Patient Safety Organizations:
A Compliance Self-Assessment Guide
September 2009

Executive Summary

The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) implements Public Law 109-41, the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), which establishes in Subpart B the requirements that an entity must meet to seek listing and remain listed as a Patient Safety Organization (PSO). The rule relies primarily upon a system of attestations that places a significant burden for understanding and complying with these requirements on the PSO. However, the rule also authorizes the Agency for Healthcare Research and Quality (AHRQ) to conduct reviews (including announced or unannounced site visits) to assess PSO compliance. To assist PSOs in making the required attestations and preparing for a compliance review, AHRQ has developed this Guide to suggest approaches for thinking systematically about the scope of these requirements and what compliance may mean for an individual PSO. The Guide provides sample questions that a PSO may want to consider in addressing each of the requirements.

The questions are illustrative. Some of the questions may be applicable to all PSOs, while others may be relevant only to specific types of PSOs, such as those employing sophisticated information technology (IT), to receive and to analyze large volumes of data. These questions do not establish new standards and are not intended to indicate the only way to meet the regulatory standards. An individual PSO—given its mission, the services and expertise it offers providers, and its operational model for carrying out patient safety activities—should use these sample questions as a starting point for assessing whether its approach to compliance has taken into account issues relevant to its operation.

Who Can Benefit From Reading This Guide?

This Guide may help–

- ***Existing PSOs*** to assess their compliance with the requirements of the Patient Safety Rule and to prepare for compliance reviews by AHRQ.
- ***PSO Contractors*** (both individuals and organizations) to understand many of the requirements that must be met when assisting a PSO to perform patient safety activities.
- ***Entities contemplating becoming a PSO*** to make a more informed judgment about what is required of a listed PSO.
- ***Health care providers*** to understand the types of services that PSOs must be able to provide and to identify the issues they should consider in searching for, and negotiating with, a PSO.

How to Use This Guide

The Patient Safety Rule provides PSOs latitude in complying with its requirements. In addition, PSOs vary in terms of size, complexity, and sophistication and, over time, PSOs will vary significantly in the breadth and scope of their activities. For example, PSOs can be local, regional, or national in orientation; they can focus narrowly or broadly in terms of the clinical or analytic services they offer providers; they can target their services toward one type of health care facility or multiple health care settings; and, they are likely to vary in the sophistication and complexity of IT employed. As a consequence, individual PSOs are likely to approach compliance from different perspectives.

AHRQ's intent in developing this Guide is to emphasize to each PSO the importance of ensuring that its approach to compliance is logical, systematic, and addresses all aspects of the stated regulatory requirements. The sample questions provided in the Guide's tables are intended to foster such thinking. As a result, this Guide does not represent the only possible approach to thinking about these requirements. It does not establish new standards or new requirements beyond those incorporated in the text of the Patient Safety Rule. This Guide does not confer any rights on any person or entity. Finally, AHRQ may revise this Guide over time as warranted by public comment and experience.

Background

The goals and major elements of the Patient Safety Act are explained elsewhere on the AHRQ PSO Web site at www.pso.ahrq.gov. Within the framework established by the Act, PSOs are a source of expert advice for providers, enabling them to take advantage of the potential for significant aggregation and analysis of patient safety events and quality concerns within the confidentiality and privilege protections of the Patient Safety Act. As a result, health care providers and those committed to improving the safety and quality of patient care have a vested interest in the integrity of PSOs and their ability to carry out this statutory mission.

The requirements governing PSOs are set forth in Subpart B of the Patient Safety Rule (42 CFR Part 3). These include:

- the eligibility requirements and process for listing an entity as a PSO for 3-year renewable periods;
- the requirements that a PSO must meet to remain listed;
- the processes for ensuring PSO compliance with the requirements of the rule, including conducting announced or unannounced compliance reviews of PSOs, and for correcting deficiencies in a PSO's compliance; and
- the process for a PSO to voluntarily relinquish its listing or, in the case of a PSO that does not correct its deficiencies, the process for a PSO to be delisted for cause.

AHRQ administers the provisions of the rule relating to listing and operation of PSOs that are the focus of this Guide. The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) is responsible for enforcing the confidentiality protections for patient safety work product.

Compliance and Technical Assistance

For an entity to be listed, and remain listed, as a PSO, the Patient Safety Rule relies primarily upon a system of attestations. An entity seeking listing for a 3-year period as a PSO must submit a form to AHRQ, *Certification for Initial Listing*, to attest that it meets the Patient Safety Rule's eligibility and listing requirements at the time the entity submits its certifications. During its period of listing, a PSO must submit a form, *Two Bona Fide Contracts Requirement*, every 24 months attesting that it has at least two contracts with different providers to perform patient safety activities. If the PSO has other relationships not related to patient safety work product, specified in section 3.102(d)(2), with any contracting provider, it must also submit the form, *PSO Disclosure Statement*, regarding its relationships with the provider and attest to the completeness and accuracy of its disclosures. Finally, to seek continued listing for an additional 3-year period, a PSO must submit the form, *Certification for Continued Listing*, and attest that it meets the requirements for continued listing. Therefore, these self-attestations should be the starting point for any self-assessment of compliance.

The Patient Safety Rule permits AHRQ to assess or verify PSO compliance with the rule's requirements at any time through requests for information or by conducting announced or unannounced reviews of, or site visits to, PSOs (see section 3.110). In addition to routine compliance reviews, AHRQ may also conduct a site visit or request additional information if AHRQ has reason to believe that a PSO may not be in compliance with the requirements of the statute or the Patient Safety Rule.[1]

If AHRQ determines that a PSO is not in compliance with one or more requirements (i.e., a deficiency exists), the Patient Safety Rule enables AHRQ to work with the PSO to correct any deficiencies as promptly as possible, without taking punitive action. While the rule provides AHRQ the authority for delisting a PSO for failure to correct a deficiency, the intent of the rule is to encourage a nonadversarial approach, whenever possible, to bring a PSO back into compliance.

Whenever possible, AHRQ will provide technical assistance to PSOs to foster understanding and compliance with the requirements of the Patient Safety Rule. A PSO can seek technical assistance by outlining the issue(s) in an e-mail to the AHRQ PSO mailbox: pso@ahrq.hhs.gov or by calling toll free 866-403-3697 or local 301-427-1111.

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[1] Part IV of the *Certification for Initial Listing* form restates the requirement of section 3.102(a)(1)(vi) of the Patient Safety Rule that a PSO must notify the HHS Secretary (Secretary) promptly if it determines that it can no longer comply with any of its attestations and the applicable requirements of the rule or if there have been any changes in the accuracy of the information submitted. A PSO should also notify AHRQ promptly if its contact information or the name of its authorizing official has changed.

The Scope of This Guide

What This Guide Addresses. This Guide contains four tables. Table 1 provides sample questions related to the eligibility, listing, and operational requirements that are set forth in section 3.102 of the Patient Safety Rule. Table 2 provides sample questions related to the requirements for the security of patient safety work product set forth in section 3.106. Table 3 is a compilation of the submission and notification requirements that PSOs, and entities seeking listing as a PSO, must meet and indicates whether a specific form must be used and the date by which the requirements must be met, if one is specified in the Patient Safety Rule. Table 4 is a reference table that provides a cross-walk of the attestations required at initial and continued listing, and the corresponding requirements from the Patient Safety Rule. The next four subsections of the Guide provide introductory and additional information related to each of the four tables.

What this Guide Does Not Address. While this Guide occasionally references requirements elsewhere in the Patient Safety Rule, it does not provide a comprehensive review of specific protections and permissible disclosures of patient safety work product with which PSOs and others holding patient safety work product must comply. PSO personnel should be thoroughly familiar with those requirements that are set forth in Subpart C of the rule. Some of those requirements, such as the disclosure of patient safety work product to or by contractors, should be reviewed by a PSO before it develops its operational policies.

For purposes of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, a PSO is considered a *business associate* of a health care provider if the relationship meets two conditions: (1) the provider meets the HIPAA definition of a *covered entity*; and (2) the PSO performs a function (such as patient safety activities) on behalf of a covered health care provider that requires the PSO to receive and use patient safety work product that contains protected health information. Since PSOs are likely to work with covered providers and receive and use patient safety work product that contains protected health information (PHI),[2] every PSO should determine at the outset when establishing a working relationship with a provider whether it is required by the HIPAA Privacy Rule to enter into a *business associate agreement* with the provider.

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[2] The Privacy Rule protects information known as PHI that is held or transmitted by a covered entity or its *business associate* in any form or media, whether electronic, paper, or oral. PHI is a subset of "individually identifiable health information" (IIHI). IIHI is information, including demographic data, that relates to the individual's past, present, or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number). PHI is all IIHI except for employment records held by a covered entity in its role as employer, education records covered by the Family Educational Rights and Privacy Act (FERPA), and certain other school records.

