

## GUIDES FOR PSOS AND PROVIDERS FOR DETERMINING PARENT ORGANIZATIONS AND AFFILIATED PROVIDERS

### Determining Which Entities Meet the Patient Safety Rule’s Definition of Parent Organization

#### **Background**

The Patient Safety Rule, at 42 C.F.R. §3.20, defines a parent organization as:

an organization that: owns a controlling interest or a majority interest in a component organization; has the authority to control or manage agenda setting, project management, or day-to-day operations; or the authority to review and override decisions of a component organization. The component organization may be a provider.

A component organization is defined as an entity that is “a unit or division of a legal entity” (including a corporation and other examples) or is “owned, managed, or controlled by one or more legally separate parent organizations.”

As explained in the Notice of Proposed Rulemaking (NPRM) for the Patient Safety Rule, the terms “parent organization” and “component organization” have different meanings than is traditional for similar sounding terms, such as “parent corporation.” See 73 Fed. Reg. 8115-16, 8118-19. Specifically, the NPRM states, at 73 Fed. Reg. 8118-19:

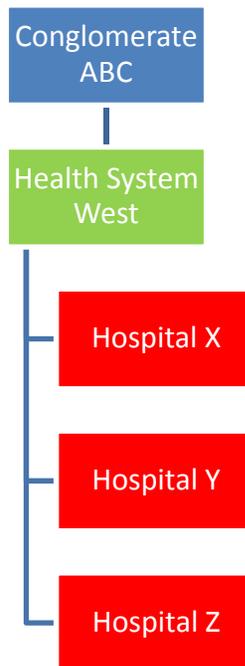
Traditionally, a parent *corporation* is defined as a corporation that holds a controlling interest in one or more subsidiaries. By contrast, parent *organization*, as used in this proposed rule, is a more inclusive term and is not limited to definitions used in corporations law. Accordingly, the proposed definition emphasizes a parent organization’s control (or influence) over a PSO [or provider] that may or may not be based on stock ownership.... Therefore, the definition of a “parent organization,” as used in the proposed regulation would encompass an affiliated *organization* that participates in a common enterprise with an entity seeking listing, and that owns, manages or exercises control over the entity seeking to be listed as a PSO. As indicated above, affiliated *corporations* have been legally defined to mean those who share a corporate parent or are part of a common corporate enterprise.

As indicated by the NPRM, for purposes of the Patient Safety Rule, the definitions of component and parent organizations emphasize the “actual organizational control, rather than the organizational structure.” 73 Fed. Reg. 8119; see also the Preamble to the Patient Safety Rule, at 73 Fed. Reg. 70734 (“The definition of component organization is intended to be read with a focus on management or control by others as its defining feature.”).



### **Direct Organizational Control**

In determining whether an entity is a component organization of a parent organization, the inquiry concentrates on management or control of the entity. See 73 Fed. Reg. 70734 (“The definition of component organization is intended to be read with a focus on management or control by others as its defining feature.”). Particularly in regards to large organizations that involve many related entities, questions arise as to whether an entity is a parent organization only if it directly controls the component organization, or whether the entity would still be considered a parent organization if it controls an intermediary entity that in turn controls the component organization. HHS interprets the control by the parent organization of the component organization as being direct control of the component entity. While the Patient Safety Rule’s definition of parent organization is more inclusive than the term “parent corporation,” HHS’ intention in this definition was not to create a scheme where a multitude of entities only peripherally associated with the component organization would be considered parent organizations. Rather, only entities that are closely tied to the component entity through the requisite level of control over the component entity itself are considered parent organizations of the component organization. For example, consider the following hypothetical scenario:



Assume Conglomerate ABC manages and controls Health System West, as contemplated by the Patient Safety Rule’s definition of parent organization, and that Health System West likewise manages and controls Hospital X. In this scenario, Conglomerate ABC would be a parent organization of Health System West, and Health System West would be a parent organization of Hospital X. However, Conglomerate ABC would not be a parent organization of Hospital X based upon its management of Health System West. In order for Conglomerate ABC to be Hospital X’s parent organization, it must meet one of the criterion set forth in the Patient Safety Rule’s definition of parent organization with respect to Hospital X, meaning:

- Conglomerate ABC owns a controlling interest or a majority interest in Hospital X;

- Conglomerate ABC has the authority to control or manage agenda setting, project management, or day-to-day operations of Hospital X; or
- Conglomerate ABC has the authority to review and override decisions of Hospital X.

