WORKING WITH CHPSO: NAVIGATING PRIVILEGES, PROTECTIONS AND REPORTING REQUIREMENTS

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For: California Hospital Patient Safety Organization

I. Overview[1]

This white paper has been prepared on behalf of the California Hospital Patient Safety Organization (CHPSO) to assist California hospitals and their counsel in evaluating some of the implications of participating in a Patient Safety Organization (PSO).[2] We will discuss:

- How to create effective systems to gather, evaluate and use information for normal hospital and medical staff operations while participating in a PSO;
- How to share information with a PSO without jeopardizing other available protections and privileges; and
- How to maintain and utilize information that may be needed for other purposes, such as peer review or reporting to other agencies, in light of some of the constraints imposed by the Patient Safety and Quality Improvement Act of 2005.[3]

While this paper will assume familiarity with the Act, a summary of a few key provisions will help set the stage for this discussion.

The Act contemplates that participating healthcare providers (for this paper, hospitals) will gather information about various events and patterns of care, will enter that information into the hospital's own Patient Safety Evaluation System (PSES),[4] and will report that information to a Patient Safety Organization (PSO)[5] with whom they have contracted for the sharing of data, evaluation, and recommendations – all for the purpose of improving patient safety, health care quality, or health care outcomes. Superimposed upon all of this is a fundamental intent to foster a "just culture," wherein providers will freely divulge, discuss, and address patient safety issues, without fear of repercussion. The information that is entered into the hospital's PSES for the

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[1] Frequently-used abbreviations:
The Act: the Patient Safety and Quality Improvement Act of 2005
AHRQ: Agency for Health Research and Quality
CHPSO: California Hospital Patient Safety Organization
PSES: Patient Safety Evaluation System
PSO: Patient Safety Organization
PSWP: Patient Safety Work Product

[2] This white paper is not intended, and should not be construed, as legal advice as to how any individual provider should proceed. Hospitals and their counsel are encouraged to review and independently evaluate the information presented in this paper in making their determinations how to proceed with their own systems and activities.

[3] Pub. L. 109-41, amending Title IX of the Public Health Service Act (42 U.S.C. 299b-21 through 299b-26).

[4] Patient safety evaluation system means the collection, management, or analysis of information for reporting to or by a PSO. 42 U.S.C. 299b-21(6) and 42 C.F.R. Part 3, § 3.20.

[5] An entity certified by the Secretary of Health and Human Services pursuant to 42 U.S.C.. 299b-24.

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purpose of reporting to the PSO is called Patient Safety Work Product (PSWP).[6] Excluded from PSWP are "any other original patient or provider information" and "information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." From the time it is designated as PSWP, information garners certain important legal protections. PSWP is protected from:

- Administrative subpoena or order;
- Discovery;
- Admission as evidence in any state or federal; civil or criminal proceedings (with narrow exceptions);
- Admission in a professional disciplinary proceeding; and
- Disclosure (e.g., pursuant to the Freedom of Information Act or similar state law).

These protections are significantly greater than any other protections currently available for hospital safety and quality activities. Among the most notable of these new protections is that they apply in federal courts, where state law protections are frequently inapplicable (see additional discussion at section IV, below).

As suggested by the above, there are constraints on what a hospital can do with PSWP – most problematic being the prohibition on use in any professional disciplinary proceeding. With respect to the professional disciplinary proceeding prohibition, the oversight agency for PSO activities – the Agency for Health Research and Quality (AHRQ) – has advised that this prohibition should not preclude a hospital from using PSWP for ***internal*** corrective measures, possibly even measures that would be deemed "disciplinary" measures. However, a strict reading of the statute and its implementing regulations appear to belie this conclusion (as more fully discussed at section III, below), which complicates hospitals' decisions about and structures for participating in PSO activities.

This white paper will explore these issues, evaluate associated laws and cases construing these laws, and suggest how hospitals may structure their activities to facilitate PSO participation, while still meeting other important operational and legal obligations, not the least of which is medical staff peer review. Too, it will explore the interplay between the PSO protections and other privileges and/or protections that may apply to various Patient Safety Activities (PSA),[7] and will assess whether these other privileges or protections are lost if protected information is reported to the PSO.

This paper demonstrates that hospitals can develop a practical system to manage PSWP that garners more protection of hospital data than is available in the absence of participating in a PSO, and that accommodates peer review and necessary disciplinary actions without loss of critical protections.

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6 Fully defined at 42 U.S.C.299b-21(7) and 42 CFR Part 3, § 3.20.

7 Defined at 42 U.S.C. 299g-21(5) and 42 CFR Part 3, § 3.20.

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II. How Is PSWP Created?

A. First a PSES.

The hospital must first identify a PSES. Most or all of the elements of a PSES already exist in hospitals, but need to be incorporated into the hospital's PSES to use the PSWP protections. This should be done via development of policies and procedures describing what the system is designed to do – which the Act tells us must include the collection, management, or analysis of information for reporting to or by a PSO – and how it is to be implemented. These policies and procedures should[8] include provision for at least the following:

