

## Patient Safety Organization Reporting: *What does it mean?*

*"PSOs are organizations that share the goal of improving the quality and safety of health care delivery....create a secure environment where clinicians and health care organizations can collect, aggregate, and analyze data, thereby improving quality by identifying and reducing the risks and hazards associated with patient care."*

- Agency for Healthcare Research and Quality (AHRQ)

### Consider -

- How often does one facility experience a wrong site/patient procedure?
- How often does one facility experience a malfunction/misuse of a particular type of medical device?
- How often does one facility experience misidentification of a particular type of medication?

We hope that the answer is rarely. And, when such events occur, we hope the healthcare team at the facility in question can learn one or two lessons and implement changes to prevent similar mistakes from occurring again.

### Consider, what could happen -

- If dozens of such events occurred across 100 facilities? Over 1,000 facilities or more?
- If the events were reported to an organization where trends, common causes and effective solutions could be identified?

Undoubtedly, the healthcare community would learn so much more about events and near misses and how to prevent them. The learning comes from identifying causes and solutions across many healthcare facilities: acute care hospitals, specialty hospitals, ambulatory surgery centers, home care agencies, skilled nursing facilities, physician offices and any other healthcare setting.

More than a decade ago the **Institute of Medicine** recommended that healthcare professionals be encouraged to report medical errors without fear of their reports being used against them. Recent studies by the **Office of the Inspector General (OIG)**, the **American Society for Healthcare Risk Management (ASHRM)**, and the **National Association for Healthcare Quality (NAHQ)** call for improving event reporting to enhance the learning that is necessary to prevent medical errors and reduce attributed patient harm and cost.

## PATIENT SAFETY ORGANIZATIONS (PSOs) ARE PART OF THE SOLUTION

In 2005, the **Patient Safety and Quality Improvement Act** became law. The measure established Patient Safety Organizations (PSOs) to:

- encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of healthcare
- promote rapid learning about the underlying causes of risks and harms in the delivery of healthcare
- share findings widely, thus speeding the pace of improvement.

The Act also created an unprecedented legal privilege and confidentiality for information reported to PSOs, fostering a culture that encourages reporting, while guaranteeing that original records, such as patients' charts, remain accessible to patients.

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## A TWIST IN MISSOURI

In 2010, Missouri became the first and only state to require hospitals and ambulatory surgery centers, per a **MoHealthNet (MHN)** regulation, to participate in a PSO and report Serious Reportable Events and Healthcare Acquired Conditions. While the federal law calls for PSO participation to be voluntary, the MHN rule required participation by its providers in conjunction with implementation of its non-reimbursement policy for these adverse events. In light of additional federal requirements for state Medicaid programs, the MHN regulation requiring PSO participation was rescinded in June, 2012.

As a result of PSO participation in Missouri being initially tied to a regulatory requirement, many facilities believe that only the MHN-defined events could be reported to the PSO, leaving many to think there is "nothing to report" to the PSO if they have not experienced these serious, relatively infrequent events.

## WHAT TO REPORT TO PSOs?

The intent of PSOs is to gather, aggregate and analyze data from across the United States that will lead to improved patient safety and quality care. With this in mind, providers are encouraged to consider what kinds of data and information will contribute the most to improving patient safety.

The following types of information could be reported to a PSO to feed learning as well as receive federal legal and confidentiality protections:

- Event, near miss and unsafe condition reports
- Root Cause Analysis, Failure Mode and Effects Analysis, Learning from Defect Analysis or other proactive risk assessments
- Notes from patient safety huddles or rounds, telephone calls or hallway conversations
- Quality outcome reports such as blood utilization, complications or Core Measure variances, and
- Quality and safety committee minutes, among others

## THE PRESENT AND FUTURE

Healthcare providers across the United States are increasingly joining PSOs for three reasons:

1. to be proactive and learn from the events that have occurred at other facilities
2. to be able to discuss events in a safe, legally protected environment
3. to meet pending federal health reform requirements.

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## PSO Protection Upheld... Again!

In the summer issue of PSO News we shared the Walgreen's case where an Illinois appellate court upheld a lower court's decision that Patient Safety Work Product (PSWP) is privileged and not subject to discovery under the 2005 Patient Safety and Quality Improvement Act (Act). Additional case law from Kentucky has now been published.

### University of Kentucky physician case -

- A suit was filed against the University physicians related to care provided to a deceased patient, requesting copies of incident reports.
- The defendants argued that the reports, reported through the University's incident reporting system and to their PSO, were protected as PSWP and privileged under the federal PSO Act.
- The trial court ruled that the incident report was not privileged resulting from the court's inaccurate interpretation of an exception to PSO protections within the Act for "a patient's medical record, billing and discharge information...."
- The defendants filed a petition to the Kentucky Court of Appeals to prevent production of the incident report.

