CLEAN VERSION (09-26-2024)

Form Approved
OMB No. 0935-0143
Exp. Date: ??/??/????

PATIENT SAFETY ORGANIZATION: DISCLOSURE STATEMENT

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorizes the creation 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 website at www.pso.ahrq.gov. All references to Secretary within this form refer to the Secretary of HHS.

Please review the Patient Safety Act and the Patient Safety Rule at sections 3.102(d)(2), 3.104(c), and the definition of provider in section 3.20. Section 3.102(d)(2)(i) of the Patient Safety Rule requires that a PSO file a disclosure statement with the Secretary if, in addition to a Patient Safety Act contract, the PSO has with the same provider any of the relationships that are described in (d)(2)(i)(A) through (D):

(A) The provider and PSO have current contractual relationships, other than those arising from any Patient Safety Act contracts, including formal contracts or agreements that impose obligations on the PSO.

(B) The provider and PSO have current financial relationships other than those arising from any Patient Safety Act contracts. A financial relationship may include any direct or indirect ownership or investment relationship between the PSO and the contracting provider, shared or common financial interests, or direct or indirect compensation arrangements whether in cash or in-kind.

(C) The PSO and provider have current reporting relationships other than those arising from any Patient Safety Act contracts, by which the provider has access to information regarding the work and operation of the PSO that is not available to other contracting providers.

(D) Taking into account all relationships that the PSO has with the provider, the PSO is not independently managed or controlled, or the PSO does not operate independently from, the contracting provider.

The disclosure statement should provide AHRQ with the information necessary to determine if the PSO can fairly and accurately perform the required patient safety activities.

A PSO must submit a disclosure statement consisting of this form and the accompanying attachment for each provider to which the disclosure requirements apply. If the required disclosure statements would be identical in all respects for each contracting provider at the time of submission, the PSO may submit a single disclosure statement form and include in its attachment a list of the names, city, and state of each of the additional providers to which the disclosure statement applies.

This form must be signed by the PSO's Authorized Official.

Please note:

- All disclosure statements and the Secretary's related findings will be made available to the public and may be posted on the PSO website; the Secretary reserves the right to withhold information that would be exempt from disclosure under the Freedom of Information Act.
- A PSO is not required to file a subsequent disclosure statement if its relationship with a provider that was the subject of a previously disclosed relationship ends or otherwise changes so that a disclosure statement would no longer be required, but the PSO is encouraged to inform the Secretary of such circumstances.

Before submitting the form, you may wish to contact the AHRQ PSO Office to discuss the nature of your disclosure or to clarify any issues or concerns about disclosure requirements. If so, please contact AHRQ via e-mail at pso@ahrq.hhs.gov or by phone at (866) 403-3697 or (866) 438-7231 (TTY). Please submit completed forms to AHRQ's PSO Office via e-mail, at pso@ahrq.hhs.gov. To submit a hard copy, please send to: PSO Office, AHRQ, 5600 Fishers Lane, MS 06N100B, Rockville, MD 20857.

Deadlines for Filing a Disclosure Statement

The Secretary must receive a disclosure statement within 45 calendar days of the date on which the PSO enters into a contract with the provider if any of the circumstances described in section 3.104(d)(2)(i)(A) through (D) of the Patient Safety Rule exists on the date the contract is entered. If these circumstances subsequently arise during the contract period, the Secretary must receive a disclosure statement within 45 calendar days of the date that any disclosure requirement in section 3.102(d)(2)(i) first applies.

If the Secretary is made aware of a relationship that required disclosure for which a disclosure statement was not filed within the 45-day reporting period, the Secretary may determine that the PSO is not in compliance with its obligations under the Patient Safety Act and Patient Safety Rule and begin the revocation process described in section 3.108 of the Patient Safety Rule for delisting a PSO.

Contents of Disclosure Statement Attachment

The disclosure statement attachment must include the following substantive information in two parts in sufficient detail to meet the requirements of 3.102(d)(2):

(A) Required Disclosures: The first part of the substantive information must provide a succinct list of obligations between the PSO and the contracting provider apart from their Patient Safety Act contract(s) that create, or contain, any of the types of relationships that must be disclosed based upon the requirements of section 3.102(d)(2)(i)(A) through (D) of the Patient Safety Rule. Each reportable obligation or discrete set of obligations that the PSO has with this contracting provider should be listed only once; noting the specific aspects of the obligation(s) that reflect contractual or financial relationships, involve access to information that is not available to other providers, or affect the independence of PSO operations, management, or control.

(B) Explanatory Narrative: The second required part of the substantive information must provide a brief explanatory narrative (1,000 words or less is recommended) succinctly describing: the policies and procedures that the PSO has in place to ensure adherence to objectivity and professionally recognized analytic standards in the assessments it undertakes; and any other policies or procedures, or agreements with this provider, that the PSO has in place to ensure that it can fairly and accurately perform patient safety activities.

Because a single arrangement between a PSO and a provider may involve multiple relationships that require disclosure, the PSO should organize the statement as a list of arrangements or obligations that exist between the PSO and provider, describe each arrangement/obligation separately, and address the relationships that require disclosure within the description of each arrangement/obligation.

DISCLOSURE STATEMENT:
PSO RELATIONSHIP WITH A CONTRACTING PROVIDER

PSO Number	PSO Name

Name of Contracting Provider	City and State

Date PSO entered into a Patient Safety Act contract with this provider:

Date the circumstances described in any of paragraphs 3.102(d)(2)(i)(A) through (D) of the Patient Safety Rule first applied to this PSO and provider:

Does the PSO have obligations and/or relationships with other providers that are identical in all respects to the one listed above?

☐ Yes ☐ No

If "Yes," in lieu of completing this form for each additional contracting provider, did the PSO include in its attachment a list of these providers' names and locations (city and state only)?

☐ Yes ☐ No

Type of Disclosure

_____ New

_____Revised: This statement is submitted to revise existing disclosure statement dated _____ (fill in date)

Required Attachment: A disclosure statement that meets the requirements of section 3.102(d)(2)(ii) of the Patient Safety Rule, providing both (a) the required disclosures and (b) the required explanatory narrative, must be attached.

CERTIFICATION OF DISCLOSURE STATEMENT

I am legally authorized to complete this form and to submit the required attachments on behalf of the PSO. I have provided all of the required disclosures of obligations and relationships with contracting providers and all of the content required for such disclosures. 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 new or revised disclosure statement, as applicable, to the Secretary within 45 days of:

- any change that renders this attestation (including descriptive disclosures in attached documents) inaccurate or incomplete with respect to an ongoing relationship with a provider; and/or
- the commencement of a relationship requiring disclosure with another provider.

Authorized Official Information

Name

Title

Organization (if different from PSO)

******This form must be signed and dated by the Authorized Official on record with AHRQ.******

Phone Extension (if applicable)

Email

Signature

Date

This completed form is considered public information.

Burden Statement

This survey is authorized under 42 U.S.C. 299a. This information collection is voluntary and the confidentiality of your responses to this survey is protected by Sections 944(c) and 308(d) of the Public Health Service Act [42 U.S.C. 299c-3(c) and 42 U.S.C. 242m(d)]. Information that could identify you will not be disclosed unless you have consented to that disclosure. Public reporting burden for this collection of information is estimated to average 3 hours per response, the estimated time required to complete the survey. 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. The data provided will help AHRQ's mission to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable. 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 (OMB control number 0935-0143) AHRQ, 5600 Fishers Lane, Room #07W42, Rockville, MD 20857, or by email to REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.