

# HEALTH LAW

## Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

## At Long Last – HHS Issues Proposed Rule to Implement The Patient Safety and Quality Improvement Act

March 12, 2008

On February 12, 2008, the U.S. Department of Health and Human Services ("HHS") issued a proposed rule to implement the Patient Safety and Quality Improvement Act of 2005 (the "Proposed Rule").<sup>1</sup> The Proposed Rule establishes a framework for the creation of "patient safety organizations" ("PSOs") and provides certain privilege and confidentiality protections for the "patient safety work product" ("PSWP") reported to PSOs. The Proposed Rule is, in HHS' words, intended to "provide the foundation for new, voluntary opportunities to improve the safety, quality, and outcomes of patient care".<sup>2</sup>

### **Background**

On July 29, 2005, President Bush signed the Patient Safety and Quality Improvement Act of 2005 (the "Act") in order to address medical errors within the health care system.<sup>3</sup> The Proposed Rule, with its framework for the creation of PSOs to which individuals and entities can voluntarily provide PSWP, implements the mandate of the Act. Under the Act, a provider of PSWP can be any individual who is licensed or otherwise authorized under State law to provide health care services, such as hospitals, pharmacies, physicians, nurse practitioners, certified social workers, and physical or occupational therapists. After a PSO receives PSWP, the PSO will analyze the information and provide feedback. The Act also requires that the Agency for Health Care Research and Quality ("AHRQ") create a network of databases to collect the information and distribute it throughout the country.

According to the Act, PSWP is any information in written or oral form that may result in improved patient safety, health care quality, or health care outcomes. In order for this information to be considered PSWP, the information must be gathered by a provider to be reported to a PSO and must be reported to or developed by a PSO for patient safety activities. The PSWP must be collected and retained in accordance with the Act's provisions. Pursuant to the Act, the following is **not** considered PSWP: (i) individual patient medical records; (ii) billing and discharge information, (iii) other original patient or provider records; or (iv) other information that is collected or maintained separate

<sup>1</sup> 73 Fed. Reg. 8111.

<sup>2</sup> 73 Fed. Reg. 8169.

<sup>3</sup> 42 U.S.C. §§ 299b-21, *et seq.*

from a patient safety evaluation process. Information that is not PSWP is not protected under the Act from discovery or admission in any civil, criminal, or administrative proceeding.

When information qualifies as PSWP, it is protected by the Act's privilege and confidentiality provisions. PSWP is not subject to subpoenas, discovery, or even a court order in civil, criminal or administrative proceeding, except in limited circumstances. Moreover, PSWP cannot be used as evidence in any professional disciplinary body established under state or authorized under state law or in any civil, criminal, or administrative proceeding. The Act also makes PSWP confidential unless it falls into one of many exceptions. In the event an individual knowingly or recklessly discloses PSWP in violation of the confidentiality restrictions, the Act provides a civil penalty of up to \$10,000.

### **Federal Privilege and Confidentiality Protection of Patient Safety Work Product**

The Proposed Rule sets forth the confidentiality and privilege protections for PSWP, the permitted disclosures, and the conditions under which the specific protections no longer apply. Under the Act and the Proposed Rule, the privilege and confidentiality protections attach to PSWP only, and only within the PSO framework, which excludes those materials maintained and developed for a use other than patient safety evaluation. Additionally, the Proposed Rule establishes the conditions under which a provider, PSO, or responsible person must disclose PSWP to the Secretary of HHS (the "Secretary") in the course of compliance activities, and what the Secretary may do with such information.

The Act and the Proposed Rule seek to balance provider concerns about the potential for damage from unauthorized release of PSWP regarding adverse patient care events with the goal of information sharing among providers and PSOs in order to improve patient safety and quality of care. The Act permits sharing of PSWP for certain purposes, but simultaneously attaches strict confidentiality and privilege protections for such PSWP wherever it is shared. The Proposed Rule would permit PSWP to be disclosed only if the PSWP disclosed is non-identifiable format or when an exception exists. PSWP that is disclosed to a PSO generally continues to be privileged and confidential, such that it may only be permissibly disclosed by the PSO for a purpose permitted by the Act or the Proposed Rule.

