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Perspective

The Patient Safety and Quality Improvement Act of 2005: Provisions and Potential Opportunities

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The Patient Safety and Quality Improvement Act (Public Law 109-41) addresses the recognized problems of uneven, state-based laws that may or may not protect patient safety efforts, as well as potential gaming of the legal system by attorneys to access safety data for lawsuit purposes.¹ Furthermore, the act addresses the lack of a national strategy and standardization for patient safety efforts.¹ It also extends legal protections for safety and quality activities beyond the hospital setting. Finally, under the provisions of the act, a legal framework has been created to fully engage in patient safety activities and to adopt lessons from other industries to accelerate safety in health care. This scheme provides

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significant opportunities to promote patient safety. Below, we review the provisions of the act and discuss some opportunities created by it.

PROVISIONS

An Overview

The act creates a federal legal infrastructure protecting a provider's "patient safety work product" from nonsafety use. To avail itself or oneself of the law's protections, a provider must assemble patient safety information and work with a "Patient Safety Organization" (PSO) in a "patient safety evaluation system."

"Patient safety work product" (work product) is safety data, reports, records, and other materials (eg, root cause analyses) in oral or written form, including deliberations or analyses that are part of a provider's patient safety evaluation system. Such information must be assembled for report to the PSO or developed by a PSO to improve quality and safety in health care delivery.

A PSO is an entity registered with the Secretary of Department of Health and Human Services (DHHS) that performs activities to improve quality and safety in health care delivery. It does so by collecting and analyzing work product, developing and disseminating tools to improve patient safety (eg, recommendations, protocols, best practices), and using work product to foster a culture of safety.

A PSO also gives provider feedback and assistance to effectively minimize patient risk, maintains procedures and security measures to preserve confidentiality of work product, uses qualified staff for its activities, and performs relevant activities to operate a "patient safety evaluation system." Health insurers cannot be PSOs. Regulations are forthcoming that will define the specific requirements to become a PSO; at present, no entities have PSO designation.

A patient safety evaluation system is a provider's system of collection, management, or analysis of information for reporting between it and a PSO. The term *provider* has its customary meaning. Of great importance is that the act's protections extend to individual providers and outpatient activities—groups and settings that traditionally have been ignored in safety efforts due to state statutory protections, such as peer review privilege, being limited to hospital efforts.²

Privilege and Confidentiality

Importantly, provider work product is confidential and privileged. Legally, confidentiality is a requirement between parties within a confidential relationship that information and/or communications shall not be disclosed to anyone outside the confidential relationship. Privilege is an exemption or grant of immunity to a specified group or party from a legal mandate, such as a discovery request.

Work product cannot be disclosed; subject to a subpoena or court order; admitted as evidence in any civil, criminal, or administrative proceeding; or divulged under a Freedom of Information Act request. Furthermore, PSOs cannot be compelled to disclose information in their possession. Indeed, such protection is strong: Congress indicated that obtaining any data or information from PSOs is prohibited unless the information is deidentified, is *not* in fact work product, and is not available from any other source. More broadly, only if the information falls within some limitation or some exception can work product be disclosed by any party.

Limitations and Exceptions

There are limits to what information is protected under the act. These are focused on materials collected and created in the provider's normal course of business, other than safety data and information. Original records such as the patient's

chart, billing records, and discharge information are not considered work product. Furthermore, materials separate from the patient safety evaluation system cannot be transformed into protected work product by simply submitting them to a PSO. These provisions are similar to most state laws regarding information and rules regarding peer review privilege.³

Exceptions to the act's protections are narrow. The first is disclosure of work product for use in a criminal proceeding. The second exception is disclosure in civil proceedings adjudicating potential violation of patient safety reporter protections or retaliation against a person for reporting safety information to a PSO. Finally, work product confidentiality and privilege is waived if authorized for disclosure by all providers identified in the work product materials.

Note that even if work product is disclosed as permitted, disclosure alone does not broadly waive the privileged and confidential nature of it. Privilege and confidentiality are linked with the work product materials themselves, not the venue in which they are created or discussed. Protections continue to apply even when disclosed to another party. This is a critical provision of the law because traditionally, creation or disclosure of privileged information created and discussed in a peer review committee meeting, such as peer review information, to third parties outside that venue eliminated any privilege that protected materials might have had before disclosure.⁴

Reporter Protections

Entities cannot take any adverse employment actions against employees or others who in good faith participate in the patient safety activities contemplated by the law. This includes reporting information to a provider with the intent of having that information reported to a PSO or reporting information relating to the provider directly to the PSO. This comports with the importance of encouraging a culture of safety to improve health care delivery.⁵

POTENTIAL OPPORTUNITIES

Patient Safety Database Networks

Sharing and aggregating information is critical to improving patient safety. The act requires the DHHS

secretary to facilitate the creation and maintenance of a patient safety network of databases. Hence, the act promotes creation of an evidence-based management resource for providers, PSOs, and others supporting safety efforts. Ultimately, this database could accept, aggregate, and facilitate analysis of nonidentifiable work product voluntarily reported by PSOs, providers, and others, similar to the Aviation Safety Reporting System (ASRS). The ASRS has had great success in advancing the safety culture and safety innovation in aviation.⁴

Furthermore, again like aviation, this database could provide a valuable point of access for research in safety and organizational trends, creating a rich source of study material that will allow a much broader array of talent to study safety issues. Information from the network could be used to analyze national and regional statistics, trends, and patterns of safety and errors, which then could be published in annual quality reports.

Encouraging System Transparency

The new law has the potential to promote operational transparency for safety assessment. System transparency is a critical component in complex, high-reliability organizations and industries that have successfully achieved safety goals, such as commercial air transportation.

