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Getting to the truth in internal investigations

an interview with Michael Johnson
CEO, Clear Law Institute

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Compliance perspectives on the developing contours of the PSQIA

» HHS recently issued new guidance on the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and its implementing regulations to clarify the scope of protections for patient safety work product.

» Under the guidance, materials required by external obligations are not protected patient safety work product.

» It is important to protect patient safety work product from improper disclosure, due to the risk of sanctions under the PSQIA.

» Regulatory reviews and quality-of-care-based enforcement actions often seek production of quality and patient safety information and underscore the importance of PSQIA compliance.

» Implementation of strong systems can reduce the risk of improper treatment of patient safety work product.

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The Department of Health and Human Services' (HHS's) focus on incentivizing better quality patient care from providers has become well known in recent years. With the ongoing move to a health program reimbursement scheme based on quality metrics, that focus figures to be at the center of HHS's activities with providers in the years to come. But with each program HHS rolls out to incentivize providers to improve patient care comes ever greater responsibilities—and serious potential legal pitfalls that can lead to monetary penalties—for healthcare compliance personnel. HHS recently highlighted that phenomenon when it released new guidance on the implementation of patient safety and quality activities incentivized by the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and its implementing Final Rule.[1]


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The PSQIA affords healthcare providers important protections from compelled disclosure of information developed internally to further patient care improvement goals, but only if the information meets statutory requirements. HHS's latest guidance clarifies which provider information does and does not qualify for legal protections, especially in the context of other external reporting obligations.

Although there remain unanswered questions about how the PSQIA's protections will work in practice, it is clear that the PSQIA will play an important role, given the potential for increasing government scrutiny of quality of care in the regulatory, civil, and criminal enforcement contexts. As we detail further below, compliance officers looking to take advantage of the

PSQIA's incentive structure will need to have strong systems in place to empower patient safety organizations and their members.

The PSQIA was originally passed by Congress during a period of growing concerns about the rate of hospital medical errors around the country; the reaction stemmed largely from a 1999 study published by the Institute of Medicine titled "To Err is Human," which reported that tens of thousands of Americans were dying each year as a result of medical errors.[2] The goal of the PSQIA was to prevent these kinds of events by fostering voluntary reporting and analysis of adverse patient safety events. To that end, the PSQIA provides for the establishment of "patient safety organizations" (PSOs) that collect and analyze patient safety data for the purpose of improving "patient safety, healthcare quality, or healthcare outcomes."[3]

To become a PSO under the PSQIA, the applying entity must be certified by HHS's Agency for Healthcare Research and Quality (AHRQ) as compliant with a long list of requirements, including those relating to the structure and patient safety-focused mission of the PSO, the existence of policies and procedures geared toward patient safety activities, and the qualifications of the PSO workforce.[4,5] A listed PSO must be recertified every three years to maintain its status.

With the PSQIA, Congress sought to promote a system in which providers could collect and analyze data and other information to address patient safety issues and improve patient care without the fear that such information would be used against them in a future legal or regulatory proceeding. As the then-director of AHRQ explained in her testimony before the House Subcommittee on Health in June 2005:

> Healthcare professionals need to feel safe to honestly acknowledge errors or 'near misses' within the institutions in which they practice. Institutions also need to feel safe to seek help in identifying and resolving organizational and system-based threats to patient safety without retribution.[6]

Thus, in exchange for going through the rigorous activities of an official PSO, the PSQIA confers a legal privilege on the data and analysis performed by the PSO as patient safety work product (PSWP). Regardless of whether the context is a federal, state, local civil, criminal, or administrative proceeding, PSWP is statutorily immune from any subpoena or discovery requests and is not admissible in court as evidence.

In the modern environment of constant government oversight of providers, these are potentially very significant protections. As such, the government expects providers to take their PSO responsibilities seriously: The PSQIA specifies that one who "discloses identifiable patient safety work product in knowing or reckless violation [of the Act] shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation."[7] That the statute imposes penalties for "reckless" disclosures of PSWP and underscores the need for good compliance systems, both at the time the PSO is created and on an ongoing basis. Such systems are necessary both to avoid improper disclosures and to create an environment that takes very seriously the internal development and analysis of critical patient care information.

Developing robust contours around information developed for the PSO is important for another reason: the government's continuing scrutiny of healthcare quality issues for potential violations of the fraud and abuse laws, including the False Claims Act. Serious adverse events at hospitals have the potential to draw allegations that the surrounding care was so deficient as to be essentially worthless to the

government health programs paying for it. The government and private whistleblowers have also increasingly brought allegations under the False Claims Act of fraudulent quality of care in the form of alleged violations of quality-related health regulations.