To learn more about the obligations of a *business associate* and the definitions of related HIPAA terms, consult the Web site for the OCR (www.ocr.hhs.gov). OCR has responsibility for enforcement of the HIPAA Privacy and Security Rules in addition to the confidentiality provisions of the Patient Safety Rule. There are additional *business associate* security provisions under the HIPAA Security Rule that apply to electronic patient health information held by *business associates*. For information regarding the HIPAA Security Rule requirements, see: http://www.cms.hhs.gov/EducationMaterials/04_SecurityMaterials.asp.[3]

Table 1. Self-Assessment Sample Questions: Requirements of Section 3.102 for Initial and Continued Listing

Beginning on page 10, Table 1 addresses the eligibility, listing, and operational requirements for PSOs that are established by section 3.102 of the Patient Safety Rule. These requirements can be categorized as follows:

- Patient Safety Activities—Rows #1–#8 restate the patient safety activity requirements that all PSOs must meet for listing;
- PSO Criteria—Rows # 9–#15 restate the seven statutory criteria for listing that all PSOs must meet;
- Component Organizations: Additional Statutory Requirements—Rows #16–#18 restate the three additional statutory requirements that all component PSOs must meet for listing;
- Component Organizations: Additional Regulatory Requirement—Row #19 restates the requirement of the rule that applies to any component PSO that seeks to contract with its parent organization; and
- Component Organizations of Excluded Entities: Additional Regulatory Requirements—Rows #20–#24 restate the additional requirements of the rule that a component PSO must meet if its parent organization is excluded from seeking listing by the Patient Safety Rule (i.e., accreditation or licensure entities, regulatory entities or agents of regulatory entities, or entities that administer mandatory reporting systems).

Patient Safety Activities

Because there is a specific documentation requirement for patient safety activities in the Patient Safety Rule, this subsection addresses the overall considerations a PSO should take into account in developing and evaluating its written documentation. Clarifications regarding the other eligibility and listing requirements (PSO criteria, component

[3] On August 3, 2009 HHS announced that responsibility for the enforcement of the HIPAA Security Rule was being transferred from the Centers for Medicare and Medicaid Services, (CMS) to OCR effective immediately. The link provided here is to the CMS Web site. This information will eventually be housed on the OCR Web site (www.ocr.hhs.gov).

organization requirements, and other regulatory requirements) are addressed in Table 1.

Section 3.102(b)(1) of the Patient Safety Rule requires an entity, at the time it seeks listing as a PSO, to have policies and procedures already in place that address how the entity will perform all eight defined patient safety activities. A PSO that seeks continued listing for an additional 3-year period must attest that it has performed, and will continue to perform, all eight patient safety activities. While the attestation regarding policies and procedures is made at first listing, a PSO is expected to continue to meet this requirement throughout its period(s) of listing.

In developing its policies and procedures, a PSO should ensure that its written documentation reflects the scope of its mission, the activities and services it offers health care providers, and its mode of operation for carrying out patient safety activities. The scope of a PSO's mission may be narrow (e.g., medication safety in nursing homes) or broad (e.g., safety issues throughout acute-care hospitals). In addressing specific patient safety activities, such as the use of qualified personnel or dissemination of information to improve patient safety, the written documentation should reflect the breadth (or targeted nature) of the PSO's mission.

For example, consider a PSO with a mission to improve medication safety. Its documentation regarding the utilization of qualified personnel (see Table 1, Row #7) should reflect its mission (i.e., focus on the recruitment of personnel with expertise in medication safety and the analysis of medication errors). Similarly, the documentation for how the PSO in this example develops and disseminates information to improve patient safety (see Table 1, Row #3) would need to address its efforts to develop and disseminate information to improve medication safety. A PSO's documentation can address all of these patient safety activities as broadly as it chooses, but in conducting a self-assessment, a PSO should determine that its documentation fully reflects its mission, activities, and mode of operation.

In addition to the requirement that, when seeking initial listing, the entity must already have policies and procedures in place, every PSO must perform each patient safety activity at some point during each 3-year period of listing. The Patient Safety Rule recognizes that several of these activities can only be performed when a PSO is receiving patient safety work product from a health care provider [i.e., the requirements related to the analysis, use, and feedback related to patient safety work product (see Table 1, Rows #2, #4, and #8)]. If a PSO has not received and is not receiving patient safety work product at the time of a compliance review, or the contracts in place at that time do not require the PSO to perform all three of these patient safety work product-dependent patient safety activities, a PSO may not be able to demonstrate that it is performing each of these patient safety activities.

To address this situation, the Patient Safety Rule preamble text accompanying section 3.102(b) draws a distinction between those patient safety activities that are and are not dependent upon the receipt of patient safety work product. With respect to the three patient safety activities listed above that are dependent upon receipt of patient safety work product, a PSO can expect that a compliance review will normally involve a review of its written documentation for these three activities since the PSO attested it had these

policies and procedures in place when it sought listing. However, AHRQ may consider the terms of any contracts or agreements that a PSO has or had with providers to determine if it is reasonable to expect demonstration of performance of these three activities at the time a compliance review takes place. A PSO will be expected to demonstrate performance of the other (non-patient-safety-work-product dependent) patient safety activities throughout its period of listing. The preamble notes that there is one exception to this approach of setting different performance expectations based upon whether a patient safety activity is dependent upon receipt of patient safety work product. When a PSO is a component of a provider organization (e.g., a large hospital system creates a component PSO) and this PSO's primary client is its parent organization, the PSO will be expected to perform all patient safety activities during its entire period of listing (see page 70753 of the November 21, 2008 FR). Entities that are components of provider organizations should note this expectation before seeking listing.

The Patient Safety Rule places the responsibility on each PSO for the development/maintenance of policies and procedures for conducting patient safety activities. If a PSO, after attesting that it has policies and procedures in place, subsequently chooses to contract with another organization for assistance in carrying out one or more of its required patient safety activities, the PSO remains responsible for having in place the required policies and procedures that it attested to at the time it sought listing. In such cases, the PSO should ensure that the contractor's policies and procedures conform to the requirements of the Patient Safety Rule. In establishing such arrangements, a PSO may also want to clarify the locus of decisionmaking (i.e., the PSO or the contractor) when judgments need to be made regarding the performance of the patient safety activity for which the contractor is providing assistance and the level of direction and oversight that the PSO will provide.

Table 2. Self-Assessment Sample Questions: Requirements of Section 3.106 for Security of Patient Safety Work Product

Beginning on page 22, Table 2 addresses the specific requirements in section 3.106 of the Patient Safety Rule for the security of patient safety work product. A PSO should carefully review these specific requirements in determining its compliance with the general patient safety activity requirements for the confidentiality and security of patient safety work product, which are restated in Rows #5 and #6 of Table 1.

Section 3.106 requires each PSO to develop specific security standards that are appropriate and scalable for the size and complexity of its organization for each element of a four-part framework outlined in subsection (b). Consequently, not all questions in this Guide may be appropriate for all PSOs. While the rule gives a PSO considerable latitude in developing the specific standards it will apply to each element of the framework, a PSO must address every element of the four-part framework. A PSO should note that it must establish security standards that apply to any contractor(s) or vendor(s) to which the PSO entrusts patient safety work product and at all locations at which patient safety work product is held (see subsection (a)).

PSOs should recognize that the security of patient safety work product is not merely an issue of compliance with the Patient Safety Rule. As discussed above (see "The Scope of This Guide" on page 4), PSOs may also be subject to the requirements of the HIPAA Privacy and Security Rules. Therefore, in addition to addressing the requirements of section 3.106, an entity should consult the HIPAA references provided in that section of this Guide to determine whether the HIPAA rules also apply. If so, the entity may be able to reduce the compliance burden by addressing the HIPAA Privilege and Security Rules and the Patient Safety Rule requirements at the same time.

While each PSO is encouraged to undertake an initial risk assessment, the PSO is required to undertake periodic risk assessments subsequently (Table 2, Row #9). An initial risk assessment is likely to serve as a foundation for the PSO's approach to security by enabling a PSO to target its resources to the greatest security threats posed by its mode of operation. It should also provide a baseline for the PSO to assess the effectiveness over time of the policies and standards it adopts.

