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THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

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In July 2005, Congress adopted the Patient Safety and Quality Improvement Act. The Act aims to improve the quality of health care by facilitating the work of “patient safety organizations,” or PSOs, which gather and analyze data on health care quality. The Act’s major effect is to make certain data disclosed by health care providers to PSOs “privileged” and “confidential,” and therefore not subject to discovery in legal proceedings. These protections are not absolute, however, and there are important exceptions which may make this data subject to discovery. It is important for those in health-care related businesses to understand what they may and may not do with information covered by the Act.

What is a “patient safety organization”?

The Act protects health care quality data that is collected and analyzed by “patient safety organizations” or PSOs. To qualify as a PSO, an entity must do more than simply store information; it must analyze the data it possesses and make recommendations based on its analysis. A PSO must also certify to the Secretary of the Department of Health and Human Services (DHHS) that it meets certain criteria related to the gathering, protection, and analysis of patient safety data. A PSO may or may not be affiliated with one or more health care providers; those that are so affiliated are subject to more intensive government scrutiny.

What kind of information is protected?

The Act provides protection for “patient safety work product,” which is any data, reports, records, memoranda, analyses, or written or oral statements which:

- are assembled or developed by a health care provider for reporting to a PSO and are reported to a PSO; or
- are developed by a PSO for the conduct of patient safety activities and could result in improved patient safety, health care quality, or health care outcomes; or
- identify or constitute the deliberations of analysis of, or identify the fact of reporting to, a “patient safety evaluation system,” which is a system that collects, manages, or analyses information for reporting to or by a PSO.

What kind of protection does the Act offer?

The Act provides both a legal privilege and confidentiality protection. The legal privilege provides, generally, that patient safety work product is protected, at the federal, state, and local levels, and in civil, criminal, and administrative proceedings, from subpoenas or orders and from discovery, and that patient safety work product is not admissible in evidence in any such proceeding. The Act also imposes confidentiality obligations on PSOs, providers, and others in possession of patient safety work product to keep such information in confidence and not disclose it.

There are some exceptions to these protections. Most fundamentally, the protections do not apply where the providers cannot be identified from the information. Furthermore, in criminal proceedings where the patient safety work product contains evidence of a criminal act, neither the privilege nor the confidentiality protection applies. The same is true if all the providers identified agree to the disclosure. In addition, the confidentiality obligations do not apply to disclosures for certain governmental and law enforcement activities.

What are the penalties for violation?

A person who discloses patient safety work product other than pursuant to an exception is subject to a civil penalty of up to \$10,000 per violation. Injunctive relief prohibiting further use or disclosure of the information is also available to providers.

What are some likely effects of the Act?

Health care providers and patients will benefit from legal protections that facilitate the aggregation and evaluation of quality data. There are some significant problems with the Act in its current form, however.

- *Increased need for protection of information.* Tight controls over records which might fall under the Act's protections will be necessary to prevent health care providers from waiving their rights. Others that acquire such information, however, must be equally careful to protect it so as not to violate the confidentiality obligations which the Act imposes. Businesses that use information that may constitute patient safety work product governed by the Act will need to develop ways of controlling the flow of such information and adapt their existing procedures to the Act's requirements.
- *Proliferation of adverse employment actions.* The Act provides a "whistleblower" provision prohibiting retaliation against employees who make good faith reports to a PSO, or who act in good faith with the intent of having information reported to a PSO. This provision will likely increase employment litigation in the health care industry.
- *State and local reporting requirements preempted.* The Act explicitly preempts state and local laws which do not offer greater protections, or that require providers to report information to a state or local agency that is not "patient safety work product" under the Act. As a result, the Act may actually remove state and local reporting requirements as well as existing protection of certain information that had been protected when reported to a state or local agency.
- *Use of patient safety work product in defense of claims.* The Act raises the question whether health care providers may use identified patient safety work product in

bringing or defending civil or criminal actions. In its present form, the Act would require health care providers to obtain the consent of all other providers identified in the information they wish to use, which could be a daunting task. Future regulations may address this question.

The Act provides an opportunity to improve health care by encouraging the candid sharing of information regarding patient care. But it also imposes a number of significant obligations on those who use that information. Businesses that possess or use information governed by the Act must ensure that they comply with the Act's requirements. They should also monitor any regulations which the Department of Health and Human Services may promulgate to carry the Act into effect.

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