

CHART Institute PSO

Webinar - *Maximizing State and Federal Protections: Lessons Learned* presented on July 18, 2019 by Michael R Callahan, Senior Attorney at Katten Muchin Rosenman LLP

Post-Webinar Questions and Answers

1. Are you aware of any hospital policy samples/templates on peer review?

As with any patient safety activity you would want to identify what activities, committees, forms, reports, analyses, etc., in your PSES policy which you are seeking to protect. You may have already done so in terms of taking advantage of your state peer review statutory protections. Another option is to cross reference to your existing peer review policy/procedures which may have been separately developed. Hospitals can decide if all or only portions of their peer review process is to be identified in the PSES policy. For example, you would not include the criteria you use for the OPPE/FPPE standards but may want to include any analysis of whether the physicians are or are not in compliance. It is your choice. Keep in mind that while you can use PSWP for remedial and even disciplinary actions taken you will not be able to introduce PSWP as evidence to support your actions in a state or federal lawsuit and therefore you need to be working with quality, risk, in-house and outside counsel when determining what activities and at what point in time to you conduct peer review outside of your PSES or treat this information as reportable, as opposed to Deliberations or Analysis, so that you are in a position to drop the information out so that it is no longer PSWP and can be used for other purposes. Keep in mind too that your state peer review statute may come into play here as well in terms of how it can or cannot be used to defend the hospital's action.

2. Are there any peer review policy templates or recommendations for inclusions?

See response above.

3. Does peer review need to be submitted to the PSO to afford the federal protections? CHART PSO has a secure platform where members can share PSWP. Does the member need to place peer review documents in their secure PSO folder?

You can either report peer review minutes, analyses or other work product to the PSO or treat as Deliberations or Analysis or use both methods depending on the particular peer review activity. I would not share any identifiable peer review activity with others.

4. When discussing SNF, you mentioned bylaws. Were you saying that the SNF needs its own bylaws?

SNFs and other ancillary providers, including physician groups, typically do not have the same quality or peer review infrastructure of a hospital. SNFs do not need bylaws but the kinds of patient safety activities of a SNF or physician group are going to be different than that of a hospital and some state peer review statutes which would protect a SNF or physician group usually require that the patient safety activities in question and which can be considered privileged need to be conducted through a committee although the Patient Safety Act does not impose this requirement. The point is that ancillary providers need some type of process which describes how the PSWP is collected, maintained, analyzed, reported or treated as Deliberations or Analysis, etc. As mentioned above, the PSES policy could cross reference to an existing process which might be in the bylaws, although probably not, or in some system wide or specifically developed policy for that ancillary provider.

5. In the hospital's bylaws, Peer Review Committee minutes are to be reported to Medical Executive Committee (MEC). The Peer Review Committee minutes include statements about PSWP and peer review statute protections. In the Peer Review Committee minutes, physicians are identified by number. Each physician is assigned a number that is the same for all reporting purposes. Is the sharing of Peer Review Committee minutes with Medical Executive Committee an appropriate use/disclosure?

Absolutely. Information definitely needs to be shared consistent with accreditation and other legal requirements.

6. Are there any concerns about sharing the Peer Review Committee minutes with MEC?

No.

7. Should a statement be included in the MEC minutes that this 'sharing' is a disclosure of PSWP?

Sharing such information is considered a permissible internal "use" and not a "disclosure" for which you would need to meet a permissible disclosure exception.

8. What is the best practice for labeling documents as PSWP to afford protections?

Labeling a document as PSWP is not required under the Act but is considered a best practice for internal and external purposes so as to inform employees, physicians, agents and third parties that the document or materials in question are privileged. If the state peer review protections apply, hospitals typically include language such as "Privileged and Confidential under the Illinois Medical Studies Act", or the "New York Peer Review Privilege Statute", as examples along with the statutory citation. If wanting to also identify as privileged under the Patient Safety Act you can simply use similar language: "Privileged and Confidential Patient Safety Work Product under the Patient Safety and Quality Improvement Act of 2005". Not including such language is not fatal especially if the activity, document or other work product is identified within your PSES but again, is a best practice and also acts to inform your workforce employees, physicians and others so that they know what documents need to be kept confidential.

9. Are there any exclusions for peer review within the PSES?

See response to Question 1. Some hospitals want to be able to demonstrate that they are in compliance with CMS, accreditation and other standards if some type of compliance survey is being conducted and therefore, as noted above, might not always treat an analysis of whether a physician is complying with an OPPE or FPPE quality criteria. There are ways to demonstrate compliance without turning over PSWP but again, that is a judgment decision in terms of what peer review activities you do and do not include in your PSES. Keep in mind that your state peer review protections and your Patient Safety Act protections are not mutually exclusive. You can assert both if both apply and so this may also affect what information you do and do not include in your PSES. Also, if you are in a state which has mandated adverse event reporting you must meet these requirements. Usually you only have to fill in or use the mandated reporting form and not the underlying analysis which you can treat as PSWP if identified in your PSES policy. BUT, if you know that the adverse event may lead to a state or federal survey or investigation, you may want to conduct your review outside of your PSES so that you can disclose your analysis to demonstrate compliance with any applicable federal and/or state or accreditation requirements. Otherwise there really are no "exclusions" per se.

