OCTOBER 19, 2022 WEBINAR

QUESTIONS & ANSWERS

	Question	Answer
No. 1	One of your slides indicated what is covered under the PSQIA and what isn't. On that slide there was an indication that companies that own licensed facilities if they have veto power are not covered. Could you please expand on that and explain under what circumstances can a company that owns licensed providers be covered by the PSQQIA?	A non-provider entity that owns, controls or manages licensed providers can be treated as a provider under the PSA and would be covered. I also have taken the position that the corporate parent's veto authority through ultimate budget approval is enough to qualify it as a parent to all affiliated hospitals and entities.
No. 2	We were always told peer review is not PSWP because it cannot be both.... Had to be one or the other....	When you say that PSWP has to be one or the other do you mean privileged under the state peer review privilege or under the Patient Safety Act? If that is your question that is wrong. At least two courts have held that information can be privileged under both state law and the Patient Safety Act. This assumes you have complied with the requirements under both statutes.
No. 3	We currently report our incidents to the PSO but we do not send all of the deliberations, minutes, RCA forms etc. Do we have to send all of these attachments for that info to be protected?	Information which is identified as deliberations or analysis in the PSES is PSWP when collected or generated. It does not need to be reported to a PSO, but the PSES needs to describe in detail what is D or A and what is being reported.
No. 4	Can a PSES "functionally report" minutes of a committee meeting to protect them as PSWP privileged? Oftentimes, the minutes contain the names of participants in a PSES committee who have analyzed the near miss or error. Plaintiff counsel often subpoena those participants to inquire about their committee participation and deliberations. State courts often may not protect those deponents or all discussions—what is your advice about applying PSWP privilege in such situations and advice to provide the deponents during their preparations?	Yes, you can functionally report as long as you tell the PSO what is being functionally reported and the PSO has access and does obtain access. Why not treat these materials as Deliberations or Analysis? This is what most providers to and is simpler although you need to reflect in your PSES. As to trying to keep names confidential most courts would hold that this information is not privileged and the names need to be disclosed. You can certainly try but are likely to fail. That said, they cannot depose them and require that they testify as to information/discussions that qualify as PSWP. This is where treating this as D or A is easier. Proving something is functionally reported is more difficult. The Rumsey v. Gutherie is a great case in which the court blocked plaintiff's effort to depose committee members regarding their discussions using the D or A analysis.

	Question	Answer
No. 5	What about Hospital Grievance Committee and related investigation or analysis. Seems like it would be problematic to protect as privileged PSWP since Hospitals are required to respond to patient complaints/grievances; also contradicts goal of transparency.	Most, if not all hospitals, have adopted policies which require that they meet with a patient and/or family members when certain unexpected certain unexpected safety or adverse events occur. These discussions provide a lot of information, factual and otherwise, without needing to reveal underlying analyses, reports or discussions which are being treated as PSWP.
No. 6	What is your opinion on whether text messages on cell phones between providers discussing a patient safety event can be considered PSWP under the analysis and deliberation bucket of allowable PSWP?	I think better to add and hope for the best, recognizing, as you have, that if there is an in camera review the OMG comments will not qualify. You can certainly argue that such text messages are PSWP. Others make the same argument although you should incorporate into your PSES. That said, I would not encourage the practice in light of security issues regarding cell phones and tablets unless there are appropriate security protections built into the devices and if using a secure methodology for texting. It would be helpful, although probably not practical, to add some type of reference to protections under the PSA as part of the text. Keep in mind that there are HIPAA issues as well. Better to call than to text.
No. 7	What if a hospital or ambulatory provider is not listed as covered under PSO contract gets info from Healthcare system – they are part of the health system, but not included under the PSO list of entities?	As a rule, and as evidence that an affiliated entity is under the PSO contract, the contract and any attachment should include all covered and contracted entities. This would serve as the best evidence of coverage. Otherwise the unlisted provider will have more difficulty in asserting the privilege protections. There may be other evidence such as adoption of a system or supplemental PSES and related policies, a history or reporting, etc., but including the entity's name on the agreement is a best practice.
No. 8	Is it a breach?	It would not be considered a breach unless the PSO would require that all covered entities be listed and now the entity is coming to the PSO claiming coverage. You would need to look at your participating provider agreement.