- A statement of intent, that highlights the overriding patient safety and quality improvement purposes – ideally incorporating appropriate language from the Act's own description of PSA.[9]
- A description of ***what*** the "system" encompasses – what kinds of data will be included; what kinds of activities will be conducted "within" the PSES; who will be involved in these activities, where the activities will take place, what equipment may be used, etc. This can and likely would include:
  - Data/information reporting – identification of what kinds of data will be collected and how the collection is to be accomplished;
  - Investigatory activities, if any – who can conduct these activities and what processes should be implemented and recorded;
  - Evaluative and analytical activities – again, who and a general description of how any evaluations and analyses will be conducted;
  - Conclusions and recommendations that result from the foregoing activities;
  - ***But not*** the actual corrective actions taken – these are ***not*** PSWP.
- A description of ***how*** information is to be entered into the PSES. This should include the methodology or means by which information enters the system, and ***must*** assure that the date of entry is recorded (or that it be deemed to occur on a date-specific, as described in the implementing policies and procedures).
  - The date of entry is critical to establishing PSWP, so it is important that this be systematically recorded and retained at the time and point of entry into the PSES.
- A description of ***what, when, and how*** information will be reported on to the PSO. Here it is important to recognize:
  - So long as it is intended to be reported, information need not actually be reported to the PSO to garner its characterization as PSWP (and the concomitant protections);
  - In theory, information can stay within the hospital's PSES indefinitely so long as there is, at the time of entry, an intent to ultimately report it to the PSO (but see discussion [at IIIA, below] of the importance of good faith intent and activity to support this lingering status);

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[8] The comments to the final rule clarify that a documented PSES is not required, but is strongly recommended. 73 Federal Register 70731, at 70738.

[9] 42 U.S.C. § 299b-21; 42 C.F.R. § 3.20.

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- Information can be removed from the PSES (and thereby be de-designated as PSWP) at any time before it is reported to the PSO. This is an important feature that, properly managed, can enhance the usefulness of a hospital's PSES and its participation in PSA (as more fully discussed below).

Given just the above parameters, it should be relatively straightforward to create policies and systems, including supportive computer systems, programs and protocols to facilitate and support transmission of information to and use of the information within a hospital's PSES. Moreover, the dilemma that grows from some of the restrictive provisions of the Act – namely how to use needed information for other purposes, such as reporting, peer review, and possibly disciplinary and/or personnel actions – is still relatively manageable so long as the information has not yet left the hospital and been reported on to either the PSO or some other agency. Thus, it would appear that a hospital can enter information into its PSES, and conduct various investigations and evaluations as part of its PSES, and still enjoy all of the protections of the Act (and, as discussed at section IV, below, other applicable protections, such as Evidence Code section 1157 protection from discovery). If at any time the hospital determines the information is needed for other purposes, yet-unreported (to the PSO) PSWP can be removed from the hospital's PSES, de-designated as PSWP, and used as needed for the alternative purposes.

B. Determining What Is (and Is not) PSWP.

One challenge posed by the Act and its regulations is determining what is and is not PSWP. The key features of the definition are:

(i)

- ***Any*** [information]
- Assembled or developed ***for reporting*** to a PSO ***and are reported*** to a PSO;
- ***and*** which could result in improved patient safety, health care quality, or health care outcomes

or

(ii)

- which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

So far, so good. This is a broad definition, and importantly, PSWP characterization (with attendant protections) is not limited to medical staff quality assurance and peer review activities. Patient Safety Activities can encompass and protect PSWP associated with a wide variety of activities so long as it is assembled or developed with the intent to report to the PSO, and enjoys the important nexus with patient safety, health care quality, or health care outcomes.

Just as importantly, however, certain information cannot be PSWP, and the wording of the statute is equally broad:

- ○ A patient's medical record, billing and discharge information, or "***any other original*** patient or ***provider record***"; ***or***

- Information that is "collected, maintained, or developed separately, or exists separately, from" a PSES.

This description of what cannot be PSWP is perplexing. The phrasing "any other original…provider record" is so broad that if read literally would seem to swallow the rule altogether. That is, if one were to assume that ***every record*** has an origin somewhere, the wording would suggest that the original of any record in the hospital (including a record created solely for PSO reporting – e.g., a completed original of the common format reporting form) could not be PSWP. But assuming no such absurd result was actually intended, nor would it be imposed by a court,[10] the key to interpreting this seems to be to not necessarily equate "document" or "data entry" with the "original …record" described in the definition, and to assume that, for purposes of the Act, "original…record" refers to that subset of documentation that is the original contemporaneous recording(s) of the event(s) or occurrence(s) that is (are) the subject matter of the report to the PSO. Indeed, the final rule slightly modifies the definition, consistent with this interpretation:

> Patient safety work product does not include….any other original patient or provider ***information***; …

The second portion of the PSWP exclusion is also somewhat problematic: What comprises information that is "collected, maintained, or developed separately, or exists separately"? More to the point, how can a hospital otherwise use the information that would or might be PSWP? Must they run parallel data collection and evaluation activities – one within a PSES and another outside of it? Assuming all hospitals have preexisting systems, policies, and protocols for collecting, maintaining, and developing data and information for quality improvement purposes, the PSO-participation possibilities include:

- Maintaining current systems intact, creating a separate PSES, and preparing distinct reports and conducting distinct activities in each;
- Drawing distinctions among current systems, so to bring at least some current quality improvement activities within the PSES but leaving some activities outside of the PSES;
- Designating all current quality improvement activities as part of the PSES; or
- Variations of any of the above models might include creation of more than one PSES within a hospital – e.g., a PSES that is managed by the medical staff and relating to medical staff quality improvement activities; and one or more others managed by other contingents of the hospital.

The structure that is ultimately established will affect how information is collected, maintained, developed, or exists, for purposes of completing the definition of what is ***not*** PSWP. While some hospitals may opt for the ostensibly conservative approach of concurrent and discrete systems, both the first and second options present some challenges that border on "information schizophrenia," and may necessitate more careful documentation of what is and is not PSWP to assure that the hospital does not wrongfully use or disclose PSWP.

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[10] See, e.g., *Lundgren v. Deukmejian* (1988), 45 Cal.3d 727 (literal meaning of words of a statute may be disregarded to avoid absurd results or to give effect to manifest purposes, that, in light of statute's legislative history, appear from its provisions considered as a whole).

