Unique Advantages and Protections Offered by PSOs to Improve Patient Care

Presented by

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Agenda

- How Does Participation in a PSO Improve Quality and Reduce Patient Risk
- What Patient Safety Activity Information Can Be Protected
- What Operational Steps are Needed to Implement Participation in a PSO
- What Steps To Take in Order to Maximize Privilege Protections

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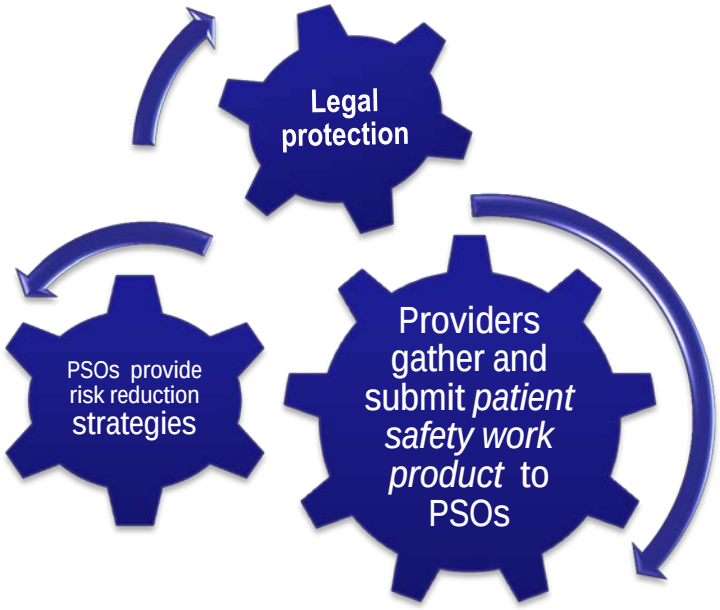
Patient Safety & Quality Improvement Act (PSQIA) of 2005



- Final regulations effective Jan 19, 2009
- Rule set out a framework for Patient Safety Evaluation Systems (PSES)
- Rule describes the federal privilege and confidentiality protections
- Agency for Healthcare Research and Quality (AHRQ), Office of Civil Rights (OCR)
- Affordable Care Act (ACA) Requirements

  Final Regulations released March 8, 2016
- MACRA and PSO membership

MACRA, MIPS, and PSOs

Proposed rule out for comment.
Comments due by June 27, 2016

COST

(10 percent of total score in year 1; replaces the cost component of the Value Modifier Program, also known as Resource Use): The score would be based on Medicare claims, meaning no reporting requirements for clinicians. This category would use more than 40 episode-specific measures to account for differences among specialties.

QUALITY

(50 percent of total score in year 1; replaces the Physician Quality Reporting System and the quality component of the Value Modifier Program): Clinicians would choose to report six measures versus the nine measures currently required under the Physician Quality Reporting System. This category gives clinicians reporting options to choose from to accommodate differences in specialty and practices.

CLINICAL PRACTICE IMPROVEMENT ACTIVITIES

(15 percent of total score in year 1): Clinicians would be rewarded for clinical practice improvement activities such as activities focused on care coordination, beneficiary engagement, and patient safety. Clinicians may select activities that match their practices' goals from a list of more than 90 options. In addition, clinicians would receive credit in this category for participating in Alternative Payment Models and in Patient-Centered Medical Homes.

ADVANCING CARE INFORMATION

(25 percent of total score in year 1; replaces the Medicare EHR Incentive Program for physicians, also known as "Meaningful Use"): Clinicians would choose to report customizable measures that reflect how they use electronic health record (EHR) technology in their day-to-day practice, with a particular emphasis on interoperability and information exchange. Unlike the existing Meaningful Use program, this category would not require all-or-nothing EHR measurement or quarterly reporting.

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How Does Participation in a PSO Improve Quality and Reduce Patient Risk

- Share lessons learned and experiences

  which may provide members with new approaches or solutions to patient safety concerns
- Learn things "the easy way"—from other organizations' problems
- PSO is able to aggregate and analyze information on rare events
- PSO provides recommendations

  to its members on ways to reduce

  patient harm

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What Patient Safety Activity Information Can Be Protected as Patient Safety Work Product?

- Medical Error or Proactive Risk Assessments, Root Cause Analysis
- Risk Management – Not all activities will qualify such as claims management, but incident reports, investigation notes, interview notes, RCA notes, etc., tied to patient safety activities within the PSES can be protected which are not required to be reported (or collected and maintained) pursuant to external legal requirements
- Outcome/Quality—may be practitioner specific
- Peer Review – information not used for disciplinary action, i.e., suspension, terminations
- Relevant portions of Committee minutes for activities included in the PSES relating to improving patient quality and reducing risks

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What Patient Safety Activity Information Can Be Protected as Patient Safety Work Product? (cont'd)

- Other reports, analyses, deliberations relating to patient safety activities
- Must be collected within the patient safety evaluation system (PSES) for reporting to a PSO and then must be physically or functionally reported and documented.

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What is NOT PSWP?