### Norton Hospital case -

- Norton Hospitals, Inc v. Cunningham, 2012-CA-00746-OA, KY Court of Appeals, August 16, 2012. The plaintiff filed a request for documents pertaining to Norton's quality assurance activities related to care of one patient.
- Some of the requested documents were developed within the hospital's Patient Safety Evaluation System (PSES) and reported to their PSO; therefore, Norton asserted those documents to be protected under the federal PSO law.
- The plaintiffs' attorney motioned to compel the release of the documents, a hearing ensued and the judge ruled the documents should be produced.
- Norton filed a petition to the Kentucky Court of Appeals to prevent enforcement of the order claiming the federal PSO protections preempt Kentucky case law; law that historically would otherwise allow discovery of the documents.

### KENTUCKY COURT OF APPEALS OPINION

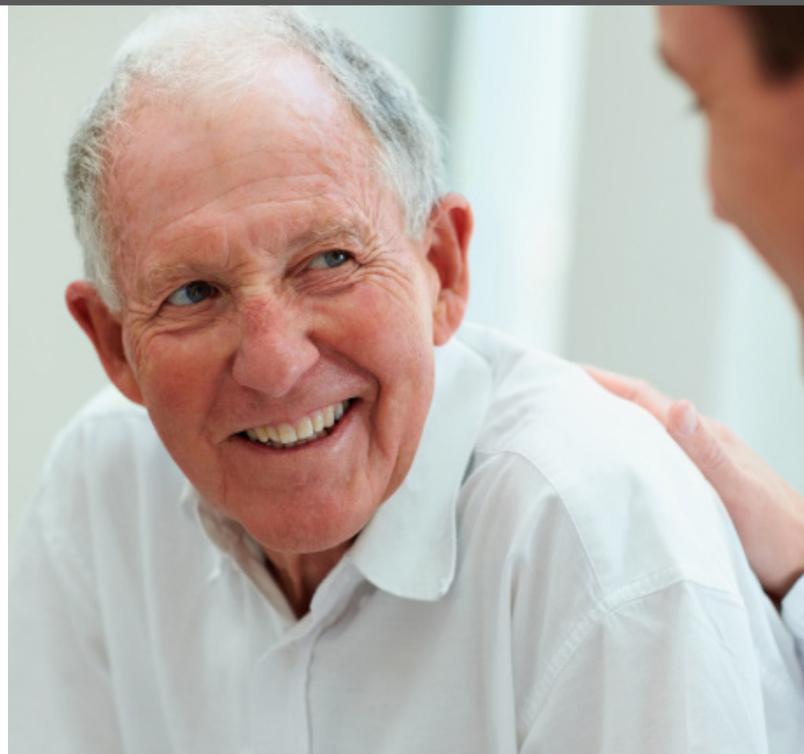
The Court granted both the University of Kentucky physicians and Norton's petitions, overturning the trial court's orders to release the documents, agreeing that the federal law preempted state laws for discovery of such information. However, the Court of Appeals defined the scope of the federal PSO privilege that is contrary to language of the PSO law, incorrectly linking it to a ruling made prior to the PSO law that references protection for "self-examining analysis". The intent of the PSO law is for protections of a much larger body of work than only "self-examining analysis".

### Next Step - the Kentucky Supreme Court

In order to obtain clarification of the Court of Appeals incorrect interpretation of the scope of the PSO protections and to reinforce the Court of Appeals confirmation of the federal PSO law preempting state law, petitions have been filed with the Kentucky Supreme Court along with a number of amicus briefs supported by national healthcare associations, healthcare organizations and PSOs.

### Summary

While there is ongoing development of case law interpreting aspects of the Act, all opinions published to date have found that the federal Act provisions preempt state law that would otherwise allow the discovery of PSWP. These early cases make it clear that an organization relying on the Act should clearly define its PSES and PSWP in policy and report to a PSO in order to conclusively establish its intent and gain available protections. ■



## AHRQ's Proposed Consumer Event Reporting System

The **Agency for Healthcare Research and Quality (AHRQ)** has announced a proposal for a new "Prototype Consumer Reporting System for Patient Safety Events" with the objective of increasing consumer reporting of unsafe practices, medical errors and near misses. Recognizing that patients, family members, caregivers or consumers could reveal important information about the safety of care that is not currently reported by healthcare providers, AHRQ intends for these confidential reports to complement and enhance provider event reports, thus producing a more complete and accurate understanding of the prevalence and severity of medical errors and near misses occurring across the United States.

