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## The Benefits and Burdens of Working With Patient Safety Organizations Under the Patient Safety and Quality Improvement Act of 2005

Paul E. Dwyer and Clint D. Watts

**ABSTRACT:** The Patient Safety and Quality Improvement Act of 2005 (PSQIA) established critical national-level protections to permit the honest and open evaluation of certain types of patient safety data relevant to internal systemic patient risk and quality control measures. As part of this scheme, Congress created a certification process permitting qualified professionals and entities to be designated Patient Safety Organizations (PSOs). Under specific circumstances, data accumulated and/or evaluated with or by providers and shared with a PSO can be protected by way of a powerful “work product” privilege specifically created by the PSQIA for this purpose. This article will present a top down view of the PSQIA, its strengths and weaknesses, and its role in the greater health care regulatory framework. We will discuss the policy purpose and content of the PSQIA, the types of information that are subject to the privilege, and identify a few points of departure between the PSQIA and corresponding state laws with the goal of inspiring providers to adopt a comprehensive approach to internal patient safety improvement.

Paul E. Dwyer & Clint D. Watts, *The Benefits and Burdens of Working With Patient Safety Organizations Under the Patient Safety and Quality Improvement Act of 2005*, J. HEALTH & LIFE SCI. L., Feb. 2020, at 56. © 2020 American Health Lawyers Association, [www.healthlawyers.org/journal](http://www.healthlawyers.org/journal). All rights reserved.

# The Patient Safety and Quality Improvement Act of 2005

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## INTRODUCTION

Spurred by data extrapolations suggesting that between 44,000 and 98,000 patients in American hospitals die annually due to preventable medical errors, Congress responded to critics of the American health care system—who concluded that patient safety had fallen by the wayside—by enacting the federal Patient Safety and Quality Improvement Act of 2005 (PSQIA).<sup>1</sup> Congress saw health care’s reliance upon the isolated, retrospective, and often reactionary tort and regulatory systems, both of which it characterized as “punitive,” as inefficient in improving patient safety. In an alternative approach, Congress sought to create a non-punitive learning environment where practitioners were free to report adverse events and near misses candidly without fear of litigants or regulators.<sup>2</sup> The patchwork system of state peer review statutes, which offered disparate levels of protection that covered some practitioners in some cases but not others, were viewed as simply inadequate to achieve this goal. By passing the PSQIA, Congress intended to influence systemic change by creating a culture of safety through a non-punitive voluntary reporting system and to ensure accountability by raising standards for continuous improvements in health care.

To achieve this goal, the PSQIA fashioned a “system and process . . . separate from, and parallel to, complementary State, Federal, and local laws and regulations designed to ensure accountability.”<sup>3</sup> In its most basic iteration, this system and process consists of communications between providers and Patient Safety Organizations (PSOs). “Providers” are defined as any person or entity licensed or authorized to render health care services under state law.<sup>4</sup> Congress further delegated broad authority to the Secretary of the Department of Health and Human Services to extend application of the PSQIA to other individuals and entities.<sup>5</sup> Any provider is entitled to benefit from the PSQIA’s protections.

A PSO is a certified cadre of experts evaluating raw data and suggesting systemic improvements. PSOs aggregate and evaluate information submitted by providers and give feedback and recommendations to providers, which can then be used to make

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- 1 H.R. REP. NO. 109–197, at 9 (2005), <https://www.congress.gov/109/crpt/hrpt197/CRPT-109hrpt197.pdf>; Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109–41, 119 Stat. 424 (2005), <https://www.congress.gov/109/plaws/publ41/PLAW-109publ41.pdf>; COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., National Academy Press, 2000), [https://www.ncbi.nlm.nih.gov/books/NBK225182/pdf/Bookshelf\\_NBK225182.pdf](https://www.ncbi.nlm.nih.gov/books/NBK225182/pdf/Bookshelf_NBK225182.pdf).
  - 2 Paul E. Dwyer & Clint D. Watts, *Providers Can Benefit from Patient Safety Organization Alignment*, MED. ECON., Dec. 17, 2018, <https://www.medicaleconomics.com/business/providers-can-benefit-patient-safety-organization-alignment>.
  - 3 S. REP. NO. 108–98, at 3 (2003).
  - 4 42 U.S.C. § 299b–21(8)(A)(i)–(ii) (2019).
  - 5 *Id.* § 299b–21(8)(B).

internal changes designed to improve patient safety.<sup>6</sup> The feedback provided by the PSOs to the practitioners are only recommendations, not mandates, which the health care provider is free to accept in whole or in part, modify, or reject entirely.

