PSO? PSES? PSWP?
You Have Questions, We Have Answers

Part 3 – November 12, 2013

This presentation is co-hosted by:

Center for Patient Safety
Vergesolutions

✓ Technical issues? Please call 888.935.8272.
✓ This webinar is being recorded.
✓ All attendee lines will be muted during the Webinar.
✓ Questions during the Webinar?
  ✓ Enter questions in the “Questions/Chat” panel in the upper right corner of your screen and click “Send” at any time during the Webinar
  ✓ Questions will be answered at the end of the Webinar as possible
✓ A link to the recording and slide desk will be sent to registrants following the presentation.
Objectives for Today’s Session

Following this Webinar, participants will be able to:

- Understand the role of Patient Safety Organizations from a national perspective
- Learn about the status of PSOs nationally
- Understand the role of PSOs and interaction with national HIT strategies and regulatory compliance activities
- Define expectations for PSO participation within the Affordable Care Act
- Understand benefits for healthcare providers in working with PSOs

National PSO Landscape / Horizon

Missouri Center for Patient Safety
12 November 2013

William B. Munier, MD, MBA, Director
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality
Agenda

- PSO Status
- Common Formats
- Patient Safety & Health IT
- PSWP & the CMS QAPI program
- Affordable Care Act

PSO Status
PSO Program Status

- There are currently 76 PSOs in 29 states & the District of Columbia
- 51 PSOs have been listed & subsequently delisted
- Maturity & financial stability of PSOs is improving; collection of quality & safety data is increasing rapidly
- 3 PSOs have to sent data to the Privacy Protection Center (PPC) for transmission to the Network of Patient Safety Databases (NPSD)
- There are a total of 19 signed data-use agreements

PSO Profile Data – 58 PSOs Reporting

Count of PSOs by Type of Business

(A PSO may choose more than one type)
PSO Profile Data

PSOs by Type of Event Reports Solicited

- All topics (no specific focus): 69%
- Multiple topics, but not all: 9%
- Blood or blood products only: 2%
- Medication or other substances only: 4%
- Other: 7%

Hospitals Working With PSOs

Hospitals by Number of Licensed Beds
(Note: PSOs did not submit bed size for 171 hospitals.)
Types of Providers

- Total providers working with PSOs = 4602
  - 1,620 general hospitals
  - 324 specialty hospitals
  - 2666 other providers

Other types of providers include nursing homes, freestanding clinics, ambulance/EMS services, ambulatory surgery centers, home health care.

- These counts are less than the actual number of participating providers

Common Formats
Common Formats

- Authorized by the Patient Safety Act in 2005
- Developed with a Federal work group comprising major health agencies (e.g., CDC, CMS, FDA, DOD, VA)
- Incorporate input from public, industry
- Reviewed by an NQF expert panel, which provides advice to AHRQ
- Promulgated as “guidance” announced in the Federal Register
- Approved by OMB (process & Formats)

Only national patient safety reporting scheme designed to meet all of the following four goals:

1. Support local quality/safety improvement
2. Provide information on harm from all causes
3. Allow comparisons over time & among different providers
4. Allow the end user to collect information once & supply it to whoever needs it (harmonization) – a long-term goal

Designed to decrease data collection burden!
Common Formats for Event Reporting

- Common Formats are site-specific (e.g., hospital)
- They apply to all patient safety concerns:
  - 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
  - Unsafe conditions – any circumstance that increases the probability of a patient safety event

Modular Focus
Hospital Version 1.2

- Blood & Blood Products
- Device & Medical or Surgical Supply, Including HIT
- Fall
- Healthcare-Associated Infection
- Medication & Other Substances
- Perinatal
- Pressure Ulcer
- Surgery & Anesthesia
- Venous thromboembolism
- All others via generic forms
Hospital Common Formats

Event Reporting

For all events, CFs assess general information.

If the event is covered by an Event-Specific Format, additional information will be requested.
Hospital Common Formats

If the event involves more than one type of adverse action, e.g., a malfunctioning device that administers too much drug, then more than one event-specific Format will be invoked.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Type</td>
<td>Patient Information</td>
</tr>
</tbody>
</table>

Hospital Common Formats

Narratives are collected on all adverse events. While they are not useful at a national level, they are invaluable at the local level.

