

THE FUTURE AWAKENS

Legal Implications of Working with a PSO

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Goals

- 1. Provide overview of the HHS PSO Guidance**
- 2. Identify the impact of the Guidance on PSES design – What are your options?**
- 3. Educate and discuss the pending PSO state supreme court cases and the Litigation Lessons Learned**

Today's Presenter



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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.

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.

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.

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.

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.
- PSO’s have sent questions asking ARQ to clarify this term.
- PSO Work Group has requested opportunity to provide its position on “sole purpose” before AHRQ responds.

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.

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.

Summary

Guidance issues	Guidance clarifications	Supplemental Brief
The providers reporting pathway (PSPW and non PSPW)	Not PSWP 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 interjects state law above statute
Separate systems	Two systems or spaces: (1) PSES for PSWP (2) separate place where it maintains records for external obligations	Leverage existing infrastructure
Options for PSWP 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 PSWP must have applicable disclosure permission and a State may not require that PSWP be disclosed

What To Do Now?

Wait for Future Developments before modifying PSES

U.S. Supreme Court met on June 23rd and denied the petition in Tibbs v. Bunnell case.

Three pending state supreme court cases:

- Charles v. Southern Baptist in Florida -- to be argued in October
- Carron v. Newport Hospital in Rhode Island;
- Baptist Redmond Hospital v. Clouse -- decision could be issued any day

What To Do Now? (cont'd)

- PSOs sent questions to AHRQ seeking further clarifications
- PSO Work Group also requested opportunity to address PSO issues and AHRQ

The universe of patient safety activities

Attempt Good Faith Compliance with Guidance

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.

What To Do Now? (cont'd)

Where the 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.

What To Do Now? (cont'd)

Bucket 3

What remains can be collected in PSES for reporting to the PSO.

What To Do Now? (cont'd)

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.

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.

Lessons Learned and Questions Raised (cont'd)

- Was it actually collected and either actually or functionally reported to the PSO? What evidence/documentation?
- What does your PSO participation agreement say about “functional reporting”?
- 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? Did you document this action?

Lessons Learned and Questions Raised (cont'd)

- Is it eligible for protection?
- Has it been used for another purpose? What was the purpose?
- Was it subject to mandatory reporting? (Bucket 1)
- 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? (Bucket 2)
 - May be protected under state law.
- 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.

Lessons Learned and Questions Raised (cont'd)

- 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.

Document, document, document

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

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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