Finally, before entering contracts for assistance in carrying out patient safety activities, a PSO should be able to demonstrate that it has taken reasonable steps to ensure the protection of patient safety work product that it has entrusted to its contractors. The PSO may want to consider issues such as:

- Do the PSO's security standards specifically state the security requirements for contractors, and are these standards reflected in the contract?
- Has the contractor been made aware of the limitations on the use of patient safety work product that are contained in section 3.206(b)(4)(ii)? Unless otherwise authorized by a PSO, this provision states that a contractor may only disclose patient safety work product back to the PSO from which it received the patient safety work product.
- If the contractor has a large workforce, does the contract limit access to patient safety work product to specific units or individuals within the contractor's organization whose expertise is needed by the PSO?
- Has the PSO specifically delineated the tasks for which the contractor may use patient safety work product?

Table 3. Required Notifications and Submissions.

Beginning on page 30, Table 3 provides a compilation of the submission and notification requirements that PSOs, and entities seeking listing as a PSO, must meet. For each requirement, the table notes whether the use of a specific form is required, whether the Patient Safety Rule sets a deadline for compliance, and—if so—whether it specifies the deadline. The requirements include those related to seeking initial or continued listing as a PSO, required notifications during a PSO's period of listing, and requirements that apply to a PSO that is subject to the processes for correction of one or more deficiencies or revocation

Because AHRQ is required by the Patient Safety Act and the Patient Safety Rule to maintain an accurate listing of currently listed PSOs, it is essential that a PSO meet the

requirement of the rule (and its attestations) to promptly notify AHRQ of any changes in the accuracy of its contact information, including the names and contact information for the individuals it has designated as its authorized official and point-of-contact.

Each PSO should consult with AHRQ before using another name ("doing business as") in advertising its services to health care providers and before entering into arrangements with other entities that would have the effect of sharing or conveying partial or complete ownership, management, or control of the PSO. Similarly, a PSO must be vigilant in ensuring that it does not undertake activities that the Patient Safety Rule does not permit PSOs to perform (see section 3.102(a)(2)). PSOs need to be aware that such actions could create confusion and concern among health care providers and, in some circumstances, would call into question the validity of the PSO's certifications for listing.

During each PSO's period of listing, a PSO is required to notify AHRQ during every 24-month period following its date of initial listing that it has two bona fide Patient Safety Act contracts with different providers for the receipt and review of patient safety work product. PSOs should note that the reference to different providers refers to the provider with which the PSO enters the two contracts. Therefore, entering one contract with the parent organization of a health system to work with its hospitals and another contract with the same parent organization to work with its nursing homes would not meet the requirement since the contracts were entered with the same provider (the parent organization). However, if the PSO entered contracts directly with different providers that have the ability to enter contracts with the PSO on their own behalf, the test would be met.

Finally, all PSOs must submit a disclosure statement if two conditions are met: (1) the PSO enters a Patient Safety Act contract with a health care provider; and (2) the PSO has other relationships specified in section 3.102(d)(2) of the rule with that provider or if any of the specified relationships are established during the period that the contract is in effect with a provider. AHRQ has included information on its PSO Web site (www.pso.ahrq.gov) that summarizes the requirements of the Patient Safety Rule on how the PSO should structure its disclosure statement.

Table 4. Reference Table: Patient Safety Rule Requirements For Which Attestations Are Required

Beginning on page 33, Table 4 provides a side-by-side comparison of the attestations required at initial and continued listing of a PSO, and the corresponding requirements in section 3.102 of the Patient Safety Rule. The requirements listed in Table 4 parallel those in Table 1. Although one of the requirements in Table 1 (Row # 19) is not addressed by either the initial or continued certification forms, it is included here for convenience. The accompanying text notes that there is no comparable attestation on either form.

Table 1
PSO Compliance Self-Assessment:
Section 3.102, Requirements for Initial and Continued Listing

Patient Safety Activities

Any entity seeking listing as a PSO must attest that, at the time it seeks listing, it has policies and procedures in place to perform the eight patient safety activities (Rows #1–#8) set forth in section 3.102(b)(1) of the Patient Safety Rule. A PSO seeking continued listing must attest that it has performed, and will continue to perform, all eight patient safety activities. Table 4 provides a crosswalk of the language from the rule and the initial and continued listing forms.

Row	Patient Safety Activities	PSO Sample Self-Assessment Questions
1	Section 3.20, definition of Patient Safety Activities: (1) Efforts to improve patient safety and the quality of health care delivery.	Has the PSO documented the patient safety and quality improvement activities that it offers health care providers? For example, does the PSO have descriptive materials that outline the patient safety and quality improvement activities offered to health care providers? Alternatively, has the PSO already met this requirement as a result of the documentation required by the patient safety activities that follow (Rows #2–#8 in this table)? Those requirements essentially require a PSO to document how it will perform all aspects of the patient safety activities it undertakes. To employ this approach successfully, a PSO should assess whether the documentation for patient safety activities #2–#8 in this table addresses all of the patient safety and quality improvement activities the PSO undertakes.
2	Section 3.20, definition of Patient Safety Activities: (2) The collection and analysis of patient safety work product.	Has the PSO documented how it will (does) collect patient safety work product from health care providers? For example, will (does) the PSO accept patient safety work product from providers through paper submissions, secure electronic transmission, use of a secure portal system, or a combination of approaches? Has the PSO documented the range of analytic services that it will (does) offer health care providers? Does the documentation specify the types of problems or tasks of methods, tools, and analytic approaches the PSO will employ to address specific types of problems or tasks? If the PSO has already undertaken such analyses, can the PSO provide specific examples of the use of analytic techniques to specific data? If a PSO enters into a contract with another organization or PSO to provide assistance with the collection or analysis of patient safety work product, are the activities, methods, or

		approaches used by the contractor(s) consistent with the attestations of the contracting PSO? If the PSO is currently receiving and analyzing patient safety work product, can the PSO provide specific examples that demonstrate or document how the PSO is complying with this requirement?
3	Section 3.20, definition of Patient Safety Activities: (3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.	Has the PSO documented how it meets this requirement? For example: • What is the scope of the PSO's existing and planned dissemination activities (i.e., is it restricted to issues for which it receives patient safety work product or will dissemination address a broader range of patient safety and quality improvement issues)? • How does the PSO evaluate the validity and reliability of the information it disseminates? • How does the PSO determine when an intervention or approach constitutes a "best practice" before disseminating the information to providers? If the PSO has already developed and disseminated such information, can the PSO provide specific examples that demonstrate or document how the PSO is complying with this requirement?
4	Section 3.20, definition of Patient Safety Activities: (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.	Has the PSO documented how it will (does) meet this requirement? For example: • How will (does) the PSO seek to foster a culture of safety within the institutional providers with which the PSO works? • Can the PSO provide feedback and assistance that may be used by providers to minimize risk to patients? If the PSO has undertaken specific activities to comply with this requirement, can the PSO provide specific examples that demonstrate or document how the PSO is complying with this requirement?
5	Section 3.20, definition of Patient Safety Activities: (5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.	Has the PSO established policies to preserve the confidentiality of patient safety work product? For example: • Do the policies and procedures apply to all workforce members and contractors with access to patient safety work product? • Do the PSO's confidentiality policies meet the requirement of section 3.102(b)(1)(i)(A) of the rule?

		This section requires a PSO's confidentiality policies to be consistent with Subpart C of the rule. • Has the PSO established procedures to ensure compliance with the confidentiality requirements? For example, does the PSO require written acknowledgement of the confidentiality protections by members of its staff and contractors with access to patient safety work product? • When patient safety work product is entrusted to contractor(s), does the PSO require contractors to acknowledge the limitations on contractor disclosure of patient safety work product (see section 3.206(b)(4)(ii) of the rule)? • Does the PSO assist reporting providers in understanding the confidentiality requirements for patient safety work product, including the statutory right (restated in section 3.206(e)) to establish greater confidentiality protections for patient safety work product than are required by the Patient Safety Rule? • Do the PSO's policies specify how the PSO will implement the Patient Safety Rule requirement (section 3.102(b)(1)(i)(B)) to notify the health care providers if confidentiality of submitted patient safety work product is breached? If the PSO has received patient safety work product, have there been any impermissible disclosures of patient safety work product?
6	Section 3.20, definition of Patient Safety Activities: (6) The provision of appropriate security measures with respect to patient safety work product.	Section 3.102(b)(1)(i)(A) of the Patient Safety Rule clarifies that a PSO's policies for the security of patient safety work product must meet the security requirements of section 3.106. The requirements of section 3.106 and sample self-assessment questions are provided in Table 2.
7	Section 3.20, definition of Patient Safety Activities: (7) The utilization of qualified personnel.	Has the PSO documented its policies for utilization of qualified staff (either as members of the PSO's workforce or as contractors)? For example, is there a linkage between the job descriptions for staff positions and the clinical, analytic, and improvement expertise needed for the PSO to meet its mission and provide the services the PSO is offering providers? [Note: questions regarding the match between the skills and expertise of the PSO's workforce and contractors and the clinical, analytic, and implementation services offered by