The proposal was submitted to **Office of Management and Budget (OMB)** on September 10th. If the OMB approves the project, questionnaires will be available at kiosks in hospitals and physician offices as early as May, 2013, inviting individuals to report an unsafe practice, medical error or near miss, when and where it occurred, whether there was harm, the type of harm and whether the event was reported to anyone. They will also be asked to identify possible contributing factors. Reports may be submitted via the web or telephone. Information describing the program will also be distributed to patients' homes, asking them to voluntarily participate in the program. Follow-up on the reports may be made by a **Consumer Reporting System for Patient Safety Events (CRSPS)** staff member, including discussion with the facility patient safety officer.

Suggestions to be prepared for this potential new event reporting system:

1. Support a culture of safety through actions and behaviors that embody a commitment to safety - promote reporting of safety concerns, education of staff on safety issues, staff empowerment to identify and mitigate hazards and risks
2. Participate in a PSO to safely share events and learn from others, taking advantage of the privileges afforded by the federal Patient Safety Act (See story on page 1)
3. Provide feedback to staff and physicians on adverse events reports including broad communication about actions taken based on analysis of the submitted reports to enhance learning from errors and support future reporting
4. Systematically assess your organizations' safety culture and commitment to patient safety.

To learn more about Center services that are available to administer and report results of a Survey on Patient Safety for hospitals, physician offices and long-term care, contact Alex Christgen at [achristgen@mcpsps.org](mailto:achristgen@mcpsps.org). ■



## Second Victims Workshops: Supporting Healthcare Providers Impacted by Error

In September, 25 healthcare professionals gathered to learn how University of Missouri HealthCare developed and successfully implemented its "For You" initiative. The program supports staff members and physicians after their involvement in unexpected clinical events.

Caregivers often feel responsible for the patient's outcome. With a sense they have failed the patient, staff members and physicians may begin to second-guess their clinical skills and knowledge.

Without intervention and appropriate support, these individuals may become depressed, leave their profession, develop personal problems, or even become suicidal.

**Read more about the University's research over the past five years and download a "2nd Victim's Toolkit"**

The Center for Patient Safety is planning another Second Victim Workshop in collaboration with the University of Missouri HealthCare in June 2013. ■

## Why RSI? Learning More About Retained Surgical Items

The Center for Patient Safety has joined PSOs in California, North Carolina, Michigan, Illinois and Tennessee in a 3-month data collection to study retained surgical items (RSI).

RSI inadvertently left in patients after surgery may include micro-needles, broken drill bit fragments and guide wires. These items appear to be retained more frequently than other objects that are countable, such as sponges. Incidents of RSI can occur in outpatient, inpatient and ambulatory surgery settings. It is also not well known how to prevent such events.

Center PSO participants were asked to be particularly aware of and report RSI events during this period of time. The Center submitted 23 event reports for the study.

RSI data from all participating PSOs will be aggregated and analyzed. Later in 2012, CPS and PSOs in partner states will provide educational opportunities for participating hospitals to obtain the results of the initiative and lessons learned.

**Read more in this related safety alert from the ECRI Institute, "Retained Foreign Objects: It's Not the Robot's Fault" ■**

## PATIENT SAFETY ORGANIZATION REPORTING

(CONTINUED FROM PAGE 1)

The federal **Affordable Care Act** contains two provisions addressing PSO participation--specifically for hospitals that have more than 50 beds and want to participate in designated health insurance exchanges, and for hospitals needing assistance in reducing readmission rates.

While the number of hospitals reporting information and the number of events reported to the Center as a PSO continues to grow, facilities are encouraged to consider any types of events, near misses or unsafe conditions that could lead to broad learning and prevention. Also, Center PSO participants are encouraged to review their Patient Safety Evaluation System (PSES) and Patient Safety Work Product (PSWP) policies to obtain the most benefit from PSO participation for your organization.

Center staff is available to provide assistance with your review.

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### THE PAYOFF: TOGETHER WE CAN DO THIS!

There are many benefits to reducing adverse events and unsafe conditions that can be achieved by being proactive, including reporting to a PSO:

- increased compliance with regulations
- decreased healthcare costs
- reduced reimbursement penalties from payers
- heightened patient safety awareness.

As learning about patient safety increases, best practices are identified and spread across the state and country. Implementation of best practices will result in enhanced safety and improved patient outcomes.

*"PSO work involves a social contract between providers and the PSO."*  
— James Battles, AHRQ

Providers agree to report complete and timely information to the PSO and the PSO agrees to use the information for feedback, learning and improvement. ■

## National Call to Action on Adverse Event Reporting: PSOs are part of the solution!

Released in October, the **National Association for Healthcare Quality** (NAHQ) Call to Action, rallies the healthcare community to eliminate preventable harm.

While recognizing that a strong, just safety culture is a key element for improvement, NAHQ acknowledges healthcare providers still fear reporting adverse events. There is a continued lag in reporting due to a lack of protective infrastructure to safeguard responsible, accurate reporting of quality and safety outcomes and concerns.

