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New Federal Opinion Is a Wake-Up Call for Hospitals and Systems

Would you ride in a car without a seat belt? Would you drive without auto insurance? It would be foolhardy – and perhaps dangerous – not to protect yourself by taking those simple steps. The same is true about hospitals and health systems that are not taking advantage of the protection for peer review information and quality data that is available under the Patient Safety and Quality Improvement Act of 2005 ("PSQIA"). They are needlessly placing themselves at risk!

A recent federal district court opinion from Kentucky – a state with no state peer review protection to speak of – illustrates why **EVERY** hospital and health system should form or participate in a Patient Safety Organization as outlined in the PSQIA, regardless of the protection that might be afforded under its state peer review statutes. **Tinal v. Norton Healthcare, Inc.**, Civil Action No. 3:11-CV-295-S (W. Ky. May 7, 2014). In states where the peer review privilege is weak or non-existent – Kentucky, Florida, and New Jersey, for example – it is almost impossible to have an effective peer review or quality improvement process because doctors fear that anything that is documented will be discovered. But even strong state peer review statutes may provide **NO** protection in federal civil rights or employment discrimination suits – exactly the claims that have been burgeoning as hospitals and health systems employ more physicians. The PSQIA does.

The *Tinal* opinion, one of the first federal decisions to interpret the PSQIA in the context of a hospital protecting quality and peer review information, involved a discovery dispute in a lawsuit brought by a pharmacist alleging that the defendant health system unlawfully terminated her employment in violation of the Americans with Disabilities Act. The health system contended that the pharmacist was terminated because she made a series of errors in dispensing medications.

Because the plaintiff had to prove she was treated differently than other similarly-situated employees, she sought root cause analyses and records involving errors of other pharmacists as well as her own in order "to show that other Norton employees, pharmacists and pharmacy staff, made drug-related errors comparable to those that allegedly led to her discharge, but were not themselves terminated from employment."

"In other words," explained the court, "Tinal hopes to prove that not only were similarly-situated employees treated less harshly than she was due to her disability, but also that the true cause or 'root cause' of the errors Norton attributes to her were actually inadequate hospital procedures for dispensing medication, rather than her own error."

Patient Safety Work Product Privilege

Norton refused to produce the requested documents, claiming that they were privileged as "patient safety work product" under the PSQIA. A magistrate judge ordered Norton to produce a privilege log, listing each of the documents that it was withholding, along with a general description of the contents of the privileged documents. It also ordered Norton to produce the documents so the judge could review them. Norton produced a privilege log listing 84 documents. Seventy-seven of the

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UPCOMING AUDIO CONFERENCES

Grand Rounds 2014 Series
First Tuesday of Every Month

How Little Is Too Little? Credentialing Low-Volume Providers
July 1

Informed Consent – Practical Questions and Answers
August 5

EMTALA & ED Call – What's Hot Now?
September 2

New Federal Opinion (cont.)

documents were listed as medication event reports. The form on which the reports were submitted was described, but the content of each individual report was not. The description included the following sentence: "The unique information with each report is not generally described within this privilege log because the factual relevancy of the event is not an element for the Patient Safety Work Product privilege."

The plaintiff objected that without descriptions of each of the documents, she could not "meaningfully discuss the reasons why the policy of broad discovery in federal civil rights actions such as her own outweighs the underlying policy of the PSQIA – an Act intended by Congress to address patient safety improvement in the context of potential claims of medical malpractice." She also claimed that the "patient safety work product privilege… does not apply to her employment discrimination case given the legislative history of the PSQIA and the well-established policy in favor of complete discovery in federal civil rights and discrimination cases."

Norton argued that "so long as [it] processed the information at issue as part of a patient safety evaluation system (PSES) for report to a patient safety organization (PSO), and the information itself falls within the designation of patient safety work product… then the information is confidential and absolutely protected." Norton further argued that because the language of the PSQIA is plain and unambiguous, there was no reason, and would be improper, for the court to construe its meaning by examining the common law meaning of its terms or referring to the PSQIA's legislative history.

PSQIA Applies Across the Board

The court acknowledged that every single point made by plaintiff was correct:

- The scope of discovery in federal civil rights litigation is intended to be broad.
- The policy of broad discovery has been relied upon by many federal courts to trump the privilege provided in state peer review statutes.
- The impetus behind the PSQIA was to limit medical malpractice exposure of health care providers and there is no indication in the legislative history of the Act that "Congress had in mind the possibility that the patient safety work product privilege would ever be asserted in the context of a federal civil rights action."