### ***Determining a PSO's Parent Organization(s)***

A PSO may have zero, one, or multiple parent organizations, as the term is defined under the Patient Safety Rule. See 73 Fed. Reg. 70738. To determine whether an entity seeking listing as a PSO has any parent organizations and thus must seek listing as a component organization, the following criteria, from the Patient Safety Rule's definition of parent organization, should be considered:

In relation to the PSO, what entity or entities –

- Owns a controlling or a majority interest in the PSO?
  - HHS interprets ownership of a majority interest of a component entity to mean owning more than 50% of the component entity (e.g., PSO).
  - The preamble to the Patient Safety Rule, at 73 Fed. Reg. 70737, indicates that controlling interest means “holding enough stock in an entity to control it.” An entity may hold enough stock in an entity to control it without holding more than 50% of the stock.
- Has the authority to control or manage the PSO's agenda setting, project management, or day-to-day operations?
- Has the authority to review and override decisions of the PSO?

Every organization that meets any of the above criteria is a parent organization of the PSO. If the PSO has a parent *corporation*, as that term is traditionally used, the parent corporation would typically be a parent organization of the PSO under the Patient Safety Rule, assuming it is the entity holding a controlling interest in the PSO through its stock ownership. However, the PSO's consideration of its parent organizations should not end there. The PSO must also consider whether there are any other entities which satisfy either of the other criteria to be a parent organization. For example, while one entity may own a controlling stock interest in the PSO, there may be a separate organization that controls day-to-day operations of the PSO and, as such, is also a parent organization of the PSO.

### **Determining Which Entities Meet the Patient Safety Rule's Definition of Provider Under Paragraph 3 and Which Entities are Affiliated Providers**

#### ***Background***

The Patient Safety Rule's definition of provider includes three categories of entities that are providers. The first category (“paragraph 1”) states:

- (1) An individual or entity 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 dietician or nutritional professional, physical or occupational therapist, pharmacist, or other individual health care practitioner;

The paragraph 1 definition of provider consists of institutional and individual health care providers that provide health care services as licensed or authorized under State law.

The second category (“paragraph 2”) relates to individuals and organizations providing health care services within the public sector. Paragraph 2 was added “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 paragraph 1 definition. 73 Fed. Reg. 70744.

The third category (“paragraph 3”) provides:

- (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.

Paragraph 3 “was intended to permit the parent organization of a health care provider system to enter a system-wide contract with a PSO” since “[t]he parent of a health system also may not be licensed or authorized by state law to provide health care services...” 73 Fed. Reg. 70744. The preamble to the Patient Safety Rule clarifies that, “[w]ith respect to paragraph (3) of the definition, the use of the term parent organization here should conform to our definition of ‘parent organization’ above.” 73 Fed. Reg. 70745.

The Patient Safety Rule’s definition of affiliated provider sets forth three ways that a provider (“Provider A” below) can be an affiliated provider with respect to another legally separate provider (“Provider B” below):

- Provider A is the parent organization of Provider B; or
- Provider A is under common ownership, management, or control with provider B; or
- Provider A is owned, managed, or controlled by Provider B.

The Patient Safety Rule includes a definition of affiliated provider to identify to whom patient safety work product may be disclosed pursuant to 42 C.F.R. § 3.206(b)(4)(iii). 73 Fed. Reg. 70734.

