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Partner PSO Learning Series



“Impact of the HHS PSO Guidance on Advancing Quality and Maximizing Privilege Protections with a PSES Policy”

Hosted by: Child Health PSO



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3

Welcome by Child Health PSO



Kate Conrad, FACHE

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- Component of Children's Hospital Association – listed in 2009
- 54 children's hospitals
- Focus on serious safety event shared learning to eliminate preventable harm
- Participant of Next Plane LLC and collaborator with other PSOs nationally



Go to

<https://childrenshospitals.org/>

for Pediatric Patient Safety Alerts

4

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Today's objectives

- Discuss concepts from recent PSO guidance and briefs related to the definition of patient safety work product
- Illustrate important concepts related to recalibrating or designing a PSES policy (“the reporting pathway”)

5

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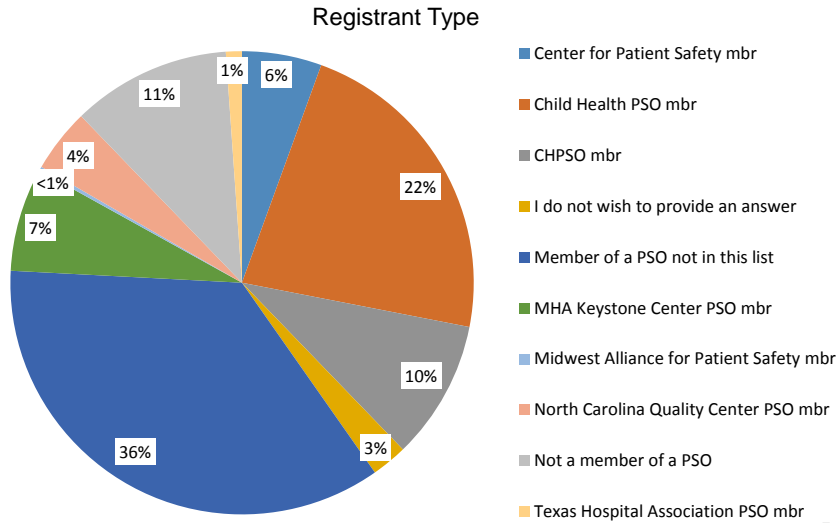
Discussion

1. Overview of the HHS Guidance
2. Impact of PSO cases and the Guidance on PSES design
3. Observations by in-house counsel in response to the Guidance
4. Getting started on and improving your PSES
5. Wrap up/conclusion

6

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Target audience: provider participants of a PSO



7
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Maximizing PSO network participation



8
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Today's Presenters



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9

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Overview of HHS PSO Guidance

- Title is "Guidance Regarding Patient Safety Work Product and Providers' External Obligations".
- Published in Federal Register on May 24, 2016 (81 FR 32655) at the same time the U.S. Solicitor General filed its amicus curie brief in Tibbs v. Bunnell.
- PSOs and providers have recognized that information and records that must be legally reported to a state and/or federal agency, such as mandated adverse event reports or a Data Bank report, cannot be collected in a PSES and reported to a PSO.

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Overview of HHS PSO Guidance (cont'd)

- The Guidance, however, goes further by stating that information which is subject to “external record keeping requirements, even if not required to also be reported, cannot qualify or is not eligible to be treated as PSWP.
- PSWP cannot be used to meet external obligations.

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Overview of HHS PSO Guidance (cont'd)

Expansion of What Constitutes an “Original Record”

- HHS also has “clarified” that “original patient or provider information” such as a “medical record, billing or discharge information” now applies to the following:
 - “Original record (e.g., reports or documents) that are required of a provider to meet any Federal, state, or local public health or health oversight requirement regardless of whether such records are maintained inside or outside of the provider’s PSES; and
 - Copies of records residing within the provider’s PSES that were prepared to satisfy a federal, state, or local public health or health oversight record maintenance requirement if such records are only maintained within the PSES and any original records are either not maintained outside of the PSES or were lost or destroyed.

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Overview of HHS PSO Guidance (cont'd)

- HHS identifies hypothetical examples to illustrate what it considers to be original provider records that are not PSWP-eligible:
 - Original records maintained separately from the PSES;
 - Original records maintained outside of PSES, if lost or destroyed, then duplicate records in the PSES for reporting to a PSO for further analysis are no longer considered PSWP;
 - The provider only maintains original records in the PSES. Such records are not PSWP eligible.

