

Delimiting Providers and Affiliated Providers under the Patient Safety Act

The Patient Safety and Quality Improvement Act of 2005 (“**PSQIA**” also known as the “**Patient Safety Act**”)¹ created Patient Safety Organizations (“**PSOs**”). PSOs contract with Providers to collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery from the participating Providers and their Affiliated Providers to identify common issues, trends, patterns, and opportunities for change among the PSO participants. This document serves as a guide for delineating a Provider and an Affiliated Provider.

Definitions

The PSQIA and the PSQIA’s implementing regulations (i.e., the Patient Safety Rule) defined the term “Provider”² to include three categories of healthcare providers:

- (1) An individual or entity³ licensed or otherwise authorized under State law to provide health care services, including—
 - (i) A hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office (includes a group practice), long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or
 - (ii) A physician, physician assistant, registered nurse, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner;

- (2) Agencies, organizations, and individuals within Federal, State, local, or Tribal governments that deliver health care, organizations engaged as contractors by the Federal, State, local, or Tribal governments to deliver health care, and individual health care practitioners employed or engaged as contractors by the Federal, State, local, or Tribal governments to deliver health care;⁴ or

¹ Pub. L. No. 109-41, 119 Stat. 424 (codified as amended at 42 U.S.C. §§ 299b-21 to 299b-26).

² 42 C.F.R. § 3.20.

³ Entity means “any organization or organizational unit, regardless of whether the organization is public, private, for-profit, or not-for-profit.” 42 C.F.R. § 3.20.

⁴ HHS (The U.S. Department of Health and Human Services) added this second category of entities to the Provider definition “because public health care entities and their staff are not always authorized or licensed by state law to provide their services and, therefore, might not be included within” the first category of entities. 73 F.R. 70744 (Nov. 21, 2008).

- (3) A parent organization⁵ of one or more entities described in paragraph (1)(i) of this definition or a federal, state, local, or tribal government unit that manages or controls one or more entities described in paragraphs (1)(i) or (2) of this definition.⁶

The Patient Safety Rule also defines “Affiliated Providers.”⁷ A Provider can have “Affiliated Providers” and qualify as an “Affiliated Provider.” An individual or entity is an “Affiliated Provider” with respect to a Provider (referred to herein as “**Provider A**”) if the individual or entity (referred to herein as “**Provider B**”) meets three requirements⁸:

- (1) Provider B is itself a Provider;
- (2) Provider B is legally separate from Provider A; and
- (3) Provider B is the parent organization of Provider A; is under common ownership, management, or control with Provider A; or is owned, managed, or controlled by Provider A.

Purpose of the Affiliated Provider

The term “Affiliated Provider” was not included in the statutory language of the PSQIA. The U.S. Department of Health and Human Services (“**HHS**”) provided for a “Affiliated Provider” in the Patient Safety Rule, “to identify to whom patient safety work product [“PSWP”] may be disclosed pursuant to 42 C.F.R. § 3.206(b)(4)(iii).”⁹ Section 3.206(b)(4)(iii) of the Patient Safety Rule allows a Provider to disclose PSWP to an Affiliated Provider¹⁰ for Patient Safety Activities.¹¹

⁵ “Parent Organization” means an organization that a) owns a controlling interest or a majority interest in a component organization, b) has the authority to control or manage agenda setting, project management, or day-to-day operations, or c) the authority to review and override decisions of a component organization. 42 C.F.R. § 3.20.

⁶ HHS added this third category “intend[ing] to permit the parent organization of a health care provider system to enter a system-wide contract with a PSO” because “[t]he parent of a health system also may not be licensed or authorized by state law to provide health care services as required by the statutory definition.” 73 F.R. 70744 (Nov. 21, 2008).

⁷ 42 C.F.R. § 3.20.

⁸ “*Affiliated provider* means, with respect to a provider, a legally separate provider that is the parent organization of the provider, is under common ownership, management, or control with the provider, or is owned, managed, or controlled by the provider.” 42 C.F.R. § 3.20.

⁹ *Guides for PSOs and Providers for Determining Parent Organizations and Affiliated Providers*, AHRQ 4 (June 2016), <https://pso.ahrq.gov/sites/default/files/wysiwyg/guides-psos-providers-determining-parent-orgs-affiliated-providers.pdf> (citing 73 Fed. Reg. 70734).

¹⁰ “§ 3.206(b)(4)(iii) of the final rule permits disclosure of identifiable patient safety work product among Affiliated Providers for patient safety activities.” 73 F.R. 70778 (Nov. 21, 2008).

¹¹ “Patient Safety Activities” means the following activities carried out by or on behalf of a PSO or a Provider that are specified in the Patient Safety Rule: (1) Efforts to improve patient safety and the quality of health care delivery; (2) The collection and analysis of patient safety work product; (3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices; (4) 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; (5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product; (6) The provision of appropriate security measures with respect to patient safety work product; (7) The utilization of qualified staff; and (8) 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. 42 C.F.R. § 3.20.

