



# Child Health PSO Implementation Webinar

## Q4 2014

Tuesday, November 4, 2014  
8:00 am PT / 9:00 am MT / 10:00 am CT / 11:00 am ET

*Champions for Children's Health*

# Reminders

- All lines have been MUTED
- Time will be allotted for Q&A during the session
- Session is being recorded

To ask a question, use one of the following:

## 1 Raise Your Hand

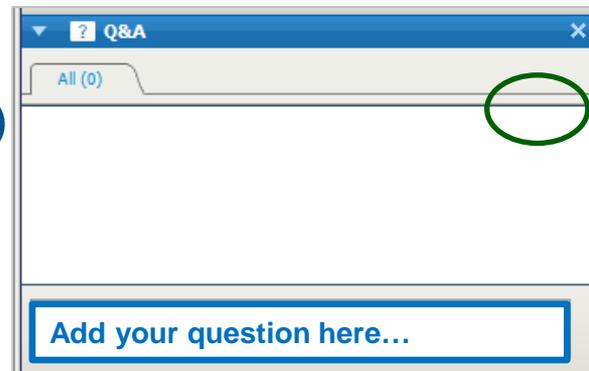
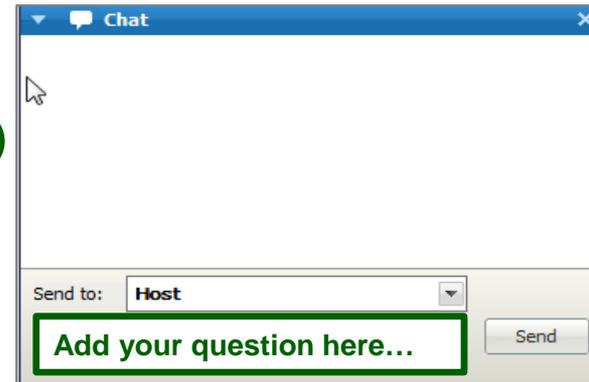
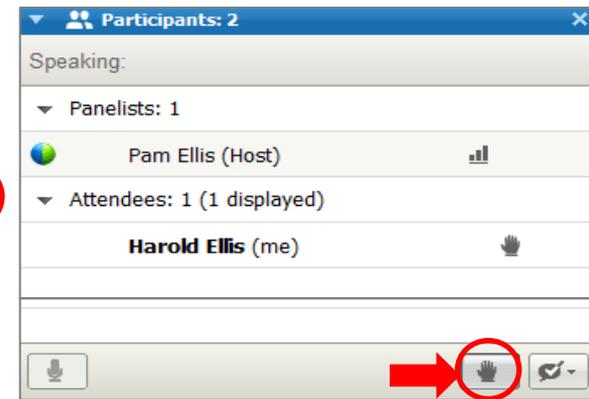
- *your line will be unmuted during Q&A*

## 2 CHAT

- *type your question*
- *send to ALL PANELISTS*
- *facilitator/presenter will respond or unmute your line*

## 3 Q&A

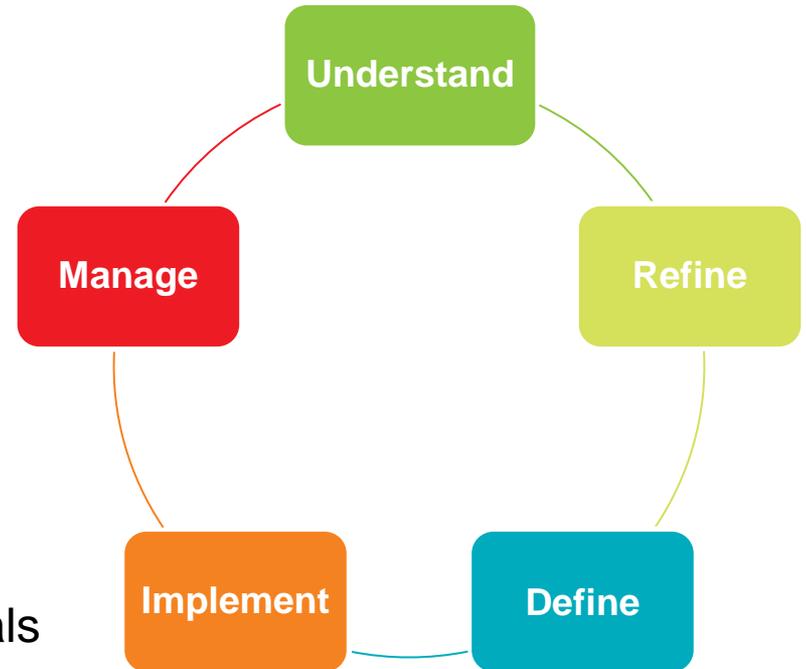
- *type your question and send*
- *facilitator/presenter will respond or unmute your line*