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Overview of HHS PSO Guidance (cont'd)

“Sole Purpose” Reference

- In its effort to clarify whether the purpose for which the information being collected in a PSES can be treated as PSWP, the Guidance created a chart which has three categories. The third category of the examples (see page 32655 in attached HHS guidance) states are as follows:
 - “Could be PSWP if information is not required for another purpose and is prepared solely for reporting to a PSO” (emphasis added).
 - This confusing and ambiguous term appears nowhere in the Act or the Final Rule. Nor does HHS attempt to clarify this term.

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Overview of HHS PSO Guidance (cont'd)

Possible responses

- Only logical interpretation is that information and records which must be reported or collected and maintained pursuant to Federal, state or local laws are not and cannot be collected for the sole purpose of reporting to a PSO.
- All other patient safety activity information collected in a PSES for reporting to a PSO for the purpose of improving quality and reducing risk is PSWP.

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15

Overview of HHS PSO Guidance (cont'd)

Available Options When Government Requests Disclosure of PSWP

- HHS identifies the following options if records, which the provider in good faith believes were not created and maintained to fulfill an external obligations, are now sought by an agency even though they have been reported to a PSO and are PSWP.
 - If mistakenly treated as PSWP and you determine that it was not eligible, it can be removed or dropped out because it was not PSWP eligible in the first place.
 - Consider use of disclosure exceptions:
 - Identified provider's written authorization
 - FDA disclosure permission
 - Voluntary disclosure to an accrediting body
 - Conduct a separate analysis on non-PSWP, i.e., medical records, outside of the PSES.

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16

Summary

Guidance issues	Guidance clarifications	Supplemental Brief
The providers reporting pathway (PSPW and non PSPW)	Not PSPW if prepared for purposes other than reporting to a PSO expanded to "sole" purpose	Privilege exceptions authorize use of info for a variety of purposes Use of "solely" inserted by the government
Meeting external obligations	Expands definitions "original record" to include recordkeeping obligations	Expansion intersects state law above statute
Separate systems	Two systems or spaces: (1) PSES for PSPW (2) separate place where it maintains records for external obligations	Leverage existing infrastructure
Options for PSPW that can't be dropped out	Providers should work with regulatory bodies to provide information needed. An option is to exercise a disclosure exception.	Disclosure of PSPW must have applicable disclosure permission and a State may not require that PSPW be disclosed

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17

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Lessons Learned and Questions Raised

- 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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Lessons Learned and Questions Raised (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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Lessons Learned and Questions Raised (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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Lessons Learned and Questions Raised (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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Lessons Learned and Questions Raised (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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23

What To Do Now?

What To Do?

- Wait for Future Developments before modifying PSES
 - U.S. Supreme Court to meet on June 23rd to rule on petition in Tibbs v. Bunnell case.
 - Three pending state supreme court cases:
 - Charles v. Southern Baptist in Florida;
 - Carron v. Newport Hospital in Rhode Island;
 - Baptist Redmond Hospital v. Clouse in Kentucky.

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24

What To Do Now? (cont'd)

- Wait for Future Developments before modifying PSES, cont'd
 - Initiate input in response to HHS Guidance to your PSO administration – they are trying to gather comments and questions from provider participants
 - Seek further clarification from AHRQ?
 - Support future Amicus Briefs?
 - Possible industry responses?

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The universe of patient safety activities

Apply Guidance to Current or Future PSES Design



What To Do Now? (cont'd)

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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29



Observations by in-house counsel in response to the Guidance

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Provider comments

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31

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Getting started on and improving your PSES

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3 steps to get you started



1. Understand the universe of patient safety data



2. Design the PSES

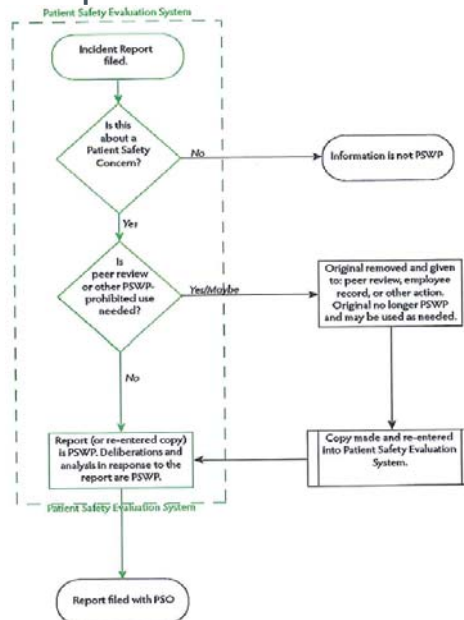


3. Document in a PSES policy

33

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Design, example



34

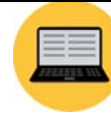
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PSES design



