

HEALTH LAW

Update

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

Final Rule Implementing the Patient Safety and Quality Improvement Act of 2005 Released

January 2, 2009

On November 21, 2008, the U.S. Department of Health and Human Services (“HHS”) issued a final rule implementing the Patient Safety and Quality Improvement Act of 2005 (the “Final Rule”).¹ The Final Rule, which takes effect on January 19, 2009, largely implements the proposed rule issued earlier in 2008.² This Health Law Update discusses the significant changes in the Final Rule.

Definitional Changes

HHS made several changes to the definitions of various terms used in the Final Rule. First, HHS expanded the definition of “patient safety work product” (“PSWP”). In the proposed rule, PSWP only came into existence upon the reporting of information to a patient safety organization (“PSO”).³ By leaving yet-to-be-reported information without the privilege and confidentiality protections of the Patient Safety and Quality Improvement Act of 2005 (the “Act”),⁴ HHS feared that providers would hastily and arbitrarily report information to obtain the Act’s protections.⁵ Under the Final Rule, information gains PSWP status upon its placement in a patient safety evaluation system.⁶ A provider may also remove such information from a patient safety evaluation system, thus stripping it of its status as PSWP and its privilege and confidentiality protections.⁷

¹ 73 Fed. Reg. 70732-70814.

² For a discussion of the Proposed Rule, see our prior Health Law Update, “At Long Last – HHS Issues Proposed Rule to Implement The Patient Safety and Quality Improvement Act”, available at <http://www.bassberry.com>

³ 73 Fed. Reg. 70741.

⁴ 42 U.S.C. § 299b-21 et seq.

⁵ 73 Fed. Reg. 70741, 70798.

⁶ 73 Fed. Reg. 70798. A “patient safety evaluation system” is “the collection, management, or analysis of information for reporting to or by a PSO.” *Id.*

⁷ 73 Fed. Reg. 70741, 70798.

The provider must document the placement and removal of information into a patient safety evaluation system.⁸ Failure to do so may prevent information entered into a patient safety evaluation system from obtaining the rule's privilege and confidentiality protections.⁹ Without documentation of such information's removal from a patient safety evaluation system, intent to report the information to a PSO will be presumed by HHS.¹⁰ This more expansive definition of PSWP allows providers to consider carefully what information should be reported to a PSO and lessens the likelihood of unnecessary or unhelpful reporting.¹¹

In the Final Rule, HHS also added to the types of entities excluded from becoming PSOs. The proposed rule excluded health insurers and components of health insurers. The proposed rule also excluded licensing and accrediting entities and other entities with regulatory oversight over providers. HHS retained these exclusions in the Final Rule and added two exclusions. The agents of such oversight agencies and governmental bodies to which providers must report information pursuant to law or regulation cannot become PSOs under the Final Rule.¹² Components of these excluded entities, however, may become PSOs.¹³

The Listing Process

The Final Rule revamps the requirements for initial and continued listing as a PSO. Under the Proposed Rule, HHS indicated that an entity seeking initial or continued PSO certification must certify that its policies and procedures provide for compliance with the rule's confidentiality and security provisions. As a corollary of this requirement, HHS added to the Final Rule, a requirement that PSOs must notify providers who submitted PSWP to the PSO of any security breach or unauthorized disclosure affecting the submitted PSWP.¹⁴

These certification requirements are part of a broader attestation process now enumerated in the Final Rule for initial and continued listing as a PSO. An applicant must also attest that it is not an excluded entity under the rule, that it has informed HHS whether the entity has been denied certification or been delisted by HHS previously,¹⁵ that it will notify HHS of any changes affecting the accuracy of its attestations, and that it will provide HHS with information HHS

⁸ 73 Fed. Reg. 70798.

⁹ 73 Fed. Reg. 70741.

¹⁰ *Id.*

¹¹ *Id.*

¹² 73 Fed. Reg. 70749-70750, 70799.

¹³ 73 Fed. Reg. 70799. The Final Rule defines a "component organization" as "an entity that: (1) Is a unit or division of a legal entity (including a corporation, partnership, or a Federal, State, or local or Tribal agency or organization); or (2) Is owned, managed, or controlled by one or more legally separate parent organizations." 73 Fed. Reg. 70797.

¹⁴ 73 Fed. Reg. 70753, 70799. HHS makes clear that the PSO must report such a disclosure or breach only to the provider submitting the PSWP, rather than every provider whose name may appear in the submitted PSWP. 73 Fed. Reg. 70753. Furthermore, because the Act deems PSOs to be business associates of providers for the purposes of HIPAA compliance, a PSO must also report unauthorized disclosures of protected health information to the provider and attempt to mitigate the harm caused by the disclosure. 73 Fed. Reg. 70753; *see also* 42 U.S.C. 299b-22(i).

¹⁵ This includes "whether any of its officials or senior managers held comparable positions of responsibility in an entity that was denied listing or delisted." 73 Fed. Reg. 70799.

deems necessary in considering certification.¹⁶ Component organizations have additional certification requirements, which are discussed below.