	Question	Answer
No. 9	What's CIN?	A CIN is a clinically integrated network. As depicted on the slide, a CIN is typically a number of affiliated health care providers that are controlled by a parent organization and are treated as a single legal entity for managed care contracting, information sharing and related purposes. A CIN usually adopts various quality improvement, risk reduction and related efforts which are implemented, monitored and enforced such that violating same has some adverse consequences, financial or otherwise.
No. 10	Are there restrictions for a component PSO to provide/disclose identifiable PSWP to another, external, larger PSO for data benchmarking purposes? Does the PSWP need to be de-identified prior to providing/disclosing to the external PSO?	Under Section 3.206(b)(4)(iv) of the Final Rule, a PSO can disclose PSWP to an external PSO only if the identifiers under this Section are removed. The only way around this is to have each provider, whose PSWP the PSO wants to share, give their written authorization to disclose identifiable PSWP. This may be impractical if not impossible but those are the rules.
No. 11	The reality is organizations need to have a "Michael Callahan" to review procedures and protections!	Agreed.
No. 12	If a provider reviews care of a patient and provides their feedback via workplace email, is this review protected under the PSO?	Yes, but as noted above, it should be described in the PSES Policy. Some hospitals actually have developed email systems which reference the Patient Safety Act at the bottom of the email. As also noted, this practice can be risky if not structured correctly.
No. 13	You mentioned that a Population Health Organization (PHO) cannot be covered by the PSQIA. I believe this may be a result of it not meeting the definition of a parent provider in the Act, but wanted to confirm this was the case or if there was a different rationale.	The PHO I was referring to was a Provider or Physician Hospital Organization. Like an Independent Physician Organization (IPA), this is a managed care contracting entity with participating providers but it not itself a licensed provider and therefore cannot be covered under the PSQIA.
No. 14	You mentioned the importance of documenting the date on which PSWP is collected. I have put in our policy that information becomes PSWP “upon creation” but of course, the date of creation may not be clear on the document itself. Do you feel that stating it becomes PSWP “upon creation” in the policy will adequately provide the privilege or should we devise a way to document when each item is created? If the answer to the latter is yes, please let me know if you have run across any best practices.	“Upon creation” is the typical reference but wouldn’t there be some independent way to know when the document was created? It is important to have a starting point. For example, if initiating an RCA there would be some internal document or communication or some other record of when it was initiated to which you can refer if necessary. Committee minutes would have dates. Some PSWP may be more easily identifiable in terms of date of creation. This is a PSA requirement. Maybe easier said than done.

	Question	Answer
No. 15	You mentioned that the requirement to participate with a PSO as part of the Affordable Care Act is no longer a requirement. I was not aware of this so could you refer me to more information about this update so I can properly communicate it to our members? We have often used this requirement to communicate one way we bring value to our members.	This requirement was later watered down by HHS when it was objected to by the AHA and others. At this point, a hospital only needs to demonstrate that they participate in an accreditation program, or QAPI which separately require efforts to improve patient safety and reduce risk. That said, in some states, managed care payers participating in Obamacare do require hospitals to participate in a PSO.
No. 16	You said that CMS couldn't ask for PSWP to determine compliance. What about a complaint visit?	I actually was involved in a situation in which state surveyors in Texas, New Mexico and I believe Louisiana showed up at separate client facilities requesting entry as well as access to PSWP. The facilities disclosed the PSO contract, policies and non-privileged information to hopefully demonstrate regulatory compliance but did not disclose PSWP. All of the facilities received a form letter advising them that their Medicare eligibility was going to be terminated. I wound up working with the client, two state hospital associations , a national hospital association and some health systems in pointing out the HHS Guidance statement that government agencies are not supposed to require providers to disclose PSWP in order to demonstrate compliance. Long story short, CMS Region 6 agreed to meet in Dallas with all of these reps. I was on a connected call. The first words out of their mouth was to repeat HHS's admonition. Apparently, the state surveyors had used a form letter which was only to be utilized if the provider refused to allow the surveyors to enter the premises which was not the case here. In response to your question, it makes no difference that the visit was prompted by a patient or other complaint. My experience is that these visits or site surveys are often prompted by a complaint. I have also found that most government officials have determined that compliance has been met through the disclosure of non-privileged information, medical records, policies and procedures and interviews not requiring the disclosure of PSWP.

