initial release of the Common Formats, Version 0.1 Beta, is currently limited to patient safety reporting for hospital inpatients. Future versions of the Common Formats will be developed for other settings such as nursing homes, ambulatory surgery centers, and physician and practitioner offices.

AHRQ coordinates the development of Common Formats for event reporting to PSOs as authorized by the Congressional act. The Common Formats optimize the opportunity for the public and private sectors to learn more about trends and patterns in patient safety, with the purpose of improving healthcare quality. Common Formats will:

- Accelerate development of the ability to aggregate comparable patient safety information to identify new opportunities for safety improvement.

- Increase the willingness of health care providers to participate in such efforts.
- Set the stage for breakthroughs in understanding how best to improve patient safety.

How will data be used?

The act facilitates the creation of a network of patient safety databases, to which PSOs, providers, or others can voluntarily contribute non-identifiable patient safety work product. This network will be maintained as an interactive, evidence-based management resource for providers, PSOs, and other entities. The statute directs AHRQ to use data from the network to analyze national and regional statistics, including trends and patterns, regarding patient safety events. Findings are to be made public and included in AHRQ's annual *National Healthcare Quality Report*.

AHRQ has established a process to receive feedback from private and public sectors and will continue to refine Common Formats and guide rapid improvement of the formats. Plans to release a second version of the formats in 6 to 9 months, depending on the nature of the initial feedback, will be announced. Once the formats are approved, they will be released annually.

AHRQ funded the PSO Privacy Protection Center (PPC) to facilitate the sharing of non-identifiable PSO information and to provide technical assistance to PSOs. For sample paper forms, use of Common Formats, and additional information, contact PSO@ahrq.hhs.gov.

As data become available from PSOs, a Network of Patient Safety Databases (NPSD) will receive, analyze, and report on de-identified and aggregated patient safety event information. The overall goal of NPSD is to facilitate aggregation and analyses of patient safety event information to help reduce adverse events and improve healthcare quality.

To what extent and how quickly will physicians, healthcare providers, and other stakeholders directly apply PSO patient safety data and information in prudent and diligent ways that significantly improve patient safety and reduce the risks and hazards associated with patient care?" That is the real question.