

PATIENT SAFETY ORGANIZATION: DISCLOSURE STATEMENT

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), and its implementing regulations at 42 CFR Part 3 (Patient Safety Rule), establish a system of Patient Safety Organizations (PSOs). The Agency for Healthcare Research and Quality (AHRQ) of the Department of Health and Human Services (HHS) administers the provisions of the Patient Safety Act and Patient Safety Rule dealing with PSO operations. Information related to PSOs is available on AHRQ's PSO Web site at www.pso.ahrq.gov.

Before completing this form, please review the requirements of the Patient Safety Rule specified in 42 CFR Part 3, especially sections 3.102(d)(2), 3.104(c), and the definition of provider in 3.20. The Patient Safety Rule requires that a PSO fully disclose to the HHS Secretary any financial, contractual, or reporting relationships the PSO has with a contracting provider(s) and, if applicable, the fact that the PSO is not operated independently, controlled independently, or managed independently from any contracting provider as required in section 3.102(d)(2)(i). A separate disclosure form is required for each contracting provider. The only exception is when the required disclosures are identical in all respects for each contracting provider. In such cases, the PSO can submit one disclosure statement with an attached sheet that lists each of the providers to which the disclosures apply.

Therefore, a PSO must submit a disclosure statement to the HHS Secretary under the following circumstances:

- (a) the PSO has entered into a contract with a provider pursuant to the Patient Safety Act and
- (b.1) the PSO has other financial, contractual, or reporting relationships with that contracting provider; or
- (b.2) the PSO is not managed independently, controlled independently, or does not operate independently from that contracting provider.

If a PSO enters into a contract with a provider but neither (b.1) nor (b.2) apply, the PSO is not required to submit a disclosure statement. Conversely, if (b.1) or (b.2) applies, but the PSO has not entered into a contract with that provider pursuant to the Patient Safety Act, there is no requirement to submit a disclosure statement.

Please submit this form to AHRQ's PSO Office via E-mail at PSO@ahrq.hhs.gov. To submit a hard copy, please send to: PSO Office, AHRQ, 540 Gaither Road, Rockville, MD 20850.

Deadlines for Filing a Disclosure Statement

If disclosure is required, the HHS Secretary must receive a disclosure statement no later than 45 calendar days after the date on which the PSO enters into a contract with the provider. These requirements also apply throughout the period that a contract is effective. If the circumstances described in (b.1) or (b.2) arise during the contract period, the HHS Secretary must receive a disclosure statement within 45 calendar days.

Whether or not a PSO has filed a disclosure statement with respect to a provider, a disclosure statement is required if: 1) the PSO enters into new or additional relationships, as described in (b.1), with that provider; or 2) that provider exerts new or additional control, as described in (b.2), 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 the PSO is encouraged to inform the HHS Secretary of such termination.

Content of a Disclosure Statement

A disclosure statement must include two sections. The first section must provide a succinct list of the obligations that exist between the PSO and the contracting provider – apart from any Patient Safety Act contract(s), which do not need to be listed – that create, or contain relationships of the type described above in (b.1) or (b.2). In the second section, the PSO must provide a brief explanatory narrative that meets the requirements described below. The required explanatory narrative enables the PSO to explain, given the relationship(s) described in the first section of the disclosure statement, why the PSO can "fairly and accurately perform patient safety activities." The second section is necessary to enable the HHS Secretary to make the determination required by section 3.104(c)(1) of the Patient Safety Rule.

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 [summarized in (b.1) and (b.2) above], 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 that addresses 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. Each paragraph would describe one study, in a sentence or two, and note which of the required disclosures apply [summarized in (b.1) and (b.2) above]. If the provider is an investor in, or owner of, the PSO, that fact should be treated as a separate obligation.

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

This statement should also be succinct (1,000 words or less) and 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 undertakes; and
- 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 PSO has no relationships to disclose, no action is required.
- All disclosure statements, 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 Web site; the HHS Secretary reserves the right to exclude information that would be exempt from disclosure under the Freedom of Information Act.
- If the HHS 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 Patient Safety Rule for de-listing a PSO.

**DISCLOSURE STATEMENT CERTIFICATION:
PSO RELATIONSHIP WITH A CONTRACTING PROVIDER**

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|----------|--------------------------|
| PSO Name | AHRQ-Assigned PSO Number |
|----------|--------------------------|

Name – Contracting Provider, including city and state

Attachment: Please attach a disclosure statement that meets the requirements of section 3.102(d)(2) of the rule that provides both (a) the required disclosures, and (b) the required explanatory narrative.

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

I am authorized to complete this form and to submit required attachments on behalf of the PSO. I have attached a statement providing the required disclosure(s) of relationships with contracting providers. The statements on this form, and in any attachments to it, are made in good faith and are true, complete, and correct to the best of my knowledge and belief. 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 HHS Secretary within 45 days of any change that renders this attestation (including descriptive disclosures in attached documents) inaccurate or incomplete. *Note: A PSO is not required to file a subsequent disclosure statement if a previously disclosed relationship (or provider control) terminates, but the PSO is encouraged to inform the HHS Secretary of such termination.*

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|--------------------------------------|-------------------------------|
| PSO Authorized Official Printed Name | PSO Authorized Official Title |
|--------------------------------------|-------------------------------|

Authorized Official Organization (if different from PSO)

| | |
|---------------------------|-------------------------|
| Authorized Official Phone | Authorized Official Fax |
|---------------------------|-------------------------|

Authorized Official Email

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| PSO Authorized Official Signature | Date |
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Burden Statement

Public reporting burden for the collection of information is estimated to average 3 hours per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer, Attention: PRA, Paperwork Reduction Project (0935-0143), AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850.