# Maximizing PSO network participation



- 1 Identify business goals/value
- 2 Assign an executive champion
- 3 Assemble multidisciplinary stakeholders
- 4 Reaffirm purpose and goals
- 5 Develop PSES
- 6 Develop PSO structure
- 7 Enter data
- 8 Actively learn



# Today's objectives

1. Legal Landscape Update: Spotlight on Tibbs v. Bunnell to prepare for similar arguments in your jurisdiction.
2. Implementation Deep Dive: Options available when PSWP submitted to the PSO is needed for other reasons (e.g., peer review, state reporting)?
3. Open Q&A

# Today's Presenter



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# Legal Landscape Update

Take advantage of opportunities to share throughout the presentations

- 1 Raise Your Hand**
  - *your line will be unmuted*
- 2 CHAT**
  - *type your question and send*
- 3 Q&A**
  - *type your question and send*

# Disclaimer

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- The opinions expressed in this presentation are those of the presenter and do not constitute legal advice or legal opinions nor do they reflect the official position of the Department of Health and Human Services (HHS), the Agency for Healthcare Research and Quality (AHRQ), the Office for Civil Rights, or the federally listed Child Health PHO.

# Before We Get Started

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- Update on the current Tibbs v. Bunnell case
- By sharing this information, we do NOT recommend that you leave today thinking that you must go and update your policy and PSES consistent with Tibbs decision
  - These issues/disputes will be decided in each state. The only binding decisions in your state affecting state versus federal claims are decisions issued by state supreme court or appellate courts – not trial courts.

# Legal Landscape Update – Tibbs v. Bunnell

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## ■ Background

- This is a medical malpractice action involving a 64 year old woman who died unexpectedly due to a bleeding complication at the end of an elective spine surgery at University of Kentucky Hospital (“Hospital”).
- Plaintiff’s estate filed action against three Hospital employed surgeons.
- Plaintiff requested copies of any post-incident event reports regarding patient’s care.
- Defendants moved for a protective order arguing that the report had been created and collected through UK Health Care’s PSES and reported to its PSO, the UHC Performance Improvement PSO and therefore was PSWP and not subject to discovery. **Katten**

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- Trial court held that the report was not PSWP under the Patient Safety Act (“PSA”) because it did not fall within the statutory definition.
- UK filed a Writ of Prohibition with the Appellate Court to prevent trial court from requiring production of the report.
- Appellate Court Decision
  - Appellate Court granted the writ.
  - In its opinion, the Court correctly ruled that the PSA pre-empted state law that otherwise would not have protected the report from discovery.
  - Under its interpretation of the scope of PSA protection, however, the Court held that the privilege only applies to documents that contain “self-examining analysis.”

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

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- In other words, the only documents subject to protection are those created by the physician, nurse or other caregivers, which analyzes their own actions.
  - Because this decision erroneously narrowed the PSA protections to a very limited set of materials, UK again filed a Writ of Prohibition to the Supreme Court of Kentucky as a matter of right.
- Supreme Court Decision
- Court granted the Writ and the case was assigned to a judge in February, 2013.
  - Decision was issued on August 21, 2014, 18 months later in a divided 4-2 opinion.

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

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- Court reversed the Appellate Court’s narrow construction of the PSA protections as being contrary to the clear intent of Congress which was to:
  - “encourage health care providers to voluntarily associate and communicate [PSWP] among themselves through in-house [PSES] and with and through affiliated [PSOs] in order to hopefully create an enduring national system capable of studying, analyzing, disseminating and acting on events, solutions, and recommendations for the betterment of national patient safety, healthcare quality, and healthcare outcomes” (Opinion at p. 5) (also citing to Walgreens case)

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

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- The Court, however, went on to rule that reports, analyses and documents that hospitals are required to establish, maintain and utilize “as necessary to guide the operation, measure of productivity and reflect the program of the facility” must be collected outside of the PSES and therefore cannot be protected under the PSA.
- Because the report in question fell into this category of documents required to be “established, maintained and utilized” under state law, the Court held it was subject to discovery.
- Court ordered that the based on this statutory construction analysis, matter must be remanded to the trial court for an in camera review to determine what aspects, if any, of the report are privileged and not subject to discovery and what information must be produced.