<table>
<thead>
<tr>
<th>Narrative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
</tr>
<tr>
<td>Event Type</td>
</tr>
</tbody>
</table>
Hospital Common Formats

Each institution, vendor, or PSO can add an unlimited number of additional questions of its own choosing.

National Drivers for Adoption of the Common Formats

- **Institute of Medicine** Report on Health IT and Patient Safety, November 2011 – recommends use of the Common Formats, as well as PSOs, for reporting IT-related adverse events

- **Office of the Inspector General** (HHS) – 2011 & 2012 reports on adverse events in hospitals recommend surveyors/accreditors evaluate hospitals regarding their use of the Common Formats

- **Office of the National Coordinator for HIT** – plans to integrate Common Formats into Meaningful Use criteria

- **CMS** – is educating their surveyors about the Common Formats to encourage their use

- **NLM** – is overseeing efforts to expand SNOMED & LOINC to cover patient safety; have begun discussions about adding codes for Formats

- **FDA** – has been working for nearly two years with AHRQ to align its device-reporting system, MedSun, with Common Formats
Event Reporting vs. Surveillance

- The Common Formats are currently designed as a **concurrent** event-reporting system
  - Contain information in the EHR & more
  - Do not include denominators
- The Formats are being adapted to be used as a **retrospective** surveillance system
  - Will include denominators; will generate rates
  - Will not address near misses & unsafe conditions
  - Based on audit of charts

Why Surveillance?

- DHHS currently has a surveillance system, the Medicare Patient Safety Monitoring System (MPSMS), which needs updating
  - Used by the Partnership for Patients to track rates
  - Limited to 21 types of adverse events
  - Labor-intensive; not built for local use
- Surveillance CF will update content, expand areas covered, & improve usability
  - Capture “all-cause harm”
  - Efficient; designed to allow use by hospitals
Event Reporting vs. Surveillance

- Event reporting systems are used by patient safety professionals during a patient stay
  - Individuals can be interviewed; sources other than the medical record can be reviewed
  - Professionals can interpret what happened
- Medical record based systems must rely on coders/abstractors
  - Judgment of coders/abstractors is undesirable outside very narrow boundaries; inter-rater reliability depends on a very objective process

Event Reporting vs. Surveillance

- Surveillance CF will not be able to address many Event Reporting CF elements, e.g.,
  - Many, if not a majority, of medication errors, which are discovered at the “near miss” stage
  - Wrong patient surgery
- Even for harm incidents, much detail from event reporting will not be in the medical record, e.g.,
  - Many device adverse events may be contributing factors to actual harm – & noted only in engineering or IT logs
Event Reporting vs. Surveillance

- Surveillance Formats are not just a “step-down” from Event Reporting Formats; they are different
- Some clinical items are the same, e.g., “error in using device” is found in both
- Some content is very different; for example:
  - “Overdose or underdose” only found in Event Reporting
  - Overdose of heparin detected in Surveillance by clinical manifestations of PTT > 100 seconds or administration of heparin antagonists (e.g., protamine)

Why Surveillance?

- Surveillance CF will allow collection of comparable performance data over time & across settings
- Hence Surveillance CF can be used for:
  - Generating adverse event rates
  - Trending performance over time
  - Establishing local, PSO, & national means (averages)
  - Benchmarking among institutions
The Challenge of Multiplicity

- Clinical representation of patient safety events
  - Adverse event reporting – external to medical record
  - Surveillance – based on medical record
  - Electronic health record – coded part of product

- Electronic data capture & transmission
  - Vocabularies, e.g., SNOMED-CT & LOINC
  - Packaging for transmission, e.g., HL7 & CDA
  - Ad hoc, custom-build solutions (many, many)

Parties at Interest

- CMS – multiple patient safety requirements, including expanded measures based on clinical data
- CDC’s NHSN
- FDA’s MedSun & MedWatch
- NQF Serious Reportable Events (SREs); now developing e-measures
- The Joint Commission – IQR & sentinel event reporting
- State reporting system requirements (each state different)
- Many others…
Ultimate Goals for Patient Safety Reporting

