Patient Safety Organizations (PSOs): What Every Physician Group and Ambulatory Services Provider Needs to Know

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Q1. Are the documents including emails related to a safety incident that are related to a peer review submitted to the PSO protected?

Answer:

EF: If the emails are considered deliberations and analysis and created within the organization's Patient Safety Evaluation System (PSES), they could be considered PSWP and privileged and confidential. They date created within PSES must be documented. Vizient PSO is able to accept all types of documents reported as PSWP. (patient safety work product) It is recommended that providers discuss this topic with their legal counsel and evaluate if the documents quality as PSWP, deliberations and analysis and their preference for reporting the documents to a PSO.

MC: As discussed during the webinar, there are two basic pathways for creating PSWP, the reporting pathway and the deliberations or analysis pathway. If seeking to assert that emails relating to a safety incident are PSWP you should first determine which pathway will be utilized and then identify same in your PSES policy. A best practice would be include within the subject line of the email the phrase "Privileged Patient Safety Work Product" or some similar reference. There actually are some software programs out there which are designed to include such a reference. We doubt that you will actually be reporting your emails to the PSO although nothing prevents you from using this option. More likely you will treat these emails as deliberations or analysis which do not need to be reported but again, you should reference your treatment of emails as D or A in your PSES policy.

Q2. If emails or other documents are created before the PSO submission are they submitted?

Answer:

EF/MC If they are deliberations and analysis created within a PSES, they are considered PSWP at the time created

Q3. With the way the Illinois Medical studies Act is written Physician Groups are not afforded the same protection as the Ambulatory Surgery centers and the Hospitals and therefore we are very limited in what we are able to do in regards to quality studies, etc. If joining a PSO would that allow the PSO to obtain the hospital data in addition to our group data so that we can perform quality studies, etc. through the PSO and have that protection? If not, then it does not make much sense for us to join a PSO.

Answer:

EF: The Patient Safety Act (PSA) provides privilege and confidentiality protections to all licensed providers and their parent organizations

MC: As Ellen points out, the PSA can apply to all licensed providers and other entities permitted under state law to provide health care services. Therefore physicians and physician groups can claim the privilege protections under the PSA if they contract with a PSO and otherwise take the appropriate steps in designing their PSES and related policies to cover both their group data and the hospital data. This raises a question as to what is being considered 'hospital data". It sounds as if this is being separately created by the hospital but shared with the physician group. The data itself, unlike group data if identified, collected, maintained and evaluated within the group's PSES, may not be PSWP upon receipt. That said, any quality studies and work product using both hospital and group data will be considered PSWP.

Q4. Can we define our own PSES and what are the requirements for doing so?

Answer:

EF/MC: Yes, the requirements are outlined in the Final Patient Safety Rule

Q5. Have PSOs been used for ambulatory peer review programs at other institutions?

Answer:

EF/MC: Yes

Q6. Does every single document (email etc) need to be submitted to the PSO for it to be protected?

Answer:

EF/MC: No – deliberations and analysis created within a PSES for the purpose of reporting to a PSO do not require reporting

Q7. What are ways to “activate” PSO protection or how do you document PSO protection?

Answer:

EF: Document the date submitted to or created within the PSES and Date reported to the PSO.

MC: Again, you need to describe what pathway you are utilizing when creating PSWP. Some work product will be treated as deliberations or analysis and therefore need not be reported. Other work product, such as incident reports, will be actually reported to the PSO. For information being reported, aside from identifying same in your PSES, you should document when it was created and when it was reported. Keep in mind it remains privileged even before it is actually reported. If the document, information, discussions, etc., relating to a patient safety activity is being treated as deliberations or analysis your PSES should describe at least generally when they become PSWP. For example, if the privileged quality portion of the minutes of the MEC are identified in the PSES as deliberations or analysis you can state: "Information, discussions and analyses relating to patient safety activities occurring within the following committees will be treated as privileged deliberations or analyses upon inception", or something similar.

A best practice is also to include language on actual documents, minutes, etc., which state: "Privileged and Confidential Patient Safety Work Product Under the Patient Safety Act". If the document also is privileged under your state statute you should include a reference to that statute as well.

Q8. Does information become PSWP only when It is entered into the PSO?

Answer:

EF/MC: No, deliberation and analysis created within a PSES is considered PSWP when created. Reporting pathway requires reporting for PSWP

Q9. Are there any documents that cannot be submitted to PSO?

Answer:

EF: Information reported to a PSO must be collected to improve patient safety, healthcare quality and healthcare outcomes

MC: Arguably, you can submit any information to a PSO irrespective of whether it qualifies as PSWP. That said, the HHS PSO Guidance takes the position that information which you are required to submit pursuant to mandated state or federal reporting statutes does not qualify as PSWP even if you reported it to a PSO. The concern expressed by HHS is that some hospitals were trying to avoid their mandated reporting obligations involving, for example, a significant adverse event, by sending the report to the PSO instead of the state and claiming the privilege. Some courts have taken the position that if a mandated report is sent to the PSO it is privileged but that the state can bring a licensure or other action against the hospital for not complying with its reporting obligations. You can certainly send a copy of the mandated report to a PSO. The copy will be privileged.