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On the other hand, the possibilities for completely restructuring to encompass all quality improvement within one or more PSES(s) merits exploration as perhaps the easiest of the models to implement. (See Implementation discussion below and Diagram 1.)

One further comment about the notion of multiple PSESs within a hospital – a concept that is not addressed in the Act or the final rule (nor is there any apparent prohibition to such a structure). If a PSES is established for ***management*** by the medical staff, this must be done with the recognition and acknowledgment that this is still under the auspices of and merely a component part of the ***hospital's*** overall PSES activities. Most medical staffs are not themselves "providers"[11] as defined in the Act, and would not independently qualify for PSO participation.

III. IMPLEMENTATION

Once the hospital does sort out how it will structure its own PSES – including what will and will not be ***assembled or developed for the purpose of PSO reporting*** – it then needs to implement its program.

A. Deciding What and When to Enter Information into the PSES.

While there are several possible approaches to deciding what information to enter into a PSES, as well as when to enter it, a straightforward approach is to ***promptly*** (i.e., initially) enter ***all*** information that is potentially PSWP (i.e., information that could result in improved patient safety, health care quality, or health care outcomes) into the PSES. Once it is entered into the PSES, all of the Act's protections immediately attach. And, while there are constraints on how that information can be used so long as it is PSWP, until it is actually reported to the PSO, the hospital has complete control of its options. If the information is required ***for*** other ***purposes that are inconsistent with its status as PSWP*** (e.g., to fulfill a reporting obligation, or to be used in a peer review proceeding), it can be de-designated as PSWP and used as necessary.

Very important to this approach is the fact that information can remain within a PSES and keep its PSWP designation (with attendant protections) for an indefinite period. Thus, where information is inconclusive as to whether it might or will be needed for other purposes, the hospital can either defer reporting to the PSO until the hospital decides it either does not need it for other uses (in which case it can then report it to the PSO and lock in the PSWP characterization), or that it does need it for other (inconsistent) uses, in which case it can "remove" it from its PSES, thereby de-designating it as PSWP and use it as needed. One note of caution, however: Clearly there needs to be a ***bona fide*** intent at the outset to ultimately report information to the PSO. Harboring information indefinitely may call into question whether the PSES is actually being used for PSA, or whether it's simply a strategy to protect otherwise vulnerable information. For this reason, policies and procedures that call for periodic assessment and criteria for determining whether information should be released to the PSO would be important indicia of good faith intent.

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[11] An exception to this might be a medical staff that is formed as a professional corporation – a proposition that this author is not advocating, and that has many repercussions beyond the scope of this paper.

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Other important features of this approach include the fact that most of the "concurrent" uses that hospitals might have for their PSWP – e.g., quality assessment and improvement – ***are*** consistent with the purposes of a PSES (i.e., these are activities that could result in improved patient safety, health care quality, or health care outcomes), and can be conducted as part of the hospital's PSES activities (as further discussed in Section III,E, below). Also of note, it does not appear that all information used in the conduct of PSA is or must be PSWP.

B. "Entering" Information into the Hospital's PSES.

Information designated as PSWP should be clearly "entered" into the hospital's PSES. In most cases, this will occur by way of a written or verbal communication delivered to an identified individual(s) or body, or by a computer entry that records or reports a particular occurrence (e.g., an incident report). The hospital's policy should delineate when the "entry" occurs.

The final rule requires that there be an identifiable date upon which the information is entered into the PSES. This is because, so long as information is "in" the hospital's PSES, it is presumed to be PSWP even though it may not yet have been reported to the PSO.[12] This entry date could be established by filling in a particular field on a document, and/or by policy that deems the entry date to be the date that the PSES is first notified of or otherwise generates the applicable information. In either case, this needs to be contemporaneously recorded and discernable.

C. Conducting Patient Safety Activities *within* the Hospital's PSES.

Once PSWP is "in" the hospital's PSES, the hospital can conduct its own Patient Safety Activities – which include, in pertinent part:[13]

> "…the following activities carried out **by …a provider**:
> (1) Efforts to improve patient safety and quality of health care delivery;
> (2) The collection and analysis of patient safety work product;
> (3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
> (4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
> …."

In light of these very general and very broad descriptions, one can readily envision how a hospital might restructure its pre-existing quality improvement activities to bring at least a significant portion (if not the majority) of them into a PSES, rather than run them alongside a PSES. Indeed, it would appear that the only significant activities that could not be successfully restructured to fit within a hospital's PSES are the external reporting requirements and

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[12] 73 Federal Register 70731, at 70798.

[13] *Id.*

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disciplinary uses – in particular medical professional disciplinary uses, as discussed at III,E, below.

Also of note, there is nothing in the foregoing that would suggest that the only information that can be used for PSA is PSWP. It appears that a hospital could conduct a wide range of internal quality improvement activities (all but medical disciplinary actions), using information that may or may not be PSWP (i.e., intended to be reported to a PSO), and further supports a decision to reorganize existing systems to bring the majority of these quality improvement activities within a PSES structure.

D. Using PSWP Outside of the PSES.

Since ***within*** the hospital, PSWP ***can*** be used for non-PSES purposes (so long as those uses do not involve reportable disciplines (see III,E, below), a hospital that chooses to maintain parallel quality improvement systems can still use PSWP in the conduct of its routine quality improvement activities. This is possible because the confidentiality provisions of the Act only apply to prevent "disclosure," and disclosure, by definition, requires dissemination to "another legally separate entity or natural person, other than a workforce member of, or a health care provider holding privileges with, the entity holding the patient safety work product…."[14] This may however, require more careful attention to when and whether to report information to a PSO because once the information is reported to the PSO, the hospital loses ***some*** potential uses for that information – i.e., it cannot use the information for discipline or to fulfill external reporting obligations (except maybe pursuant to an authorized disclosure, as discussed at V,B, below). Close coordination of PSO reporting and possible unpermitted uses of PSES (e.g., for medical discipline) will be essential to compliance with the Act.