Accelerating financial models based upon quality and safety outcomes raise the stakes associated with adverse events. Coming changes reinforce the need for an infrastructure that encourages accurate reporting.

The NAHQ calls for leaders in all healthcare settings to:

"implement protective structures to assure accountability for integrity in quality and safety evaluation and comprehensive, transparent, accurate data collection, and reporting to internal and external oversight bodies."



Actionable items contained in the NAHQ call to action include:

- establishing accountability for the integrity of safety systems
- protecting those who report concerns
- reporting data accurately
- responding to concerns with robust improvement

**Patient Safety Organizations** (PSOs) support each of NAHQ's actionable items. Furthermore, PSOs are a source of learning about and improving safety systems while providing federal-based legal and confidentiality protections for reporters. PSOs can help collect detailed data using common data formats established by the **Agency for Healthcare Research and Quality** (AHRQ), and serve as conveners across large numbers of providers to learn, share the learning and support broad-based improvement efforts.

Source: NAHQ, Call to action, Safeguarding the Integrity of Healthcare Quality and Safety Systems, October 2012. ■

## Upcoming Events

### Winter 2012

- December 6 Last day to register for January round of SOPS  
 December 6-7 Missouri HEN Collaborative Session (Columbia)  
 December 18 PSOM 101 Webinar, Topic: Running Reports

### Spring 2013

- January 30 PSO Advisory Panel Meeting  
 March 7 Last day to register for April round of SOPS

### Summer 2013

- April 17 4th Annual MOCPS PSO Participant Day (Columbia)  
 June 5 Last day to register for July round of SOPS  
 June 20 PSO Advisory Panel Meeting  
 TBA Second Victim Workshop

### Fall 2013

- September 4 Last day to register for October round of SOPS  
 October 24 PSO Advisory Panel Meeting

## MOCPS Takes its Mission Nationwide as the Center for Patient Safety

The Missouri Center for Patient Safety is pleased to share with our PSO participants our evolution to the Center for Patient Safety (CPS). As the Center for Patient Safety, we hold the same vision and mission as the MOCPS, while reinforcing and expanding on our work that has historically and will continue to cross the Missouri borders.

If you haven't yet done so, be sure to join us on LinkedIn, Twitter, and Facebook to keep up to date on our activities!

We thank the individuals and organizations that have joined with us in the push toward improving the quality and safety of care and eliminating patient harm. We look forward to continuing to work with you in this crusade! ■

## The Harm of Disrespectful Behavior

The Journal of the Association of the American Medical College recently published two enlightening articles highlighting the harmful effects of disrespect in hospitals. The authors state, "A culture of disrespect is harmful for many reasons, but it is its effect on the safety and well-being of our patients that makes it a matter of urgency. In simple terms, **we believe that a health care organization that supports and tolerates disrespectful behavior is unsafe for its patients and hostile for its workers.**" The negative impact of disrespectful behaviors in healthcare organizations is far reaching and can also significantly influence patient and employee satisfaction, turnover, and therefore, financial sustainability.

The authors' goal is to provide definitions and discussion of disrespectful behavior to enhance awareness and understanding of the harm that such behavior causes for everyone on the healthcare team and the patients they serve. The authors indicate many challenges for overcoming a culture that supports disrespect, but some suggestions for remedy include a cultural shift that supports transparency with a foundation of a "just culture".

Learn more about the harmful effects of disruptive behavior as well as steps you can take to improve your safety culture by reading the entire articles:

- [http://journals.lww.com/academicmedicine/Full-text/2012/07000/Perspective\\_\\_A\\_Culture\\_of\\_Respect,\\_Part\\_1\\_\\_The.10.aspx#](http://journals.lww.com/academicmedicine/Full-text/2012/07000/Perspective__A_Culture_of_Respect,_Part_1__The.10.aspx#)
- [http://journals.lww.com/academicmedicine/Full-text/2012/07000/Perspective\\_\\_A\\_Culture\\_of\\_Respect,\\_Part\\_2\\_\\_.11.aspx](http://journals.lww.com/academicmedicine/Full-text/2012/07000/Perspective__A_Culture_of_Respect,_Part_2__.11.aspx) ■

### FOR MORE INFORMATION

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For additional information on the Center's PSO activities, resources, toolkits, upcoming events, safety culture resources, and more, visit our website at [www.centerforpatientsafety.org](http://www.centerforpatientsafety.org) or follow us on Twitter @PtSafetyExpert for the most up-to-date news.

### ABOUT MOCPS

*The Missouri Center for Patient Safety, dba Center for Patient Safety, was founded by the Missouri Hospital Association, Missouri State Medical Association and Primaris as a private, non-profit corporation to serve as a leader to fulfill its vision of a healthcare environment safe for all patients and healthcare providers, in all processes, all the time.*