Committee/individual	Role
Executives/ Management	<ul style="list-style-type: none"> - Enforces confidentiality and appropriate use of PSWP. - Designates a Patient Safety Evaluation System Administrator - Communicates PSO participation progress/barriers to CEO
Patient Safety Evaluation System Administrator	<p>The individual in this role understands the Patient Safety Act and regulations, HIPAA, state law protections, state reporting mandates, and other laws, regulations, and mandates that may impact the operation and management of the PSES. S/he is responsible for the following tasks:</p> <ul style="list-style-type: none"> - Develops PSES policies and procedures. - Coordinates and implements policies and procedures within organizational departments. - Identifies all relevant workforce members and oversees their training with respect to PSES operation and management. - Oversees execution of PSES Data Management Plan(s). - Interacts with contracted PSO; defines and monitors interaction of other (Hospital) staff members with PSO. - Manages approval and, as indicated, documentation of permissible disclosures. - Receives and responds to potential security and confidentiality breaches. - Monitors and evaluates the effectiveness of the PSES. - Ensures retention of all PSES documentation in accordance with all applicable laws (federal and state), accreditation bodies, professional organizations, and (Hospital) organizational policies.
Legal Counsel	<ul style="list-style-type: none"> - Reviews and approves PSES structure and all related policies and procedures. - Assists, supports, and advises the PSES Administrator and Executives/Management regarding the implementation and ongoing management of the (Hospital) PSES.
Workforce/ employees	<ul style="list-style-type: none"> - Understand and comply with (Hospital) policies and procedures regarding operation of the PSES and management/use of PSWP.

PSES design



System	Role
PSO Workgroup	<ul style="list-style-type: none"> - Vice President for Safety - Legal Counsel - Safety Administrator - PSES Administrator - PSO Administrator - Director of Patient Safety
Event reporting systems	<ul style="list-style-type: none"> - (Hospital) employs the use an electronic system for capturing work force event reporting - Access determined by PSO work group - Name of event reporting system
Intranet	<ul style="list-style-type: none"> - Name of folders containing PSWP electronic files: minutes, notes, investigations - Name of encrypted drive
Email	<ul style="list-style-type: none"> - Secure email used to communicate with the PSO - Name of encrypted drive for storing email
PSO	<ul style="list-style-type: none"> - Fields for event reporting - Document repository - Name(s) of PSO and contracted vendor

PSES designation log supplements policy



Description	Date Added	Date Removed	Logged by (full name)	Location	Security Measures (passwords, locked cabinet, etc)	Staff with access
Electronic event records	1/1/2009		Susie Que	Event reporting system name	logins and passwords	PSES administrator
Quality Committee meeting	1/1/2009		Susie Que	Board room	closed door	Quality committee members (workforce)
Quality Committee minutes	1/1/2009		Susie Que	Shared drive (location path)	logins and passwords	Quality committee members (workforce)
PSO work group meeting - meetings and activities	1/1/2009		Susie Que	Board room	closed door	PSO work group members
PSO work group minutes - actions	1/1/2009		Susie Que	Shared drive (location path)	logins and passwords	PSO work group members
Safety event analyses	1/1/2009		Susie Que	Shared drive (location path)	logins and passwords	PSO work group members
Surgery safety team meeting	1/1/2009		Susie Que	Surgery conference room	closed door	SST members
Medication safety team meeting	1/1/2009		Susie Que	RX conference room	closed door	MST members

Records should not be deleted or removed from the log. An “audit trail” of all entries must be maintained

37

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Document in policy



1. Purpose/objectives
2. Definitions
 - A. Patient Safety Organization
 - B. Patient Safety Work Product
3. Procedures (key concepts to consider)
 - A. Confidentiality
 - B. Collection**
 - C. Scope
 - D. Evaluation
 - E. Security
 - F. Removal
 - G. Copy
 - H. Disclosure
 - I. Other

38

Examples attached (note: these are four pre-guidance examples) Champions for Children's Health

Closing thoughts: 3 more steps to maintain what was started



1. Understand universe



2. Design the PSES



3. Document as a policy



4. Policy refresh
(fill gaps)



5. Approve, when
needed



6. Repeat annually

39

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Closing thoughts: Staying in the loop with industry changes

1. Ensure your documentation supports your design and implementation
2. Continue to ask questions and assess your design
 - Your counsel
 - Your PSO Administration
3. Support your PSO
 - Provide input on questions/concerns

PSO leaders poll on guidance by NAPSO

Questions? Email reaker@ascensionhealth.org,
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40

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Thank you for attending



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