Hospitals that maintain discrete PSO and quality improvement functions must therefore decide whether parallel activities and information collection will be conducted or whether information will be shared between both activities. If the latter, it will also need to determine whether information will be entered into the PSES by exception, once the regular QI function has been fulfilled, or whether it will first enter the PSES, then be removed by exception as needed for other uses.

The main point here is that hospitals retain significant discretion how to structure any PSES, and how to use information, including PSWP, both within and outside of the PSES. However, the more independent the activities, the more need for good communications and systems to assure that the PSES does not prematurely report to the PSO, and that the non-PSES quality improvement (QI) activities do not misuse PSWP information. Again, defining the PSES as broadly as possible simplifies the situation.

E. How Can PSWP Information Be Used for Individual Disciplinary Actions?

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[14] 42 C.F.R. 3.20.

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A dilemma for hospitals is: How can information that the hospital might otherwise want to designate as PSWP be used to support individual peer review/disciplinary action, in the case of medical staff members, or personnel action, in the case of other hospital personnel? This challenge arises because of the language of the Act that:

> "…patient safety work product shall be privileged and shall not be –
> . . .
> (5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.[15]

Apparently interpreting the foregoing language as referring only to an entity ***outside*** the hospital, the AHRQ has attempted to clarify, both in the preamble to the final rule, and via non-regulatory communications, that this provision does not prevent an in-hospital peer review body from ***itself*** using PSWP for internal discipline:

> *Comment:* One commenter asked if permissible disclosures of patient safety work product for patient safety activities…could include disclosures for credentialing, disciplinary, and peer review purposes.
>
> *Response:* … as explained above, uses of patient safety work product within a legal entity are not regulated and thus, patient safety work product may be used within an entity for any purpose, including those described by the commenter, so long as such use does not run afoul of the statutory prohibition on a provider taking and adverse employment action against an individual based on the fact that the individual in good faith reported information either to the provider with the intention of having the information reported to a PSO or directly to a PSO.[16]

1. Medical Staff Peer Review.

One cannot help but question whether this interpretation would pass judicial muster in California. For one thing, the commentary focuses on whether or not use in the hospital's own peer review constitutes a "disclosure," (which according to the definition of disclosure,[17] it does not), and not on the more explicit prohibition on use of the PSWP for purposes of being "admitted in a professional disciplinary proceeding of a professional disciplinary body, established or specifically authorized under State law."[18] The more pertinent inquiry would seem to be: Is a medical staff peer review proceeding a proceeding of a "professional disciplinary body….specifically authorized under State law"? It is difficult to

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15 42 U.S.C. 299b-22(a)(5).

16 73 Federal Register, at 70779.

17 See footnote 16.

18 This same line of reasoning can be employed in exploring the possibility that a medical staff member might "authorize" use of PSWP in medical staff peer review, thereby qualifying for the exception to the privilege described at 42 CFR §§ 3.204(b)(3) and 3.206(b)(3). While one might question why a physician would voluntarily consent to use of PSWP in peer review, the fact is that the hospital can proceed with peer review and information that either has never been designated as PSWP or that has been de-designated as PSWP, in which case it also does not enjoy the added protections applicable to PSWP. A physician might decide that he/she is better off (e.g., in a third-party lawsuit) with this information garnering more protection from discovery and admissibility (especially if the third party action is in federal court) than he/she might otherwise be if the information is de-designated, used against him/her, and more available to litigants and regulators. However, this approach is significantly complicated by the Medical Board reporting requirements described above.

conceive how a California medical staff peer review proceeding, required and conducted pursuant to Business and Professions Code sections 809 *et seq*., would not cross this threshold.

Added to this, once an in-hospital peer review proceeding has been completed, adverse medical disciplinary actions must be reported to the Medical Board of California, and the Medical Board thereafter has a right to receive copies of all of the evidence presented in the hearing. Armed with this information, the Medical Board may thereafter initiate its own disciplinary actions. With this statutory reporting obligation, hospitals do not have the option of conducting an insular peer review proceeding that cannot serve as the basis for subsequent disciplinary action by some other peer review body or government agency.

But, as suggested above, it is certainly possible to retain all PSWP that is potentially needed for peer review in the hospital's PSES (or within a PSES that is managed by the medical staff) until such time as a decision is made either: that the information is not and will not be needed for a reportable medical disciplinary action (in which case it can be reported on to the PSO) or that it is needed for such action (in which case it is "removed" from the PSES, thereby de-designated as PSWP, and available for other uses). Moreover, it is still possible to report this same de-designated information to the PSO as non-PSWP (thereby enabling the PSO to incorporate the information into its data base and studies, and possibly resulting in better information and feedback for the hospital), quite arguably without loss of other protections that would apply to this information whether the hospital is participating in a PSO or not. (See discussion at Section IV, below, regarding effect of reporting on other available privileges and protections.)

As a "footnote" to this general discussion, in addition to the commentary above about internal uses of PSWP, AHRQ staff have suggested there may be meaningful range of non-"disciplinary" actions that would not cross the "professional disciplinary" threshold described in the Act. In California, we currently have less discretion in this arena, as many of the "lesser" remedial actions (such as restrictive proctoring imposed for medical disciplinary reasons) must be reported to the Medical Board and thereby trigger a professional disciplinary proceeding.[19]

2. Other Personnel Actions

Relying on the fact that the Act does not limit a hospital's internal uses of PSES, it appears that other personnel actions, including disciplinary actions that are not conducted by a "professional disciplinary body" or do not require reporting to a professional disciplinary body or other agency, can be conducted using PSWP (so long as such actions are not retaliatory for an individual's PSO-reporting activities).[20]

Of course, it is possible that any such personnel action might later be challenged by the employee, and that the hospital would need to access this information to defend the challenge. Thus, even though the Act appears to permit the internal disciplinary action using PSWP, a more prudent approach would seem to be to handle the matter similarly to the approach

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[19] Enactment of pending legislation (SB 632) calling for "voluntary remediation" may create more leeway, in consonance with the purposes of Act.