Critically, the system and process created by the PSQIA is secured through a new category of protected information called “Patient Safety Work Product” (PSWP).<sup>7</sup> Similar in concept to attorney work product, patient safety work product is subject to strong privilege and confidentiality protections prohibiting both compelled and voluntary disclosures, with narrow exceptions.<sup>8</sup>

Patient safety work product is broadly defined<sup>9</sup> but essentially means any information, data or report, whether in written or verbal form, which has the potential to improve patient safety, and, with few exceptions,<sup>10</sup> is transferred, whether physically,

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6 *Id.*

7 For an in-depth discussion of Patient Safety Work Product, its strengths, requirements, and limitations, see Paul E. Dwyer & Clint D. Watts, *Collecting Information to Ensure Patient Safety Work Product Protections*, COMPLIANCE TODAY, July 2019.

8 In order to preserve the PSQIA's privilege and confidentiality protections, a provider's evaluation of patient safety work product must be done within the confines of the provider's Patient Safety Evaluation System (PSES). See 42 U.S.C. § 299b–21(7)(A)(ii). A PSES is simply a network or procedure through which providers assemble, evaluate, and manage information for reporting to or by PSOs. *Id.* § 299b–21(6). A PSES is also used by a PSO to collect and evaluate information. A PSES need not be documented. While the deliberations conducted within the PSES are privileged and confidential, any newly implemented policies or procedures regarding patient safety are not.

9 *Id.* § 299b–21(7). (“Patient safety work product—(A) In General. Except as provided in subparagraph (B), the 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; or (II) are developed by a patient safety 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. (B) Clarification—(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record, (ii) Information described in subparagraph (A) 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. (iii) Nothing in this part shall be construed to limit—“(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding; (II) the reporting of information described in this subparagraph to a Federal, State or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or (III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State or local law.”)

10 *Id.* § 299b–21(7)(A)(ii). (There is no statutory or regulatory requirement that documents data and the like “which identify or constitute the deliberations or analysis of or identify the fact of reporting pursuant to, a patient safety evaluation system” need be transferred to a PSO in order to receive the statutory benefits.)

electronically, or “functionally,”<sup>11</sup> to a PSO. Neither original patient and provider records<sup>12</sup> nor “information which is collected, maintained or developed separately, or exists separately, from a patient safety evaluation system” fall within the statutory definition of patient safety work product and are therefore ineligible for protection.<sup>13</sup>

The exclusion of original patient and provider records fulfills Congress’s promise to maintain access to the evidence patients injured through professional negligence need to support their allegations. Congress’s intent has always been to ensure that the statute’s protections “do not extend backward to underlying factual information contained within or referred to in the patient safety data reported to a PSO.”<sup>14</sup> The medical error is not privileged; the analysis of it by or for the provider in collaboration with the PSO receives the statutory protections.<sup>15</sup> Plaintiffs retain the panoply of rights which they had before the passage of PSQIA.<sup>16</sup> They may obtain medical records and related original source information and continue to have the right to depose witnesses, including medical professionals, “involved in a patient’s care regarding their knowledge at the time of the alleged malpractice.”<sup>17</sup> As before PSQIA, plaintiffs must obtain this evidence through sources other than patient safety work product.<sup>18</sup>