System transparency, which provides shared access to knowledge of the system's daily function and foibles, permits a culture that supports intellectual honesty. It creates the ability and culture to openly acknowledge system problems so they can be addressed. Previously, the fear of tort litigation was a powerful deterrent to this process within health care. Blame, shame, denial, cover-up, and shifting accountability were common because of the incentives created by potential tort litigation. Because the law protects and encourages discussions across and between providers in all settings, there is the potential to effectively encourage health care participants to report and discuss safety issues.

Encouraging Reporting

Intimately related to system transparency is reporting. The enhanced ability to safely report errors and systems issues is critical in the context of the extremely limited success of most medical reporting structures. For example, in Minnesota, hospital reporting on 27 serious events, along with a

summary of the corrections implemented by hospitals, is mandated by state law. Yet in its first year, a *total* of only 99 events were reported from all hospitals statewide.⁶

Because the act advocates, protects, and creates infrastructures for reporting, the process is encouraged and provides the opportunity for those previously reticent—but who had important insights and information—to report errors and system weaknesses. Together, the combination of a culture of transparency and increased reporting could rapidly accelerate system learning and improvement in the health care delivery system, just as the commercial aviation industry has experienced and continues to experience.

Standardization

System transparency and participant reporting are critical foundations to improving safety in complex systems. Yet if the reporting system itself is confusing, inconsistent, and expensive, transparency and willingness to report will be insufficient to effectively promote patient safety. Standardization for the reporter must be present to promote safety improvement.

The purpose of reporting systems is to accumulate information regarding the occurrence and causes of errors and system weakness to determine trends and identify areas requiring attention. However, the current amalgam deemed the health care reporting “system” has been described appropriately as a chaotic nonsystem.⁷

The Institute of Medicine (IOM) concluded that there is no universal safety nomenclature, and health care lacks standardized formats for routine monitoring of the extent to which health care is safe and effective or at least moving in that direction.⁸ Indeed, there are more than 150 private, public, and professional terminology systems currently in use.⁹⁻¹² A study commissioned by the Agency for Healthcare Research and Quality (AHRQ) noted the extensive variation and diversity in health care taxonomies, their formats, and the challenges to coordinate them all.¹³ Furthermore, each promulgating entity determines the required content of its reports, resulting in little comparable information, creating unrealistic demands on providers, and fueling avoidance of provider reporting as well as increasing costs.

As a result of this confusion, the IOM recommended a common reporting format that would serve as a common language for patient safety reporting, research, and analysis.¹¹ The act provides for such

an infrastructure; this is likely one of its most important provisions. Critically, the act mandates data standardization for aggregate patient safety databases. As such, it will provide reporters with a consistent set of components for reporting and consequently begin the creation of a body of information that will be comparable within and between providers, geographic areas, and over time. Importantly, it is likely that other systems will adopt or at least move toward this national standard because of the federal imprimatur associated with it.

The result would be that this common format could facilitate comparisons and feedback of information to providers and reduce the burden of capturing and reporting data for safety improvement purposes. Analysis and creation of useful information would therefore be enhanced on a level previously unattained in the delivery system.

Patient Safety Organizations and Information Sharing

The IOM and AHRQ identified the fragmented nature of patient safety data, reporting, and information dissemination. Facilities literally across the street from each other would have to independently learn lessons that could have been communicated had an organized system been in place for sharing information and legal barriers not chilled such discussions. Facilities also faced the burden of not having the skill set to assess safety issues.

The act, in recognition that all health care is local, provided for PSOs, which can provide both expertise in data analysis as well as patient safety information dissemination on regional levels. The needs and lessons of particular providers with specific geographic and population characteristics may be addressed and shared while also providing data in a standardized format to a national database for additional analysis and learning when relevant. Entities without in-house expertise could avail themselves of safety information while also contributing data for deeper safety analysis. Hence, through a regionally centralized as well as national aggregation of standardized information, providers can benefit from and have access to a more efficient and, it is hoped, more effective resource for safety improvement. This dual-level activity also will support the research and analysis goal of promoting safety improvement on regional

as well as national fronts through broad-based data availability.

Outpatient and Inpatient Inclusion

Much of the patient safety focus has been on the inpatient level. Yet in many instances, most care is provided in the outpatient setting. The act, through providing an infrastructure that expressly includes reporting and legal protections for safety activities in the outpatient setting, has great potential to raise awareness regarding safety there. In addition, development of tools and improvements as well as research in outpatient-inpatient interfaces, such as handoffs and other important components of care, is greatly enhanced by inclusion of both the outpatient and inpatient providers of care within the act's provisions.

SOME UNANSWERED QUESTIONS

There are unanswered questions associated with the act. For example, how will independent research projects on safety and quality be addressed? How much PSO involvement is necessary for the privilege and confidentiality protections to apply, and when must this involvement begin? Does one permitted patient safety purpose qualify data for legal protection for all purposes—including purposes such as billing or cost analyses? Does one nonpatient safety purpose vitiate all protections, even if the information is clearly related to patient safety activities?

Finally, there is the question of conflict between state and federal law. The act's provisions clearly contemplate that it should be a floor of protection, and states may strengthen its protections. But what if a state acts legislatively, resulting in direct or indirect conflict with the law, such as the Florida constitutional amendment providing patients with access to all adverse event materials?¹⁴ These issues need policy maker and provider attention for the full potential of the law to be realized in the health care delivery system.

Overall, the Patient Safety and Quality Improvement Act of 2005 has provided an unprecedented opportunity to improve health care delivery safety. Much potential exists under the act for us to do so. Our patients are relying on us to fulfill that potential.

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