



Partner PSO Learning Series



“Impact of Recent PSO Regulatory and Legal Developments on PSOs and Participating Providers”

Hosted by: MHA Keystone Center PSO
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Overview and Impact of Recent HHS PSO Guidance, the Guides and the Clouse Decision on PSOs and Providers

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Agenda

1. Overview of the HHS Guidance Regarding PSWP and Providers' External Obligations
2. Impact of the Guidance on PSES design – What are your options?
3. Overview of the Guides for PSOs and Providers for Determining Parent Organizations and Affected Providers
4. Discussion of Clouse and pending PSO state supreme court cases and 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.

Overview of HHS PSO Guidance (cont'd)

- 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, and cannot be collected in a PSES and reported to a PSO.
- 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 pages 6-7 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.
- PSOs have sent questions asking AHRQ 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 can qualify as PSWP.
- Kentucky Supreme Court's holding on Baptist Redmond Hospital v. Clouse arguably rejects or at least did not address or rely on a "sole purpose" argument in reaching its decision even though trial and appellate courts relied on this approach in the discovery dispute.

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 external obligations, are now sought by an agency even though they have been reported to a PSO and therefore 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	Comment
The providers reporting pathway (PSWP and non PSWP)	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 “sole purpose” inserted by the government
Meeting external obligations	Expands definitions “original record” to include recordkeeping obligations	State laws might apply where Patient Safety Act does not
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 an agency 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 -- Argued in October
 - Carron v. Newport Hospital in Rhode Island -- pending
 - Baptist Redmond Hospital v. Clouse -- see discussion
- PSOs sent questions to AHRQ seeking further clarification
- PSO Work Group also requested and AHRQ agreed to schedule “listening sessions” to address the issues of “sole purpose” language, peer review as PSWP, and AHRQ Guides

What to Do Now (cont'd)

- Attempt Good Faith Compliance under the Guidance



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 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, information is still PSWP
 - If the laws identify a record that must be collected and maintained but there is no required form and the law does not identify what must be included, develop your own form.

Bucket 3

- What is not in Bucket 1 or 2 and is collected in the PSES for reporting to a PSO and is reported is PSWP

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.

Baptist Health Richmond v. Clouse

■ Factual Background

- A medical malpractice case was filed against Baptist Health Richmond (“Hospital”) following the death of a patient who died following a laproscopic procedure
- In addition to seeking original hospital and medical records relating to the patients records, the plaintiff brought the following:
 - All incident reports
 - Investigation reports
 - Sentinel event reports
 - Root cause analysis reports
 - Joint Commission reports
 - Medicare/Medicaid reports
 - Peer review reports
 - Copies of and all documentation reviewed, analyzed, used, utilized or referenced regarding these reports

Baptist Health Richmond v. Clouse

- Hospital objected to the production of these documents because they were collected within its PSES for reporting to the Kentucky Institute for Patient Safety and Quality (“PSO”) and included a supporting affidavit
- In response to the plaintiff’s motion to compel the trial court ruled that:
 - “The hospital shall produce any and all said material requested by Plaintiff, except for those specific documents certified by the hospital as having been collected, maintained or developed for the sole purpose of disclosure to a [PSO] pursuant to the [Act]. Specific documents collected, maintained, or developed for any additional purpose beyond PSO disclosure, such as compliance with the requirements of [Kentucky statutes], are not privileged under the [Act] and must be produced.”

Baptist Health Richmond v. Clouse

- The Hospital's petition for writ of prohibition to the Court of Appeals was denied as the basis that the trial court's "sole purpose" interpretation "largely applied the principles set forth in the Tibb's decision."
- The Kentucky Supreme Court granted the Hospital's direct appeal and issued its decision on September 22, 2016
- Decision
 - The Court initially noted that the Tibbs decision was a plurality opinion meaning less than a majority agreed on the reasoning of the case, although a majority agreed with the outcome it was not binding on the courts in Kentucky.
 - The Tibbs decision concluded that the incident report in question, which the hospital had collected and reported to its PSO, did not qualify as patient safety work product "since its collection, creation, maintenance, and utilization is mandated by the Commonwealth of Kentucky as part of its regulatory oversight of its healthcare facilities".

