Form Approved
OMB No. ____
Exp. Date: _____

PATIENT SAFETY ORGANIZATION (PSO):

SUPPLEMENTAL ATTESTATIONS REGARDING FOOD AND DRUG ADMINISTRATION (FDA) REPORTING OBLIGATIONS OF PSOs

On December 30, 2010, the Department of Health and Human Services issued Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005 [Guidance]. The Guidance clarifies the obligations that an entity must meet to be listed and that a PSO must meet to remain listed as a PSO when the entity or PSO is an FDA-regulated reporting entity, i.e., it has mandatory FDA-reporting obligations under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. and its implementing regulations, or is organizationally related to an FDA-regulated reporting entity. Before completing this attestation form, please review the Guidance document. It is available on AHRQ's PSO Web site at www.pso.ahrq.gov under "Legislation, Regulations and Guidance."

For entities seeking initial listing as a PSO, this form should be completed by the individual submitting certifications on behalf of the entity seeking, along with the entity's initial listing certification form. For currently-listed PSOs, this form should be completed and submitted by the authorized official of the PSO. This form should also be submitted whenever an authorized official of a PSO submits certifications for continued listing. Please submit this form to AHRQ's PSO Office by email, if possible, at PSO@ahrq.hhs.gov or by mail at: PSO Office, AHRQ, 540 Gaither Road, Rockville, MD 20850.

PART I: ATTESTATION

Name of entity or PSO: _____

1. Is the entity an FDA-regulated reporting entity or organizationally related to an FDA-regulated reporting entity? ____ yes ____no

   [If the answer to question #1 is "no", proceed to Part II]

2. Is the entity listed as a component PSO or seeking listing as a component PSO? _____yes _____no

   [If the answer to question #2 is no, please proceed to Part II, complete and submit this form, then contact the AHRQ PSO program office immediately. If the answer to question #2 is yes, please answer questions #3 and #4.]

3. Has the entity reviewed the Guidance regarding the obligations of a PSO that is an FDA-regulated reporting entity, or is organizationally related to such an entity, and concluded that it can and will meet its mandatory FDA-reporting requirements (including (a) disclosing relevant PSWP held by the component PSO to the FDA-regulated reporting entity and to the FDA, and providing FDA with

access to such PSWP (held at the PSO); and (b) having the component PSO disclose relevant PSWP to the FDA-regulated reporting entity of which it is a part in order to ensure that such entity meets its FDA-reporting requirements) during its period of listing as a PSO? _____ yes _____no

4. Does the entity understand that failure of a component PSO to comply with its FDA-reporting requirements (including the failure to (a) disclose relevant PSWP held by the component PSO to the FDA-regulated reporting entity and to the FDA, and provide FDA with access to such PSWP (held by the PSO); and (b) have the component PSO disclose relevant PSWP to the FDA-regulated reporting entity of which it is part in order to ensure that such entity meets its FDA-reporting requirements) will constitute a conflict of interest and will be a basis for delisting a component PSO? _____ yes _____ no

[After completing Questions #3 and #4, proceed to Part II, complete and submit this form.]

PART II: CERTIFICATION OF ATTESTATIONS

I am authorized to complete this form and certify that all statements 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 can be punished by fine or imprisonment or both (United States Code, Title 18, Section 1001). I also understand that the rule requires that if any change takes place that would render any attestation inaccurate or incomplete, or if there is a change in the contact information provided, the listed PSO or entity seeking listing must promptly notify the Secretary of any such change by contacting AHRQ's PSO Office via email at PSO@ahrq.hhs.gov or toll free at (866) 403-3697 or (866) 438-7231 (TTY).

Authorized Official Printed Name:

_____

Authorized Official Title:

_____

Authorized Official Signature:

_____

Date: _____

This completed form is considered public information.

Burden Statement

Public reporting burden for the collection of information is estimated to average 15 minutes 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.