		the PSO are raised in #10 below.]
8	Section 3.20, definition of Patient Safety Activities: (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	Has the PSO documented how it will (does) meet this requirement? For example: • If the PSO only conducts Patient Safety Act activities, does its patient safety evaluation system encompass the entire PSO and all staff? If so, documentation can be more limited and focused on specification of the activities being undertaken. • If a PSO engages in non-Patient Safety Act activities, does the PSO's documentation describe the space that is allocated for patient safety evaluation system activities and which staff have access to patient safety work product? How is it possible to determine when "shared staff" perform patient safety evaluation system and non-patient safety evaluation system activities? • Has the PSO documented how it will (does) communicate with, and provide feedback to, participants in each patient safety evaluation system of the providers with which it works? If the PSO is actually providing feedback to participants on a provider's patient safety work product, can the PSO provide specific examples that demonstrate or document how the PSO is complying with this requirement?
PSO Criteria All entities seeking listing as a PSO must attest that, upon listing, they will comply, and remain in compliance with the following seven PSO criteria (Rows #9–#15) set forth in section 3.102(b)(2) of the Patient Safety Rule.		
Row	**PSO Criteria**	**PSO Sample Self-Assessment Questions**
9	Section 3.102(b)(2)(i)(A): The mission and primary activity of the PSO must be to conduct activities that are to improve patient safety and the quality of health care delivery.	Does the PSO undertake activities other than those authorized or required by the Patient Safety Act? If not, the PSO will automatically meet this requirement. If a PSO undertakes activities other than those undertaken pursuant to the Patient Safety Act, can the PSO demonstrate, taking into account all of the activities it performs, that the improvement of patient safety and health care delivery constitute its "primary" activity? Two possible ways of meeting this requirement would be to demonstrate that these activities: • Account for the "majority" of activity by its workforce; or • Account for the majority of revenue or expenditures of the entity.

10	Section 3.102(b)(2)(i)(B): The PSO must have appropriately qualified workforce members, including licensed or certified medical professionals.	Can the PSO document how the expertise and skills of its personnel (either PSO workforce members or contractor staff) are an appropriate match for the clinical, analytic, and improvement activities that the PSO offers providers? Can the PSO document that it has the services of a licensed or certified medical professional (either PSO workforce members or contractor staff)? Can the PSO document that there is a reasonable relationship between the expertise and skills of its medical professional(s) and the clinical issues the PSO addresses?
11	Section 3.102(b)(2)(i)(C): The PSO, within the 24-month period that begins after the date of initial listing as a PSO, and within each sequential 24-month period thereafter, must have two 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.	If a PSO has submitted certification that it has two contracts with different providers, do the two contracts cited by the PSO meet the regulatory requirements? Specifically: • Do the contracts meet the definition of bona fide (i.e., the contracts are written and entered in good faith)? • Do the contracts require receipt and review of patient safety work product by the PSO? • Were the contracts entered into with different providers? The Patient Safety Rule focuses on the provider entity entering the contract and not the providers covered by the contract. For example, entering two contracts with the same headquarters of a health system (one covering its hospitals and another covering its nursing homes) would not meet the requirement since the contracts are being entered with the same corporate entity. If the PSO has met the two contract requirement, has the PSO submitted the required notification?
12	Section 3.102(b)(2)(i)(D): The PSO is not a health insurance issuer, and is not a component of a health insurance issuer.	Can the PSO confirm its attestation that it is not a health insurance issuer or a component of a health insurance issuer? Is a health insurance issuer involved in the governance or financing of the PSO?

13	Section 3.102(b)(2)(i)(E): The PSO must make a disclosure to the Secretary as required under section 3.102(d), in accordance with 3.112 of this subpart. Note: Section 3.102(d)(2) requires that a PSO shall fully disclose— (i) any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and (ii) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity	Has the PSO documented how it has complied with this requirement, including being able to demonstrate the following: • Every time the PSO entered a Patient Safety Act contract with a provider, did the PSO conduct the required assessment to determine whether the PSO had other relationships with that provider that would require the PSO to complete and submit a disclosure statement? • If the PSO chose not to file a disclosure statement regarding a provider with which it entered a Patient Safety Act contract, can the PSO document that it made the determination that a disclosure statement was not required? • If the PSO developed any other relationships with that contracting provider during the contract period, did the PSO conduct the required re-assessment to determine whether the PSO needed to complete and submit a new or revised disclosure statement? • Did each disclosure statement submitted fully comply with the Patient Safety Rule?
14	Section 3.102(b)(2)(i)(F): 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. See section 3.102(b)(2)(iii), which establishes a different standard for continued listing, which is summarized here: At continued listing, the PSO must attest that it is using, and will continue to use, either (A) the Secretary's published guidance for common definitions and reporting formats (AHRQ Common Formats) or (B) an alternate system of formats and definitions in its collection of patient safety work product that permits valid comparisons	Is the PSO collecting patient safety work product in a standardized manner as required by the Patient Safety Rule? If the PSO is not using AHRQ's Common Formats, what system is the PSO using? If it is not using any standardized approach, what is the PSO's rationale? Once a PSO submits the *Certification for Continued Listing*, the requirement for compliance changes and the PSO should consider: • Is the PSO using AHRQ's Common Formats? • If the PSO is using another system, is the PSO prepared to demonstrate that the system it is using permits valid comparisons of similar cases among similar providers? • If the PSO is not collecting patient safety work product in a standardized manner, can the PSO provide a compelling rationale for why it is not practical or appropriate to use AHRQ's Common Formats or another standardized system?

	among similar providers. If the PSO cannot make either attestation, it must attest that it is not practical or appropriate to comply with the options A or B by submitting a clear explanation of why it is not practical or appropriate for the PSO to comply with those options.	
15	Section 3.102(b)(2)(i)(G): The PSO must utilize patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.	Has the PSO received patient safety work product from a provider seeking review and feedback? If so, can the PSO demonstrate or document how it has complied with this requirement?
Additional Requirements That Apply to All Component PSOs The following requirements (Rows #16–#19) only apply to PSOs that are component organizations. All component PSOs also must meet requirements applicable to all PSOs (Rows #1–#15). In each case, compliance with these additional requirements is the same at initial and continued listing.		
Row	**Requirements To Be Met By All Component PSOs**	**PSO Sample Self-Assessment Questions**
16	Section 3.102(c)(2)(i), Separation of Patient Safety Work Product: A component PSO must maintain patient safety work product separately from the rest of the parent organization(s) of which it is a part, and establish appropriate security measures to maintain the confidentiality of patient safety work product.	Can the component PSO demonstrate its compliance with this requirement? For example: • Does the component PSO have written policies and procedures and security measures in place to prevent access to its patient safety evaluation system and patient safety work product by staff of the parent organization? • If the component PSO has a shared information system with its parent organization, can the PSO demonstrate how its security controls are effective and/or would be effective in circumstances encompassed by its policies and procedures and operations? • If the parent organization provides IT support, does the component PSO have written confidentiality, nondisclosure agreements in place (see Row #19 below) to ensure that they understand and acknowledge restrictions regarding patient safety work product? The agreements could be with the IT support staff or with the parent organization that would have written agreements with the IT support staff. Similarly, if the parent organization provides services that require access to locations where patient safety work product is

		held, how does the component PSO handle physical security and access issues? • If the component PSO shares staff with its parent organization, how does the PSO ensure that these individuals fully understand the importance of: (1) maintaining patient safety work product separately from the parent organization, and (2) avoiding unauthorized disclosures? Do the PSO's confidentiality and security policies and procedures (Rows #5 and #6 above) adequately and appropriately address these issues? • Has the PSO experienced any incidents involving inappropriate access to its patient safety evaluation system or patient safety work product or "close calls" of breaches of security of patient safety work product?
17	Section 3.102(c)(2)(ii), Nondisclosure of Patient Safety Work Product: A component PSO must require that members of its workforce and any other contractor staff not make unauthorized disclosures of patient safety work product to the rest of the parent organization(s) of which it is a part.	The questions in Row #16 also apply here.
18	Section 3.102(c)(2)(iii), No Conflict of Interest. The pursuit of the mission of a component PSO must not create a conflict of interest with the rest of the parent organization(s) of which it is a part.	Can the component PSO demonstrate how it avoids situations (described in the preamble language accompanying section 3.102(c)(2)(iii) of the Patient Safety Rule) that might create a conflict of interest with its parent organization? For example, with respect to any staff members whom the component PSO shares with its parent organization, can the PSO point to the steps it took to review the responsibilities of such individuals before sharing identifiable patient safety work product with him or her? The preamble discussion notes that a component PSO would create a conflict of interest by sharing patient safety work product with a member of the parent organization whose job responsibilities would involve taking adverse personnel actions against providers based on the information available to him or her.
19	Section 3.102(c)(3), Written Agreements for Assisting a Component PSO in the Conduct of Patient Safety	If the component PSO has asked its parent organization for assistance in conducting patient safety activities, did the PSO enter the required written agreements? Do these written agreements meet the requirements of this