Patient safety work product does not include “information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.”<sup>19</sup> This exclusion would seem to permit a provider to declare that it is now collecting or maintaining state-mandated reports in its patient safety evaluation system and, therefore, is no longer obligated to comply with state reporting requirements. Actually, the opposite is true. Such an interpretation ignores Congress’s further directive that nothing in the federal act is to be construed to restrict reporting or record keeping requirements contained in other federal, state, and local laws or

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11 Neither the statute nor the regulations dictate that a particular method of reporting be used. They are broadly written to permit alternative methods of reporting. *See* Patient Safety and Quality Improvement, 73 Fed. Reg. 70732, 70741 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3) (“Functional reporting” means authorizing a PSO access to specific patient safety work product with the ability to process and analyze the information “comparable to the authority a PSO would have if the information were physically transferred to the PSO”). PSOs employing functional reporting are still required to maintain adequate security control over the information to which they are granted access.

12 42 U.S.C. § 299b–21(7)(B)(i) (2019).

13 *Id.* § 299b–21(7)(B)(ii).

14 S. REP. NO. 108–196, at 5 (2003), <https://www.congress.gov/108/crpt/srpt196/CRPT-108srpt196.pdf>.

15 H.R. REP. NO. 109–197, at 15 (2005), <https://www.congress.gov/109/crpt/hrpt197/CRPT-109hrpt197.pdf>; Patient Safety and Quality Improvement, 73 Fed. Reg. at 70743.

16 H.R. REP. NO. 109–197, at 9; Patient Safety and Quality Improvement, 73 Fed. Reg. at 70732.

17 S. REP. NO. 108–196, at 8.

18 Patient Safety and Quality Improvement, 73 Fed. Reg. at 70742.

19 42 U.S.C. § 299b–21(7)(B)(iii) (2019).

regulations for public health or oversight purposes.<sup>20</sup> The subject provision is intended to preserve current state regulation and to permit continued regulation in the future. Both the legislative history and the Secretary's comments are replete with examples of state and federal regulations calling for the production of materials which might otherwise qualify as patient safety work product which survive the passage of PSQIA.<sup>21</sup> These include state and federal laws requiring production of incident reports,<sup>22</sup> adverse drug event reports to the U.S. Food and Drug Administration, licensing records for compliance with health oversight agency requirements, reports to the National Practitioner Data Bank, and various mandated Medicare reports.<sup>23</sup>

If Congress and the medical community concluded that the punitive aspects of the tort and regulatory system discouraged reporting of adverse incidents, and that PSOs offer the strongest privilege protection for adverse event reports, eschewing contracting with a PSO inherently undermines patient safety. Such a choice rewinds the clock to an era predating the insights offered in *To Err Is Human*.<sup>24</sup> It is a choice most welcomed by the plaintiffs' bar.

### **THE PSQIA'S PATIENT SAFETY WORK PRODUCT PROTECTIONS ARE BOTH BROAD AND SPECIFIC**

The PSQIA places patient safety work product beyond federal, state, or local civil, criminal, and administrative agency subpoena power.<sup>25</sup> The privilege prevents such materials from being subject to discovery in any federal, state, or local civil, criminal, or administrative proceedings, including disciplinary proceedings against a provider.<sup>26</sup> The privilege removes patient safety work product from the ambit of the Freedom of Information Act and any other similar federal, state, or local law.<sup>27</sup> It excludes materials sheltered under its umbrella from admission as evidence in any federal, state, or local civil, criminal, or administrative rulemaking or adjudicatory proceeding.<sup>28</sup> Finally, the privilege excludes patient safety work product from admission before disciplinary

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20 *Id.* § 299b-21(7)(B)(iii)(II)-(III).

21 Patient Safety and Quality Improvement, 73 Fed. Reg. at 70742-43.

22 S. REP. NO. 108-196, at 8-9.

23 Patient Safety and Quality Improvement, 73 Fed. Reg. at 70742-43.

24 COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., National Academy Press, 2000), [https://www.ncbi.nlm.nih.gov/books/NBK225182/pdf/Bookshelf\\_NBK225182.pdf](https://www.ncbi.nlm.nih.gov/books/NBK225182/pdf/Bookshelf_NBK225182.pdf).