As Ellen points out, if collected for a purpose unrelated to improving patient safety a court would likely rule that the document would not be considered PSWP. This is why your PSES policy should be carefully drafted in a way which will support your privilege claim over the documents and information for which you are asserting the privilege.

Q10. Is employment disciplinary action (not medical board, credentialing) considered outside of the scope of a PSO protection?

Answer:

EF: Before reporting to the PSO, an organization can remove, data collected via the reporting pathway and use the data for another purpose. The date of removal must be documented by the provider. Analysis of factual information performed within PSES can be repeated outside of PSES for another purpose.

MC: Based on comments in the Preamble to the Final Rule, PSWP can be used for disciplinary actions but you cannot discipline someone based on the fact that they reported information to a PSO. The Final Rule does not define the term "disciplinary action". What is considered discipline is in the eye of the beholder. Most practitioners would limit its application to terminations or suspensions. Therefore other remedial measures such as probation, monitoring, an FPPE plan, etc., would not be considered disciplinary irrespective of whether it involved an employee or an independent practitioner.

There is also some debate on whether, in this era of "just culture", PSWP should be used to support a termination or suspension. If we moving away from the "blame game" and attempting to encourage practitioners to be objective and accept responsibility for their actions, whether negligent or purposeful, relying on their admissions and resulting PSWP to then terminate someone for being honest is counter-productive.

Keep in mind to that PSWP is not discoverable or admissible into evidence in any and all state and federal proceedings by any party. In other words, a hospital, physician group, ancillary provider, etc., cannot introduce the PSWP on which it relied to support a termination, into evidence to support its actions if the terminated individual challenges the termination based on myriad grounds, i.e., illegal discrimination, breach of contract, tortious interference, etc.

For these reasons it is very important to be working with your in-house and/or outside legal counsel if it appears that you are moving down a path which could lead to a termination, suspension or other action which could result in litigation.

Q11. If we decide to take employment disciplinary action based on findings documented through our PSES in the PSO, does an entirely independent review for disciplinary action have to occur or can some of the data (i.e., facts of case and analysis from peer review) within the PSO be used?

Answer:

EF: An independent review would be best. The facts of case should be from the medical records and other documents and are available for an independent analysis. As discussed above, there is a process for removing data from your PSES before reporting it to a PSO. Please consider Mike's comments on Just Culture.

MC: This again is a judgment call which you need to make with the right people, including legal counsel, especially if you are anticipating a legal challenge. As Ellen points out, facts are not privileged and can be taken from the medical record and other similar sources. Also, outcomes or decisions are not privileged. The issue is whether the facts alone will suffice when taking action and defending the decision in court. For example, if Dr. Callahan has had 6 significant post op infections in a 6 month period despite efforts to assist him in avoiding these outcomes is this fact alone sufficient? Could be but probably not. An independent review outside of the PSES would make more sense as Ellen suggests but keep in mind that your state privilege, if applicable, also comes into play. If this independent analysis also cannot be admissible into evidence under state law then you may have a problem.

Q12. If we do a separate review process, do the findings in the PSO remain confidential?

Answer:

EF/MC: Yes

Q13. Can any information submitted to PSO be removed for disciplinary action?

Answer:

EF: No. Information sent to PSES via reporting pathway may only be removed and used for another purpose before reporting to the PSO and the date of removal must be documented.

MC: I would modify your response as follows: "Once information is reporting to a PSO or treated as D or A it cannot be dropped out or removed and used for any other purpose unless you meet one of the permissible disclosure exceptions. For example, if you reported an RCA to a PSO and then are being investigated by CMS or a state agency, they may demand access to the RCA. Although CMS is on record as not requiring a hospital or other licensed provider to turn over PSWP, the provider could decide ot disclose its RCA under the written authorization disclosure exception. Even though disclosed it remains PSWP.

That said, no one would take the view that a provider can remove PSWP and use it to terminate someone. As suggested above, you either rely on the facts or do an independent review outside of the PSES.

Q14. Can some of the same leaders involved in peer review process be involved in disciplinary action process?

Answer:

MC: The answer may be controlled by your existing bylaws or policies. The best practice is that individuals involved in the peer review process should not be involved in any hearing process where they will be making a decision based on actions they recommended or took. You want to avoid claims of a conflict of interest as best you can. Hospitals have fairly clear guidelines in this regard but physician groups and other ancillary providers probably do not. The larger the organization the better you are in being able to involve independent practitioners who have not been involved in the peer review process leading up to the disciplinary action. This may be easier said than done.

Q15. Or do individuals involved need to be entirely separate?

Answer:

EF/MC: Separate would be best

Q16. What tools or platforms have other organizations who have an ambulatory quality program use to collect and aggregate data prior to PSO submission?

Answer:

EF/MC: There are many peer review and event reporting software modules available.