Nonetheless, the court held that the documents at issue were privileged. It agreed with Norton that the language of the PSQIA "speaks in plain, unequivocal terms that encompass all federal, state or local civil or criminal proceedings" and that "nowhere in the…language is there any limitation or exception for federal civil rights or employment discrimination cases."

The court continued: "The…portion of the statute…on confidentiality is likewise unambiguous in its plain language. Patient safety work product is to be treated as being confidential and is not to be disclosed 'notwithstanding any other provision of federal, state or local law.'" (There are two limited exceptions in the statute which were not applicable here.)

The court concluded: "In the absence of any explicit exception to the plain language [of the Act] for federal civil rights actions, it is clear to the Court that the privilege created for patient safety work product is intended to apply across-the-board to all other types of claims. We certainly have no authority through the means of statutory construction to judicially create any exception that Congress did not provide for in the language of the statute. … [W]e are required by [United States Supreme Court decisions regarding statutory construction], along with the plain language of the statute, to hold that the patient safety work product privilege applies to Tinal's ADA and other claims against Norton."

Quoting the Sixth Circuit Court of Appeals that "[t]he judiciary is not 'licensed to attempt to soften the clear import of Congress's chosen words whenever a court believes those words lead to a harsh result,'" the court here concluded: "We have no authority to go behind the plain meaning of the statute even though its application in the present case places substantial obstacles in Tinal's efforts to discover the potential disparate treatment of other similarly situated Norton pharmacy employees."

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Requested Documents Were "Patient Safety Work Product"

Having determined that the confidentiality provisions of the PSQIA apply in a federal discrimination lawsuit, the court then looked at whether the documents Norton claimed were privileged met the statutory definition of patient safety work product. (See the relevant statutory definitions in the accompanying box.) Based on its own examination of the documents at issue and affidavits filed by Norton, the court held that the documents "met the statutory prerequisites for the protection of the patient safety work product privilege in their entirety."

The court wrote: "Norton undisputedly is a healthcare provider…which instituted a reporting tracking process for patient safety information beginning in January 1, 2009, as part of a patient safety evaluation system (PSES)…The documents included with the privilege log for the Court's review were reported by Norton to a listed PSO on various dates as part of its PSES. The various columns of information set forth in Norton's privilege log contain information sufficient to establish that the documents at issue satisfy the statutory definition of patient safety work product….There is no indication from the court's *in camera* review that any of the otherwise qualifying patient safety work product was voluntarily removed by Norton from its PSES prior to being reported to the PSO so as to lose its privilege status. Also, none of the responsive documents provided to the Court along with the privilege log appears to include a patient medical record, billing or discharge information or other original patient or provider records not eligible for treatment as patient safety work product."

The court continued: "... [Norton] further advises that the patient safety information found in the contested documents does not exist separately from Norton's PSES nor was it publicly disclosed or reported. It therefore appears to the Court that the conditions for application of the statutory privilege for patient safety work product have been met as to all of the documents now being withheld based on a claim of such privilege. The Court accordingly concludes that, first, the patient safety work product privilege applies outside the context of malpractice litigation given the plain language of the statute, and second, the documents being withheld satisfy the statutory criteria to be considered privileged patient safety work product protected from discovery or admission at trial."

Relevance Is Irrelevant

The final question facing the court was whether the general description Norton provided in its privilege log met the rules of federal civil procedure requiring a description of "the nature of the documents…not produced or disclosed…in a manner that, without revealing information itself privileged…will enable other parties to assess the claim." The plaintiff claimed that Norton violated this rule and that the generic description provided by Norton "prevents her from assessing the relevance of the withheld documents in relation to the elements of the ADA claims."

Whether the documents were relevant to her ADA claim was not the issue, however. The issue was whether the generic description provided enough information to determine whether the statutory elements of the patient safety work product privilege were satisfied. The court found that it did, stating:

"…[T]he question is whether the withheld documents contain patient safety information gathered as part of a PSES and reported by the provider to its PSO without being previously removed from the PSES or otherwise disclosed apart from the PSES. The privilege log provided by Norton is sufficient to permit Tinal to evaluate whether the statutory elements are met. The fact that it provides her no opportunity for weighing the relevance of any particular document, while obviously disappointing to Tinal, is not determinative."