25 42 U.S.C. § 299b-22(a)(1).

26 *Id.* § 299b-22(a)(2).

27 *Id.* § 299b-22(a)(3).

28 *Id.* § 299b-22(a)(4).

bodies existing pursuant to state law.<sup>29</sup> The confidentiality provision prohibits disclosure of patient safety work product unless the release of information falls within one of the enumerated exceptions.<sup>30</sup> Even disclosures to state agencies must fall within a permissible category.<sup>31</sup>

Once disclosed, whether permissibly or impermissibly, patient safety work product retains its privileged and confidential nature with two notable exceptions:<sup>32</sup> (i) when patient safety work product is disclosed for use in a criminal proceeding as set forth in PSQIA,<sup>33</sup> or (ii) when non-identifiable patient safety work product is disclosed.<sup>34</sup> The statute is explicit that “the privileged and confidential nature of [the disclosed] work product” continues to “apply to such work product in the possession or control of a person to whom such work product is disclosed.”<sup>35</sup> Unlike waiver of the attorney-client privilege in the litigation context where disclosure of a single communication can waive the privilege as to all communications on the same subject matter,<sup>36</sup> only the protection applicable to the work product actually disclosed is lost or limited under the PSQIA.<sup>37</sup>

### **PSOs HAVE EMERGED AS AN IMPORTANT ELEMENT OF THE HEALTH CARE SYSTEM ECOLOGY**

Patient Safety Organizations have become entrenched in the health care landscape, most notably by a regulation from the Centers for Medicare and Medicaid Services (CMS), which requires hospitals with greater than fifty beds that contract with

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29 *Id.* § 299b–22(a)(5).

30 *Id.* § 299b–22(c)(1)–(c)(2).

31 Patient Safety and Quality Improvement, 73 Fed. Reg. 70732, 70743 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3). External reporting obligations cannot be fulfilled by using patient safety work product. *Id.* at 70742.

32 42 C.F.R. § 3.208(a) (2019).

33 *Id.* § 3.208(b)(1).

34 *Id.* § 3.208(b)(2).

35 42 U.S.C. § 299b–22(d)(1).

36 XYZ Corp. v. United States (*In re* Keeper of the Records), 348 F.3d 16, 22–24 (1st Cir. 2003); *In re* von Bulow, 828 F.2d 94, 101–03 (2d Cir. 1987); Sedco Int’l, S.A. v. Cory, 683 F.2d 1201, 1206 (8th Cir. 1982); United States v. Aronoff, 466 F. Supp. 855, 862 (S.D.N.Y. 1979); State v. Von Bulow, 475 A.2d 995, 1007 (R.I. 1984); MARK S. BRODIN, WEINSTEIN’S FEDERAL EVIDENCE § 503.41(1) (2nd ed. Matthew Bender Elite Products 2010) (collecting cases).

37 42 U.S.C. § 299b–22(d)(3) (The language used in the statute actually states that the court shall not construe paragraph 42 U.S.C. § 299b–22(d)(2) as “terminating or limiting” the protections provided for in subsections (a) and (b), which suggests that the court has discretion to provide some lesser sanction for disclosures other than complete waiver.).

Qualified Health Plans<sup>38</sup> to align themselves with PSOs or meet the *reasonable exception criteria* by implementing an evidence-based initiative to improve health care quality.<sup>39</sup> Some states have permitted certain health care providers to satisfy Continuous Quality Improvement mandates by contracting with PSOs.<sup>40</sup> At least two states, New Jersey and Rhode Island, enacted their own Patient Safety Acts along the lines of the federal PSQIA.<sup>41</sup> More about these two states is discussed later in this article.