Baptist Health Richmond v. Clouse (cont'd)

- The plurality opinion, however, also concluded that the matter be remanded to the trial court to separate the information “normally contained...in state mandated incident reports” from “material properly privileged under the Act” so as to permit discovery of the non-privileged information.
- While the case was still pending on appeal, the Court noted that HHS issued its PSO guidance which expanded the interpretation of “original provider records” and takes the position that such records which “are required of a provider to meet any Federal, state, or local public health or health oversight requirements regardless of whether such records are maintained inside or outside of the provider’s patient safety evaluation system” did not qualify as PSWP.

Baptist Health Richmond v. Clouse (cont'd)

- Consequently, the Court determined that “reports that are required by the Commonwealth do not become privileged because the provider puts them in its patient safety evaluation system” and “permitting hospitals to place and leave otherwise discoverable information in the [PSES] in order to shield it from discovery is equally unacceptable....”
- At the same time, the Court agreed with the dissenting opinion in Tibbs that allowing a trial court to invade a hospital’s PSES every time there is a discovery dispute would “discourage participation in the patient safety system by Kentucky’s health care providers” (quoting from the dissenting opinion in Tibbs).

Baptist Health Richmond v. Clouse (cont'd)

- The Court made the following rulings:
 - A hospital “may collect information within it’s [PSES] that complies with the Act and that also complies with state statutory and regulatory requirements.”
 - That being said, the hospital must still comply with record reporting and recordkeeping requirements and if “information collected in the provider’s internal [PSES] is needed to comply with those state requirements, it is not privileged.”
 - If the hospital fulfills these statutory obligations the trial court “has no reason to review the information in the provider’s [PSES]”
 - It is only when a provider does not meet these statutory obligations that the Court can conduct an in-camera review of the PSES documents.
 - “In conducting that review, the Court should separate the information that is usually contained in state-mandated reports from information that is not usually contained in those reports and therefore can be treated as PSWP.”

Baptist Health Richmond v. Clouse (cont'd)

- The hospital bears the burden of proving that it complied with the statutory and regulatory requirements.
- If the provider fails in meeting this burden, the parties seeking the information then must establish that the information requested is generally contained in state-mandated reports.
- Based on the Court's holding, the trial court's order to require the Hospital to produce documents was vacated with instructions to "undertake the review" set forth in the decision.

Baptist Health Richmond v. Clouse (cont'd)

- Analysis and Impact:
 - Although the Guidance simply reflects the government's interpretation of the Patient Safety Act, and its view that mandated reports and recordkeeping reports cannot be considered PSWP and therefore is not binding on the courts, the Kentucky Supreme Court clearly accepted and relied on the Guidance to support its decision.
 - Although the Clouse decision is only binding on Kentucky courts, we expect that other courts may be more likely than not to follow the decision and the Guidance when faced with discovery disputes under the Patient Safety Act.

Baptist Health Richmond v. Clouse (cont'd)

- Interestingly, the Court made absolutely no reference to, nor did it rely on a “sole purpose” theory to support its decision. One can therefore argue that the Court rejected this so-called standard or certainly did not need to accept or rely on the position of the trial and appellate courts in reaching its decision.
- The decision, however, does not answer all of the questions which providers will face because, despite the Court’s comments, a hospital’s “recordkeeping” obligations are not very clear.
- For example, the Kentucky statutory reference to “incident investigation reports” does not specify a particular form nor does the statute explain what information must be contained in such reports.
- Where a lack of clarity exists and the state has not taken any action to further identify what falls into the Bucket 2 recordkeeping category, the hospital can produce its own report to meet these statutory obligations.

