

DISCLOSURE STATEMENT – INSTRUCTIONS

PATIENT SAFETY ORGANIZATION RELATIONSHIP WITH A CONTRACTING PROVIDER

Before submitting a disclosure statement, review the requirements of the Interim Guidance Implementing the Patient Safety and Quality Improvement Act (available at www.pso.ahrq.gov), especially sections 3.102(d)(2) and 3.104(c).

When the Requirement Applies

Section 924(b)(1)(E) of the Patient Safety and Quality Improvement Act of 2005 requires that a PSO fully disclose to the Secretary any financial, contractual, or reporting relationships the PSO has with a contracting provider and, if applicable, the extent to which the PSO is not operated independently, controlled independently, or managed independently of a contracting provider.

Therefore, 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 financial, contractual, or reporting relationships with the PSO; and if applicable,
- (c)** that contracting provider has some form of control over the operation of the PSO.

If a PSO enters a contract with a provider but neither (b) nor (c) apply, the PSO is not required to submit a disclosure statement. Conversely, if (b) or (c) apply but the PSO has not entered a contract with that provider pursuant to the Patient Safety Act, there is no requirement to submit a disclosure statement.

Deadlines for Filing a Disclosure Statement

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.

Content of a Disclosure Statement

A disclosure statement must comply with the statutory requirement to fully disclose the PSO's other relationships with a contracting provider and the extent to which (if applicable) the contractor can exercise control over the PSO; and, a second section in which the PSO explains, given the relationship(s) described, why the PSO can "fairly and accurately perform patient safety activities." The PSO may want to include a second section as described below:

Section 1: Describing the Relationships Between the PSO and the Contracting Provider

Because any arrangements between a PSO and a provider may involve several relationships for which the statute requires disclosure (e.g., financial, contractual, reporting, or relationships affecting the independence of the PSO), the PSO should organize the statement as a list of obligations that exist between the PSO and provider and treat the required disclosures as aspects of each obligation. Each obligation should be described succinctly in a short paragraph and, within that paragraph, address the required statutory disclosures. As an example, if a PSO conducts two different analyses for this provider, apart from its Patient Safety Act contract, the PSO would have two different obligations and should include two paragraphs in this section. Each paragraph would describe one study in a sentence or two and note which of the required disclosures apply (e.g. whether this obligation was contractual, had financial or reporting aspects, etc). If the provider is an investor in, or owner of, the PSO, that fact should be treated as a separate obligation. Note that the statute requires disclosure if any obligation affects the independence of the PSO.

Section 2: Statement Describing How the PSO Can Fairly and Accurately Perform Patient Safety Activities.

This optional statement should also be succinct (1,000 words or less) and, if included, should address:

- The policies and procedures the PSO has in place to ensure adherence to objectivity and to existing and evolving professional analytic standards in the analyses it undertake
- Any other policies, procedures, or agreements that are in place to ensure that the PSO can fairly and accurately perform patient safety activities (these should be linked, if appropriate, to the specific relationships and issues of control that are listed in section 1).

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 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 disclosure statement providing: **(a)** brief descriptions of the other relationship(s) between the PSO and the above-named contracting provider(s) outside of their Patient Safety Act contract(s) and, optionally, **(b)** a brief narrative statement that addresses why the PSO, given these relationships, can still fairly and accurately perform patient safety activities.

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