Delineating Providers and Affiliated Providers under the Patient Safety Act

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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.

Background
The term “Provider”\(^2\) includes three categories of healthcare providers:

1. An individual or entity\(^3\) 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

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\(^2\) 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 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 organization 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.

Providers can also have and be “Affiliated Providers.” There are three requirements for an individual or entity to meet the regulatory status of an Affiliated Provider: The individual or entity must be:

1) A Provider;
2) Legally separate from the first Provider; and
3) The parent organization of the first Provider; under common ownership, management, or control with the first Provider; or owned, managed, or controlled by the first Provider.

**Purpose of the Affiliated Provider Regulatory Status**

The regulatory status of Affiliated Provider was not included in the statutory language of the Patient Safety Act. The U.S. Department of Health and Human Services (“HHS”) included the regulatory status in the Patient Safety Rule, which is the PSQIA’s implementing regulations, “to identify to whom patient safety work product [“PSWP”] may be disclosed pursuant to 42 C.F.R. § 3.206(b)(4)(iii).” The Patient Safety Rule regulation cited by HHS is the disclosure exception to the confidentiality provisions which allows a Provider to disclose PSWP to an Affiliated Provider for Patient Safety Activities.

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.”

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.” In those situations, Affiliated Providers are permitted to

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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 “intends[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.” 73 F.R. 70744 (Nov. 21, 2008).

7 42 C.F.R. § 3.20.


9 “Patient Safety Activities” are certain activities carried out by or on behalf of a PSO or a Provider that are specified in the Patient Safety Rule. 42 C.F.R. § 3.20.

10 73 F.R. 70778 (Nov. 21, 2008).

11 Id. at 70739.
disclose PSWP with each other as a Patient Safety Activity. Note that it is optional for a Provider to disclose PSWP to an Affiliated Provider and a Provider may choose not to do so.

**Importance of Identifying Affiliated Providers**

Under the PSQIA, PSWP is confidential and shall not be disclosed excepted as permitted under the PSQIA. As described above, once such permitted exception is the disclosure of PSWP for Patient Safety Activities by a Provider to an Affiliated Provider.

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 and 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.

Therefore, it is critical that the Provider 1) know which individuals and entities they wish to share PSWP and 2) determine whether such individuals and entities meet the definition of Affiliated Provider.

**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:

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.

3) To determine Affiliated Providers, the Provider should evaluate:
   a) *Whether the Provider and the other individual and/or entity are legally separate.*

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12 42 C.F.R. § 3.206(b)(4).
14 See 42 C.F.R. § 3.102.
16 *Id.* at 4-5.
b) **Whether the other individual and/or entity meets the definition of Provider.**

c) **The relationship between the Provider and the second Provider.**
The relationship must meet one of the three tests set forth in the Affiliated Provider definition:

  i. The Provider is the parent organization of the second Provider;
  
  ii. The Providers are under common ownership, management, or control; or
  
  iii. The second Provider 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.

*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 Department at legal@team-iha.org or 630-276-5506.*

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17 “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.” *Guides for PSOs and Providers for Determining Parent Organizations and Affiliated Providers* at 6.