	Activities (summarized here): A component PSO may provide access to identifiable patient safety work product to one or more individuals in, or to one or more units of, its parent organization(s) if the component PSO enters into a written agreement with such individuals or units which requires that: (i) Access to patient safety work product is only provided to enable such individuals or units to assist the component PSO in its conduct of patient safety activities, and (ii) Such individuals or units may only use or disclose patient safety work product as specified by the component PSO, will take appropriate security measures to prevent unauthorized disclosures and will comply with the other certifications the component PSO has made regarding unauthorized disclosures and conducting the mission of the PSO without creating conflicts of interest.	section? For example: • Are the agreements limited to tasks that assist the PSO in carrying out patient safety activities? • Do the agreements contain provisions stipulating the required security measures? • Do the agreements specify how the component PSO will ensure that the individuals or units of the parent organization have met, are meeting, and will meet their responsibilities to avoid unauthorized disclosures? • Has the PSO ensured that the agreements are with individuals or units of the parent organization that will not pose a conflict of interest (see previous Row #18)?

Additional Requirements for PSOs that are Component Organizations of Excluded Entities The following requirements only apply to PSOs that are components of entities excluded by section 3.102(a)(2)(ii) of the Patient Safety Rule. Such PSOs are also responsible for compliance with all of the requirements listed above (Rows #1–#19). In each case, compliance with these additional requirements is the same at initial and continued listing.		
Row	**Additional Requirements for a PSO that is a component of an Excluded Entity**	**PSO Sample Self-Assessment Questions**
20	Section 3.102(c)(4)(i): A component organization of an (excluded) entity must: (i) Submit the following information with its certifications for listing: (A) A statement describing its parent organization's role, and the scope of the parent organization's authority, with respect to any of the following that apply: accreditation or licensure of health care providers, oversight or enforcement of statutory or regulatory requirements governing the delivery of health care services, serving as an agent of such a regulatory oversight or enforcement authority, or administering a public mandatory patient safety reporting system	Does the component PSO have a mechanism (1) to review if there are changes in the mission or activity of its parent organization and, if so, (2) to revise the written statement, and submit it to AHRQ?
21	Section 3.102(c)(4)(i): A component organization of an (excluded) entity must: (i) Submit the following information with its certifications for listing: (B) An attestation that the parent organization has no policies or procedures that would require or induce providers to report patient safety work product to their component organization once listed as a PSO and that the	How does the component organization determine if its parent organization has prohibited policies or incentives?

	component PSO will notify the Secretary within 5 calendar days of the date on which the component organization has knowledge of the adoption by the parent organization of such policies or procedures, and an acknowledgment that the adoption of such policies or procedures by the parent organization during the component PSO's period of listing will result in the Secretary initiating an expedited revocation process in accordance with § 3.108(e).	
22	Section 3.102(c)(4)(i): A component organization of an (excluded) entity must: (i) Submit the following information with its certifications for listing: (C) An attestation that the component organization will prominently post notification on its Web site and publish in any promotional materials for dissemination to providers, a summary of the information that is required by paragraph (c)(4)(i)(A) of this section. (see Row #20).	Does the PSO periodically review its Web site and promotional materials to ensure that the required summary statement regarding the role and authority of the parent organization is provided, and is current?
23	Section 3.102(c)(4)(ii), Comply with the following requirements during its period of listing: (A) The component organization may not share staff with its parent organization(s).	Can the component PSO document that it does not share staff with its parent organization(s)? Note the distinction between the prohibition on shared staff and the ability to enter a written agreement for assistance in carrying out patient safety activities pursuant to a written agreement required by the rule text in Row #24.
24	Section 3.102(c)(4)(ii), Comply with the following requirements during its period of listing: (B) The component organization may enter into a written agreement pursuant to paragraph (c)(3) but such	Has the PSO entered a written agreement with its parent organization for assistance in carrying out patient safety activities? If so, do these agreements meet the limitations of the rule?

	agreements are limited to units or individuals of the parent organization(s) whose responsibilities do not involve the activities specified in the restrictions in paragraph (a)(2)(ii) of this section.	

Table 2 PSO Compliance Self-Assessment: Section 3.106, Security Requirements for Patient Safety Work Product		
Row	**Patient Safety Rule Requirement**	**Sample PSO Self-Assessment Questions**
Application		
1	Section 3.106(a) A PSO must secure patient safety work product in conformance with the security requirements of paragraph (b) of this section. These requirements must be met at all times and at any location at which the PSO, its workforce members, or its contractors receive, access, or handle patient safety work product. Handling patient safety work product includes its processing, development, use, maintenance, storage, removal, disclosure, transmission, and destruction.	Has the PSO established security standards that meet the requirements of this section, including the standards that address all locations at which patient safety work product is held? Does the PSO have, or expect to have, contracts in place with outside contractors (e.g., consultants and vendors) to whom patient safety work product will be entrusted? If so, has the PSO: • Established specific security standards that its contractors must meet when they have access to patient safety work product? • Considered options that do not require the physical transfer of patient safety work product to contractors (such as providing electronic access through a secure network)? • Reviewed with contractors the protections and security requirements for patient safety work product, including the limitations on further disclosure of patient safety work product (section 3.205(b)(4) of the Patient Safety Rule states that a contractor may not further disclose patient safety work product except to the PSO or provider from which it received the patient safety work product)? • Defined clearly the permissible tasks for which the contractor may use patient safety work product and specified the individual(s) or unit(s) of the contractor(s) that may have access to patient safety work product? • Ensured that its contractors or vendors enter written agreements with each member of their workforce (both employees and subcontractors) with access to patient safety

		work product that require acknowledgement of the protections and limitations regarding its use and disclosure? • Established processes to monitor the patient safety work product that is in the possession of contractors?
Security Management		
2	Section 3.106(b)(1)(i) Maintenance and effective implementation of written policies and procedures that conform to the requirements of this section to protect the confidentiality, integrity, and availability of the patient safety work product that is received, accessed, or handled; and to monitor and improve the effectiveness of such policies and procedures.	Do the PSO's written policies and procedures: • Establish standards for <u>each</u> element of the security framework in section 3.106(b)? • Outline the processes by which the PSO (1) decides to disclose patient safety work product, (2) verifies that a proposed disclosure is permissible, (3) ensures that the patient safety work product being disclosed has been appropriately anonymized or rendered contextually nonidentifiable, if required by the rule, and (4) tracks to whom patient safety work product is disclosed and the specific information that was disclosed? • Address the entire spectrum of data activities from receipt, processing, use, storage, return to providers (if requested), and/or destruction? • Specify how the PSO will undertake "recovery" from emergencies, system failures, or security breaches? • Require documenting security breaches and evaluating their causes in an attempt to prevent reoccurrence? If the PSO (or its parent organization) uses an IT vendor, are there contractual provisions that: (1) ensure that disclosure determinations can only be authorized by the PSO; (2) require prompt notification of the PSO if data system emergencies, failures, or security breaches occur; (3) specify how "recovery" will take place, and (4) provide for evaluation of the causes of data system emergencies, failures, or security breaches? If the PSO is a component of another entity with which it shares an IT system, has the component PSO:

		• Ensured that there can be no unauthorized access by individuals or units of the parent organization(s) (section 3.102(c)(2)(i) of the Patient Safety Rule)? • Entered into, or required confidentiality agreements, with IT staff of the parent organization(s)? Note: IT staff of the parent organization(s) may have the ability to access patient safety work product.
3	Section 3.106(b)(1)(ii) Training of the PSO workforce and PSO contractors who receive, access, or handle patient safety work product regarding the requirements of the Patient Safety Act, this Part, and the PSO's policies and procedures regarding the confidentiality and security of patient safety work product.	With respect to staff and contractor training: • How soon does an individual receive training regarding the confidentiality and security protections for patient safety work product? • Does the PSO provide inservice (refresher) training? If so, how frequently? • Is there a process for: (1) reminding departing employees/contractors of their continuing confidentiality obligations regarding patient safety work product to which they had access during their period of employment; (2) retrieving any patient safety work product in their possession; and (3) deactivating their access to patient safety work product? • Does the training address electronic security (e.g., discuss creating strong passwords, virus/spyware/spam awareness, and security of electronic communications)? Does the PSO conduct background checks as part of its hiring processes? If the PSO is a component of one or more parent organization(s), how has the PSO ensured that its workforce and contractors understand that patient safety work product cannot be shared with individuals or units of its parent organization(s) except as authorized by the rule? Specifically: • Do the PSO's policies prohibit all "shared" staff members from removing patient safety work product from the component PSO and require signed confidentiality agreements that prohibit discussions of patient safety work product with anyone in the parent organization(s)?