10. What is best practice for managing information when a portion of it is mandated for reporting? How do you 'identify' the portion that is not mandated as PSWP?

Typically, in your PSES policy and through appropriate labeling. For example, some software systems are set up so that the "above the line" facts, usually from the medical records, are typed into the electronic form and the "below the line" analysis is treated as PSWP and labeled as such on the form itself. Again, mandated reporting forms are typically utilized by the state and therefore you use the forms and provide whatever information is required. The rest can be considered PSWP.

One gray area of the law to keep in mind, which has become more complicated by the HHS PSO Guidance, is HHS's and AHRQ's position that information which a hospital is required to "collect and maintain", as opposed to report, cannot be considered as PSWP and must be made available to the state upon request. There is much debate about this position and most state statutes are not particularly clear about what has to be collected and maintained but, more importantly, made available upon request. You need to work with your local or outside counsel to determine whether your state statutes impose this requirement.

A good case to look at because the Appellate Court did an extremely deep dive analysis as to whether the State of Kentucky required hospitals to maintain, collect and make available to state officials "incident investigation reports" is the decision in *University of Kentucky v. Bunnell* (532 S.W. 3rd 658 (2017)). The Kentucky Supreme Court previously held that the state did impose such a requirement, but the decision was not binding. When the Appellate Court in this decision examined both the statute, its legislative history and other factors it determined that the use or creation of incident investigation reports was in fact voluntary and not mandated. I would encourage everyone to review this decision as it might serve as useful way to analyze your applicable state statutes.

11. What is the best practice for identifying the analysis portion of a committee meeting such as a Patient Safety Committee as PSWP?

As noted above, your PSES can include and identify that any analysis and deliberations conducted by your list of identified committees when engaging in one or more of the patient safety activities set forth in your PSES will be treated as PSWP using the Deliberations and Analysis pathway as opposed to the reporting pathway. Deliberations and Analysis does not require a report although you can certainly report anyway to the PSO. Labeling this portion as PSWP, as discussed above, is also recommended.

12. Any best practices for creating our PSES: areas for consideration/lessons learned?

I believe that CHART has provided a list of activities the work product of which could be considered PSWP. If not, I can provide such a list. This is a useful tool for taking an inventory of what activities to include, or not, in your PSES based on your existing quality, peer review and risk activities. That is the starting point but you need to utilize a multi-disciplinary team or committee which includes reps from quality and risk, your in-house and/or outside counsel, CMO, etc., to review the list in order to make a final decision on what to include in the PSES. The definition of what can be considered as a patient safety activity is very broad. Again, you get to decide what is in and out. Some organizations focus initially on high risk areas and incidents rather than every single incident report which it generates. It then expands from there. Because there are so few appellate court decisions in this area there are not a lot of legal lessons learned other than what was discussed in the power point materials. At the end of the day the better you document the better your chances of upholding the privilege protections if challenged. You also need to appropriately educate and train your workforce members who need to use PSWP to carry out their responsibilities. This is key.

Tools Available on the Member Portal - PSO

[*Patient Safety Evaluation System Inventory Tool*](#)

[*Patient Safety Evaluation System Checklist*](#)

13. Do we need to conduct confidentiality training for our PSO workforce annually?

This is a best practice. If you train on HIPAA annually you should do the same for your workforce. New court decisions, new Guides or Guidances from HHS or AHRQ may affect your training. Also, your policies are likely to evolve and the number of affiliated entities which are covered in our system-wide PSES might increase. Any new workforce members also need to be trained at the outset.

14. Does peer review need to be submitted to the PSO to afford the federal protections? CHART PSO has a secure platform where members can share PSWP. Does the member need to place peer review documents in their secure PSO folder?

You can either report peer review minutes, analyses or other work product to the PSO or treat as Deliberations or Analysis or use both methods depending on the particular peer review activity. I would not share any identifiable peer review activity with others.

15. What is the best practice for dropping PSWP out of our PSES before it is sent to the PSO?

- a. Do not treat as Deliberations or Analysis in your PSES because it automatically becomes PSWP and cannot be dropped out.
- b. Use a multi-disciplinary team or identified individual well versed in the Act to determine whether you may need to drop the information out and use for a different purpose.
- c. Because most information intended to be reported might be done immediately or automatically you probably need to somehow flag those types of incidents or events that will require further review before doing so.
- d. Document why the information is not yet being reported under these circumstances. For example, if the adverse or sentinel event triggers an RCA, you can come up with a policy that all RCAs will be reviewed in more detail in order to determine whether to hold on to the report, report it, or drop it out. Although the PSA does not require that such information intended to be reported must be reported within a specific period of time, you want document why you are holding on the RCA. If your statute of limitations is 2 years, you would document that you are holding on to the RCA, if helpful to your cause, for this two year period in case you want to use to disclose to an agency of for use in the hospital's defense in a med mal claim. If the statute runs and no claim is filed, you can then report.
- e. Document the date you dropped it out or the date it was reported.