### ***Determining Providers, Under Paragraphs 1 and 3, and Affiliated Providers in Health Care Systems<sup>1</sup>***

#### Determining Paragraph 3 Providers, in Relation to Paragraph 1(i) Providers

The paragraph 3 definition of provider requires that the entity be a parent organization of an entity “licensed or otherwise authorized under State law to provide health care services.” Therefore, it is helpful, as a first step, to determine which entity (or entities) is delivering health care services as authorized under State law, e.g., a hospital, renal dialysis facility, pharmacy, or health care practitioner’s office. Once the entity that meets the paragraph 1(i) definition of provider is identified, it is helpful as a next step to turn to the Patient Safety Rule’s definition of parent organization to determine whether any entity is the parent organization of the paragraph 1(i) provider and thus meets the paragraph 3

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<sup>1</sup> The discussion that follows is limited to considering entities who meet the paragraph3 definition of provider based, in part, upon their relationship with a paragraph 1(i) provider. Entities can also meet the paragraph 3 definition of provider based, in part, upon their relationship with a paragraph 2 provider, but further consideration of this part of the definition is outside the scope of this discussion.

definition of provider. To determine whether any entity is a parent organization of the entity that meets the paragraph 1(i) definition of provider, the following questions should be considered:

In relation to the paragraph 1(i) provider, what entity or entities –

- Owns a controlling or a majority interest in the paragraph 1(i) provider (e.g., the hospital)?
  - HHS interprets ownership of a majority interest of a component entity to mean owning more than 50% of the component entity (e.g., the hospital).
  - The preamble to the Patient Safety Rule, at 73 Fed. Reg. 70737, indicates that controlling interest means “holding enough stock in an entity to control it.” An entity may hold enough stock in an entity to control it without holding more than 50% of the stock.
- Has the authority to control or manage the paragraph 1(i) provider’s (e.g., the hospital’s) agenda setting, project management, or day-to-day operations?
- Has the authority to review and override decisions of the paragraph 1(i) provider (e.g., the hospital)?

As discussed above, in order for an entity to be a parent organization of a component organization, HHS interprets that the parent organization must have direct control over the component organization through at least one of the criteria set forth in the Patient Safety Rule’s definition of parent organization. The implication for determining whether an entity meets the paragraph 3 definition of provider is that the parent organization must directly control an entity “licensed or otherwise authorized under State law to provide health care services” in order to meet the provider definition under paragraph 3.

#### Determining Affiliated Providers

Once it is determined which entities are considered providers under the Patient Safety Rule, a provider’s next step may be to determine whether it has any affiliated providers, in the event it may want to disclose patient safety work product (PSWP) to any such entities. It is optional for a provider to disclose PSWP to an affiliated provider, and a provider may choose not to do so if it believes that such disclosures would impact provider participation. *See* 73 Fed. Reg. 70778. Additionally, a provider may choose not to disclose PSWP to an affiliated provider or limit the affiliated provider’s ability to subsequently re-disclose the PSWP, if the provider wants to exercise greater control over the sharing of the PSWP.

To determine whether another entity is an affiliated provider, the provider should first confirm the other entity is a legally separate entity. Next, the provider should address whether the other entity meets the Patient Safety Rule’s definition of provider. The other entity could meet the definition of provider through either paragraph 1, 2, or 3. Finally, the provider should review the relationship between itself and the second provider. If the provider is the parent organization of the second provider; if the providers are under common ownership, management, or control; or, if the second provider owns, manages, or controls the provider, then the two providers are affiliated providers.

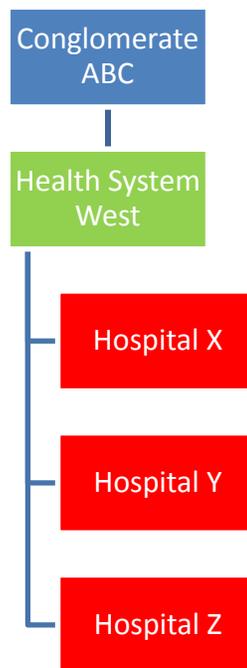
Notably, while a provider that is a parent organization or component organization of another provider is included in the definition of affiliated provider, affiliated providers are not limited to provider parent and provider component organizations. Affiliated providers also include, more broadly, providers under common ownership, management or control. Such providers are considered affiliated providers, “in recognition 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.” 73 Fed. Reg. 70778. HHS interprets providers as being “under common ownership, management, or control” as contemplated by the definition of affiliated provider in a manner that provides generous flexibility as to what providers are considered affiliated providers, within the bounds of the regulatory text. For purposes of the definition of affiliated providers, 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. A multi-organizational enterprise is an undertaking with separate corporations or organizations that are integrated in a common business activity. 73 Fed. Reg. 70734.