#### *Privilege Protections*

The Proposed Rule would import the Act's provisions establishing that PSWP is privileged and thus: (i) is not subject to Federal, State or local civil, criminal or administrative proceedings or orders; (ii) is not subject to disclosure under the Freedom of Information Act or similar Federal, State or local laws; and (iii) may not be admitted into evidence in any Federal, State or local civil, criminal or administrative proceeding or the proceedings of a disciplinary body established or specifically authorized under State law. However, there are several exceptions to the application of this privilege protection including: (A) disclosure of identifiable PSWP in a criminal proceeding where, *in camera*, the court determines that such information contains evidence of a criminal conduct, is material to the proceeding, and is not reasonably available from other sources; (B) disclosure of non-

identifiable PSWP; and (C) disclosure of PSWP where necessary for the Secretary to enforce the requirements of the Act and the Proposed Rule.<sup>4</sup>

Neither HHS, nor any agency of HHS can enforce the privilege protection because the extent of privilege protections is determined by the court system. Thus, the Proposed Rule does not provide for enforcement of privilege standards. However, the Proposed Rule does provide for HHS to enforce the confidentiality protections, as will be discussed next.

### *Confidentiality Protections*

The Act establishes a confidentiality protection of PSWP so long as the specific information is identifiable and has not been disclosed in a criminal proceeding, and sets forth exceptions to such protection. HHS proposes to implement the statutory exceptions with an eye to permitting disclosure in certain circumstances, rather than mandating disclosure.<sup>5</sup> As such, the exceptions give the holder of PSWP the discretionary power as to when and whether to disclose PSWP. The exceptions include:

- Criminal proceedings, where certain conditions are met;
- Disclosure for purposes of providing those reporting PSWP with equitable relief;
- Disclosure between a provider and a PSO;
- Disclosure of non-identifiable patient safety work product;
- Voluntary disclosure to an accrediting body;
- Disclosure to attorneys, accountants and other professionals for purposes of business operations; and
- Disclosure to law enforcement where the reporting person reasonably believes the information constitutes the commission of a crime.

Though HHS would permit disclosure of confidential PSWP in the above instances, HHS strongly encourages narrow and limited disclosures. In particular, HHS counsels providers "to consider the purposes of which the disclosures are made...We encourage any entity or person making a disclosure to consider the amount of PSWP that is being disclosed as well as the amount of identifiable information disclosed."<sup>6</sup> Further, HHS asks that as much identifiable information as feasible be removed, regardless of whether either the privilege or confidentiality privilege permits the information to be included. HHS also reminds providers that, to the extent such providers are also covered entities for purposes of HIPAA, such providers must ensure that any reporting or disclosure of PSWP meets the requirements of HIPAA to the extent that PSWP includes personal health information.

Where PSWP is disclosed, permissibly or impermissibly, it generally continues to be privileged and confidential (exceptions are discussed in the next section). Essentially, any entity or person who receives PSWP becomes subject to the confidentiality protections established by the Act and the

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<sup>4</sup> 73 Fed. Reg. 8141-42, 8157. Note that the Secretary may disclose PSWP to the extent necessary to enforce the Act and would even be able to use PSWP to enforce HIPAA confidentiality protections.

<sup>5</sup> 73 Fed. Reg. 8142. The only disclosure that is mandated is where the Secretary requires access to PSWP in order to enforce the Act and administer the certification of PSOs.

<sup>6</sup> 73 Fed. Reg. 8142.

Proposed Rule. Consequently, such an entity or person is subject to the accompanying restrictions on disclosure and to civil penalties for knowingly or recklessly violating the requirements.

### *Termination of Privilege and Confidentiality Protections*

There are two circumstances under which either the confidentiality or both the confidentiality and privileged protections terminate. First, where PSWP is disclosed pursuant to the exceptions related to criminal proceedings, the PSWP will continue to be privileged, but is no longer confidential. Second, where PSWP is made non-identifiable, as defined in the Proposed Rule, the information is no longer privileged or confidential.