OCTOBER 26, 2022 WEBINAR

QUESTIONS & ANSWERS

	Question	Answer
No. 1	If you include policies in your PSES policy do you have to claim privilege on those policies and if so do you violate the statute by providing the policies to the public?	Policies are not privileged under the Patient Safety Act. In fact, at least for purposes of defending against discovery demands for PSWP, you want to disclose your PSES and related polices as proof that you have contracted with a PSO. Further, that you have supporting PSES policies as additional evidence that the materials requested were collected and maintained in the PSES and were either reported to a PSO or treated as Deliberations or Analysis. Therefore, disclosure of the policies to the public or other third party is not a violation of the Patient Safety Act.
No. 2	I receive emails from our risk management department, requesting over reads on imaging cases due to risk events, patient complaints, physician complaints etc. - a lot of the requests come to me without our PSORG/PSES being cc'd and or PSORG tag line statement. I end up forwarding these myself - should original requests from risk management be sent to PSORG/PSES when sent initially?	Good question. It depends on the purpose of Risk Management's request and if you are seeking to treat these messages as PSWP. As stated during the presentation, if RM's request is for purposes of claims or litigation management purposes, then the emails/requests will not be PSWP. If, on the other hand, RM is carrying out a defined patient safety activity you are able to claim that the communications are PSWP and the better practice is to copy the PSORG/PSES. The next question is whether that follow up review is intended to be PSWP. I assume it is. But even if the request was for claims or litigation management purposes I would err on the side of treating the follow up reviews as PSWP. Bottom line, it really depends on the purpose behind RM's requests and whether the reviews are intended to be PSWP.
No. 3	"Report to PSO - Must document date of report" - Should this date be documented onto the actual reports?	Ideally, the date PSWP was reported to the PSO should be on the reported information itself. Some software reporting systems automatically include the date. If not, you need to be able to otherwise demonstrate the actual date of reporting. Perhaps the PSO dates the reporting PSWP upon receipt.
No. 4	Should FMEA projects be included in PSWP?	If you have identified one or more FMEA projects as an activity designed to improve patient safety and/or to reduce risks to patients then it could be included in your PSES policy in order to be treated as PSWP. Again, you need to decide whether the resulting work product, analyses, discussions will be reported to a PSO or treated as Deliberations or

	Question	Answer
		Analysis. It could be a mixture of both, i.e., you report the analysis but discussions or minutes are treated as D or A. Your choice.
No. 5	What is the best way to drop out/document PSES that is deliberation and analysis?	You cannot drop out PSWP which you are treating as deliberations or analysis. You would have to repeat the activity which generated the information you want to drop out, outside of the PSES. If you knew in advance that you might want to drop out this PSWP, which you usually would treat as D or A, you could document that you intended for those materials to be instead reported to the PSO which would then give you the option of dropping out. You should clearly document this decision because if not, a plaintiff's attorney, who would have your PSES policy, will argue that you that cannot drop out the disputed information if described as D or A.
No. 6	(1) I understand from your representation that reports and studies prepared by the PSO remain PSWP. When creating your own educational materials for the workforce within the single legal entity contracting with the PSO, is it better (i.e., should you? the rules suggest you can1) to use and disseminate aggregate information (general best practice guidelines, protocols, etc.) as opposed to identifiable and non-anonymized information to avoid potential unauthorized disclosures of PSWP to workforce who is not members of the PSES who conduct the actual deliberations and analysis and may not be as cautious with the information as the members of the PSES? (2) I understand that you cannot share PSWP or educational with unaffiliated entities and certain affiliates of the single legal entity which are not appropriate to share such information (for e.g., claims - litigation management department, PSOs and physician groups, joint venture entities, etc.), but an important targeted audience is the medical staff with privileges at a hospital, who may be employees of other entities, of course. What precautions if any must the PSO member be aware of when educating these medical staff professionals?	Your question is confusing. Workforce members, i.e., members who need access to PSWP to carry out all or some of their responsibilities, can receive PSWP. Sharing would be considered a use. Workforce members would be considered "members of the PSES" and so I am having a problem understanding how you are distinguishing between the two. As a general matter, you should only share enough detail necessary to achieve your educational goals/training. If I was on your medical staff I would not want my identifiable PSWP or state privileged information to be used as part of your educational materials. If you can "use and disseminate aggregate information" and non-identifiable and anonymized information and still achieve your goals, the better. You can share PSWP with risk and claims-litigation management department. They would need to create their own non-privileged forms, interviews, investigations, etc., which would not be considered PSWP and therefore are discoverable unless attorney-client work product, insurer-insured or other privileges are available. PSWP can be shared with affiliated entities IF they are under your PSO contract. If not, PSWP cannot be shared unless you meet one or more of the disclosure exceptions.

	Question	Answer
		In terms of educating medical staff members why not use the same materials as you do for workforce training? Or develop "hypothetical" scenarios as an educational tool which could be valuable for all targeted groups?
No. 7	Where in the act does it mention the disclosure exception?	See Section 3.206(b) in the Final Patient Safety Rule for all of the disclosure exceptions.
No. 8	How do you handle when the Director of Quality for the system is also the Director for the PSO ... I personally sent at peer review. Can you please explain functional reporting ...	The Patient Safety Act allows the use of shared employees by and between a PSO and the health system. There needs to be a shared employee agreement in place along with policies and the means to prevent the sharing of PSWP unless the recipient of the PSWP is also a workforce member for a participation provider who needs access to PSWP to carry out their job responsibilities. As a Director of Quality having access to peer review PSWP would be within your responsibilities. Functional reporting is another way of creating PSWP in addition to the reporting and Deliberations or Analysis pathways. For functional reporting, the participating provider needs to identify to the PSO which categories of information are being collected in its PSES but are not being reported directly and not being treated as D or A. For example, let's say a hospital is treating its peer review minutes as functionally reported. It would inform the PSO of this fact through sharing, for example, its PSES policy identifying same. The parties must then identify how the PSO can obtain access to this functionally reported PSWP, i.e., by request, by allowing the PSO access to a separate server holding this PSWP, and the PSO must demonstrate that they have in fact accessed this PSWP Because of the administrative hassles of setting up this arrangement most providers and PSOs do not use this method.
No. 9	Our attorneys developed the PSES and PSO polices to read like the actual PSA – I have issues with this and have seen examples elsewhere that are descriptive as you presented today ... Should all the legal jargon be included?	Including "legal jargon" such as the definitions and provisions in the PSA is fairly typical because it serves as a means of educating your internal workforce members but also third parties seeking access to PSWP. That said, the policies need to describe how PSWP is collected, generated, shared, reported or treated as D or A, etc., as described in the power