		• If any individual or unit of the parent organization—other than a "shared" staff member—has access to patient safety work product held by the component PSO, does the PSO have a written agreement meeting the requirements of section 3.102(c)(3) to authorize this access? See Table 1, Row #19. • Has the PSO documented that other members of its workforce (nonshared staff) and its contractor(s) are aware of the prohibition on making unauthorized disclosures of patient safety work product to individuals or units of the PSO's parent organization(s)?
Distinguishing Patient Safety Work Product		
4	Section 3.106(b)(2)(i) Maintenance of the security of patient safety work product, whether in electronic or other media, through either physical separation from non-patient safety work product, or if co-located with non-patient safety work product, by making patient safety work product distinguishable so that the appropriate form and level of security can be applied and maintained.	If the PSO undertakes non-Patient Safety Act activities: • Has the PSO defined the physical and virtual (electronic) space that comprises its patient safety evaluation system? • Do the PSO's policies require that patient safety activities must be conducted exclusively within its defined patient safety evaluation system? • Does the PSO restrict access to patient safety work product to members of its staff that work in its patient safety evaluation system? Does the PSO maintain patient safety work product within its patient safety evaluation system? If not, how does the PSO ensure that staff performing non-Patient Safety Act work do not have inappropriate access to its patient safety work product? If the PSO undertakes only patient safety activities, has the PSO specified whether its patient safety evaluation system encompasses the entire PSO? How do the PSO's policies and procedures ensure that: • Patient safety work product submitted by a provider is always distinguishable from non-patient safety work product? Note: If its listing is revoked, a PSO must be able to return to a provider its patient safety work product. If the PSO merges patient safety work product with non-patient safety work product files, and the patient safety work product cannot be separated from the non-patient safety work

		product, then the entire merged file that is held by the PSO is patient safety work product. • Patient safety work product is always maintained at the appropriate level of security?
5	Section 3.106(b)(2)(ii) Protection of the media, whether in electronic, paper, or other media or format, that contain patient safety work product, limiting access to authorized users, and sanitizing and destroying such media before their disposal or release for reuse.	Do the PSO's policies and procedures: • Permit patient safety work product to be used off-site by its workforce, contractors, or vendors? If so, how does the PSO provide for the encryption of patient safety work product in any electronic storage device for transfer or use offsite (e.g., laptops, portable hard drives)? If not, how does the PSO ensure the protection of patient safety work product? • Prohibit the use of wireless access to patient safety work product that is not encrypted? • Provide for the complete sanitation of equipment and media that contained patient safety work product when it is being taken out of service? If the PSO is not using hard drive erasure software, how will it ensure complete sanitation? • Ensure an appropriate level of security/strength for passwords of authorized users? How frequently are the passwords changed?
6	Section 3.106(b)(2)(iii) Physical and environmental protection, to control and limit physical and virtual access to places and equipment where patient safety work product is received, accessed, or handled.	Does the PSO have: • A physical security plan to prevent unauthorized external access to the portion of the facility in which patient safety work product is handled (as defined in section 3.106(a))? For example, do the PSO's offices or facilities have guards, video surveillance, timed locks, etc.? • Controls to prevent unauthorized physical access, tampering, and theft of patient safety work product within the facility? These could include locked doors, signs warning of restricted areas, surveillance cameras, alarms, and identification numbers and security cables on computers. • An individual who is responsible for maintaining physical and/or electronic security

		(i.e., responsible for administering access keys or user logins/passwords)? • Policies and procedures for how this security will be maintained (e.g., new hire review, periodic, recurring access level review, timeframe for removal of terminated employees)? • Additional security measures in place to protect workstations with patient safety work product, such as using privacy screens, enabling password protected screen savers or an automatic logoff functionality for inactive workstations? • Records of when maintenance workers who are not part of the PSO's workforce (e.g., plumber, electrician, painter, facility staff) have access to locations in which patient safety work product is maintained? Has the PSO adopted safeguards against the potential threat of electronic intrusion? For example, does the PSO have— • Hardware firewalls to prevent intrusion from hackers or malicious software? If not, does the PSO take other steps to preclude external intrusion (e.g., maintaining patient safety work product on computers that are not connected to the internet)? • Does the PSO have port restrictions for wired jacks that connect to a network to ensure users cannot plug home/unmanaged/inappropriate devices into a network that may contain patient safety work product?
Security Control and Monitoring		
7	Section 3.106(b)(3)(i) Identification of those authorized to receive, access, or handle patient safety work product and an audit capacity to detect unlawful, unauthorized, or inappropriate receipt, access, or handling of patient safety work product.	Is the PSO able to: • Authenticate authorized users (internally) and authorized recipients externally (e.g., contractor staff, providers, etc.) submitting patient safety work product to the PSO? • Track access by authorized users? • Determine if patient safety work product has

		been received, accessed, or handled by an unauthorized user?
8	Section 3.106(b)(3)(ii) Methods to prevent unauthorized receipt, access, or handling of patient safety work product.	In addition to the questions posed elsewhere in this table— • Is it possible to access patient safety work product from outside the PSO's facility? If so, what types of security are required to obtain access? • Are there policies and procedures in place for monitoring server logs to review unauthorized attempts at access to the information system(s) containing patient safety work product?
Security Assessment		
9	Section 3.106(b)(4)(i) Periodic assessments of security risks and controls to establish if its controls are effective, to correct any deficiency identified, and to reduce or eliminate any vulnerabilities.	Did the PSO conduct a risk assessment before developing its security standards? Did any such risk assessment meet prevailing industry standards or practices? What did the PSO determine were its principal points of vulnerability for the protection of patient safety work product and how do its security standards address those major vulnerabilities? If the PSO did not conduct a risk assessment before developing its security plan for patient safety work product, how did the PSO determine that the standards it adopted were adequate and reasonable? Has the PSO established a schedule for periodic risk analyses? If so, on what basis did the PSO establish the frequency with which it will conduct risk analyses?
10	Section 3.106(b)(4)(ii) System and communications protection to monitor, control, and protect PSO receipt, access, or handling of patient safety work product with particular attention to the transmission of patient safety work product to and from providers, other PSOs, contractors or any other responsible persons.	How has the PSO addressed the vulnerabilities that exist when patient safety work product is transmitted? For example: • How does the PSO ensure the secure transportation and/or transmission to the PSO of patient safety work product to and from health care providers? • How does the PSO ensure secure communications with its reporting providers (all such communications are patient safety work product)? Do the PSO's policies address using secure email, avoiding discussion of

		patient safety work product when using cell phones that may be easily compromised, avoiding the use of unsecure fax machines, etc.?

Table 3
Required Notifications and Submissions by PSOs

Four requirements described below note that the use of specific forms is required. Those forms are available at www.pso.ahrq.gov. The forms must be submitted in their entirety and AHRQ will not accept a form that has been retyped or altered in any way. If you experience difficulty in downloading a form, submit an email to the AHRQ PSO email box (pso@ahrq.hhs.gov) and specify the form(s) you need. Several notification requirements do not require the use of a specific form. As noted below, those notifications can simply be submitted to the AHRQ PSO email box.

The Certification for Initial Listing form requires the individual completing the form to certify that he or she has the authority to make legally binding commitments on behalf of the entity seeking listing (i.e., the Authorized Official). Once listed, the PSO must notify AHRQ if there is a change in its designated Authorized Official. To ensure that the PSO submissions and notifications it receives are valid, AHRQ will expect all submissions and notifications to be sent by the Authorized Official.

