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PSO 101: Overview of the Patient Safety Act

Questions and Answers

1. The Graduate Medical Education Committee, part of the PSES, obtains PSWP (Infection Control case), and creates an educational PowerPoint to train residents about catheters and UTIs. Is this PSWP? If requested by ACGME, can it be voluntarily disclosed?

   Response: If the deliberation and analysis was conducted within the PSES, it is protected PSWP. That being said, the question is whether the Power Point contains any PSWP or is simply providing factual information and steps to take when dealing with UTIs. If not containing sensitive information you may not need to keep it protected and therefore it would be available to disclose to the ACGME. These questions about whether to keep these kinds of reviews, presentations, etc., protected should be kept in mind when creating educational and other materials in response to an adverse event. If you need to keep the Power Point protected, as with any inquiry by a governmental agency, you should try to demonstrate compliance by disclosing policies, procedures, actions plans, etc., without sharing PSWP. As a last resort, if all of your efforts fail and you are facing a possible denial of certification or licensure, or loss of Medicare eligibility, however remote, there is a written authorization disclosure exception that could be utilized under the Final Rule but you should consult with legal counsel before considering this option.

2. Follow-up question to Graduate Medical Education Committee quest: How does one practically document this as PSWP other than labeling it? If functional reporting, do you need to keep a database identifying each and every report deemed PSWP?

   Response: The report could be considered deliberations and analyses and may not require functional reporting although if you are simply addressing the Power Point presentation, this might be a stretch. The other safe option is to treat this information as being functionally reported to the PSO. This form of reporting needs to be reflected in your PSO member agreement which requires that the PSO be given access to all PSWP which is being functionally reported and describes how access is obtained. Your PSES also must identify when information is functionally reported as well as to document when reporting actually occurs.

3. As a jail under DOJ monitoring, can we withhold release of our incident reports from the DOJ?

   Response: If the incident reports were collected within your PSES and reported to a PSO, and assuming you have no mandatory federal regulatory reporting obligation concerning the incident report, it is PSWP and you can withhold recognizing there may be consequences. If you have simply held on to the report in your PSES and had not yet sent it to the PSO, it could be dropped out. You could also consider the written disclosure option referenced above in Response No. 3.

4. Please comment more on the "2 versions of common formats" in use.

   Response: There are 2 versions of a common format. PSOs usually define which version their providers utilize.

5. What staff members would you recommend be involved in supporting PSES activities?

   Response: Many organizations utilize safety, quality and/or risk management staff. You should also include in-house or outside counsel. A multi-disciplinary team is important.

6. Could you clarify "copy rule" ? If a report is submitted to state, is that copy report sent to PSO considered PSWP?

   Response: The original report is not PSWP. The copy reported to the PSO has the privilege and confidentiality protections of PSWP.

7. Data excluded from the PSES may be reported to the PSO as NON PSWP and may be included in patient safety initiatives analysis.

   Response: Correct. Also, whatever the PSO produces would be considered PSWP.

8. I am unclear on the "copy" submission to a PSO. How can that information have confidentiality and privilege protections if the exact information has been dropped out of the PSES and used as non-PSWP (i.e. for disciplinary action)?

   Response: The original report dropped out is not PSWP and does not have the privilege and confidentiality protections although it could may be protected under state law. The copy itself sent to the PSO is PSWP.

9. If I understand correctly, you are saying that if I have something that cannot be PSWP due to its requirement to be reported to the state, that if I send a copy of the data to a PSO the copy I retain will be considered PSWP?

    Response: The copy sent to the PSO will be considered PSWP. The original to the state may or may not be protected depending on state law.

10. Are all the national PSO's sharing data for trending?

    Response: There is some limited sharing but no real national sharing at this time.

11. For committee work on agenda---instead of having separate set of minutes, what about identifying what is and what is not PSWP on the agenda and/or minutes itself?

    Response: That is certainly an option.

12. When functionally reporting minutes of a PSES executive session, can you de-identify the information so as to not implicate the name of the provider? Would you need the providers consent?

    Response: There is no need to obtain provider permission to report identifiable information to the PSO and if shared internally to Work Force members particularly if members of the medical staff. If there is no need to identify the provider you can certainly de-identify if you want to but this is not necessary.

13. Question about Florida regarding PSO, am I correct in that you stated peer review reported to a PSO is discoverable to medical malpractice attorneys?

    Response: No, if it is PSWP it is privileged and confidential under the Patient Safety Act.

14. What is the relevance to the PSO itself if it is receiving a copy or PSWP? Does it use that data in a different manner? Or is it really only relevant to the provider as it determines if documentation submitted to its PSO is discoverable?

    Response: PSO can use the information received to conduct protected patient safety activities and analyses like any other PSWP which it receives.

15. The Act contemplated the federal government would create or cause to be created a "super PSO" which would gather and analyze data from composite PSOs- what is it's status?

    Response: The Network of Patient Safety Databases exists and PSOs are sending data to the NPSD

16. I heard a suggestion that data submitted to a PSO is no longer available to the provider to hand over if requested. Does this mean that the electronic record on the provider side should be destroyed or removed once submitted to a PSO electronically?