- Patient's medical record, billing and discharge information, or any other original patient records
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES. *Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP* – the copy can be PSWP
- PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES is no longer considered PSWP if:
  - Information has not yet been reported to a PSO; and
  - Provider documents the act and date of removal of such information from the PSES

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What is NOT PSWP? (cont'd)

- Mandated adverse event and similar reports to state, federal or local agencies, i.e. wrong site surgery, surgery on wrong body part, unanticipated death
- HHS PSO Guidance – information/records which are subject to federal, state or local recordkeeping requirements are also considered "original records" by HHS and therefore cannot be treated as PSWP

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What Operational Steps are Needed to Implement Participation in a PSO

- Join a PSO – contract with a PSO

  list of approved PSOs at https://pso.ahrq.gov/listed
- Need to identify your core team that oversees your PSO membership and implements your membership
- Make your staff/providers aware of your PSO membership and the benefits
- Push out PSO information, recommendations, and resources to individuals in your organization that would benefit

What Operational Steps are Needed to Implement Participation in a PSO (cont'd)

- Establish your Patient Safety Evaluation System (PSES) and maintain and review regularly. This will ensure the federal protections of confidentiality and privilege from discovery and admissibility that a PSO membership includes.
- Actively participate in the PSO submitting your data and other Patient Safety Work Product (PSWP) materials you place in your PSES
- Ensure that human resources personnel, managers and supervisors with disciplinary authority, and members of medical staff credentialing and peer-review committees are trained with regard to the PSQIA's whistleblower provisions

What Operational Steps are Needed to Implement Participation in a PSO (cont'd)

- Report harm, near misses and unsafe conditions to your PSO using the AHRQ Common Formats
- Establish a record keeping system to show what materials are part of your PSES and have been submitted to your PSO
- Securely send your PSWP materials to your PSO or perform Functional Report with your PSO
- Actively work with your PSO use their resources and expertise to help you address your patient safety concerns and goals

What Steps to Take to Maximize Privilege Protection

- Most plaintiffs/agencies will make the following types of challenges in seeking access to claimed PSWP:
  - Has the provider contracted with a PSO? When?
  - Is the PSO certified? Was it recertified?
  - Did the provider and PSO establish a PSES? When?
  - Was the information sought identified by the provider/PSO as being collected with a PSES?
  - Was it actually collected and either actually or functionally reported to the PSO? What evidence/documentation?
    - Plaintiff will seek to discover your PSES and documentation policies.

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What Steps to Take to Maximize Privilege Protection
(cont'd)

- If not yet reported, what is the justification for not doing so? How long has information been held? Does your PSES policy reflect a practice or standard for retention?
- Has information been dropped out? Do you document this action?
- Is it eligible for protection?
- Has it been used for another purpose? What was the purpose?
- Was it subject to mandatory reporting?
- Was it collected for the sole purpose of reporting to a PSO?
- Is the provider required to collect and maintain the disputed documents pursuant to a state or federal statute, regulation or other law or pursuant to an accreditation standard?
  - May be protected under state law.

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What Steps to Take to Maximize Privilege Protection
(cont'd)

- Is provider/PSO asserting multiple protections?
  - If collected for another purpose, even if for attorney-client, or in anticipation of litigation or protected under state statute, plaintiff can argue information was collected for another purpose and therefore the PSQIA protections do not apply.
- Is provider/PSO attempting to use information that was reported or which cannot be dropped out, i.e., an analysis, for another purpose, such as to defend itself in a lawsuit or government investigation?
  - Once it becomes PSWP, a provider may not disclose to a third party or introduce as evidence to establish a defense.

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What Steps to Take to Maximize Privilege Protection
(cont'd)

- Document, document, document
  - PSO member agreement
  - PSES policies
  - Forms
  - Documentation of how and when PSWP is collected, reported or dropped out
  - Detailed affidavits

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What Steps to Take to Maximize Privilege Protection
(cont'd)

- Advise PSO when served with discovery request.
- Educate defense counsel in advance – work with outside counsel if needed.
- Get a handle on how adverse discovery rulings can be challenged on appeal.

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The universe of patient safety activities

Apply Guidance to Current or Future PSES Design

What To Do Now?

Bucket 1

- Mandated Reports

Bucket 2

- External Obligations
  - Need to review Medicare CoPs, in particular QAPI standards.
  - Need to review other applicable Federal, state and local record keeping requirements.
  - Compare these laws to what you are currently collecting and reporting or functionally reporting to the PSO.
  - Modify PSES if necessary.

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What To Do Now? (cont'd)

- Where laws on what records you need to collect and maintain are not clear or are ambiguous, you can:
  - Keep in your PSES and not report in order to remove if necessary;
  - If reported to PSO you can utilize the written authorization disclosure exception.

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What To Do Now? (cont'd)

Bucket 3

- What remains can be collected in PSES for reporting to the PSO.
- Treat the Guidance as Non-Binding.
  - Rely on supportive state and/or federal court decisions.
  - Prepare for possible legal challenges knowing that attorneys and courts may or will look to the Guidance to support the challenge.
  - You always have the option to drop out if not reported or to use written authorization to disclose.

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