Submission of Certifications By an Entity Seeking Listing as a PSO	
Requirement	***Required Date***
Certification for Initial Listing Form The form must be submitted by an entity seeking a 3-year period of listing as a PSO.	The Certification for Initial Listing form can be submitted at any time. The protections of the law are not in place until the entity is listed by AHRQ. The rule does not establish any deadlines for submission. There are no limits on the number of PSOs that can be listed.
Notifications or Submissions Required of Every PSO During Its Period of Listing	
Requirement	***Required Date***
Two Contract Notification A PSO must use this form to attest that it has entered two contracts for receipt and review of patient safety work product with two different providers. [Section 3.102(d)(1)]	No later than 45 calendar days before the end of each 24-month period following the PSO's initial listing date. [PSOs are encouraged to submit the notice as soon as the requirement is met.]
Disclosure Statement A PSO must use this attestation form and attach the required statement to notify AHRQ that the PSO has entered a Patient Safety Act contract with a provider with which it has other types of relationships specified in the rule. This attestation form and a disclosure statement are also required if a PSO subsequently establishes such relationships with a provider with which it has a Patient Safety Act contract. [Section 3.102(d)(2)]	If any of the specified relationships are present when a contract is entered, AHRQ must receive the statement within 45 calendar days of the date the contract is entered. If any of the specified relationships arise during the period the contract is in effect, AHRQ must receive the disclosure statement within 45 calendar days of the date on which a relationship is established.

Changes in the Accuracy of a PSO's Certifications reflected in Initial or Continued Listing Forms [email notification to pso@ahrq.hhs.gov] —If there are changes in the contact information for the PSO: address, telephone, fax, authorized official, point-of-contact, email addresses. —If the PSO begins using another name to market its PSO services (i.e., "doing business as…"). —If another legal entity gains ownership of, or has the ability to control or manage the PSO (e.g., merger). —If the PSO is recognized to be in noncompliance with any of its attestations. [Section 3.102(a)(1)(vi)]	The PSO must promptly notify AHRQ if any of these changes occur. Note that if a PSO enters into a relationship with another legal entity that can now exert control or management over the PSO, or another legal entity develops an ownership interest in the PSO, this may render the PSO's attestations incompatible with the PSO's new organizational structure. A PSO anticipating such changes is encouraged to discuss the changes with AHRQ staff prior to implementation.
Submission of Certifications for Continued Listing by a PSO	
Requirement	***Required Date***
Certification for Continued Listing Form This form must be submitted by a PSO seeking continued listing as a PSO for another 3-year period. [section 3.102(a)(3)]	PSOs must submit this certification form no later than 75 calendar days before the expiration of a PSO's current period of listing.
Notifications Required of PSOs that are Components of an Excluded Entity	
Nature of Requirement	***Required Date***
Notification if an Excluded Parent Organization Induces Providers to Report to its Component PSO [email notification to pso@ahrq.hhs.gov] A PSO that is a component of an excluded entity must attest at listing that its parent organization has no policies or procedures that would require or induce providers to report PSWP to the component PSO. During its period of listing if the PSO has knowledge that its parent organization has adopted such policies or procedures, the PSO must notify AHRQ. [Section 3.102(c)(4)(i)(B)]	AHRQ must be notified within 5 calendar days of the date on which the PSO has knowledge of the adoption of such policies and procedures.

Notifications Required of PSOs for Correction of Deficiencies and Revocation Process	
Requirement	***Required Date***
Opportunity to Question Accuracy of a Preliminary Finding of Deficiency [email notification to pso@ahrq.hhs.gov] After a PSO receives a Preliminary Finding of Deficiency notice, the PSO has an opportunity to question the factual basis of the notice. Unless evidence is received that the finding is factually incorrect, the PSO will be expected to meet the correction timetable in the notice. [Section 3.108(a)(2)(ii)]	The PSO must submit any evidence that the finding is factually incorrect within 14 days of actual or constructive receipt of a notice, whichever is longer. [Note: constructive receipt—In the absence of evidence of the date of receipt of a notice, the notice is presumed to be received 5 calendar days following the date on which it was mailed.]
Notify AHRQ that a deficiency has been corrected. [email notification to pso@ahrq.hhs.gov] A PSO must promptly provide AHRQ with documentation that the deficiency has been corrected. [Section 3.108(a)(3)(i)]	Unless the deficiency notice sets a specific date, AHRQ must receive documentation within 5 calendar days of the last day of the correction period in the notice of deficiency.
Opportunity to Respond to a Notice of Proposed Revocation [email notification to pso@ahrq.hhs.gov] Whenever a PSO receives a notice of proposed revocation, the PSO has an opportunity to submit a substantive written response to the deficiency findings in the notice. [Section 3.108(a)(4)(i)]	A PSO has until midnight, 30 calendar days after the date of actual or constructive receipt of a notice of proposed revocation, to submit a response.
Notification required following a decision to revoke the listing of a PSO [email notification to pso@ahrq.hhs.gov] Following notification of a decision to revoke its certifications and delist a PSO, the former PSO must submit confirmation to the Secretary that it has notified each provider whose PSWP it collected or analyzed of the revocation decision. [Section 3.108(b)(2)(ii)]	The PSO must submit the notification to AHRQ within 15 calendar days of being notified of the revocation decision.

Table 4 Patient Safety Rule Requirements For Which Attestations Are Required		
Patient Safety Activities		
Patient Safety Rule Text	**Initial Listing Form**	**Continued Listing Form**
42 Code of Federal Regulations, Part 3	An entity attests that it has policies and procedures in place to perform all 8 patient safety activities	A PSO attests that it is (a) currently performing, and (b) will continue to perform, each of the statutorily required patient safety activities throughout the period of continued listing.
Section 3.20, definition of Patient Safety Activities: (1) Efforts to improve patient safety and the quality of health care delivery	Part III, Attestation 1: Does the entity have policies and procedures to improve patient safety and the quality of health care delivery?	Part III, Attestation 1: Undertaking actions to improve patient safety and the quality of health care delivery?
Section 3.20, definition of Patient Safety Activities: (2) The collection and analysis of patient safety work product	Part III, Attestation 2: Does the entity have policies and procedures for the collection and analysis of patient safety work product?	Part III, Attestation 2: Collecting and analyzing patient safety work product?
Section 3.20, definition of Patient Safety Activities: (3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices	Part III, Attestation 3: Does the entity have policies and procedures to develop and disseminate information with respect to improving patient safety, such as recommendations, protocols, and best practices?	Part III, Attestation 3: Developing and disseminating information to improve patient safety?
Section 3.20, definition of Patient Safety Activities: (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	Part III, Attestation 4: Does the entity have policies and procedures to utilize patient safety work product to encourage a culture of safety, to provide feedback, and to provide assistance to effectively minimize patient risk?	Part III, Attestation 4: Utilizing patient safety work product to encourage a culture of safety, and to provide feedback and assistance to effectively minimize patient risk?

Section 3.20, definition of Patient Safety Activities: (5)The maintenance of procedures to preserve confidentiality with respect to patient safety work product	Part III, Attestation 5: Does the entity have policies and procedures to preserve confidentiality of patient safety work product in conformity with the rule and the authorizing statute?	Part III, Attestation 5: Implementing and maintaining procedures to preserve confidentiality of patient safety work product in conformity with the rule and authorizing legislation?
Section 3.20, definition of Patient Safety Activities: (6) The provision of appropriate security measures with respect to patient safety work product	Part III, Attestation 6: Does the entity have policies and procedures to protect patient safety work product in conformity with the rule and the authorizing statute?	Part III, Attestation 6: Implementing and maintaining security measures to protect patient safety work product in conformity with the rule and the authorizing legislation?
Section 3.20, definition of Patient Safety Activities: (7) The utilization of qualified staff	Part III, Attestation 7: Does the entity have policies and procedures in place to assure the utilization of appropriately qualified staff?	Part III, Attestation 7: Using appropriately qualified staff to improve patient safety and quality of health care delivery?
Section 3.20, definition of Patient Safety Activities: (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.	Part III, Attestation 8: Does the entity have policies and procedures in place to perform the collection, management, and analytic activities related to the operation of a patient safety evaluation system (PSES), including the provision of feedback to participants in a PSES?	Part III, Attestation 8: Performing the collection, management, or analytic activities related to the operation of a patient safety evaluation system (PSES), including providing feedback to participants in a PSES?
PSO Criteria		
Patient Safety Rule Text	**Initial Listing Form**	**Continued Listing Form**
42 Code of Federal Regulations, Part 3	An entity attests that, upon listing, it will comply with all seven PSO criteria.	A PSO attests that it is (a) currently complying with, and (b) will continue to comply with, each of the PSO criteria throughout the period of continued listing.
Section 3.102(b)(2)(i)(A): The mission and primary activity of the PSO must be to conduct activities that are to improve patient safety and the quality of health care delivery.	Part III, Attestation 9: Will improvement of patient safety and the quality of health care delivery be both (a) the entity's mission and (b) the entity's primary activity? A "yes" answer attests that both	Part III, Attestation 9: Making the improvement of patient safety and the quality of health care delivery (a) the PSO's mission and (b) the PSO's primary activity? A "yes" answer attests that both

