Advisory
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Final Federal Patient Safety Regulations Provide Broad Protection to Patient Safety Data

On November 21, 2008, the Department of Health and Human Services (HHS) promulgated final regulations establishing a framework to certify patient safety organizations (PSOs) under the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and prescribing the process through which voluntary reporting to PSOs on a privileged basis may occur. With the promulgation of the final regulations, which went into effect on January 19, 2009, providers can now begin to take advantage of the PSQIA's protections. The PSQIA and the final regulations apply broadly to any provider "licensed or authorized" under state law to provide health care (including any parent organization), such as hospitals, nursing homes, home health care agencies, ambulatory surgery centers, pharmacies, behavioral health providers, physician practices and individual licensed practitioners.

Health care providers historically have been reluctant to report patient safety information, such as medical errors and near misses, for quality improvement analysis because of the perceived risk that the information could be used against a provider in a civil lawsuit or otherwise to impugn a provider's reputation. The PSQIA laid the foundation for the first national voluntary patient safety reporting system, allowing health care providers to report certain patient safety information—called "patient safety work product" (PSWP)—to PSOs without fear that the information will be available to plaintiffs in civil actions or otherwise made public. By providing federal privilege and confidentiality protection to PSWP, the PSQIA aims to encourage providers to share patient safety data for quality improvement analysis in order to better understand errors and enhance the quality of patient care. For providers that choose to report PSWP to a PSO, the PSQIA regulations may provide an opportunity for greater protection to patient safety information than existing peer review or other protections under state law.

This advisory highlights the key provisions of the final PSQIA regulations and the opportunity they present to enhance the protection of sensitive patient safety information.

PSO CERTIFICATION

Any public or private entity that devotes its primary activities to improving patient safety and quality of health care delivery may become a PSO, subject to some exceptions. To become certified as a PSO, an organization must attest that it meets 15 different requirements. Among other requirements, the PSO must certify that it engages in patient safety activities, such as collecting and analyzing PSWP and developing and disseminating information to providers for the purpose of quality and safety improvement. Within 24 months of

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being certified, a PSO must enter into contracts with at least two different providers for reporting and analyzing PSWP. PSOs also must satisfy various operational requirements, such as maintaining written policies and procedures addressing the confidentiality and security of PSWP.

HHS envisioned that hospitals, health systems, and other large providers might want to create their own PSOs and thus approved the creation of "component PSOs." The final regulations define a component PSO as a PSO that is a unit or division of another legal entity, or is owned, managed, or controlled by one or more legally separate parent organizations. For example, the final regulations would permit a multi-hospital health system to establish a component PSO through a subsidiary entity; the hospitals could report privileged and confidential PSWP to the component PSO, which could analyze the data and provide the hospitals with valuable feedback concerning patient safety and quality improvement. Organizations that are certified as component PSOs must satisfy additional requirements to ensure the confidentiality of information maintained by the PSO and to address potential conflicts of interest.

The Agency for Healthcare Research and Quality (AHRQ) is responsible for overseeing the PSO certification process and has certified at least 41 PSOs to date, most of them prior to publication of the final regulations. A list of certified PSOs is available at www.pso.ahrq.gov/listing/psolist.htm.

PRIVILEGE AND CONFIDENTIALITY

Only patient safety work product (PSWP) is confidential and receives legal protection from disclosure under the PSQIA statute and regulations. This means that information that constitutes PSWP, as defined in the final regulations, may not be used against a provider in civil, criminal, or administrative proceedings, including professional disciplinary proceedings, and is not subject to a subpoena or order issued in federal, state, local, civil, criminal, administrative, or tribal cases. PSWP also is not subject to disclosure under freedom of information laws or similar federal, state, local, or tribal laws. In addition, PSOs that receive PSWP from providers may not disclose the information except as permitted by the regulations.

The types of information that may qualify as PSWP include data, reports, records, memoranda, analyses (such as root cause analyses), and written or oral statements that "could improve patient safety, health care quality, or health care outcomes." PSWP also includes information developed by a PSO for the conduct of patient safety activities. However, patient medical records, billing records, discharge information, and other original patient

records are not considered PSWP. While the proposed regulations limited the definition of PSWP to information that was collected solely for reporting to a PSO and was in fact reported to the PSO, the final regulations define PSWP more broadly to include information that, while not yet reported to a PSO, is documented by the provider as being collected or developed for reporting to a PSO. This potentially would allow, for example, a provider to treat as PSWP information gathered during a preliminary investigation of a serious adverse event, even if the information is not yet reported to a PSO.

In contrast to the proposed regulations, the final regulations also allow providers to subsequently determine that certain information should *not* be designated as PSWP subject to the PSQIA's confidentiality requirements (and corresponding sanctions for confidentiality violations), and to "de-designate" such information as PSWP. This flexibility to designate and de-designate PSWP allows a provider, for example, to protect information as PSWP while the provider considers whether the information is needed to meet state reporting requirements. The provider subsequently can de-designate information as PSWP if it determines that state reporting obligations require the information to be disclosed.

Although broad federal protection is provided to PSWP, the privilege, among other things, does not prevent:

- disclosure of PSWP if authorized by each provider identified in the PSWP;
- disclosure of non-identifiable PSWP;
- disclosure in a criminal proceeding of PSWP that contains evidence of a criminal act (provided certain requirements are met);
- disclosure of PSWP to the extent necessary to enjoin an act or practice that violates the PSQIA and to obtain other appropriate equitable relief to address such violation; or
- disclosure of PSWP in connection with HHS investigation and enforcement activities.

ENFORCEMENT

HHS granted the Office for Civil Rights (OCR) the authority to enforce the confidentiality provisions of the PSQIA regulations, including investigating complaints and resolving complaints informally. OCR also may request information or conduct inspections of PSOs—announced or unannounced—to assess or verify PSO compliance with the regulatory requirements. A knowing or reckless violation of the confidentiality provisions is punishable by civil monetary penalties of up to $10,000 per violation. Penalties may be assessed not only against an individual who commits a violation,

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but also against such individual's employer or principal. The Secretary of HHS also has the authority to revoke an entity's certification as a PSO if the Secretary determines that the PSO is not fulfilling its regulatory obligations.

Now that HHS has issued final regulations, providers have the ability to contract with or create PSOs to allow the reporting and aggregating of confidential patient safety data under a federal privilege. Providers should consider the added protections that the final regulations offer, as well as the processes and contractual relationships that will need to be established, to determine whether creating a component PSO and/or establishing a reporting relationship with a PSO under the PSQIA regulations is worthwhile.

For more information on the PSQIA regulations, contact Michelle Wilcox DeBarge at 860.297.3702 or mdebarge@wiggin.com, or Alyssa Cunningham at 860.297.3723 or acunningham@wiggin.com. Note that Wiggin and Dana plans to provide additional information on the final regulations over the next few months through subsequent advisories and educational sessions.