### **Qualifying as a Patient Safety Organization**

Any entity, except a health insurance issuer or certain other entities, may request certification and listing as a PSO by submitting a completed certification form to the Secretary. The process of certification and listing of PSOs will be implemented by the AHRQ. In the Proposed Rule, HHS also proposes that any entity that conducts regulatory oversight of health care providers, such as licensure agencies or accreditation organizations, be precluded from forming a PSO. HHS seeks to foster a "culture of safety," which allowing the aforementioned entities to function as PSOs would undermine.<sup>7</sup>

As a general matter, an organization must meet the following criteria to be certified as a PSO:

- Certification that the organization has policies and procedures regarding (i) eight patient safety activities as defined in the Act, (ii) the confidentiality provisions in the Proposed Rule, and (iii) the appropriate security measures required to comply with the Proposed Rule;<sup>8</sup> and
- Certification that the organization meets the seven criteria of a PSO, which are listed in the footnote below.<sup>9</sup>

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<sup>7</sup> 73 Fed. Reg. 8127.

<sup>8</sup> See 42 USC § 299b-21(5). Patient safety activities include (A) Efforts to improve patient safety and the quality of health care delivery; (B) The collection and analysis of patient safety work product; (C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices; (D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk; (E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product; (F) The provision of appropriate security measures with respect to patient safety work product; (G) The utilization of qualified staff; and (H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

<sup>9</sup> See 73 Fed. Reg. at 8174. The seven criteria of a PSO are "(i) The mission and primary activity of a PSO must be to conduct activities that are to improve patient safety and the quality of health care delivery; (ii) The PSO must have appropriately qualified workforce members, including licensed or certified medical professionals; (iii) The PSO, within the 24-month period that begins on the date of its initial listing as a PSO, and within each sequential 24-month period thereafter, must have entered into 2 bona fide contracts, each of a reasonable period of time, each with a different provider for the purpose of receiving and reviewing patient safety work product; (iv) The PSO is not a health insurance issuer, and is not a component of a health insurance issuer; (v) The PSO must make disclosures to the Secretary as required under Sec. 3.102(d), in accordance with Sec. 3.112 of this subpart; (vi) To the extent practical and appropriate, the PSO must collect patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers; and (vii) The PSO must utilize patient

HHS anticipates that PSOs may be established by a wide array of health-related organizations including hospitals, nursing homes, and health systems, health care professional societies, academic and commercial research organizations, and governmental units. A health system with at least two providers (and therefore with at least two facilities that could contract with a PSO) could create a PSO to serve its own facilities in the effort to improve patient safety. Such "component organizations" of health systems will be discussed next.

### *Component Organizations*

A "component organization" is any entity that is either a unit of a corporate organization or a separate organization that is owned, managed, or controlled by at least one other organization.<sup>10</sup> All applicant PSOs that fall within the scope of the definition of "component organization" must certify to the separation of confidential PSWP and staff from the rest of any organization or multi-organizational enterprise of which they are a part. Component organizations must also certify that their stated mission can be accomplished without conflicting with their parent organization.

Due to the overlapping nature of the confidentiality and security requirements on component organizations, Congress has a heightened concern that there is a "need to maintain a strong 'firewall' between a component PSO and its parent organization."<sup>11</sup> In fact, HHS considered prohibiting a PSO from contracting with any affiliated provider. However, HHS ultimately chose not to impose that restriction and is instead focusing on how a component PSO will maintain its independence.

Thus, component organizations are subject to following additional criteria in order to qualify as a PSO:

- The entity maintaining the PSWP must do so separately from the rest of the organization, and establish appropriate security measures to maintain the confidentiality of the PSWP;
- The entity does not make unauthorized disclosures of PSWP to the rest of the organization in breach of confidentiality;
- The mission of the entity does not create a conflict of interest with the rest of the organization.

HHS interprets these criteria strictly to ensure that a component PSO operates independently of its parent organization. First, where a component PSO could enter arrangements involving the use of PSWP of its parent or affiliates, the component PSO retains responsibility for the security of the PSWP. Second, a component PSO would not be permitted to have a shared information system with the rest of the organization since this might give rise to unauthorized access. For example, HHS intends to prohibit a component PSO from storing any PSWP in information systems or databases to which the rest of the organization would have access or the ability to transmit a copy.<sup>12</sup> Third, the

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safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk."

<sup>10</sup> 73 Fed. Reg. 8172; *See also* 73 Fed. Reg. 8115–16. HHS also believes that recognizing a subsidiary as a component of a parent organization is consistent with a trend, in HHS's observance, that various court decisions attribute legal responsibilities based on actual behavior in organizations relationships, rather than on corporate formalities.

<sup>11</sup> 73 Fed. Reg. 8116.