	Question	Answer
		point presentation, and as reflected in the example PSES provisions I provided. Legal jargon alone is not enough.
No. 10	Our processes include identifying a quality of care complaint that cites provider performance, a case review of the record with a RM and key medical leaders to include assigning models and coaching, and then presentation at the larger peer review committee to review and assign a severity score. We currently have the case review and the peer review meetings identified as PSWP, however, the patient compliant portal and incident reporting system are not .. I want to include these but have received push back from internal counsel. Can I use arguments presented today to include these in the PSES?	Yes. Most systems certainly include incident/adverse event reports. Am not sure if your reports are simply factual or if they also include some commentary or initial analysis you would want them treated as PSWP. The same applies to patient complaints but that is a judgment call as well as whether a complaint is already set forth in the patient's medical record. In the Daley appellate court decision, the hospital included patient complaints in its PSES which was reported to its PSO. The appellate court ruled that they were PSWP because the hospital met all of the requirements.
No. 11	Our 'system' is a collection of PCs (urgent care and convenient care centers) owned by physicians ... under the management of a Management Service Organization. We have contracts with each for reporting to the PSO. Regarding "use" vs "disclosure" – is it considered use if we are discussing the individual providers or incidents from one PC with a larger group for purposes of discussions/analysis/process improvement purposes?	"Use" applies to internal sharing of PSWP within a PC. If sharing PSWP outside of the PC you must fall under one of the disclosure exceptions. If sharing identifiable PSWP of an individual provider you must obtain the provider's written authorization as described in the presentation.

NOVEMBER 2, 2022 WEBINAR

QUESTIONS & ANSWERS

	Question	Answer
No. 1	If an organizations uses PSWP to fire a person (HR purpose) isn't letting go of low performing person also important for patient safety?	Yes but as I explained during the presentation, if you rely exclusively on PSWP to terminate an employee, you cannot introduce it into evidence if you are sued in state or federal court. HR can access PSWP relating to an underperforming or problematic employee but should then trigger a separate review, interviews, etc., which are outside of the PSES and therefore will not qualify as PSWP. The results of this review can be placed in the employees file and can be used as evidence to support the termination.
No. 2	We are a PSO with providers in several states. How do you recommend we guide our providers for P&P? My in house counsel does not want us providing 'legal advice' to our providers. Any suggestions?	I would characterize any comments you make about a member's policies and procedures as "suggestions" or "recommendations" and specifically note or document that such comments are not to be considered "legal advice" as was true for my presentation suggestions and recommendations. I was not giving legal advice.
No. 3	Is there a template available that can be used by providers to sign in order to authorize disclosure of PSWP outside the PSO, for example, to another/external PSO?	Use of each or any of the disclosure exceptions will be unique to each disclosure. The Patient Safety Act does not dictate what language to use for this reason. For example, if using the written permissible disclosure exception which would allow a provider to disclose its own PSWP under Section 3.206(b)(3) of the Final Rule, you would want to describe both the information which is being disclosed and the purpose for which it is being disclosed. Each such disclosure will be unique.
No. 4	Why can't we claim PSA and attorney client privilege?	The point I was making is that you cannot claim the attorney-client work product privilege and the Patient Safety Act privilege for the same document. For example, the creation of a root cause analysis, RCA, is for the purpose of improving patient safety and reducing risk. RCAs are specifically identified in the PSA as a PSWP example. RCAs are not prepared by legal counsel in anticipation of litigation which is the standard for asserting the attorney-client work product privilege. There clearly could be other documents that will qualify as attorney client work product but not any information you are treating as PSWP. Courts have already pointed this out when a party argued that both privileges apply

	Question	Answer
		to the same document. The better choice is to treat information as PSWP if identified as such in your PSES. The privilege protections under the PSA are far broader than ACWP and can never be waived unlike the ACWP.