HHS recognized that “certain provider entities with a common corporate affiliation, such as integrated health systems, may have a need, just as a single legal entity, to share identifiable and non-anonymized patient safety work product among the various provider affiliates and their parent organization for patient safety activities and to facilitate, if desired, one corporate patient safety evaluation system.”¹² HHS also recognized that “[t]here may be situations where establishing a single patient safety evaluation system may be burdensome or a poor solution to exchanging patient safety work product among member hospitals.”¹³

In those situations, Affiliated Providers are permitted to disclose PSWP with each other for Patient Safety Activities.¹⁴ Note that it is optional for a Provider to disclose PSWP to an Affiliated Provider and a Provider may choose not to do so.¹⁵

Importance of Identifying Affiliated Providers

Under the PSQIA, PSWP is confidential and shall not be disclosed excepted as permitted under the PSQIA.¹⁶ As described above, once such permitted exception is the disclosure of PSWP for Patient Safety Activities by a Provider to an Affiliated Provider.¹⁷ Consequently, when joining a PSO, Providers should know which individuals and entities, if any, they wish to share identifiable and non-anonymized PSWP for Patient Safety Activities. Once the Provider has identified these individuals and entities, the Provider must ensure they meet the definition of Affiliated Provider.

If the individuals or entities do not meet the definition of Affiliated Provider, and the Provider shares PSWP with such individuals and/or entities, then the disclosure of identifiable PSWP may constitute a violation of the PSQIA. The PSQIA provides for the Secretary of HHS to impose civil monetary fines of up to \$10,000 per act constituting a knowing or reckless disclosure of identifiable PSWP in violation of the PSQIA’s confidentiality provisions.¹⁸ Therefore, it is critical that the Provider (1) know which individuals and entities they wish to share PSWP with and (2) determine whether such individuals and entities meet the definition of Affiliated Provider.

¹² 73 F.R. 70778 (Nov. 21, 2008). “For example, a hospital chain that operates multiple hospitals may include the parent organization along with each hospital in a single patient safety evaluation system. Thus, each hospital may share patient safety work product with the parent organization and the patient safety evaluation system may exist within the parent organization as well as the individual hospitals.” 73 F.R. 70738.

¹³ *Id.* at 70739. “To address this concern, we have modified the disclosure permission for patient safety activities to permit affiliated providers to disclose patient safety work product with each other based on commonality of ownership.” *Id.*

¹⁴ 42 C.F.R. § 3.206(b)(4)(iii). “For a multi-provider entity, the final rule permits either the establishment of a single patient safety evaluation system or permits the sharing of patient safety work product as a patient safety activity among affiliated providers.” 73 F.R. 70738.

¹⁵ See 73 Fed. Reg. 70778 (Nov. 21, 2008) (“We emphasize that provider entities can choose not to use this disclosure mechanism if they believe that doing so would adversely affect provider participation, given that patient safety work product would be shared more broadly across the affiliated entities.”).

¹⁶ 42 U.S.C. § 299b–22(b) & (c); See 42 C.F.R. § 3.206.

¹⁷ 42 C.F.R. § 3.206(b)(4)(iii).

¹⁸ 42 U.S.C. § 299b-22(f)(1); 42 C.F.R. § 3.402(a).

Identification of an Affiliated Provider

The Agency for Healthcare Research and Quality (“AHRQ”), the division of HHS responsible for PSQIA oversight, recommends the following steps to identify an Affiliated Provider:¹⁹

- (1) The individual or entity wishing to participate in a PSO should consider whether it meets the definition of Provider.
- (2) Once the individual or entity determines it is considered a Provider, the Provider should determine whether it has any Affiliated Provider(s) in the event the Provider wants to disclose PSWP to such individuals and/or entities.²⁰
- (3) To determine whether “X” (an entity or individual) is an Affiliated Provider, the Provider should evaluate:²¹
 - a) *Whether the Provider and X are legally separate.*
 - b) *Whether X meets the definition of Provider.*
 - c) *The relationship between the Provider and X.*

The relationship must meet one of the three tests set forth in the Affiliated Provider definition:

 - i. The Provider is the parent organization of X;
 - ii. The Provider is under common ownership, management, or control with X;²²
or
 - iii. X owns, manages, or controls the Provider.

For information about how to join a Patient Safety Organization, contact the Midwest Alliance for Patient Safety (“MAPS”) at MAPSHelp@team-iha.org or 630-276-5657. MAPS is a federally certified Patient Safety Organization and an IHA company.

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This document is intended to be a guide for IHA members and does not constitute legal advice. For questions about this document, please contact the IHA Legal Affairs Department at legal@team-iha.org or 630-276-5506.

¹⁹ *Guides for PSOs and Providers for Determining Parent Organizations and Affiliated Providers* at 4-5.

²⁰ *Id.* at 5.

²¹ *Id.* at 4.

²² “HHS interprets providers as being ‘under common ownership, management, or control’ as contemplated by the definition of affiliated provider in a manner that provides general flexibility as to what providers are considered affiliated providers, within the bounds of the regulatory text. . . . HHS considers two legally separate providers as being ‘under common ownership, management, or control’ if they are ultimately part of the same multi-organizational enterprise, even if their common ownership, management, or control is indirect. . . 73 Fed. Reg. 70734.” *Id.* at 6.