**Examples**

To illustrate how to determine which entities meet the Patient Safety Rule’s definitions of provider and affiliated provider, consider the following hypothetical examples:

Example 1:



For this example, we will use the following assumptions: Conglomerate ABC manages and controls Health System West, as contemplated by the Patient Safety Rule’s definition of parent organization. Health System West manages and controls Hospital X, Y, and Z and is the only entity that directly controls these hospitals. Also assume that Hospital X, Y, and Z are licensed under State law to provide health care services but the other entities on the chart are not.

*Who Are the Providers?*

Applying the Patient Safety Rule to this scenario, Hospital X, Y, and Z would meet the paragraph 1(i) definition of provider. As Health System West is a parent organization of these hospitals and the hospitals are providers under the paragraph 1(i) definition, Health System West meets the paragraph 3 definition of provider. Conglomerate ABC does not meet the Patient Safety Rule’s definition of provider. Because it is not licensed to provide health care services, Conglomerate ABC does not meet the

paragraph 1 definition of provider; nor does Conglomerate ABC meet the paragraph 2 definition of provider. While it is a parent organization of Health System West, this relationship does not satisfy the paragraph 3 definition of provider because Health System West does not meet the paragraph 1(i) definition of provider. Further, while Conglomerate ABC may be able to exercise authority or control over Health System West, which in turn may exercise authority or control over Hospital X, Y, or Z, Conglomerate ABC is not able to exercise direct authority or control over Hospital X, Y, or Z.

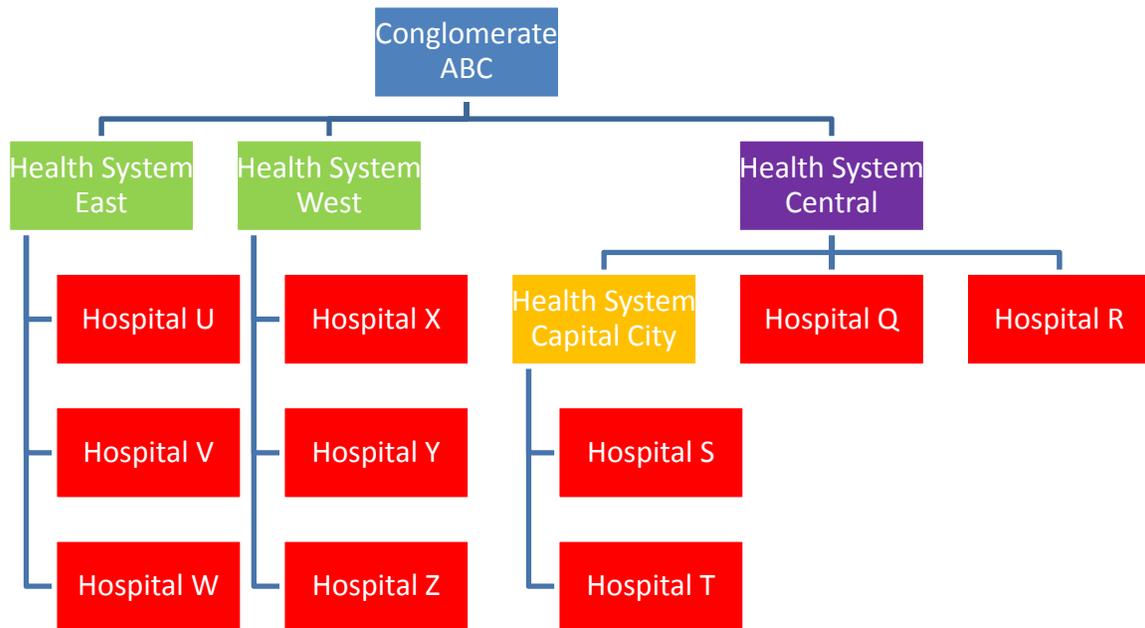
Because Health System West and the hospitals all meet the Patient Safety Rule's definition of provider, this presents options for how these organizations engage with a PSO. One option is for Hospital X, Y, and Z to each enter into its own separate contract with a PSO. A second option is for Health System West to enter into one system-wide contract with a PSO that would include all three hospitals. Of note, PSOs should be mindful that the Patient Safety Rule requires them to have two bona fide contracts, each with a different provider, for the purpose of receiving and reviewing patient safety work product. See 42 C.F.R. § 3.102(b)(2)(i)(C). If a PSO enters into a single contract applicable to a healthcare system, such as Health System West in this example, the PSO would still be required to have a second bona fide contract to meet the minimum contract requirement. See 73 Fed. Reg. 70753.