The CMS has confirmed that a hospital of more than fifty beds can satisfy its reasonable exception criteria by membership in a Quality Improvement Organization (QIO),<sup>42</sup> Hospital Engagement Network (HEN),<sup>43</sup> or through Joint Commission accreditation.<sup>44</sup> Contracting with a federally listed PSO, however, offers a provider a distinct advantage over membership in a QIO, HEN, or even by satisfying the federal mandate through the Joint Commission: the privilege and confidentiality protection that a provider can only secure through a PSO. While the Joint Commission boasts that it has secured some protection over the materials, in the same breath it encourages PSO participation.<sup>45</sup>

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38 According to Healthcare.gov, “An insurance plan that’s certified by the Health Insurance Marketplace, provides essential health benefits, follows established limits on cost-sharing (like deductibles, copayments, and out-of-pocket maximum amounts), and meets other requirements under the Affordable Care Act. All qualified health plans meet the Affordable Care Act requirement for having health coverage, known as “minimum essential coverage.” *Qualified Health Plan*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/qualified-health-plan> (last visited Jan. 22, 2020).

39 The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, § 1311(h) (2010).

40 See, e.g., N.H. REV. STAT. ANN. § 318:45-a IV. (a)(1) (2019); VA. CODE ANN. § 54.1-3434.03 (2019). Continuous Quality Improvement (CQI) programs are mandated by states requiring providers to examine certain patient safety events and develop strategies and tactics intended to avoid recurrence. Unlike the PSQIA, CQI programs tend to be event-driven.

41 N.J. REV. STAT. § 26:2H-12.23-.25 (2019); 23 R.I. GEN. LAWS § 23-17.21-1 *et seq.* (2019).

42 Quality Improvement Organizations are “group(s) of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare.” Created by directive of the Social Security Act, these groups or cohorts specialize in supporting patient safety or patient community initiatives in Medicare or Medicaid populations. *Quality Improvement Organizations*, CMS.gov, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index> (last modified June 10, 2019).

43 Hospital Engagement Networks (HENs) are associations created to facilitate the development of learning collaboratives at the national, regional, state, and hospital system level with a patient safety and quality improvement focus.

44 See generally, THE JOINT COMM’N, <https://www.jointcommission.org/> (last visited Jan. 22, 2020).

45 JOINT COMMISSION ONLINE, Oct. 5, 2016. Print copy on file with authors.

## THE PSQIA PREEMPTS LESS STRINGENT STATE LAWS

The PSQIA preempts state laws that offer protection to patient safety work product that is equal to or lesser than the federal act, including state court rules of civil procedure.<sup>46</sup> The preemptive language of the PSQIA is found within its privilege and confidentiality provisions.<sup>47</sup> Both the privilege and confidentiality provisions begin with the preamble: “Notwithstanding any other provision of Federal, State or local law,” patient safety work product is declared privileged or confidential as the case may be.<sup>48</sup> Congress declared that nothing in the PSQIA shall be interpreted as preempting any state or local law regulating information that is not patient safety work product.<sup>49</sup> This savings clause can only be viewed as a clarification because certain information is excluded from the definition of patient safety work product and the statute only extends its protection to patient safety work product.<sup>50</sup> State regulation of non-patient safety work product, including state-mandated reporting requirements, was never endangered by the PSQIA.

The PSQIA’s first rule of construction declares that nothing within the section dealing with privilege and confidentiality shall be interpreted as preempting any federal, state, or local law cloaking patient safety work product with greater privilege or confidentiality protections than the PSQIA.<sup>51</sup> The language revives state laws more protective of patient safety work product than the PSQIA.<sup>52</sup> Given that the savings clause of the Health Insurance Portability and Affordability Act (HIPAA), a related statute,<sup>53</sup> is similar to that found in the PSQIA,<sup>54</sup> courts interpreting the preemptive effect of the PSQIA will likely turn to decisions on the issue under HIPAA. Similar to the PSQIA, HIPAA regulations do not preempt any state law that imposes “more

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46 42 U.S.C. § 299b–22(g)(1) (2019).

47 *Id.* §§ 299b–22(a)–(b).

48 *Id.* The PSQIA permits voluntary disclosures of patient safety work product if those disclosures fall within one of the exceptions to the confidentiality provision found in *Id.* § 299b–22(c).

49 *Id.* § 299b–22(g)(5); *see also Id.* § 299b–22(g)(2).