The PSQIA is far from clear about what sorts of *voluntary* disclosures of PSWP are permitted to rebut such allegations of fraud on government (or commercial) payers. But in such cases, just the existence of a strong PSO, implemented by the provider in good faith with the goal of improving patient care and addressing safety issues as they arise, can be strong evidence that the provider lacked the knowledge or intent required to establish culpability.

Finally, yet another reason for developing strong PSO processes was highlighted in May 2016, when AHRQ and HHS's Office for Civil Rights (OCR) released their "Guidance Regarding Patient Safety Work Product and Providers' External Obligations."[8] The PSQIA itself is not clear about how information that is developed for reporting to the PSO but becomes subject to separate external reporting obligations can be safeguarded to avoid the penalties for outside disclosure. The Guidance clarifies how providers should approach those situations and, more broadly, offers some useful parameters regarding the scope of protection for healthcare providers' patient safety activities.

HHS's new PSWP Guidance

The primary purpose of HHS's May 2016 Guidance is to respond to providers' questions and concerns around the fact that many providers simultaneously report patient safety data and analysis to the PSO and report adverse events to mandatory state reporting systems, and to clarify that the PSQIA was never intended to prevent the latter. Indeed, the Guidance repeatedly explains that the PSQIA is not intended to limit the reporting of non-PSWP to government agencies for investigative, health oversight, or other purposes. Rather, HHS notes that the PSQIA was "intended to spur the development of *additional* information created through voluntary patient safety activities and to provide privilege and confidentiality protections for such *new* information" while maintaining accountability and transparency to external entities (emphasis in original).

Indeed, the Guidance repeatedly explains that the PSQIA is not intended to limit the reporting of non-PSWP to government agencies for investigative, health oversight, or other purposes.

Accordingly, the Guidance states that records created and/or reported under a legal requirement or other external obligation are not PSWP, but additional materials beyond those requirements are protected as PSWP, if created for the PSO. Such non-PSWP includes "original patient and provider records," such as a "patient's medical record, billing information, and discharge information," which are required to be compiled irrespective of their residency in a provider's patient safety evaluation system (PSES) created under the PSQIA. The crux of determining whether PSWP safeguards apply to provider work product is the purpose for which that work product was created, and the Guidance provides examples of documents that are and are not eligible for PSWP protection depending on their purpose. For example, according

to the Guidance, a list of provider staff present at the time of a patient incident would *not* be PSWP if it was prepared to ensure proper staffing levels or for other regulatory compliance purposes. But that same list *would* be PSWP if it was prepared for reporting to the PSO to enable the PSO to analyze the staff composition involved with that class of incidents generally.

> …the Guidance presents a useful reminder that providers need to develop strong systems to avoid improper disclosures of confidential PSWP

To further distinguish between protected and non-protected work product, the Guidance recommends that providers maintain two recordkeeping spaces: (1) a PSES for the storage of PSWP, and (2) a separate space for the storage of records for outside reporting obligations. A PSO need not maintain a third location for information whose status has yet to be determined; information that may be (but has not yet been) reported to the PSO can be maintained in the PSES. Information prepared for reporting to the PSO and stored in the PSES, but never actually reported to the PSO, may be used instead for an external reporting obligation under the "drop out" provision of the PSQIA's preamble. The Guidance makes clear, however, that if a record relates to both systems, the copy kept for external reporting reasons must be maintained regardless of the duplicate information residing in the protected PSES.

Finally, the Guidance addresses situations where information has been collected for the PSO and not for external obligations, but "where a regulator later seeks the same information as part of its oversight or investigatory responsibilities." The Guidance states that this information is still considered confidential PSWP, but the provider may still have several options to satisfy its obligation to the regulator. Specifically, the Guidance suggests that providers can (1) remove the information from the PSES if, after further review, it is deemed not to be eligible for PSWP protections; (2) determine whether one of the statutory exceptions permits disclosure, such as to the FDA or accrediting bodies, or where the identified providers give authorization for disclosure; or (3) recreate the information or analysis in question using non-PSWP materials outside of the PSES.