[20] 42 U.S.C.S. § 299b-22(c).

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used for medical staff disciplinary actions – i.e., to first de-designate it as PSWP so that it is available for all potential uses. Alternatively, the hospital could retain the information as PSWP, use it for internal employee discipline, but not report it to the PSO until the statute of limitations has run, or some other disposition is achieved that assures that the hospital will not need the information for other purposes.

IV. What Privileges/Protections Are at Issue?

A. PSO Protections – What Are They and When Do They Apply?

The Act's protection of PSWP is substantial. It is:

- Privileged – meaning it is not:
    - Subject to federal, state, local, or tribal civil, criminal, or administrative **subpoena**;
    - Subject to federal, state, local, or tribal civil, criminal, or administrative **discovery**;
    - Subject to Freedom of Information Act (or similar federal state, local, or tribal law) **disclosure**;
    - **Admissible** as evidence in any federal, state, local, or tribal civil, criminal, or administrative rulemaking or adjudicatory proceeding; or
    - **Admissible** in any professional disciplinary proceeding of a professional disciplinary body established or authorized under State law.
- Confidential – meaning it may not be "disclosed," unless an applicable exception applies.[21]

These protections are significantly broader than the protections afforded by state peer review laws (see IV,B, below), but they are not absolute. There are exceptions to both the privilege and the confidentiality protections – most notably: an exception that would permit access and possible use in criminal proceedings ***if*** a court determines, after in-camera review, that the PSWP contains evidence of a criminal act, PSWP is material to the proceeding, ***and*** the information is not reasonably available from another source; and a series of other permitted disclosures (to facilitate equitable relief for reporters, as authorized by named providers, for patient safety activities, or of nonidentifiable PSWP). However, PSWP disclosed under any of these exceptions remains privileged and confidential, except for PSWP disclosed as evidence of a criminal act (in which case privilege is retained but confidentiality is not).

The rule clarifies that these protections attach as soon as, and so long as information is designated PSWP. Thus, the minute it enters a hospital's PSES, the protections apply, and they remain there until and unless the hospital de-designates it as PSWP and removes it from its

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[21] "Disclosure" is defined at 42 CFR § 3.20, and clearly excludes (*ergo* permits) internal uses of the PSWP.

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PSES.[22] This is a key reason a hospital should consider immediately entering all potentially-reportable (to the PSO) information into its PSES, and then assessing whether other potential (incompatible) needs for the information compel its removal for alternative use. While it is possible this approach could result in nothing more than a "touch and go landing" of some PSWP within a PSES, it is the approach that seems most efficient if one assumes that most information will not need to be removed from the PSES – especially if the hospital designates all its internal quality improvement functions as part of the PSES. It does need, however, to be carefully managed, as the removal option only applies so long as the hospital has not yet reported the information – ***as PSWP*** – to the PSO,[23] and is accomplished by documenting the act and date of removal of the information from the PSES.[24]

Of note, nothing stops the hospital from de-designating the information, reporting it to the PSO as ***non***-PSWP, and relying solely on other possible protections, as discussed at IV,B, below. Moreover, any other available protections can be fortified by de-identifying provider-specific information that might be reported in this manner. When considering this option, the hospital can take some comfort in the fact that deliberations on and decisions as to whether or not to report information to the PSO is itself deemed to be PSWP – and this particular portion of the definition is ***not*** tied to reporting of PSWP, rather it is tied only to reporting (of any information) to another PSES (i.e., the PSO's PSES).[25]

In sum, even though information might be needed for purposes that necessitate it being removed from a PSES and de-designated as PSWP, the hospital retains discretion to report it – or not – to the PSO. Quite possibly, too, other available protections remain intact.

B. Evidence Code Section 1157 – To What Does It Apply, and Is It Subject to Waiver?

California Evidence Code section 1157 provides the most commonly relied upon protection of medical staff peer review records. However, it does have its limitations – namely it only applies to protect the records of medical staff peer review committees; it does not protect information from administrative subpoena; it may not apply in criminal cases (where "discovery" is not the means by which records are accessed); and it may not apply in federal cases (where the Federal Rules of Evidence are applied and a court may decide not to apply state law protections and/or to recognize a common law privilege [such as the privilege of self-critical analysis]).[26]

Many hospitals do conduct their hospital-wide quality assurance activities under the auspices of one or more medical staff committees – not only to try to avail of Evidence Code section 1157 protections, but also in response to the various regulatory and accreditation requirements imposing on the medical staff responsibility to oversee the quality of care in the

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22 42 C.F.R. § 3.20 (definition of Patient Safety Work Product, paragraph (1)(i)(A)).

23 *Id*¸ at paragraph (2)(ii).

24 *Id*, at paragraph (2)(ii)(B).

25 *Id*, at paragraph (1)(ii).

26 F.R.E. 501 instructs: "Except as otherwise provided by Constitution or Act of Congress… [the court is] to be governed by the principles of the common law as they may be interpreted by the courts of the United States in light of reason and experience." In the Ninth Circuit, the privilege of self-critical analysis has not been applied to protect medical staff peer review. *Burrows v. Redbud Community Hospital District*, 187 FRD 606 (9th Circ. 1998) [depublished]. See also, *Teasdale v. Marin General Hospital,* 138 F.R.D. 691 (1991) (USDC No. Cal).