50 H.R. REP. NO. 109–197, at 16–17 (2005), <https://www.congress.gov/109/crpt/hrpt197/CRPT-109hrpt197.pdf>.

51 42 U.S.C. § 299b–22(g)(1).

52 *Id.*

53 *Id.* § 299b–22(g)(3) makes clear that the HIPAA confidentiality rules remain in effect as to PSOs and providers.

54 Health Insurance Portability & Accountability Act, Pub. L. No. 104–191, 110 Stat. 1936 § 264(c)(2) provides “Preemption—A regulation promulgated [by the Secretary of Health and Human Services] shall not supersede a contrary provision of State law, if the provision of state law imposes requirements, standards or implementation specifications that are more stringent than the requirements, standards or implementation specifications imposed under the regulation.” The “more stringent” standard is further defined in associated regulations. *See* 45 C.F.R. § 160.202 (2019).

stringent” requirements than HIPAA regulations.<sup>55</sup> The HIPAA “more stringent” standard means that “laws that afford patients *more* control over their medical records” are not preempted.<sup>56</sup> That is, any state statute that fails to provide patients—*i.e.*, the persons who are ultimately entitled to control the disclosure of their own health care information—with greater ability than HIPAA regulations to restrict the release and dissemination of such information is superseded. When interpreting the preemption language and savings clauses of the PSQIA, courts likely will hold that PSQIA pre-empts state statutes and regulations that give providers and PSOs—*i.e.*, the persons and entities controlling patient safety work product—less ability to restrict the release of patient safety work product than federal law. For example, in Rhode Island, to the extent there are fewer exceptions to the state confidentiality rule (thereby giving individual practitioners greater control over patient safety work product), it may be that the Rhode Island patient safety act confidentiality provision provides greater protection for patient safety work product than does the PSQIA. If so, the state confidentiality provision would survive preemption analysis.

### THOUGHTFUL PRACTICE MEANS COMPARING ALTERNATIVE PROTECTIVE AUTHORITIES

Objections to PSO participation typically share a single unifying narrative: concern regarding the perceived administrative and economic costs of alignment. However, rules implementing the PSQIA were in fact designed by the Department of Health and Human Resources (HHS) to *ease* administrative and financial burdens. Recognizing that requiring providers to develop dual systems for collecting information that is clearly patient safety work product and other information that might be necessary to satisfy governmental reporting requirements would discourage participation, HHS permits all such information to be maintained in a single protected patient safety evaluation system.<sup>57</sup> Rules permit affiliated providers<sup>58</sup> to share patient safety work product,<sup>59</sup> and there are virtually no restrictions to the use of patient safety work product *internally within a legal entity*.<sup>60</sup> Specialized PSOs that contract with numerous health care providers can minimize financial costs while providing access to robust

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55 45 C.F.R. § 160.202 (2019).

56 *Law v. Zuckerman*, 307 F. Supp. 2d 705, 709 (D. Md. 2004) (and cases cited therein) (emphasis in original); *Allen v. Wright*, 644 S.E. 2d 814, 816–17 (Ga. 2007).

57 Patient Safety and Quality Improvement, 73 Fed. Reg. 70732, 70741–42 (Nov. 21, 2008).

58 An “Affiliate Provider” under the implementing regulations is, with respect to the provider, a legally separate parent organization of the provider, is under common ownership, management or control with the provider, or is owned, managed or controlled by the provider.

59 42 C.F.R. § 3.206(b)(4)(iii).

60 Patient Safety and Quality Improvement, 73 Fed. Reg. at 70736–37, 70779.

reporting systems and extensive data libraries.<sup>61</sup> Even smaller practitioner groups can find an affordable PSO.<sup>62</sup> These are just a few examples of how administrative and financial hurdles, which might otherwise discourage providers' participation, can be minimized under the PSQIA and its implementing rules.