Compliance implications

The PSQIA affords crucial protections to provider-developed patient care information, but as the May 2016 Guidance indicates, such information is often at the crossroads of numerous different legal obligations and interests, both internal and external. The Guidance recognizes that "regulatory agencies and other entities requesting information of providers or PSOs" also must be aware that PSWP "is privileged and confidential, and it may not be used to satisfy external obligations." But the Guidance understates (if not ignores) the inherent tension when regulators or other health oversight authorities seek information pertaining to patient safety issues that was developed for the purpose of reporting to the PSO. For instance, when a licensing surveyor arrives to investigate an adverse event and requests information that is valid PSWP, the provider is put to the difficult choice between: (1) disclosing protected information, and thereby

risking being subject to administrative penalties, and (2) withholding the information, and thereby risking antagonizing the regulator. Neither the statute nor the Guidance does enough to clarify whether a provider "voluntarily" disclosing information sought by health oversight officials in such scenarios would be subject to the statutory penalties for "knowing" or "reckless" disclosures.

More broadly, however, the Guidance presents a useful reminder that providers need to develop strong systems to avoid improper disclosures of confidential PSWP while also ensuring that external requirements are met. Compliance officers striving to meet these goals should consider implementing some of the following practices.

Conduct periodic reviews of Patient Safety Organization policies and activities
AHRQ requires policies and procedures establishing the PSO framework as part of the certification process. But providers should ensure those policies clearly state the distinctions between information that is protected PSWP and information that is not, using illustrative practical examples from the providers' specific patient-safety or quality-improvement activities. PSO policies should also delineate the specific kinds of patient safety and quality improvement activities it engages in to demonstrate the provider's good faith work on patient care in investigations by health oversight authorities. These policies should also be reviewed periodically and cross-referenced against applicable reporting requirements which, as the Guidance recognizes, may change after the PSES is established.

Create distinct repositories for different kinds of patient safety-related work product
Providers should implement separate systems for maintaining materials that qualify for PSWP protections and materials that are subject to external reporting obligations. Under the Guidance, copies of reports that must be disclosed to third parties cannot be maintained solely in the PSES in an attempt to establish privilege protections. Providers should also consider limiting access to the PSES to avoid overuse.

Develop an identifying brand
To help demarcate PSWP from other materials subject to external disclosure, establish an identifying brand or stamp, to be used exclusively by PSO workforce members. Because the application of PSWP protections depends on the purpose for which the document was created, the use of such a brand is not a substitute for thoughtful designation of a document as PSWP.

Identify key members and their roles
Develop organizational charts or other materials that designate the members of the Patient Safety Organization and their individual roles, including a clear designation of PSO compliance responsibilities. Clearly identify those individuals who generate and analyze patient safety work product. This further aids in identifying protected material and ensuring appropriate personnel are entering materials into the PSES for reporting to the PSO.

Implement ongoing audits and reviews
Conduct ongoing back-end audits of the material posted to the PSES to ensure that it meets the standard for PSWP protection and to check for materials that are subject to other reporting requirements. Designated individuals who have appropriate expertise should conduct these reviews regularly. Reviewing the eligibility of materials for PSWP protections is important both to ensure appropriate execution by the PSO

workforce and to adapt to developing regulatory requirements.

Provide trainings for all relevant employees
Employees participating in patient safety and quality activities should be educated on the distinctions from the Guidance between PSWP and materials that are separately or additionally subject to external requirements. Among other key lessons from the Guidance, employees must also appreciate that compliance with separate reporting requirements must be maintained alongside PSWP processes and protections. Trainings should also have the related goal of educating employees on the distinctions between factual information, which may be subject to separate reporting obligations, and *analysis*, which can be protected as PSWP.

Conclusion

The PSQIA gives providers important protections to incentivize patient safety and quality improvement activities, especially in a time when regulatory and enforcement agencies are increasingly focused on quality issues. While the May 2016 Guidance on the PSQIA may not answer some of the most difficult questions about how the Act works in practice, it does make clear that providers need to consider carefully how their patient safety and quality systems are implemented to meet the Act's requirements and limitations. With strong internal systems and policies, providers will be well positioned to take advantage of the statutory patient safety work product framework.

1. 42 U.S.C. 299b-21-b-26;42 CFR. part 3. Patient Safety Organization Program. Available at http://bit.ly/2beZ70c
2. *Patient Safety and Quality Initiatives: Hearing Before the Subcommittee on Health of the House Committee on Energy and Commerce*, 109th Cong. 1 (2005). Available at http://bit.ly/2bD0Z73
3. Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §299b-21-b-26 (2005).
4. Idem, § 299b-24 (2005);
5. DHHS: Agency for Healthcare Research and Quality: Compliance Self-Assessment Guide. 2009. Available at http://bit.ly/2bD0Dxi
6. Ibid Ref #2, statement of Carolyn M. Clancy, Director, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.
7. Ibid Ref #3 at § 299b-22 (2005).
8. Patient Safety and Quality Improvement Act of 2005—HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations, 81 Fed. Reg. 32655. May 24, 2016.