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hospital.[27] And, as described above (see Section III,E), it does appear to be possible to conduct all but the medical-disciplinary aspects of medical staff peer review within the confines of a PSES – thereby expanding upon the potential protections available to shield these activities.

But there will be circumstances where a hospital does have to either not enter information, or remove information from its PSES, so that it can be used to discipline a member of the medical staff. This likelihood leads to the question whether this automatically places all of this information off-limits for reporting to the PSO, or whether it is possible and advisable to report it to the PSO, without claiming that the information is PSWP. The primary considerations in making this determination are:

- Is there a potential benefit to the hospital, or if not specifically the hospital, then to the healthcare system that, in the hospital's assessment, weighs in favor of reporting, whether the information is protected as PSWP or not?

- Does reporting to the PSO "waive" or otherwise negate 1157 protection?

If the answer to the first question is no, then the inquiry would likely stop there, and no report should be made. But assuming the hospital anticipates some potential benefit from contributing its information to the PSO pool of information, and subjecting that information to what one would hope would be a richer analysis of potential issues and actions to improve health care, then the next assessment needs to be whether reporting to the PSO waives or negates 1157 protection. Quite arguably, it does not.

Evidence Code section 1157 is not a "privilege" under Division 8 of the Evidence Code, and thus is not subject to waiver by disclosure under Section 912 of the Evidence Code. Rather, Evidence Code section 1157 appears in Division 9 of the Evidence Code, which division describes "evidence affected or excluded by extrinsic policies." As repeatedly confirmed by the California courts, these provisions are not "waived" by disclosure. Nonetheless, the question remains whether such information, in the possession of another entity (i.e., the PSO), retains its protection. The following cases are of particular relevance:

- In 1974, the California Court of Appeal, in *Matchett v. Superior Court,*[28] clarified that:

> Literally, section 1157 establishes an immunity from discovery but not an evidentiary privilege in the sense that medical staff records are excluded from evidence.[29]

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27 22 C.C.R. § 70703(a): "Each hospital shall have an organized medical staff responsible to the governing body for the adequacy and quality of the medical care rendered to patients in the hospital." 42 C.F.R. 482.22: "The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital." The Joint Commission standard LD.01.05.01: "The organized medical staff oversees the quality of care, treatment and services provided by those individuals with clinical privileges."

28 40 Cal.App. 3d 623 (1974).

29 *Id*¸ at p. 629.

More importantly, the court concluded that the information remains protected whether it is in the custody of the peer review body or not. In that case, the information at issue was asserted to be in possession of the hospital administrator. The court directed the lower court to reconsider a plaintiff's motion to compel discovery of the administrator's files, but clearly excepted from this order files of medical staff committees that may have been in possession of the administrator.[30]

- In 1978, the Court of Appeal considered whether introduction of a peer review committee record in an administrative mandamus proceeding constituted a waiver or otherwise caused loss of the protection. *Henry Mayo Newhall Hospital v. Superior Court.*[31] Once again, the court found there was no waiver, concluding that allowing the hospital to file the transcript in the mandamus proceeding was consistent with the purposes of the statute, and hence did not comprise a waiver.[32] (This consistency with the purposes of the statute is a very helpful argument in the context of PSO reporting.)

- The 2000 decision in *Fox v. Kramer*[33] conveys the California Supreme Court's affirmation of the protection, notwithstanding that the records had been provided to the California Department of Health Services (DHS) as part of a DHS investigation of the health facility. The DHS' records were subpoenaed, and DHS resisted the subpoena, claiming that both Evidence Code section 1157 and Evidence Code section 1040 applied. The Court concluded that the hospital's records did not lose their 1157 protection when reviewed by the DHS investigator, *and* that records made of that disclosure by the investigator were likewise protected.[34] Interestingly, the Court went on to analyze and conclude that Evidence Code section 1040 also applied.[35] (This is analytically confusing because 1040 *is* in the "Privilege" chapter of the Evidence Code, and clearly applies to "privileged" communications.) However, this appears to have been a cumulative basis for denying the plaintiff's access to the DHS record, and not a necessary component to the outcome.

While it must be noted that each of these cases involve circumstances where the report outside of the peer review committee appeared to be part of an otherwise required function of the hospital (i.e., reporting peer review information to the hospital administrator is an essential element of keeping the hospital board informed, as otherwise required by law; entering peer review information into an administrative mandamus record was essential to the full play-out of a peer review proceeding; and allowing access to the DHS was required by other applicable law), there is every reason to believe that a court would conclude that a peer review record in the custody of another body (the PSO) that is created to further quality improvement activities (a wholly consonant purpose) would likewise remain infused with the 1157 protection.

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30 *Id,* at pp. 631-632.

31 81 Cal.App. 3d 626.

32 *Id*, at p. 635.

33 22 Cal. 4th 531.

34 *Id*, at p.

35 *Id*, at p. 542.

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The Act itself provides:

> A patient safety organization ***shall not be compelled to disclose*** information collected or developed under this part [42 U.S.C.S. §§ 299b-21 *et seq*.] ***whether or not such information is patient safety work product*** unless such information is identified, is not patient safety work product, and is not reasonably available from another source[36]

– and

> Nothing in this section shall be construed – (1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections .… [or] (4) to limit the authority of any provider, patient safety organization, or other entity to enter into a contract requiring greater confidentiality[37] or delegating authority to make a disclosure or use in accordance with this section.[38]

While it is not possible to say with certainty that these provisions would compel a reviewing court to recognize 1157 protection as to non-PSWP documents held by the PSO, the building blocks are certainly in place for that to happen. Until it does, however, de-identification of any non-PSWP that may be provided to the PSO would seem prudent. Additionally, any information that the hospital wants to protect under 1157 should be clearly identified as such when and if it is reported to the PSO.