#### *Who Are Affiliated Providers?*

Conglomerate ABC: It cannot be an affiliated provider because, as discussed above, it does not meet the Patient Safety Rule's definition of provider.

Hospital X: Hospital Y and Z are affiliated providers of Hospital X because they are legally separate entities, meet the paragraph 1(i) definition of provider, and are under common management or control with Hospital X. Additionally, Health System West is an affiliated provider of Hospital X because it: is a legally separate entity; meets the paragraph 3 definition of provider, as discussed above; and, manages and controls Hospital X.

Example 2:



This more intricate example represents one multi-organizational enterprise, under the umbrella of Conglomerate ABC. The hospitals (all in red blocks) are the only entities authorized under State law to provide health care services. Assume that Health System East is the only entity that controls Hospital U, V, and W, as contemplated by the parent organization definition, and the same is true with respect to Health System West and Hospital X, Y and Z. Health System Central is more complex; assume it directly controls Hospital Q and R as well as Health System Capital City. In turn, assume Health System Capital City directly controls Hospital S and T. Conglomerate ABC owns Health System East, West, and Central, which, as indicated above, are not licensed to provide health care services.

*Who Are the Providers?*

The hospitals are paragraph 1(i) providers under the Patient Safety Rule’s definition. Based upon their respective parent organization relationships with the Hospital U, V, W and Hospital X, Y, and Z, Health System East and West are providers under the paragraph 3 definition. Conglomerate ABC does not meet the Patient Safety Rule’s definition of provider. It is not a provider under paragraph 1 or 2, and it is not the parent organization of a provider under paragraph 1(i), i.e., the hospitals.

Health System Capital City is a paragraph 3 provider based upon its parent relationship with Hospital S and T. Health System Central is a provider under paragraph 3 based upon its parent relationship with Hospital Q and R, but it is not a parent based upon its relationship with Health System Capital City (or its indirect relationship with Hospital S or T). As such, Health System Central could enter into a Patient Safety Act contract with a PSO on behalf of Hospital Q and R, but not on behalf of Hospital S and T.

*Who Are Affiliated Providers?*

Conglomerate ABC: It cannot be an affiliated provider because, as discussed above, it does not meet the Patient Safety Rule’s definition of provider.

Hospital U: Health System East is an affiliated provider of Hospital U because it: is a legally separate entity; meets the paragraph 3 definition of provider, as discussed above; and, manages and controls Hospital U. Because all of the hospitals and health systems are separate legal entities, meet the paragraph 1 or 3 definition of provider, and are under common management or control by being part of one multi-organizational enterprise, Hospital U is an affiliated provider with all of the other hospitals and health systems depicted above.

Health System West: Hospital X, Y, Z are also affiliated providers with Health System West since they are legally separate entities, meet the paragraph 1(i) definition of provider, and they are all controlled by Health System West. Because all of the hospitals and health systems are separate legal entities, meet the paragraph 1 or 3 definition of provider, and are under common management or control by being part of one multi-organizational enterprise, Health System West is an affiliated provider with all of the other hospitals and health systems depicted above.

Health System Central: Hospital Q, Hospital R, and Health System Capital City are affiliated providers of Health System Central because they are legally separate entities, meet the paragraph 1(i) definition of provider, and are directly controlled by Health System Central. Although Hospital S and T are not component organizations of Health System Central, they are still affiliated providers of Health System Central because they are separate legal entities, meet the paragraph 1 definition of provider, and are under common management or control by being part of one multi-organizational enterprise. Health System Central is likewise an affiliated provider of the remaining hospitals and health systems depicted above because they are all separate legal entities, meet the paragraph 1 or 3 definition of provider, and are under common management or control by being part of one multi-organizational enterprise.