- Clinical & electronic definitions must be consistent throughout all software applications & reporting levels – and be interoperable where appropriate
- Core systems need to operate at institutions delivering care (e.g., hospitals, nursing homes, etc.)
- All data for reporting need to derive from that collected once by those institutions
- Reporting burden needs to be only as heavy as is justified by the value of data / information collected
Big Data & the EHR

- Transformation of clinical information processing from paper to electronic form has been painfully slow
- Great promise offered 1st by the EHR, now Big Data
- Job to be done before the promise is realized – the structuring of clinical concepts before coding:
  - Care processes, patient outcomes
  - Quality standards
- Promise is likely to be fulfilled – but over a much longer time period than first envisioned

IT Contributions to Safety & Quality

- Enhancements
  - Improved recordkeeping (EHR & other) & improved access to information
  - Increased value of IT devices
  - More powerful & cost-effective measurement for quality & safety improvement
- Risks
  - New risks from health IT devices themselves, e.g., software bugs, data entry errors, usability issues
**Health IT Risk**

- Infusion of $25.8 billion for health information technology investments & incentives, through the American Recovery and Reinvestment Act (the Stimulus Act) in 2009, ignited concern over the potential risks of these new technologies

- Federal efforts included:
  - Support of Institute of Medicine (IOM) November 2011 report: *Health IT and Patient Safety: Building Safer Systems for Better Care*
  - Revision of AHRQ’s Common Formats to enhance detail on HIT safety concerns

**PSOs & HIT**

- IOM’s *Health IT and Patient Safety: Building Safer Systems for Better Care* envisions a prominent role for PSOs & Common Formats
  - PSOs can assist providers in understanding HIT risk
  - Aggregation of information at the PSO & national levels (NPSD) using the Common Formats can speed identification & rectification of HIT risks

- Important note: most IT-related safety problems manifest as contributing factors, not primary causes, to events & near misses
PSOs & HIT

- AHRQ’s Common Formats v1.2 for hospitals (the most recent version) contain the expanded HIT section
- The Office of the National Coordinator (ONC) is encouraging expansion of knowledge on HIT safety:
  - Seeking active participation of PSOs in various projects, including expanding knowledge about the types & rates of HIT-related adverse events
  - Exploring what defined fields in EHRs can be used to populate Common Formats systems automatically

PSWP & the CMS QAPI Program
Accountability & Voluntary QI

- CMS & PSQIA regulations share a common goal – patient safety – but have different approaches

  - **Key issue:** meeting the needs of CMS surveyors vs. protection of PSWP

  - **ACCOUNTABILITY** – CMS surveyors must verify that entities maintain effective internal QI & patient safety improvement programs & meet other standards to protect patient safety

  - **VOLUNTARY QI** – PSQIA provides confidentiality & privilege protections to voluntary QI & patient safety improvement programs; there is no explicit permission to disclose PSWP to CMS

Tensions Have Arisen

- Hospitals working with a PSO:
  - Have protected information requested by Medicare surveyors
  - Have occasionally told Medicare surveyors that PSQIA trumps their regulations; it does not

- Medicare surveyors:
  - Often display little knowledge of PSQIA or PSWP
  - Have been aggressive with hospital staff (we've been told), who feel caught between CMS & PSQIA
What Does The Patient Safety Rule Say?

- “…these protections do not relieve a provider from its obligation to comply with other Federal, state, or local laws pertaining to information that is not confidential or privileged under the Patient Safety Act…” (73 FR 70732)

- “Information is not PSWP if it was collected to meet external obligations such as:
  - …State incident reporting requirements…
  - …required disclosures…pursuant to Medicare conditions of participation or conditions of coverage…” (73 FR 70742-70743)

Why the Conflict Persists

- Inability of hospitals to anticipate everything CMS surveyors will request

- No viable “permission” for hospital to disclose PSWP to CMS; once a provider protects information (that surveyors subsequently request), protection can’t be removed; (exception – the “drop-out” provision)

- Lack of awareness by some hospitals that PSQIA does not trump CMS rules; non-PSWP must be used to demonstrate compliance with Medicare COP & QAPI – & to meet state incident reporting & other state requirements
Why the Conflict Persists