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

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- UK has since filed a Motion and Petition for Rehearing for the purpose of remanding the case back to the Appellate Court because the statutory construction argument was never presented to the trial and Appellate Court and therefore was never addressed by the parties.
- This Petition was supported in separate motions by the AHA, AMA, The Joint Commission and over 30 other amicus parties along with additional arguments as to how the Court erred. These include the following:
  - Court did not correctly interpret Congress's intent as to the full scope of the PSA's protections.

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

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- PSA does not preclude a hospital from collecting and maintaining incident reports within its PSES unless required to submit these reports to the state or federal government.
- Court glossed over the fact that Kentucky does not require these incident reports to be reported to the state.
- While information collected outside the PSES cannot be protected, the report in question clearly was collected and maintained in UK's PSES.
- The fact that a state mandated the establishment, collection and maintenance of a record does not automatically mean it cannot be accomplished within a PSES – it can be dropped out later and reported if required.

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

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- Even if a mandated report was incorrectly reported to a PSO, the hospital cannot disclose unless it specifically authorizes disclosure consistent with the PSA requirements.
- If not disclosed, the hospital runs the risk of being cited, fined or otherwise penalized unless it can otherwise demonstrate compliance with state/federal laws.
  - Neither CMS nor TJC requires a PSO or provider to turn over PSWP.

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

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- Amicus motions in support of Petition for Rehearing were denied but UK's Petition is still pending and a ruling is expected within the next 2 to 4 months.
- If Rehearing is granted, a revised decision could take another year before it is issued.
- What Legal Impact Does Tibbs Have?
  - Decision is not really final until Petition for Rehearing is resolved – decision could be modified.
  - Even if decision is not modified, it is only binding on courts, PSOs, and providers located in Kentucky and no other state.

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

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- There are still procedural issues and potential discovery disputes being played out in the Tibbs case and therefore the final outcome on what information ultimately needs to be produced has not been determined.
- Once issue that has been raised is whether AHRQ/OCR would fine UK if it turned over the report – could serve as a vehicle to get into federal court because you would have a state court decision conflicting with a federal statute and potential agency action.
- A concern is that the wrong analysis in Tibbs could be embraced by other courts looking for a way to limit the PSA protections, but keep in mind trial court decisions in other jurisdictions are only binding on the parties involved in the litigation

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

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- Should PSOs/Hospitals limit scope of what to collect in their PSES consistent with Tibbs decision?
  - No!
  - These issues/disputes will be decided in each state. The only binding decisions in your state affecting state versus federal claims are decisions issued by state supreme court or appellate courts – not trial courts.
- Reminders
  - In a state with mandated reporting only provide what is minimally required – limit reports to the facts if permitted.

# Legal Landscape Update – Tibbs v. Bunnell (cont'd)

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- What you are not required to report to the state (or federal government) can be collected in your PSES and reported to the PSO.
- To protect against a Tibbs analysis consider re-titling reports. In other words, the patient incident report you may be required to collect and maintain under state law can be limited to the facts and the impressions, reviews and assessments can be included in a separate “quality assessment report” or “occurrence report”, collected in your PSES and reported to the PSO.

# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons

Take advantage of  
opportunities to share  
throughout the  
presentations

- 1 Raise Your Hand**
  - *your line will be unmuted*
- 2 CHAT**
  - *type your question and send*
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# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons

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## ■ Hypothetical

- Dr. Smith performed wrong site surgery on a 50 year old patient who had commercial insurance.
- Hospital and Dr. Smith did not bill but patient complained to State Department of Public Health.
- State has a mandated adverse event reporting requirement for wrong site surgery but does not require that the hospital conduct or report any subsequent root cause analysis.
- Hospital submitted its mandated report but also performed both an RCA and a peer review analysis because this was Dr. Smith's second wrong site surgery in 6 months.
- RCAs and peer review analyses are collected within the hospital's PSES.
- Department of Public Health shows up at the hospital to investigate patient complaint and demands to see RCA and peer review analysis.

# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons

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- Retroactive Look: Information has already been reported to the PSO, but now is needed for other uses
- What are my options?
  - Option 1 – Consider Valid Authorized Disclosure
  - Option 2 -- Refuse to Authorize Disclosure

# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

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- Option 1 – Information Already Reported: Consider Valid Authorized Disclosure
  - Under Section 3.206(a)(3) identifiable patient safety work product can be disclosed with a valid authorization from each provider identified in the work product prior to disclosure. Authorization must:
    - Be in writing and signed by the provider from whom authorization is sought.
    - Contain sufficient detail to fairly inform provider of nature and form of disclosure.
    - Authorization must be retained by disclosing entity for six (6) years from the date of the last disclosure and made available to HHS Secretary.

# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

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- Here, hospital and Dr. Smith would need to sign valid authorization if both names were being provided.
  - Might be able to avoid disclosing Dr. Smith's name and identity.
- Disclosure does not constitute a waiver of the PSA protections.

# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

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- Option 2 – Information Already Reported: Refuse to Authorize Disclosure
  - There may be reasons for not wanting to prepare a valid authorization, especially if the information is sensitive and/or your state confidentiality and privilege status would not apply as back-up protection.
  - CMS and TJC have taken the position that they will not demand production of PSWP.
    - Remember that the PSA allows for a voluntary disclosure to accrediting bodies but identifiers have to be removed (Section 3.206(b)(8)).

# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

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- If not disclosing your need to be prepared to otherwise demonstrate compliance with state/federal/accreditation laws and standards, whichever are applicable.
- Remember, however, that AHRQ takes the position that any analysis and deliberation conducted in PSES is automatically considered PSWP even if not reported.

# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons

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- Prospective Look: Information not yet reported to the PSO, but needed for other uses
- What are my options?
  - Option 3 – Collect and Hold in PSES but use Drop Out Provision
  - Option 4 – Disclose and Send Copies to PSO

# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

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- Option 3 – Collect and Hold in PSES but Drop Out
  - Hospitals generally have a good sense as to when certain adverse events are going to trigger a patient complaint, lawsuit or a government or other third party investigation.
  - Hospitals have the option of collecting RCA and peer review analysis and not reporting it, either physically or functionally, in case they want to be able to drop it out of the PSES and disclose.
  - The information is still protected while it is being held on the PSES.
  - Once it is dropped out it cannot later be reported to the PSO and therefore cannot be treated as PSWP.
  - Must document removal from PSES.

# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

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- Information may be protected, however, under state confidentiality and privilege statutes.
- If never requested and not dropped out you can then report to PSO.
- Should incorporate into your PSES or through other documentation why the information is being held and not reported within your usual time frames.

# Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

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- Option 4 – Disclose and Send Copies to PSO
  - PSA allows you to send copies of ineligible information, i.e., mandated reports or information that has been dropped out, to the PSO.
  - Copies will be considered PSWP.
  - In terms of whether the materials you have reported or dropped out are otherwise discoverable will depend on whether there is an alternative federal and/or state confidentiality/privilege statute available.

# Questions & Discussion

Take advantage of opportunities to share throughout the presentations

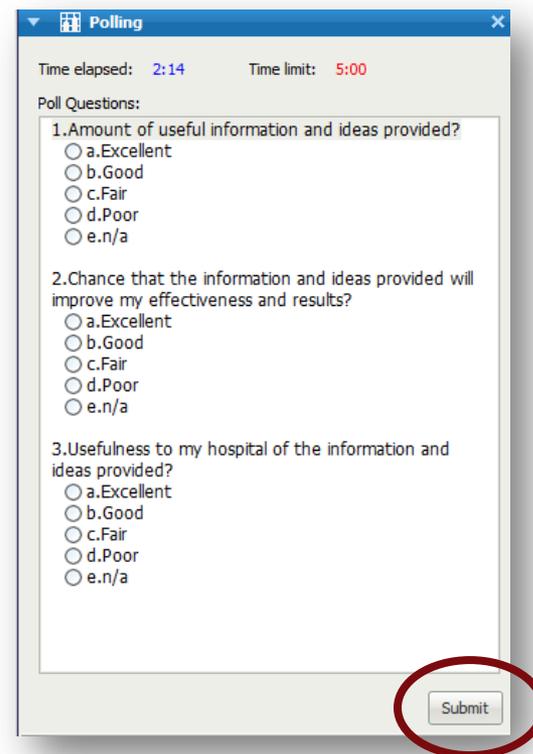


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# Webcast Evaluation

**Please evaluate today's session using the poll on the right side of your screen**

- Provide response to evaluation questions
- Click "SUBMIT"



▼ Polling

Time elapsed: 2:14      Time limit: 5:00

Poll Questions:

1.Amount of useful information and ideas provided?

a.Excellent  
 b.Good  
 c.Fair  
 d.Poor  
 e.n/a

2.Chance that the information and ideas provided will improve my effectiveness and results?

a.Excellent  
 b.Good  
 c.Fair  
 d.Poor  
 e.n/a

3.Usefulness to my hospital of the information and ideas provided?

a.Excellent  
 b.Good  
 c.Fair  
 d.Poor  
 e.n/a

Submit

**Poll Open!**

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