Under the proposed rule, HHS's certification requirements mandated that all component PSOs maintain a completely separate information system from their parent organizations and also prohibited the sharing of staff between parent organizations and component PSOs. HHS largely abandoned these prohibitions in the Final Rule. Now, component PSOs must simply segregate PSWP from the parent organization in a way that does not permit unauthorized access by the parent organization and also prohibit unauthorized disclosures to the parent organization.¹⁷ HHS also no longer prohibits component PSOs and their non-excluded parent organizations from sharing staff.¹⁸ Component PSOs are also required to certify that its work will not create a conflict of interest with its parent organization.¹⁹ When applying for initial or continued listing, component PSOs must supply HHS with its parent organization's contact information.²⁰

The Final Rule imposes additional requirements on component PSOs of excluded entities seeking initial or continued listing. In addition to the requirements for component PSOs discussed above, these component PSOs must provide a statement "describing its parent organization's role, and the scope of the parent organization's authority, with respect to any" of the activities that make the parent organization an excluded entity under the rule.²¹ The component PSO must publish a summary of this information in promotional materials and on its website.²² The component PSO must also attest that the parent organization's policies do not "require or induce providers to report patient safety work product to their component organization once listed as a PSO" and requires the component organization to notify HHS if any such policies are adopted.²³ Unlike an ordinary component organization, a component PSO and its excluded parent organization cannot share staff.²⁴

Component PSOs are not forbidden from all contact with their parent organizations. If the parent organization is not an excluded entity under the Final Rule, the component PSO can contract with individuals or units of the parent organization and provide them with access to PSWP "to assist the component PSO in its conduct of patient safety activities" so long as measures are in place to prevent unauthorized disclosures or the creation of conflicts of interest.²⁵ Component PSOs of excluded parent organizations can contract with individuals or units of the excluded parent organization, but only if their responsibilities are not related to activities warranting the parent organization's exclusion from becoming a PSO under the rule.²⁶

¹⁶ 73 Fed. Reg. 70798-70799.

¹⁷ 73 Fed. Reg. 70757, 70800.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ 73 Fed. Reg. 70800.

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

Collecting PSWP

Congress adopted the Act with hopes of improving quality of care through the sharing of information while alleviating providers' fears of liability for disclosing certain information.²⁷ This program, however, will only be useful if providers and PSOs speak the same language. Thus, HHS requires a PSO at initial and continued listing to certify that it will collect PSWP "in a standardized manner that permits valid comparisons of similar cases among similar providers."²⁸

HHS incorporated into the Final Rule a new provision aimed at ensuring this standardization occurs. A PSO has three options: (1) use the common formats and definitions developed by the Agency for Healthcare Research and Quality ("AHRQ"), (2) use alternative formats and definitions that will facilitate the consistency of comparisons envisioned by the rule, and (3) explain to HHS why complying with either of these options "is not practical or appropriate . . . at this time."²⁹ Upon a PSO's application for continued listing, the PSO is deemed to be in compliance with the rule under the first option. In the alternative, the PSO must "satisfactorily demonstrate" the applicability of either of the two remaining options to remain in compliance with the rule.³⁰

Enforcement

HHS adopted the enforcement provisions of the Proposed Rule without significant modification. In the Final Rule, however, HHS provided for an expedited delisting process. In adopting this process, HHS recognized that "there may be situations in which a PSO's conduct is so egregious that the Secretary's acceptance of the PSO's certification should be revoked without the opportunity to cure because there is no meaningful cure."³¹ Notably, HHS also makes clear in the Final Rule that it may require the disclosure of PSWP to investigate compliance with the HIPAA Privacy Rule, as many PSOs will fall under the purview of both the Final Rule and the HIPAA Privacy Rule.³²

Conclusion

The framework outlined in the Final Rule will ensure that entities seeking to become PSOs can be and will remain effective agents in the promotion of a "culture of safety."³³ PSOs will not be funded by the federal government. However, HHS expects that contracting providers will ultimately determine their worth in helping to build a culture of quality improvement and

²⁷ See 73 Fed. Reg. 70732.

²⁸ 73 Fed. Reg. 70799.

²⁹ *Id.*

³⁰ 73 Fed. Reg. 70799-70800.

³¹ 73 Fed. Reg. 70768. HHS provides an opportunity to correct deficiencies and expects most deficiencies to be resolved in this process. *Id.* But in the following circumstances, HHS may not be so lenient: "(i) The PSO is not in compliance with this Part because it is or is about to become an [excluded entity]; (ii) The parent organization of the PSO is an [excluded entity] and requires or induces health care providers to report patient safety work product to its component PSO; or (iii) [The PSO is not abiding by its certifications] and the Secretary has determined that there would be serious adverse consequences if the PSO were to remain listed." 73 Fed. Reg. 70804.

³² 73 Fed. Reg. 70771-70772, 70785, 70787.

³³ 42 U.S.C. § 299b-21.

safety.³⁴ If you have any questions about any of the topics covered in this Health Law Update, please contact one of the attorneys in our Healthcare Industry Practice listed below.

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³⁴ 73 Fed. Reg. 70746.