    Response: No. The data is typically maintained within the PSES and the organization uses the data for patient safety activities.

PSO 201: PSO Standards Applied to Real-World Scenarios

1. When you say "invite that nurse into your PSES" during the call to RM about the fall/cardiac arrest, how do you legitimize that invitation? Document that invitation?

   Response: Identify the PSES Log-Date, the staff present and why they are there, as well as the details of the discussion tied to patient safety and risk reduction activities. It might be a good practice to inform staff that the conversation you are about to have will be occurring within your PSES and protected as PSWP. The provider should also inform the staff of their confidentiality obligations related to PSWP.

2. If TJC determines an event at our organization is a sentinel event and we then provide TJC our RCA, do we submit a copy of the RCA to the PSO? Or do we not submit the event or RCA to the PSO?

   Response: There are several ways to accomplish this. If the original RCA sent to TJC is PSWP, it can be disclosed under the permissible disclosure exception to accrediting bodies. The RCA remains PSWP. If the RCA was not conducted in your PSES for reporting to a PSO, a copy may be sent to the PSO. The original RCA is not PSWP, but the copy will be protected as PSWP.

3. Please clarify what was said regarding what info is given to state when reporting an adverse event.

   Response: Organizations must continue to meet their state reporting requirements using whatever forms or submitting whatever information is required by the state, but nothing else. These mandated reports are not PSWP but copies can be sent to the PSO and the copies will be considered PSWP.

4. On slide 51, please explain more re: what is meant by "Affidavit should include analyses conducted with the data".

   Response: This is to demonstrate that the data was collected in the PSES for conducting analyses, reports, etc., to be reported to a PSO which are then protected because they are being used to improve patient safety.

5. Just want to clarify slide 58, first bullet...we should not report adverse events to the PSO, only a copy?

   Response: Information or reports which you are mandated to send to the state or federal government should not be reported first to a PSO because it becomes PSWP and arguably cannot be then shared with the government. We are only talking about the mandated report itself. The adverse event likely triggers other reports, studies, etc., which do not need to be sent to the government and therefore can and should be sent to the PSO.

6. We submit to NYS electronically. what is the difference between an "original" document and a "copy"?

   Response: The organization retains the original copy outside of the PSES when sending a copy to the PSO.

7. Fitness for duty report may have overlap in HR and patient care. So, how do you address this problem? It can be difficult to separate. Do you redact in part?

   Response: Response: It depends on where you want to collect the information, i.e., in your PSES or for HR purposes, and how you want to use the information. This is a judgment that you need to make on the front end recognizing that while a fitness for duty evaluation can serve multiple patient safety purposes and the results can be used to educate/remediate the physician, it cannot be used as a basis to support termination. You need to consult with legal counsel when making these determinations.

PSO 301: Discussion of PSO Court Cases and the Litigation Lessons Learned

1. Had Walgreen's retrospectively submitted events covering 2007 prior to the subpoena?

   Response: Not to my knowledge but we do not know for sure.

2. Could states work around the pre-emption argument by establishing a mandate to memorialize incidents outside of a PSO? E.g., for licensing purposes, in the pharmacist situation. Or adverse incident reporting. Or would that itself be pre-empted?

   Response: The concern is that states could expand mandated reporting requirements. But even if that occurs, providers could still create yet different reports which are not mandated which is what they do now. If a state, on the other hand, tried to pass legislation requiring that reports of any kind relating to patient safety activities had to be made available, so as to effectively render the Patient Safety Act null and void, I think a court could use the preemption argument. The current battles being fought in court are principally over the issue of whether information which need not be reported can be treated as PSWP if required to be collected and maintained under state or federal law. That is the question currently before the U.S. Supreme Court in the Tibbs case.

3. Does a PSO have any sort of statutory requirement to educate its members on what they must do in order to maintain PSWP protection? It seems like in some of these court cases that the PSO members perhaps didn't know what they needed to do.

   Response: While there is no specific duty for PSOs to educate their members there is certainly, in our opinion, the expectation that these educational efforts are provided. Many PSOs, in fact, do schedule conference calls and educational webinars for this very purpose.

4. What was the name of the last case before the KY Supreme Ct not summarized?

   Response: Baptist Health Richmond v. Agee.

5. Define mapping exercises.

   Response: There are some software vendors who may have tools available to help providers map their format into the Common Format specified by a PSO to enable reporting.

6. 3.206(b)(3) says that you can disclose PSWP consistent with an authorization if authorized is obtained from each provider IDed in the work product - how does that impact your statement that once it becomes PSWP provider cannot use as evidence for defense?

   Response: The scope of how this written authorization disclosure exception can be utilized is not altogether clear. The Final Rule is fairly straight forward and does not reference any limitations on scope of use. The notice of proposed rule-making back in 2008, however, stated that this exception could not be used to disclose PSWP to a federal agency but a subsequent comment by CMS in 2014 stated otherwise,. As is true for most of the PSO and Final Rule, the interpretations and implementations are untested in court.

7. What is the significance of 1/1/17?

   Response: Response: Qualified Health Plans providing coverages to insureds in the state insurance exchanges under the Affordable Care Act can only contract with hospitals with more than 50 beds if they are participating in a PSO.