	(a) and (b) will be met.	conditions are met.
Section 3.102(b)(2)(i)(B): The PSO must have appropriately qualified workforce members, including licensed or certified medical professionals.	Part III, Attestation 10: Will the entity's employees or contractors both (a) be appropriately qualified and (b) include licensed or certified medical professionals?	Part III, Attestation 10: Having staff (employees or contractors) who are both (a) appropriately qualified and (b) include licensed or certified medical professionals?
Section 3.102(b)(2)(i)(C): 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 two 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. .	Part III, Attestation 11: Will the entity meet the requirement to enter at least two bona fide contracts within 24 months of its initial listing (and meet that test in every subsequent 24-month period)?	Part III, Attestation 11: Meeting the requirement to enter into at least two bona fide contracts within each of the required sequential 24-month periods following initial listing?
Section 3.102(b)(2)(i)(D): The PSO is not a health insurance issuer, and is not a component of a health insurance issuer.	Part III, Attestation 12: Will the entity comply with the prohibition Part III, Attestation 12: that it may not be a health insurance insurer or a health insurance insurer component?	Part III, Attestation 12: Not being a health insurance issuer or a component of a health insurance issuer?
Section 3.102(b)(2)(i)(E): The PSO must make disclosures to the Secretary as required under § 3.102(d), in accordance with § 3.112 of this subpart.	Part III, Attestation 13: Will the entity meet the requirement to fully disclose to the Secretary relationships with contracting providers?	Part III, Attestation 13: Fully disclosing to the Secretary relationships with contracting providers?
Section 3.102(b)(2)(i)(F): 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.	Part III, Attestation 14: Will the entity collect patient safety work product in a standardized manner that permits valid comparisons of similar cases? Note: The Secretary is providing guidance on common definitions and reporting formats, known as Common Formats, which is available at www.pso.ahrq.gov.	Part III, Attestation 14: A. Using the Secretary's published guidance for common definitions and reporting formats (Common Formats) in its collection of patient safety work product? B. Using an alternate system of formats and definitions in its collection of patient safety work product that permits valid comparisons among similar providers? C. Attest that it is not practical or appropriate to comply with the

		options described in questions 14A or 14B. If the answer is "yes", attach a separate sheet with a clear explanation of why it is not practical or appropriate for the PSO to comply with those options. D. If the answer to 14C is "yes", is the required explanatory statement attached to this form?
Section 3.102(b)(2)(i)(G): The PSO must utilize patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.	Part III, Attestation 15: Will the entity utilize patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk?	Part III, Attestation 15: Using patient safety work product to provide feedback and help to providers in order to minimize patient risk?
Additional Requirements That Apply to All Component PSOs		
Patient Safety Rule Text	**Initial Listing Form**	**Continued Listing Form**
42 Code of Federal Regulations, Part 3	A component organization attests what it will do if listed.	The PSO attests that it is (a) currently complying with, and (b) will continue to comply with, each of the additional statutory requirements for component PSOs throughout the period of continued listing
Section 3.102(c)(2)(i): A component PSO must maintain patient safety work product separately from the rest of the parent organization(s) of which it is a part, and establish appropriate security measures to maintain the confidentiality of patient safety work product.	Part III, Attestation 16: Will the component entity maintain patient safety work product separately from the rest of the parent organization(s) and establish appropriate security measures to maintain the confidentiality of patient safety work product?	Part III, Attestation 16: Maintaining patient safety work product separately from the PSO's parent organization(s) and has established appropriate security measures to maintain the confidentiality of patient safety work product?
Section 3.102(c)(2)(ii): A component PSO must require that members of its workforce and any other contractor staff not make unauthorized disclosures of patient safety work product to the rest of the parent organization(s) of which it is a	Part III, Attestation 17: Will the component entity require that members of its workforce and any other contractor staff not make unauthorized disclosures of patient safety work product to the rest of the parent organization(s)?	Part III, Attestation 17: Requiring that members of its workforce and any other contractor staff not make unauthorized disclosures of patient safety work product to the rest of the parent organization(s)?

part.		
Section 3.102(c)(2)(iii): The pursuit of the mission of a component PSO must not create a conflict of interest with the rest of the parent organization(s) of which it is a part.	Part III, Attestation 18: Will the component entity ensure that the pursuit of its mission will not create a conflict of interest with the rest of its parent organization(s)?	Part III, Attestation 18: Ensuring that the pursuit of its mission is not creating a conflict of interest with the rest of its parent organization(s)?
Section 3.102(c)(3), Written Agreements for Assisting a Component PSO in the Conduct of Patient Safety Activities	Note: There is not a corresponding attestation.	Note: There is not a corresponding attestation.
Additional Requirements for PSOs that are Component Organizations of Excluded Entities		
Patient Safety Rule Text	**Initial Listing Form**	**Continued Listing Form**
Section 3.102(c)(4)(i)(A): A statement describing its parent organization's role, and the scope of the parent organization's authority, with respect to any of the following that apply: accreditation or licensure of health care providers, oversight or enforcement of statutory or regulatory requirements governing the delivery of health care services, serving as an agent of such a regulatory oversight or enforcement authority, or administering a public mandatory patient safety reporting system	Part II, Attestation C1: Have you attached a statement outlining the role and authority of the parent organization as required by section 3.102(c)(4)(i)(A)?	Part II, Attestation B4: Has the component PSO complied with the requirements of section 3.102(c)(4) of the rule during its current period of listing? Part II, Attestation B5: If the Secretary approves the request for continued listing, will the component PSO comply with the requirements of section 3.104(c)(4) during its period of continued listing?

Section 3.102(c)(4)(i)(B): An attestation that the parent organization has no policies or procedures that would require or induce providers to report patient safety work product to their component organization once listed as a PSO and that the component PSO will notify the Secretary within 5 calendar days of the date on which the component organization has knowledge of the adoption by the parent organization of such policies or procedures, and an acknowledgment that the adoption of such policies or procedures by the parent organization during the component PSO's period of listing will result in the Secretary initiating an expedited revocation process in accordance with § 3.108(e);	Part II, Attestation C2: Does the parent organization have policies and procedures in place that would require or induce providers to report patient safety work product to the component if listed as a PSO? [See the prohibition in section 3.102(c)(4)(i)(B).] Part II, Attestation C3: If listed as a PSO, will the component notify the Secretary within five calendar days if the parent organization adopts such policies or procedures that would require or induce providers to report patient safety work product to the component? [See section 3.102(c)(4)(i)(B).]	Part II, Attestation B4: Has the component PSO complied with the requirements of section 3.102(c)(4) of the rule during its current period of listing? Part II, Attestation B5: If the Secretary approves the request for continued listing, will the component PSO comply with the requirements of section 3.104(c)(4) during its period of continued listing?
Section 3.102(c)(4)(i)(C): An attestation that the component organization will prominently post notification on its website and publish in any promotional materials for dissemination to providers, a summary of the information that is required by paragraph (c)(4)(i)(A) of this section. [See Row #20 above]	Part II, Attestation C4: If listed as a PSO, will the component prominently post notification on its Web site, and publish in any promotional materials for dissemination to providers, a summary of the parent organization's role and authority as required by section 3.102(c)(4)(i)(C)?	Part II, Attestation B4: Has the component PSO complied with the requirements of section 3.102(c)(4) of the rule during its current period of listing? Part II, Attestation B5: If the Secretary approves the request for continued listing, will the component PSO comply with the requirements of section 3.104(c)(4) during its period of continued listing?
Section 3.102(c)(4)(ii)(A): The component organization may not share staff with its parent organization(s).	Part II, Attestation C5: If listed as a PSO, will the entity comply with the restrictions of section 3.102(c)(4)(ii)(A) that prohibits the sharing of staff with the parent organization?	Part II, Attestation B4: Has the component PSO complied with the requirements of section 3.102(c)(4) of the rule during its current period of listing? Part II, Attestation B5: If the Secretary approves the request for continued listing, will the component PSO comply with the requirements of section

		3.104(c)(4) during its period of continued listing?
Section 3.102(c)(4)(ii)(B): The component organization may enter into a written agreement pursuant to paragraph (c)(3) but such agreements are limited to units or individuals of the parent organization(s) whose responsibilities do not involve the activities specified in the restrictions in paragraph (a)(2)(ii) of this section.	Part II, Attestation C6: If listed as a PSO, will the entity comply with the additional restrictions on contracting with the parent organization in section 3.102(c)(4)(ii)(B) of the rule?	Part II, Attestation B4: Has the component PSO complied with the requirements of section 3.102(c)(4) of the rule during its current period of listing? Part II, Attestation B5: If the Secretary approves the request for continued listing, will the component PSO comply with the requirements of section 3.104(c)(4) during its period of continued listing?