16. Are there concerns/issues if we belong to a PSO but never submit any PSWP to the PSO?

Yes. First of all, your PSES should distinguish what information is being reported and what information is considered Deliberations or Analysis. If you have identified information, such as incident reports, as needing to be reported to CHART but do not do so, you set yourself up for the argument that you have not complied with the Act and the information therefore cannot be considered PSWP. Technically once information is collected within your PSES it is considered PSWP and the privilege can never be waived but courts do not like any privilege statute. You will be accused of simply hiding information with no real intention of complying with the Act. In addition, all of the appellate court decisions to date involve hospitals that collected and actually reported the disputed documents to a PSO. Even if you have identified all of the activities and work product in your PSES as Deliberations and Analysis such that a report is not required a best practice is to report information and work product in matters which are likely to trigger litigation especially if this information is useful to a plaintiff.

Also, the other benefit of joining a PSO is resulting analyses, bench marking studies, safety reports and other work product produced by the PSO which is all considered PSWP. But the PSO needs information and reports from its members in order to provide this benefit to its members. You should begin reporting as soon as possible.

17. Can we share PSWP with healthcare providers that do not have privileges within our hospital/system?

PSWP can be shared by and between a systems affiliated providers/facilities which are also members of the PSO. This PSWP can be identifiable or non-identifiable. It is your choice. Identifiable PSWP regarding a health care practitioner can be shared or used for patient safety activities whether they have privileges or not. In order to share physician/practitioner PSWP between affiliated entities you need to obtain the individual's prior written authorization.

If disclosing to providers or other third parties which are not affiliated with the system you need to meet one of the permissible disclosure exceptions under the Act. Otherwise such disclosure would be treated as a violation and would subject you to civil fines.

18. If during peer review it is determined that the 'technical skill' of a provider was concerning, how do we act upon this information if it is PSWP?

The Act intends that PSWP can and should be used for internal patient safety activities including peer review. This is true of all PSWP otherwise why would any hospital join a PSO in the first place? As I mentioned during the presentation, if the concern is that anything a physician says in response to an adverse vent or concern about his or her "technical skills" can be used against them under NY law, all such statements, discussions, peer review work product developed during this review will be privileged PSWP and not subject to discovery IF included in the PSES policy. See responses above about the possible limitations if the review results in an action to terminate the physician and he or she subsequently files a law suit in state or federal court.

19. What is best practice for obtaining permission to disclosure identifiable PSWP according to the 'authorized by identified providers' disclosure? Is there an agreement that providers should sign upon hire? For example, voluntarily disclosure information to our accrediting body. If there is an agreement, is there an example/template?

My general recommendation is that written authorization to disclose a physician's/practitioner's identifiable PSWP be baked into your appointment/reappointment applications/employment agreement. It becomes a standing authorization. Some state laws, such as Illinois, already imposes this requirement. Example language could be as follows: "By signing this appointment/reappointment application/employment agreement (use the applicable reference in the form) I am specifically authorizing the hospital to disclose my identifiable patient safety work product to other hospitals and affiliated entities in furtherance of efforts to improve patient care and to any state, federal or accrediting agency or body if necessary and if requested in order to demonstrate compliance with any legal requirements."

There is no specific language which must be used. While disclosure among affiliated entities, such as when a practitioner is providing services throughout the system, is to be expected, disclosure to governmental and accrediting bodies is not. You should apply a “minimum necessary” standard when demonstrating compliance hopefully without the need to disclose identifiable practitioner PSWP. It should be the rare circumstance where the identity of the practitioner is really required. And although you would have already obtained authorization to do so, you should consider advising the practitioner of any required disclosure under these rare circumstances.

20. What is best practice for disclosure of PSWP regarding an event to law enforcement?

Consult with legal counsel to make sure that you are complying with this permissible disclosure exception. You would want to clearly document the basis on which the disclosure was made and to set forth the reasons why the information relates to the commission of a crime and is NECESSARY for criminal law enforcement purposes. You would want them to explain why the information is really needed and that other sources are not available, and you should apply a minimum necessary standard when deciding how much PSWP really needs to be disclosed. As noted above when responding to a governmental inquiry you may have non-privileged information which may suffice without having to disclose PSWP.

21. If you utilize functional reporting, do you need a separate agreement with the PSO if it was not outlined in the initial agreement?

You and the PSO need to understand what information is being functionally reported to the PSO as well as the manner and method by which you give the PSO access to this information any time they request it. If on a server they need the passcode, if in a cabinet what is the process for how they obtain access, etc. You don't need a separate agreement although explaining this process in writing so that everyone is on the same page makes sense. You also want to distinguish in your PSES what information is being reported, functionally reported or is Deliberations and Analysis.

22. Does each 'owned' office practice need a separate agreement with the PSO if it is part of the health system that has an agreement with the PSO?

No, but you would want to have the office practice and any other affiliated entity you want included in the agreement with the PSO.

Additional Resources Available on the Member Portal – PSO

[CHART Institute PSO – Disclosure and Confidentiality Video](#)
[CHART Institute PSO – PSWP Video](#)