- Lack of understanding / knowledge of surveyors about PSQIA, its provisions, & the value they can provide in establishing a culture of safety

- Concern on the part of hospitals that in order to be ready for CMS surveyors, they must hold so much potential PSWP as non-protected that:
  - They are at risk vis-à-vis legal privilege for quality & safety analyses that are held out of their PSES
  - They must create “duplicate systems”

- Potential dilemma: PSQIA or CMS, but not both

Steps to a Path Forward

- Provide greater clarity regarding what information surveyors need – but regulators generally are reluctant to limit their authority to request information

- Improve education of surveyors – but only goes so far

- Expand PSO’s provider education on what cannot be protected – but, again, current “dueling regulations” create the potential for unnecessary duplication of efforts in order to comply with CMS
Steps to a Path Forward

- Explore options (changes to rule and/or statute) to expand provisions for permitted disclosures, e.g.,
  - Added permission for disclosure to CMS for purposes of meeting QAPI requirements
  - Added permission for disclosure under defined circumstances to states to meet their reporting & audit requirements
- Various parties-at-interest have varying reservations about expanding disclosure provisions, e.g., physicians, administrators, other accreditors

High Priority

- AHRQ & CMS agree that this problem needs to be solved urgently
- It’s unfair to leave it to the field: surveyors & hospital administrators cannot be expected to sort this out
- AHRQ & CMS are continuing to meet to identify viable solutions
- Both agencies are committed to resolving the issues
- PSOs, AHA, & TJC have been proactive in providing valuable advice from the field
The Affordable Care Act: A National Driver for PSOs

The ACA contains two provisions that give PSOs new roles & responsibilities:

1. **Health Insurance Marketplace**: Qualified Health Plans (QHPs) operating through the new Health Insurance Marketplace can only contract with hospitals > 50 beds if they have a patient safety evaluation system (PSES) – *which means a PSO* – as of January 1, 2015

2. **Readmissions**: AHRQ is to make available a program for eligible hospitals to improve their readmission rates *through the use of Patient Safety Organizations*
Marketplace – PSO Requirement

Two major points on Marketplace requirements:

1. “The Secretary may establish reasonable exceptions to the requirements described...”

2. CMS has not issued implementing regulations

AHA issued a Member Advisory on July 31, 2013
- AHA facts were correct, interpretation reasonable
- Position was supportive of PSOs without getting ahead of Federal guidance

Roughly 70% of listed PSOs responding to the last information form survey reported that they accept a broad spectrum of hospital-based events, & over 60% of PSOs indicate that they are prepared to work with providers across the nation

Nonetheless, it is not entirely clear that there is sufficient PSO capacity to enable all hospitals subject to this provision to contract with PSOs

It is thus reasonable to expect that this requirement will be phased in, with the methods of phasing to be delineated through CMS regulations
Marketplace – PSO Requirement

- Suggestions in the AHA Member Advisory certainly will be considered
- AHRQ expects to work closely with CMS in determining the content & timing of the regulations
- It would not be surprising to see additional PSO applicants in response to the projected increased demand
- Properly implemented, this requirement should have salutary effects on PSOs – as well as quality & safety nationwide

Expanding Involvement with PSOs

- Like any new initiative, the PSO program has issues that need to be resolved/improved
- Yet its start has been remarkably smooth: 76 PSOs, many focused on safety; some doing exciting work in quality analysis & in settings outside the hospital
- PSOs will gain more traction as ACA goes forward
- They represent the best forum for in-depth analysis of quality & safety – with protection from discovery!
- Get involved with your PSO (if you aren’t already) !!
Contact Information

Information on the Common Formats
www.psoppc.org

William B. Munier, MD
william.munier@ahrq.hhs.gov

Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

To Learn More

Tuesday, November 19 NAPSO Health IT Webinar – ONC and ECRI Staff -
https://www1.gotomeeting.com/register/484980993

AHRQ PSO Page  http://www.pso.ahrq.gov/

Center for Patient Safety PSO Resources & Information -  http://www.centerforpatientsafety.org/patient-safety-organization-pso/