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Compliance Today - July 2019
Collecting information to ensure patient safety work product protections

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Most healthcare providers know that the Patient Safety and Quality Improvement Act (PSQIA or the Act) created a new kind of "work product" privilege to protect providers that choose to collect and analyze information for the purpose of improving patient safety. But many organizations have failed to consider exactly how a provider should go about collecting data to ensure that sensitive materials obtain and maintain that protection. The lack of critical thought on this issue creates uncertainty in litigation and presents an unacceptable risk for the provider. The quandary typically arises after a provider has evaluated Patient Safety Work Product (PSWP) within its own Patient Safety Evaluation System (PSES) and has decided that additional investigation or data is necessary to draw conclusions. The dilemma is whether to collect such information pursuant to the "Reporting Pathway" of PSWP, which must be reported to a Patient Safety Organization (PSO) in order to enjoy the privilege, or under the "Deliberations and Analysis Pathway," which is privileged without reporting the information to a PSO. The statute reads in pertinent part:

> [T]he term 'patient safety work product' 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; … 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.[1]

In this case, the provider is forced to ask a difficult question: Can we collect additional primary data in conjunction with our internal deliberations and analysis, and can we expect that information to be protected if we do not intend to report it to a PSO?

The Patient Safety and Quality Improvement Act

In 2005, Congress passed the PSQIA in an attempt to facilitate collection and analysis of data and materials evidencing medical errors and near misses for the purpose of improving overall patient care. It did so by creating strong privilege and confidentiality protections for PSWP, a new kind of protected material that did not exist outside of the Act or its state-law corollaries. Prior to the Act, relentless litigation and heavy-handed regulation created a disincentive for physicians, clinicians, and provider representatives to speak openly and think critically about patient safety. The privilege now provides a safe space for this kind of activity, but a provider can only avail

itself of the privilege if it aligns itself with a federally listed PSO. It is also a "best practice" to document an analysis and reporting framework called a PSES. Even then, only certain materials are protected.

The privilege exists at the crossroads of two diametric interests. The first interest is the ability of the privilege holder, (assuming the privilege applies) to deny its adversary access to protected material. The second, equally compelling interest is the ability of the privilege holder's adversary to obtain relevant non-privileged information. These principles are in constant tension. Congress sought to strike a balance when enacting the PSQIA by stating that the privilege does not prohibit discovery of information and material falling outside the parameters of the statute or affect any other laws pertaining to non-privileged information.[2] Strict adherence to statutory language insulates the provider against the pendulum swinging between these powerful and legitimate interests, and that means respecting the categories of protected materials delineated by Congress. The statute's protections "do not extend backward to the underlying factual information contained within or referred to in the patient safety data reported to a PSO."[3] The medical error itself is not privileged; the Act protects analysis of the error by or for the provider in collaboration with the PSO.

The PSQIA created three distinct types of privileged PSWP, each with its own elements that must be satisfied in order for protection to attach. This article will focus on the two provider-generated categories, often described as "pathways." The first pathway, the Reporting Pathway, permits a provider to collect, assemble, and develop certain delineated material and report that material to a PSO. Importantly, all materials collected in the Reporting Pathway must either be reported or identified as materials intended to be reported and ultimately reported to a PSO, or else the privilege will not attach. The second pathway, the "Deliberations and Analysis Pathway," protects deliberations or analysis, and documents reflecting these processes, conducted within the PSES. This category also protects reports, records, memoranda, and the like "[w]hich ... identify the fact of reporting, pursuant to, a patient safety evaluation system."[4] In other words, the Deliberations Pathway protects the analysis of materials and the process of reporting. Collecting data for analysis is conspicuously absent from Congress's definition of the second pathway. The third category must be developed by a PSO conducting patient safety activities.