Don't Delay – Get a PSO TODAY!

It's surprising that more hospitals and health systems haven't taken advantage of the confidentiality and privilege protections offered under the PSQIA. Perhaps there was confusion about what information can be protected or how information that is reported to a PSO as described in the PSQIA can be used for other purposes, such as credentialing and

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The
Peer Review Clinic

2014
October 23-25
The Ritz-Carlton San Francisco

December 4-6
Marriott Marquis New York

2015
January 15-17
The Ritz-Carlton Naples

April 30-May 2
The Ritz-Carlton New Orleans (Jazz Fest Week!)

October 22-24
The Ritz-Carlton San Francisco

December 3-5
Marriott Marquis New York

New Federal Opinion (cont.)

peer review. The *Tinal* opinion demonstrates just how valuable the protection is, and now is the time for hospitals and health systems that have not yet joined or formed a PSO to do so.

The PSOs that are currently listed by HHS are available on the Agency for Healthcare Research and Quality website. Some of them are regional only and others are not established for hospitals. So, it may be more advantageous for hospitals and health systems to establish their own PSOs. It definitely provides more control over the information that is protected. This is a broad outline of the steps that would be required to do so.

Educate Board Members, Management, Administrative Staff and Physician Leaders about the protections and requirements of the PSQIA and how to utilize a PSO to take advantage of them.

Create a Task Force of management and support staff who will be the architects of the Patient Safety Evaluation System and the PSO.

Define the PSO's Mission, as required for initial certification by HHS.

Determine Information, Individuals and Committees to be included in the Patient Safety Evaluation System.

Determine Structure and Processes for the Patient Safety Evaluation System and the PSO. It is often helpful to illustrate these through detailed flowcharts.

Prepare Organizational Documents for a PSO if it is being set up as a new legal entity.

Prepare PSO Governing Body Documents outlining how members will be appointed to the governing body.

Prepare and Approve PSO Policies, including one outlining how Patient Safety Activities will be conducted, a Confidentiality Policy, Security Policy, and Patient Safety Evaluation System Policy.

Complete Certification for Initial PSO Listing by HHS.

Establish PSO Website.

Contract with Providers. ■

PSQIA Definitions

Patient Safety Activities (PSA) means

(A) Efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety work product.

(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

(D) 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.

(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

(F) The provision of appropriate security measures with respect to patient safety work product.

(G) The utilization of qualified staff.

(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

Patient Safety Evaluation System (PSES) means the collection, management, or analysis of information for reporting to or by a patient safety organization.

Patient Safety Organization (PSO) means a private or public entity or component thereof that is listed by the Secretary pursuant to [provisions in the statute.]

Patient Safety Work Product (PSWP) means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements

(i) which —

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety

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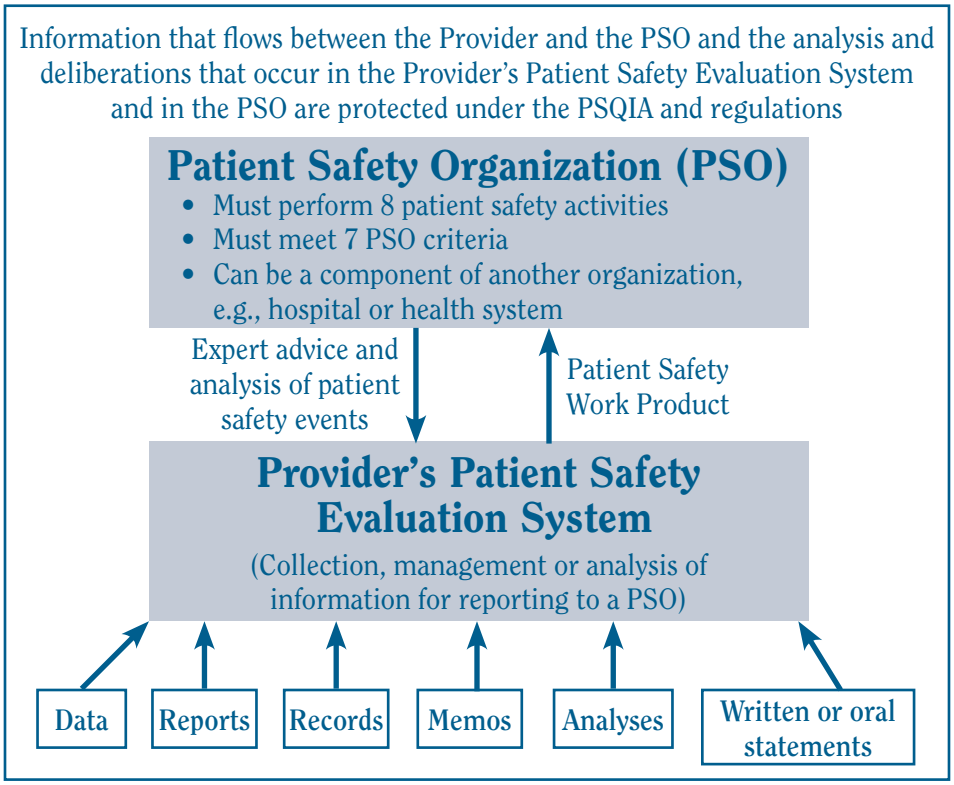
PSQIA Definitions (cont.)