C. Attorney-Client Privilege.

Attorney-Client privilege intersects these issues in a variety of ways. Attorneys' communications with their clients relating to quality, peer review, and compliance issues are frequently imbedded in the records that may also be of interest to the PSO. The attorney-client privilege[39] is, however, subject to waiver if the privilege-holder voluntarily discloses a significant part of the communication or otherwise consents to the disclosure.[40] For this reason, attorney-client communications should not be provided to the PSO unless there has been an affirmative determination that the hospital intends to waive attorney-client privilege.

This generic discussion of the attorney-client privilege takes on even more relevance in the context of hospital incident reports. Some hospitals have constructed their incident reporting system under the auspices of attorney-client privilege – with the incident report being prepared for the ostensible purpose of alerting the hospital attorney of potential legal claims, and

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36 42 U.S.C § 299b-22(d)(4) (emphasis added).

37 The CHPSO Participating Hospital Contract obligates CHPSO to maintain confidentiality, to assert all available protections, and to cooperate with the hospital in the event records are subpoenaed.

38 42 U.S.C. § 299b-22(g).

39 Evidence Code § 950 *et seq*.

40 Evidence Code § 912.

contemporaneously documenting (again for the attorney's potential use in evaluating and/or defending potential claims) surrounding facts and circumstances.

Properly implemented, this can be very effective. However, it must be kept in mind that any communications to others who are not essential to the consultation with the attorney can cause a waiver of the privilege, and this applies even to communications "within" a PSES. For example, communications for the general purpose of quality improvement or patient safety, and not intended for or necessary to the attorney-client consultation would likely result in a waiver of the attorney-client privilege.

That said, discussions with counsel as to the advisability of reporting certain information to the PSES would be an appropriate attorney-client communication that may be both attorney-client and PSWP privileged (because PSWP includes communications "which identify or constitute the deliberations or analysis of…reporting to a [PSO],"[41] yet these particular communications are not required to be assembled for the purpose of reporting them on to the PSO).

In sum, transmitting an incident report to the PSO would result in waiver of any attendant attorney-client privilege, in which case only the PSWP privilege would apply. However, as noted above, if these are also maintained as medical staff committee records (as many are), then 1157 protection would arguably still apply, as 1157 is not subject to the same rules of waiver. Moreover, communications with counsel as to the advisability of reporting, would enjoy attorney-client privilege, so long as that is not itself reported on to the PSO; would enjoy PSWP protection whether or not reported to the PSO; and may well retain 1157 protection, as also discussed above.

V. GENERAL DISCUSSION

Hospitals participating in PSOs can do so via discrete PSO-focused document collection and PSWP reporting systems, or they can reorganize existing systems to minimize the need for parallel activities. Either way, the principles are the same:

- Information that could result in improved patient safety, health care quality, or health care outcomes, is collected and entered into the hospital's PSES, and once it is so entered and assuming a bona fide intent to report it to the PSO, the information is protected as PSWP, whether or not it is actually reported.

- Hospitals can use PSWP for ***internal*** purposes, including quality improvement activities.

- If the information is needed to fulfill ***external*** obligations (such as event reporting), it must be not entered into the PSES as PSWP from the outset; or if already entered, it must be removed from the PSES and de-designated as PSWP in order to be used for other purposes.

41 42 C.F.R. § 3.20 (definition of PSWP).

- Similarly, if information is or may be needed for certain peer review obligations (in particular, those entailing reportable medical disciplinary actions), either it must be excluded from the PSES as PSWP from the outset; or it must be removed from the PSES and de-designated as PSWP in order to be used for medical disciplinary peer review.

- Until information is reported to the PSO, information can be designated and de-designated as PSWP, at the hospital's option.

- The hospital's PSA can use both PSWP and non-PSWP.

- A hospital could maintain more than one PSES, including a medical staff PSES.

- Once PSWP is reported to the PSO, all privileges and confidentiality protections lock in.

- These privileges and protections are in addition to all existing protections and privileges of state law.

- A hospital can report non-PSWP to the PSO, and the Act itself does not cause loss of any other applicable privileges or protections. Reporting ***privileged*** information will cause a waiver of the privilege. It is not yet known whether the existing protection of 1157 would apply to the PSO (although strong arguments can be made that the protection will remain intact).

- Whether or not 1157 can be asserted by the PSO to successfully protect a hospital's peer review records, a PSO cannot be compelled to produce information that is not "identified" or that is available from another source.

With these fundamentals in mind, consider the following specific scenarios.

A. A Medication Error Results in Serious Disability.

Evidence of the error is recorded in the patient's medical chart, as well as in the pharmacy ordering and dispensing records. An incident report is prepared (for purposes of further discussion, we will assume this incident report is maintained as part of the hospital's QI system, and is not restricted as an attorney-client communication). An Adverse Event report to the California Department of Public Health is required, and only documentation of some of the reportable facts and circumstances appear in the incident report. The error was the result of the attending physician writing an ambiguous order that was not clarified by the nurse. It was the first occurrence of this kind for this physician.

The original medical and pharmacy records will never become PSWP. As to the incident report and subsequent evaluative activities, it will depend on which structure the hospital implements, as illustrated below.

1. Hospital's PSES has been reorganized to encompass all QI activities; potentially reportable information is immediately entered into the PSES.