<sup>12</sup> 73 Fed. Reg. 8130. Note that HHS has preliminarily concluded that most security measures, such as password protection, are too easily circumvented.

Proposed Rule provides that the workforce of the component PSO must not engage in work for the rest of the organization if such work could be informed or influenced by the individual's knowledge of identifiable PSWP. For example, while a component PSO could share accounting or administrative support staff with the parent organization (because the work of these individuals for the rest of the organization would not be informed or influenced by their knowledge of PSWP), a physician who served on a parent organization's credentialing committee could not also work for the component PSO.

### *Ongoing Requirements for PSOs*

The Proposed Rule requires PSOs to publish the disclosure statements that they complete to attain and maintain certification as a PSO in order to prevent a provider unknowingly obtaining the services of a PSO that is in fact associated with a competitor. Without that confirmation, voluntary disclosure and improved patient safety may be inhibited.

HHS intends to monitor PSOs' compliance with these criteria by conducting "spot-checks" to assess or verify PSO compliance with the requirements of the Act and the Proposed Rule.<sup>13</sup> HHS anticipates that 5-10% of PSOs will be subject to the verifications during any one calendar year. HHS justifies these verification checks on the basis that attaining certification as a PSO is relatively simple and therefore PSOs will require more policing to ensure ongoing compliance with the standards.

### **Enforcement**

HHS views the privilege and confidentiality protections as essential to encouraging providers to produce and disclose PSWP. While HHS is not authorized to prosecute breaches of the privilege protection, it is authorized to enforce the confidentiality requirements of the Act and the Proposed Rule. The enforcement program as set forth in the Proposed Rule establishes a framework to enable the Secretary to monitor and ensure compliance with the Act and Proposed Rule. The Secretary is empowered to impose a civil money penalty for breaches of confidentiality.

Any person who knowingly or recklessly discloses PSWP in violation of the confidentiality protections may be subject to civil money penalties not to exceed \$10,000 per violation. In determining the amount of any civil penalty, the Secretary will consider the following factors: the nature of the violations; the circumstances of the violation; whether the violation was beyond the control of the respondent; the respondent's compliance history with regard to the act; and the respondent's financial condition. Additionally, a provider or PSO may be held responsible for the actions of an employee or agent when such person discloses PSWP in violation of the confidentiality provisions while acting within the scope of that person's agency relationship with the provider or PSO. However, a parent organization will not necessarily be liable for the impermissible disclosure by its subsidiary PSO.

HHS will impose a penalty for each act constituting an impermissible disclosure.<sup>14</sup> However, HHS provides limited guidance as to what constitutes a single impermissible disclosure. HHS does indicate that where a disclosure is made as evidence in a proceeding or through a subpoena, a court order or any other exception to privilege, but not is made permissibly according to the terms of the

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<sup>13</sup> 73 Fed. Reg. 8139.

<sup>14</sup> 42 USC § 299b-22(f)(3).

exception, such disclosure amounts to an impermissible disclosure of that PSWP to all parties who receive the information or who have access to the PSWP admitted to the proceeding.<sup>15</sup> Therefore, such an instance of impermissible disclosure could constitute multiple violations, each subject to the civil money penalty. Note that any disclosure violating both the Act and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") shall be subject to penalties under one of the statutes, but not both.<sup>16</sup>

### **Conclusion**

In summary, the Proposed Rule is designed to implement the goals of the Act by allowing a wide array of entities to qualify as a PSO and by enforcing the privilege and confidentiality protections provided for PSWP in the Act and Proposed Rule. At the same time, a PSO is subject to a number of restrictions which limit how the PSWP can be used and how the subsidiary PSO can share staff and infrastructure with a parent organization. The Secretary will continually be monitoring whether an organization can maintain its status as a PSO.

It should also be noted that the definition of protected PSWP is narrow. The Act and the Proposed Rule will not protect materials collected for peer review, for risk management and other uses which regulate how health care professionals and facilities deliver care. Thus, while the Act and Proposed Rule create an opportunity for health care providers to improve patient safety and quality of care, the breadth of that opportunity remains limited. If you have any questions about this Health Law Update, please contact one of the attorneys in our Healthcare Industry Practice Area listed on the following page.

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<sup>15</sup> 73 Fed. Reg. 8141.

<sup>16</sup> 42 USC § 299b-22(f)(3).

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