organization for the conduct of patient safety activities

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 patient safety evaluation system.

Patient Safety Work Product does not include a patient's medical record, billing and discharge information, or any other original patient or provider record. It also "does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product."



Bylaws Tip of the Month: How to Roll Out New Bylaws Successfully

For the last several years, we have been providing monthly bylaws tips to help leaders identify evolving best practices. Best practices may not help much if you can't get them adopted! Change management requires planning and care. Regulatory and accreditation compliance is important, but bylaws can and should be so much more! Bylaws and companion documents create a framework for a medical staff culture of excellence and collegiality, in which the issues that will inevitably arise are addressed with the least restrictive option consistent with good care, using the concept of progressive steps. Educating the entire staff about this conceptual change is a critically important part of the process.

How have successful leaders managed comprehensive bylaws revision and approval by the medical staff?

Appoint a task force of physicians. If you have a standing Bylaws Committee, consider adding a few others to provide different perspectives. For example:

- Consider including one anticipated naysayer! While it may slow the process down, including someone who is likely to raise objections will get any potential objections out early. And, in many instances, that individual becomes one of the strongest proponents for the new bylaws because he or she feels a sense of ownership.
- Include physicians who are experienced in credentialing and peer review, including past department chiefs.
- Involving a Board member can help pave the way for better communication and trust in the future.
- One of the most important people to include is the medical staff professional for continuity, corporate memory, and subject matter expertise.
- It helps if all or most of the members of the task force have been educated in medical staff leadership, credentialing, peer review and bylaws.

Schedule a kickoff meeting, especially if you are embarking on a complete revision. Invite medical staff leadership, including the Medical Staff President/Chief of Staff, MEC, Credentials Committee, Peer Review Committee and the Bylaws Committee.

Alert the entire staff that the project is underway and invite them to participate by providing input on draft language and attending open meetings.

Involve legal counsel from the very beginning. Even if special outside counsel is used to prepare the bylaws documents, it's important for hospital in-house counsel or local general counsel to be aware of the process even if they don't have the time to attend every meeting. Involving experienced counsel will help guide the task force so that the bylaws and companion documents comply with state law, the Medicare Conditions of Participation and other legal requirements.

Assign the review of new draft language in portions of the bylaws to one or two physicians, as opposed to having the entire committee work through drafts page by page.

Use a checklist for compliance with accreditation standards. Of the four accrediting bodies, the Joint Commission has the most prescriptive requirements. A checklist or crosswalk between Joint Commission standards and the new bylaws documents can be helpful to have in hand for future Joint Commission surveys. (The other accrediting bodies allow more flexibility, but all organizations must comply with the Medicare Conditions of Participation.)

Solicit input and comments along the way. Don't wait until the last minute – the meeting at which the vote is to take place – to solicit comments and input. One person's objection at the meeting when the vote is scheduled may sway others who have not been following the process. If an objection is raised at the final meeting, it can be addressed by the Chief of Staff noting the many opportunities staff members were given to provide input and comments, thanking all of those who did submit comments, and informing the individual who raised the objection that the new amendment process will be much easier and that suggestions will be welcomed, but that the

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Bylaws Tip of the Month (cont.)

vote on the bylaws will go forward thanks to the efforts of those who did participate actively.

Open communication and transparency are critically important, but 100% agreement is not necessary. Physicians have traditionally been very respectful of each other's opportunities for expressing their views, and that should continue! Some staff members may choose not to participate actively, but they should empower those who do the work to lead. ■

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