

DISCLOSURE STATEMENT – INSTRUCTIONS

PATIENT SAFETY ORGANIZATION RELATIONSHIP WITH A CONTRACTING PROVIDER

Before submitting a disclosure statement, review the requirements of the regulation implementing the Patient Safety and Quality Improvement Act (Patient Safety Act), 42 CFR Part 3 (available at www.pso.ahrq.gov), especially sections 3.102(d)(2) and 3.104(c).

A PSO must submit a disclosure statement to the Secretary under the following circumstances: (a) the PSO has entered into a contract with a provider pursuant to the Patient Safety and Quality Improvement Act and (b) that contracting provider has other relationships with the PSO and/or that contracting provider has some form of control over the operation of the PSO. A PSO does not need to file a disclosure statement unless the circumstances described in (a) and (b) are present. A summary of how the regulation defines “relationships” and “control” is provided below.

Section 924(b)(1)(E) of the Patient Safety and Quality Improvement Act of 2005 requires that a PSO fully disclose to the Secretary the nature of any other relationships the PSO has with a provider with which it has entered a contract to carry out patient safety activities and/or the extent to which the contracting provider has any control over the PSO. In developing the disclosure statement to accompany this form, a PSO should review the basis on which the Secretary will make a determination regarding the ability of the PSO to fairly and accurately carry out required patient safety activities. The basis for the Secretary’s determination is set forth in section 3.104(c) of the regulation. As noted in that section, the Secretary may decide to list an entity as a PSO, continue to list an entity as a PSO, decline to list an entity as a PSO, revoke the listing of a PSO, or condition the listing of a PSO, i.e., clarifying or establishing requirements that it must meet to ensure that the entity can fairly and accurately perform its patient safety activities.

A PSO is first required to assess whether it must submit a disclosure statement to the Secretary when it enters a Patient Safety Act contract with a provider. If disclosure is required, the Secretary must receive a disclosure statement no later than 45 days after the effective date of the contract with the provider. These requirements also apply throughout the period that a contract is effective. If any circumstance described below arises during the contract period, the Secretary must receive a disclosure statement within 45 days. If a PSO has filed a disclosure statement with respect to a provider, a subsequent disclosure statement is required only if: 1) the PSO enters new or additional relationships with that provider, or 2) that provider exerts new or additional control over the PSO’s operation. A PSO is not required to file a subsequent disclosure statement if a previously disclosed relationship, or provider control, terminates, but it may do so.

Circumstances that require a PSO to submit a disclosure statement to the Secretary.

A PSO must submit a disclosure statement if the PSO has entered a Patient Safety Act contract with a provider AND the circumstances described in (1) AND / OR (2) are present.

1. A Patient Safety Organization has any financial, reporting, or contractual relationships with a contracting provider, in addition to a Patient Safety Act contract. Examples of the types of relationships that require the filing of a disclosure statement include:
 - a. An additional contractual relationship with a contracting provider, whether a formal contract or an oral or written arrangement, that imposes responsibilities on the Patient Safety Organization beyond the requirements of its Patient Safety Act contract with the provider.
 - b. A financial relationship with a contracting provider that involves any kind of direct or indirect ownership, investment relationship, or direct or indirect compensation arrangement, whether in cash or in-kind. For example:
 - If the PSO receives any type of financial payment or in-kind services from a provider organization as a result of relationships other than the Patient Safety Act contract with this provider;
 - If a contracting provider organization has an ownership or investment interest in the PSO as a result of any relationship other than the Patient Safety Act contract; or
 - If the PSO has a financial debt owed to a contracting provider organization as a result of a relationship other than its Patient Safety Act contract with this provider.
 - c. A reporting relationship with a contracting provider that gives the provider access to information that is not available to other contracting providers, or control (either directly or indirectly) over the work of the Patient Safety Organization.
2. A Patient Safety Organization is not independently managed or controlled, or it does not operate independently from any contracting provider(s). The PSO must take into account all relationships, including its Patient Safety Act contracts, in determining whether a disclosure statement must be filed under this circumstance. For example, a disclosure statement must be filed:
 - If there is any form of inter-locking governance structure with the contracting provider organization. This would include situations in which the contracting provider organization recommended or designated individuals to govern the PSO, reviewed or influenced PSO hiring decisions or staff assignments; or
 - If the contracting provider organization exercises a degree of control or management authority, e.g., over the PSO’s budget, fees, and operations, or the findings of work performed for the provider.