Once the fears of the administrative and financial impediments are assuaged, the provider must consider whether PSO participation is superior to alternative systems. While the privilege and confidentiality protection under the PSQIA will almost always be stronger than those provided by any state act, there are exceptions. For example, the PSQIA privilege and confidentiality protections do not extend to federal or state-mandated reports.<sup>63</sup>

Many if not all jurisdictions have implemented peer review statutes, but these statutes are inherently limited by their age and narrow focus. Peer review statutes pre-date the widespread emergence of new types of health care providers. National and regional pharmacy chains and nursing clinics did not exist when most peer review statutes were enacted. Now, nursing clinics rarely fall within the protection of state peer review statutes, and pharmacies fare only slightly better. By contrast, PSQIA protections extend to virtually any health care practitioner licensed by any state.<sup>64</sup>

### **New Jersey and Rhode Island As Examples**

A few states offer exceptionally strong peer review or patient safety protections that may approach those offered by the PSQIA. The thoughtful practitioner must therefore conduct a comparison of the protections afforded by the state peer review statute, or any state patient safety act. For example, in addition to peer review protections, New Jersey and Rhode Island have passed their own patient safety legislation.

#### *New Jersey*

The New Jersey act requires health care providers to establish patient safety committees and to submit reports about serious preventable adverse events to the state's Department of Health.<sup>65</sup> Such reports would never be considered patient safety work

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61 *See id.* at 70777.

62 Paul E. Dwyer & Clint D. Watts, *Providers can benefit from patient safety organization alignment*, MED. ECON., Dec. 17, 2018, <https://www.medicaleconomics.com/business/providers-can-benefit-patient-safety-organization-alignment>.

63 42 U.S.C. § 299b-22(B) (2019); Patient Safety and Quality Improvement, 73 Fed. Reg. 70732, 70742 (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3).

64 42 U.S.C. § 299b-21(8); 42 C.F.R. 70732, 70744 (Nov. 21, 2008).

65 N.J. STAT. ANN. § 26:2H-12.25(c.) (2019).

product under the PSQIA and, therefore, would not benefit from the federal privilege or confidentiality provisions of the PSQIA. However, the New Jersey act expressly makes such reports privileged and not discoverable or admissible in court proceedings, not subject to the public records law, and unavailable for use in adverse employment actions or credentialing and licensing decisions.<sup>66</sup> New Jersey's patient safety act encourages, but does not mandate, the reporting of less significant adverse events and near misses to the state agency and extends the same privilege protection to those events.<sup>67</sup> An entity that can take advantage of the New Jersey act may rightly question whether it benefits from implementation of a safety program under the PSQIA.

### *Rhode Island*

The Rhode Island patient safety act requires a different calculation. First, the Rhode Island act involves PSOs that only service state-licensed hospitals, nursing facilities, and freestanding ambulatory surgical centers.<sup>68</sup> This is only a small subset of the health care providers who may benefit from the PSQIA. Second, the Rhode Island act has fewer voluntary exceptions to the confidentiality rule prohibiting disclosure than does the federal act and its accompanying regulations.<sup>69</sup> Because there are fewer exceptions to the confidentiality provision, the state act does give individual health care practitioners more control over the disclosure of patient safety work product than the PSQIA. In that context, the confidentiality provisions of the Rhode Island state act may survive preemption analysis.<sup>70</sup>

## CONCLUSION

While there are many ways to improve patient safety and many related statutory schemes in force from jurisdiction to jurisdiction, the protection extended by the PSQIA in the form of the patient safety work product privilege is unique in its combination of strength and breadth. Patient safety is not a one size fits all objective. System size and particularized provider needs will always require a thoughtfully tailored approach. However, that approach should necessarily include due consideration of PSO alignment in addition to other complementary protective measures. **1**

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66 *Id.*

67 *Id.* § -12.25(e.) (1).

68 23 R.I. GEN. LAWS § 23-17.21-4(g), (k) (2019); *id.* § 23-17.21-6(b).

69 *See id.* § 23-17.21-8(c) (1)-(2).

70 *Id.* § 23-17.21-8(c)(1)(B); § 23-17.21-8.

## Author Profiles



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