Under this scenario, the incident report would, upon delivery to the appropriate hospital individuals (whether by hand delivery of a paper report, or by inputting information via computerized reporting system), take on its character as PSWP. Hospital officials, in their capacity as Patient Safety Work Force,[42] would evaluate the information and could determine that some or all of the incident report must be removed from the PSES to enable reporting to the State. However, as an alternative to relying on the incident report as their information source, they would also have the option of going directly to the individual(s) who completed the incident report(s) and interviewing them, and using the information from the interview to complete the Adverse Event report. Doing the latter, they could maintain the PSWP protection afforded the incident report.

If the hospital has brought medical staff peer review activities within the purview of a PSES, then further evaluation of the incident could occur, using the PSWP within the PSES. If the medical staff concludes that the single incident is not sufficient to discipline, but that close tracking and trending is called for, they could retain the information in the PSES and defer reporting to the PSO. (Alternatively, if they felt there was value to prompt reporting to the PSO, but that it still might be necessary to be able to use the information for later medical-disciplinary purposes, it could remove the information from the PSES/PSWP characterization, and retain it simply as 1157-protected information. It could then elect to report the information to the PSO as non-PSWP, perhaps de-identifying it to help assure it could not be compelled to be disclosed by the PSO in the event a court were to decline to apply 1157 non-discovery rules.)

As for possible discipline against the nurse who did not bother to clarify the order, in theory this can be done, using PSWP as needed, without having to remove it from the PSES and de-designate it. This is because this is an internal use, and does not have to be reported to any external agency. (However, if the hospital felt there might be need to use this information for some external use – e.g., if the nurse might be expected to sue for wrongful termination or discrimination, then it would want to remove the information from the PSES prior to reporting it to the PSO, so that it would be available for entry into evidence in defense of that litigation.)

This approach has the benefit of permitting needed internal uses of the information as part of routine PSA, achieving maximum possible protection of PSWP at the earliest possible time, yet retaining discretion to de-designate the PSWP and use it for other purposes as needed – whether to meet the Adverse Event reporting obligation, or to use in medical disciplinary action when and if the need arises, or for any other anticipated purposes.

2. Hospital maintains discrete PSES and other QI functions.

Under this scenario, it still is possible to immediately enter information into the PSES, and then remove it; or it is possible to defer entry into the PSES until it has been determined that other uses are not needed. While this latter approach appears to be the more conservative approach – in that it entails an affirmatively reasoned decision whether to maintain each bit of information inside or outside of the PSES – it also appears to be the more cumbersome of the models, in that it does entail a level of duality that (depending on what types of information the hospital decides to enter into its PSES) may be more difficult to manage.

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[42] See definition of "Workforce" at 42 C.F.R. § 3,20.

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B. A Root Cause Analysis Is Conducted on the Above Event.

The commentary to the final rule states, "Providers must fulfill external reporting obligations with information that is not patient safety work product."[43] According to this instruction, if the hospital prepares the root cause analysis (RCA) and forwards that to another entity pursuant to external reporting ***obligations,*** that same RCA cannot be PSWP. Thus, it must either have been prepared outside of the hospital's PSES, or if prepared as a PSES activity, then it must be removed from the PSES and de-designated as PSWP (prior to its having been reported to the PSO) in order to file the mandatory report with another entity.

However, there is provision in the final rule for ***voluntary disclosure*** of the RCA to an accrediting body so long as any identified provider agrees to the disclosure or the provider's identifiers are removed.[44] In theory, agreed-upon disclosures could be accomplished as a matter of form by including such an authorization[45] in a physician's application for medical staff membership; or with respect to hospital employees who are providers,[46] via authorization signed at the time of employment.

Moreover, despite the above-referenced commentary that obligatory reporting must use non-PSWP, it would also appear that an RCA that is PSWP could be reported to other entities, such as the State Department of Public Health, even pursuant to obligatory reporting requirements, so long as any identified providers specifically authorize the disclosure.

Additionally, there is provision for disclosure of nonidentifiable PSWP.[47] Nonidentification is accomplished via documented application of generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, or by removal of not only the direct identifiers described in Section 3.206(b)(iv)(A), but also all geographic identifiers, dates, and any other unique identifying number, characteristic, or code (except as permitted for re-identification).[48] Nonidentifiable PSWP is no longer privileged or confidential, and is no longer subject to regulation.[49]

VI. CONCLUSION

The Patient Safety Act and the final rule adopted pursuant to the Act provide substantial opportunities for hospitals to enhance their patient safety activities. They also provide significant protections, beyond those available to hospitals that do not participate in PSO reporting. While there is some uncertainty about how these activities interface with other obligations of the hospital, the bottom line remains that the goals of improved patient safety and

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43 73 Federal Register 70739.

44 42 C.F.R. § 3.206(b)(8).

45 An authorized disclosure must: (a) be in writing and signed by the provider; (b) contain sufficient detail to fairly inform the provider of the nature and scope of the disclosures being authorized; and must be retained for six years from the date of the disclosure. 42 C.F.R. § 3.206(b)(3).

46 Provider is defined at 42 C.F.R. § 3.20, and includes licensed health care entities and licensed health care providers, as more specifically delineated in the definition.

47 42 C.F.R. § 3.206(5).

48 42 C.F.R. § 3.212.

49 42 C.F.R. § 3.208(b)(2).

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quality should outweigh the adjustments needed in peer review and mandatory reporting activities. In evaluating the options, a hospital must keep in mind that the difficult issues discussed in this white paper do not apply to the vast majority of information that would be involved in PSO reporting. Carefully structured PSES policies and procedures, properly infused with a "just culture" persona, can stimulate productive quality improvement and peer review activities, can accommodate the infrequent need for inconsonant uses of some of the information, can result in significantly enhanced protections for a much broader range of information without significant additional burden on the organization, and ultimately should result in significantly enhanced healthcare delivery systems.

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