The circumstances described in #2 are not intended to require a disclosure statement when a contract for patient safety activities specifies the tasks to be done or the patient safety events to be reviewed. Such requirements reflect the nature of Patient Safety Act contracts. The statutory focus is on control that could compromise the ability of the PSO to fairly and accurately perform patient safety activities.

If the PSO has relationships with a contracting provider requiring disclosure under either of the above two circumstances, the PSO is required to attach a narrative to this attestation form that describes each reportable relationship in relevant detail to meet the statutory requirement to "fully disclose" all such relationships. The attestation below certifies that the attached narrative is true and complete and that the PSO has complied with the requirement for timely submission. If applicable, the narrative statement should also describe any actions, safeguards, or other actions that the PSO has taken to mitigate the risk that the reported relationship would prevent the PSO from fairly and accurately performing its patient safety activities. PSOs are also urged to indicate the relative significance of the reported relationship(s) (e.g., in relation to the PSO's total budget or in relation to PSO obligations to other contracting providers).

Please note:

- If a Patient Safety Organization has no relationships to disclose, no action is required.
- *All disclosure statements, and the Secretary's findings and any conditions, or actions taken based on these statements, will be made public to inform potential PSO customers about their options and may be posted on the PSO website, except the Secretary reserves the right to exclude information that would be exempt from disclosure under the Freedom of Information Act.*
- If the Secretary discovers a relationship that required disclosure for which a disclosure statement was not filed within the 45-day reporting period, such failure to file will be treated as a deficiency and may trigger the revocation process described in section 3.108 of the regulation for de-listing a PSO.

DISCLOSURE STATEMENT CERTIFICATION PATIENT SAFETY ORGANIZATION RELATIONSHIP WITH A CONTRACTING PROVIDER

NAME – PATIENT SAFETY ORGANIZATION:

NAME – CONTRACTING PROVIDER(S):

ATTACHMENT:

Please attach a narrative disclosure statement describing: **(a)** the nature of the respective relationship(s) between the PSO and the above-named contracting provider(s) outside of their Patient Safety Act contract(s) and/or **(b)** the extent to which the(se) contracting provider(s) manage, control, or limit the independent operation of the PSO that could or does compromise the ability of the PSO to fairly and accurately perform patient safety activities. The statement should list any safeguards implemented, or other actions taken to mitigate the risk of such other relationship(s) or forms of control asserted by providers.

Disclosure (check one): New Revision to disclosure statement of _____ (fill in date)

ATTESTATION:

I am authorized to complete this form and provide required attachments on behalf of the PSO. I have attached a document providing the required disclosures of relationships with contracting providers. The statements on this form, and in any attachments to it, are true, complete, and correct to the best of my knowledge and belief and are made in good faith. I understand that a knowing and willful false statement on this form or in any required attachment can be punished by fine or imprisonment or both (United States Code, Title 18, Section 1001). I also certify that I will submit a revised disclosure statement to the Secretary within 45 days of any change that renders this attestation (including descriptive disclosures in attached documents) inaccurate or incomplete. [NOTE: A revised disclosure statement may be voluntarily submitted when a relationship or form of control (described in a previous statement submitted to the Secretary) terminates. It is not required.]

PSO Authorized Official Printed Name: _____

PSO Authorized Official Title: _____

PSO Authorized Official Signature: _____

Date: _____

Burden Statement

Public reporting burden for the collection of information on this complaint form is estimated to average 30 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201