Baptist Health Richmond v. Clouse (cont'd)

- Under these circumstances, the mandated reports and recordkeeping reports can then be made available to the Federal and state agencies in a format that does not contain written analyses, impressions and other information which the provider can therefore treat as PSWP.
- If other courts follow the Kentucky Supreme Court method of assessing burdens of proof, the hospital should be prepared to demonstrate that it has complied with its external requirements through forms, reports, etc., that have not been collected and treated as PSWP which must be reported and/or collected and maintained pursuant to state or Federal law. The burden will then shift to the plaintiff to establish that the reports which the hospital is seeking to treat as PSWP contain mandated record reporting and recordkeeping information.

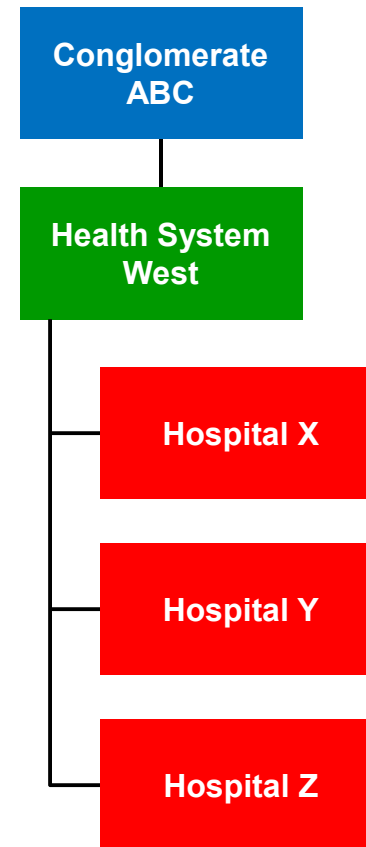
Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers

- The Patient Safety Rule (“Rule”) defines a parent organization as follows:
 - An organization that owns a controlling interest or a majority interest in a component organization.
 - Has the authority to control or manage agenda setting, project management, or day-to-day operations;
 - Or has the authority to review and override decisions of a component organization. The component organization may be a provider.
- The Rule defines a component organization as an entity that is a “unit or division of a legal entity” (including a corporation and other examples) or is “owned, managed, or controlled by one or more legally separate parent organizations.”
- The concept and intent behind the term “parent organization” is to be more inclusive and is not limited to the definitions used in corporate law. Organizational structure alone will not determine whether a corporate entity is a parent organization.

Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

Example 1 – Direct Organizational Control

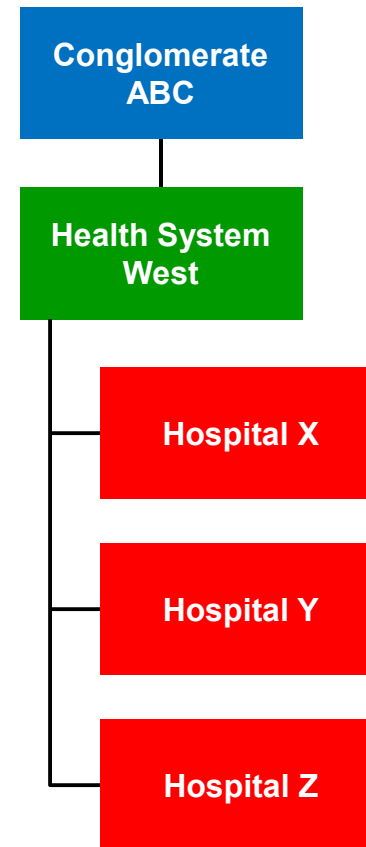
- In this organizational chart, Conglomerate ABC directly manages or controls Health System West and Health System West manages and controls Hospital X.
- Conglomerate ABC is the parent organization of Health System West, and Health System West is the parent organization of Hospital X.
- Conglomerate ABC would not be a parent organization of Hospital X based solely on its ownership and management of Health System West.



Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

Example 1 – Direct Organizational Control

- However, if Conglomerate ABC owns a controlling or majority interest in Hospital X, or has the authority to control or manage the agenda setting, project management, or day-to-day operations of Hospital X, or if it has the authority to review and override decisions of Hospital X, then Conglomerate ABC can be considered a parent organization of Hospital X.
- Consequently, if Conglomerate ABC meets any of these definitions of a parent organization, Hospital X could have two parents, Conglomerate ABC and Health System West.



Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

Example 1 – Direct Organizational Control

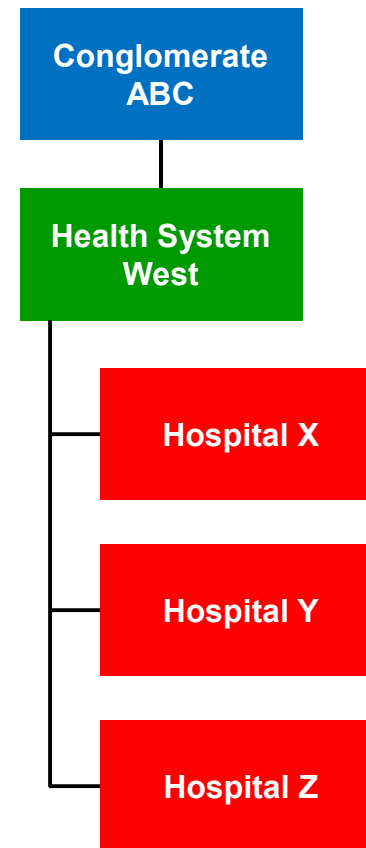
Determining Which Entities are Providers and Which Entities Are Affiliated Providers Under the Final Rule

- Under the Rule, a provider is defined as an individual or entity licensed or otherwise authorized under state law to provide health care services.
- The typical examples include a hospital, nursing facility, out-patient rehab facility, home health agency, a physician, a physician assistant, registered nurse, nurse practitioner, etc.
- Aside from public health care entities, which are also considered providers even if not authorized or licensed under state law, a parent organization of a licensed provider is considered a provider even though the parent is not itself a licensed provider.
- The intent behind this standard that a non-licensed parent organization of a licensed provider qualifies as a provider is “to permit the parent organization...to enter into a system-wide contract with the PSO” on behalf of itself as well as its affiliated providers (see discussion below).

Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

Example 2 – Determining Which Entities Are Providers and Which Entities are Affiliated Providers

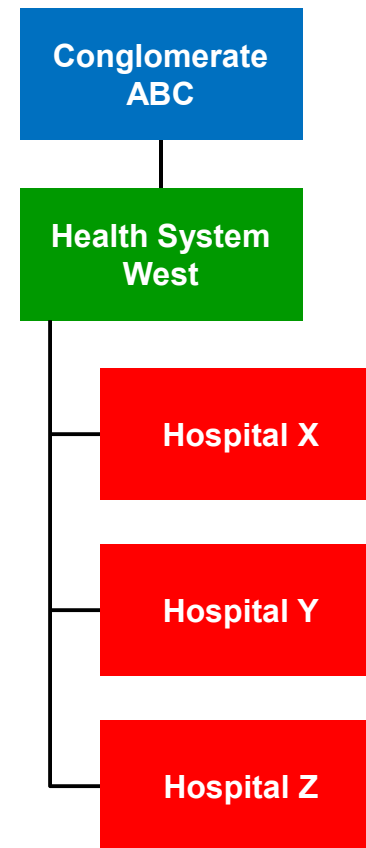
- Which are the providers?
 - Hospitals X, Y and Z are licensed providers under state law.
 - Because Health System West in this example owns, manages, or controls Hospitals X, Y and Z, it too is considered a provider under the Rule even though it is not a licensed provider.
 - Conglomerate ABC is not also a provider unless it meets one of the definitions of a parent organization.



Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

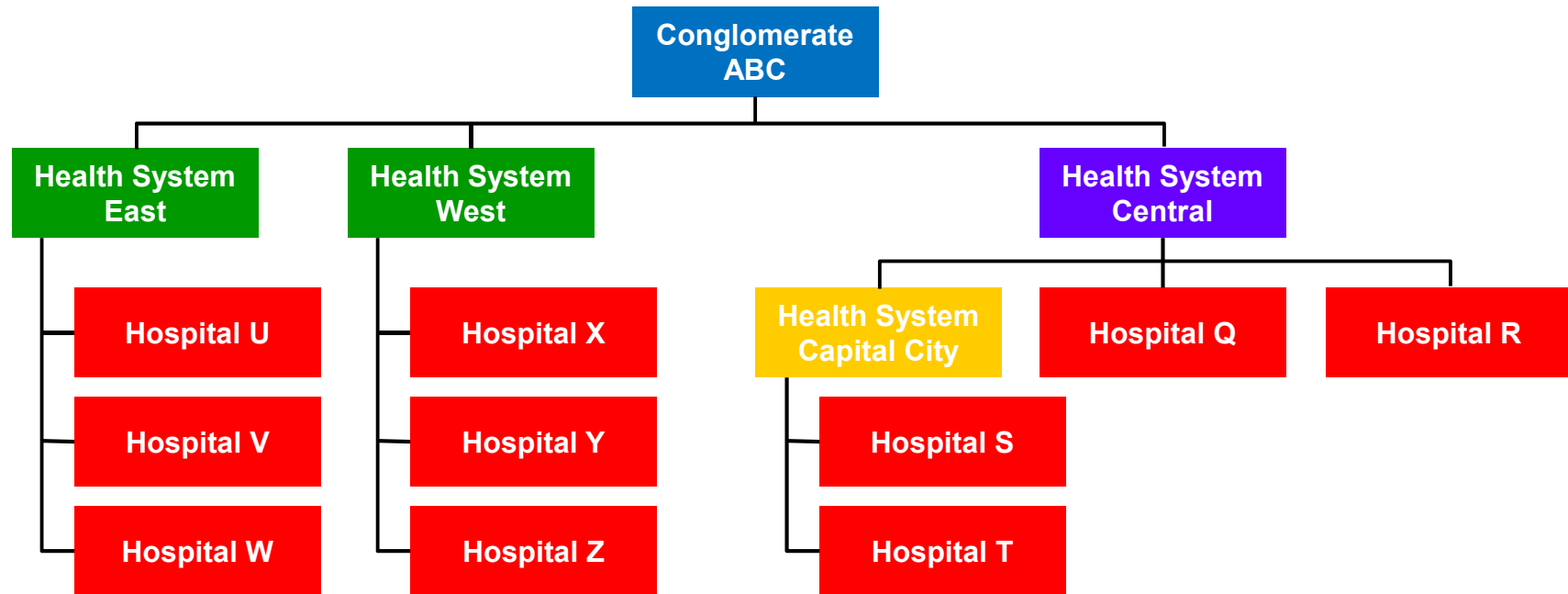
Example 2 – Determining Which Entities Are Providers and Which Entities are Affiliated Providers

- Which are affiliated providers?
 - Conglomerate ABC is not an affiliated provider unless it meets the definition of a parent organization.
 - Hospitals X, Y and Z are affiliated providers because they are legally separate entities, meet the definition of a provider, and are under common management or control with Hospital X.
 - Health System West also is an affiliated provider because it is a legally separate entity and qualifies as a provider because it manages and controls Hospital X.



Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

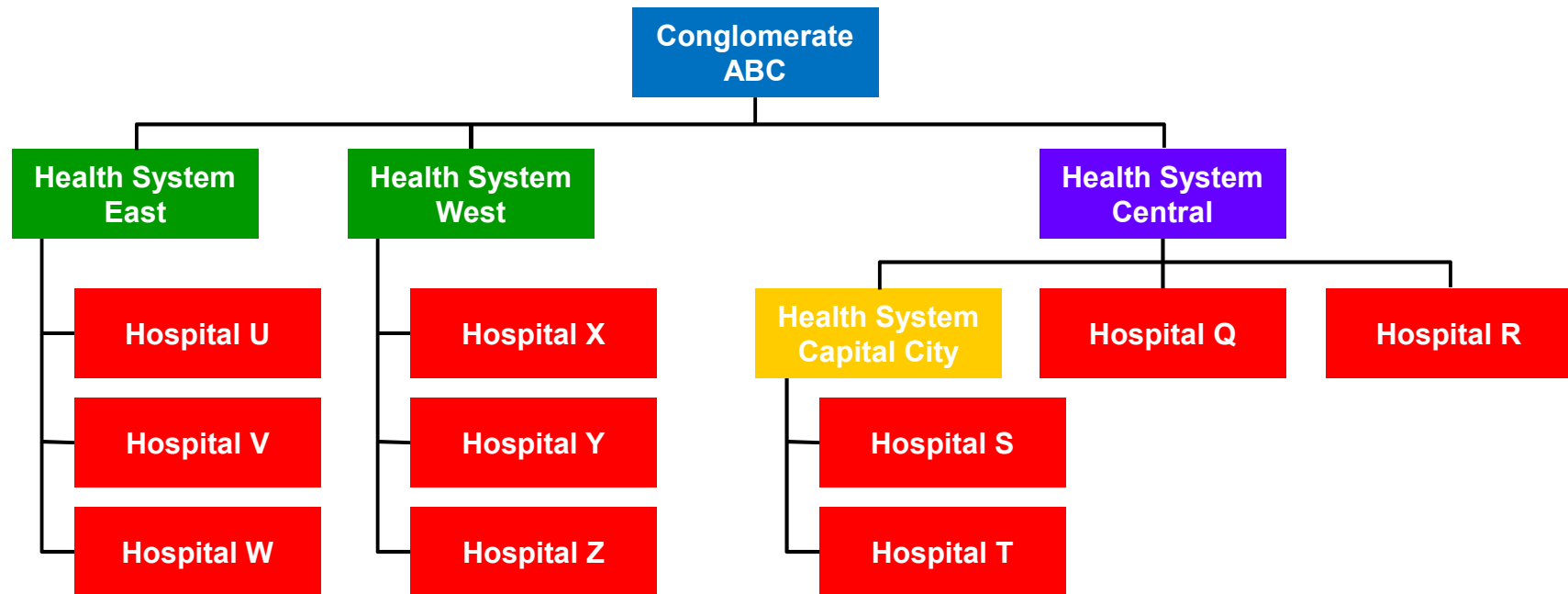
Example 3 – Multisystem Corporate Organization



- Which are the providers?
 - Hospitals U, V, W, X, Y, Z, S, T, Q, R are all licensed providers.
 - Health System East is an affiliated provider of hospitals U, V and W because it owns and controls these hospitals.
 - Health System West is an affiliated provider because it owns and controls Hospitals X, Y and Z.
 - Health System Capital City is an affiliated provider of Hospitals S and T for the same reason.
 - Health System Central is the affiliated provider for hospitals Q and R.

Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

Example 3 – Multisystem Corporate Organization



- Conglomerate ABC is not an affiliated provider because it is not a licensed provider and unless it meets the definition of a parent organization of the actual licensed providers, it cannot be considered an affiliated provider.
- Which are affiliated providers?
 - Health Systems East, West, Central and Capital City along with all of the licensed hospitals are considered affiliated providers because they are all separate legal entities, meet one of the definitions of a provider and are under common management or control by being part of a multi-organizational enterprise.

Guides For PSOs and Providers for Determining Parent Organizations and Affiliated Providers (cont'd)

Example 3 – Multisystem Corporate Organization

- The benefits of participating in a multi-organizational enterprise with affiliated providers includes the following:
 - If Conglomerate ABC in fact met the definition of a parent organization, it can enter into a contract with a PSO on behalf of all of the other affiliated entities in this example.
 - If Conglomerate ABC does not qualify as a parent organization, then each system would have the ability to contract on behalf of the affiliated licensed providers under its management and control.
 - The other option is that each licensed provider can contract separately with a PSO.
- Affiliated entities are allowed to share identifiable and non-anonymized PSWP by and among other affiliated providers, although this is not a requirement and the affiliated providers have the option of not disclosing identifiable PSWP.

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)

- What does your PSO participation agreement say about “functional reporting”?
 - Plaintiff will seek to discover your PSES and documentation policies.
 - Have you identified what information is being functionally reported and disclosed this to the PSO?
- 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
 - Demonstrated compliance with external record reporting and record keeping requirements.

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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