Form Approved
OMB No. 0935-XXXX
Exp. Date XX/XX/20XX

PATIENT SAFETY ORGANIZATION: CERTIFICATION FOR INITIAL LISTING

Before completing this form, please review the requirements delineated in the regulation implementing the Patient Safety and Quality Improvement Act of 2005, 42 CFR Part 3 (available at www.pso.ahrq.gov). Section 3.102 and the definitions in section 3.20 will assist you in completing this form as will Section 3.106 which contains criteria to be met regarding security. Excerpts from these sections are in a separate file on the website. To review the confidentiality requirements consult Subpart C of Part 3 of the regulation.

An entity seeking initial listing by the Secretary as a Patient Safety Organization (PSO) must complete this form, which restates the 15 statutory requirements that all PSOs must certify they meet and the 3 additional statutory criteria that Component PSOs must meet. The form also includes several other attestations required by the regulation.

The Secretary will list an entity as a PSO based on responses to this attestation form. There may be situations in which a PSO that has been delisted by the Secretary may again seek initial listing (under its own or another name), or one or more officials of a delisted PSO may be members of the workforce of an entity seeking initial listing. If the answers in Part II of this form indicate that there may be relevant history for consideration, an applicant may be required to supply additional information or assurances before the Secretary can make a listing determination. The Secretary will notify the entity in writing of his acceptance or non-acceptance of this certification. If this certification is accepted, the Secretary will list the PSO for three years beginning on a date and time specified in the notice.

An entity is encouraged, but not required, to submit a supplementary narrative that addresses: 1) how the entity will approach its mission and carry out required patient safety activities, and 2) outlines the expertise of its personnel (both employees and contractors) to carry out its mission. If submitted, the Secretary will make this information publicly available and may post it on a public website established pursuant to § 3.104(d). The Department will provide this information, without any implied endorsement, to assist providers seeking PSO services. Departmental guidance may be provided on these optional narratives (see: www.pso.ahrq.gov).

PART I: ORGANIZATION CONTACT INFORMATION

NAME AND ADDRESS – ENTITY SEEKING LISTING AS A PATIENT SAFETY ORGANIZATION

Street Address	**City**	**State**	**Zip Code**

Mailing Address (if different)	**City**	**State**	**Zip Code**

Telephone Number	**Website Address**	**Fax Number**

PART II: ATTESTATION REGARDING COMPLIANCE WITH REGULATORY REQUIREMENTS

Does the entity have regulatory authority over providers (such as accreditation or licensure)? ☐ YES ☐ NO

Note: Please refer to section *3.102(a)(1) of the regulation.*

Is the entity a component organization? ☐ YES ☐ NO

Note: If you check yes, you must attach to this form the name and address of all of the component organization's parent organization(s). To determine whether an entity is a component or parent organization, consult the preamble discussions (available at www.pso.ahrq.gov) *regarding the definitions of component and parent organizations in* section 3.20 of the regulation) .

Has the Secretary ever declined to list or delisted this entity under another name? ☐ YES ☐ NO

Has any member of the entity's workforce or its contractors been employed by a delisted PSO, either before or at the time of delisting? ☐ YES ☐ NO

Note: Please refer to 42 CFR section 3.104(a)(2)*, which requires the Secretary to consider* any relevant history in making a listing determination and the definition of the term workforce in section 3.20. The Secretary may require additional information or assurances from the entity if these circumstances apply.

PART III: ATTESTATIONS REGARDING STATUTORY REQUIREMENTS FOR INITIAL CERTIFICATION

1.	Does the entity have policies and procedures to improve patient safety and the quality of health care delivery?	☐ YES	☐ NO
2.	Does the entity have policies and procedures for the collection and analysis of patient safety work product?	☐ YES	☐ NO
3.	Does the entity have policies and procedures to develop and disseminate information with respect to improving patient safety, such as recommendations, protocols, and best practices?	☐ YES	☐ NO
4.	Does the entity have policies and procedures to utilize patient safety work product to encourage a culture of safety, to provide feedback and assistance to effectively minimize patient risk?	☐ YES	☐ NO
5.	Does the entity have policies and procedures to preserve confidentiality of patient safety work product in conformity with the regulation and the authorizing statute?	☐ YES	☐ NO
6.	Does the entity have policies and procedures to protect patient safety work product in conformity with the regulation and the authorizing statute?	☐ YES	☐ NO
7.	Does the entity have policies and procedures in place to assure the utilization of appropriately qualified staff?	☐ YES	☐ NO
8.	Does the entity have policies and procedures to perform the collection, management and analytic activities related to the operation of a patient safety evaluation system (PSES) including the provision of feedback to participants in a PSES?	☐ YES	☐ NO
9.	Upon listing, will improvement of patient safety and the quality of health care delivery be the entity's mission and primary activity?	☐ YES	☐ NO
10.	Upon listing, will the entity's employees or contractors include licensed or certified medical professionals?	☐ YES	☐ NO
11.	Upon listing, will the entity meet the requirement to enter at least two bona fide contracts as defined by the regulation within 24 months of its initial listing (and meet that test in every subsequent 24-month period)?	☐ YES	☐ NO
12.	Does the entity comply with the prohibition that it may not be a health insurer or a health insurer component?	☐ YES	☐ NO
13.	Upon listing, will the entity meet the requirement to fully disclose to the Secretary relationships with contracting providers as required by section 3.102(d)(2) of the regulation?	☐ YES	☐ NO
14.	Upon listing, will the entity collect patient safety work product in a standardized manner, to the extent practical and appropriate, informed by ongoing guidance provided by the Secretary on common formats and consistent definitions that permit valid comparisons of similar cases?	☐ YES	☐ NO
15.	Upon listing, will the entity utilize patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk?	☐ YES	☐ NO
	ONLY ANSWER QUESTIONS 16-18 IF YOUR ENTITY IS A COMPONENT ORGANIZATION		
16.	Will the component entity maintain patient safety work product separately from the rest of the parent organization(s)? *Note: 45 CFR § 3.102(c)(1) prohibits shared data systems and limits subcontracts.*	☐ YES	☐ NO

17.	Will the component entity prevent unauthorized disclosure of patient safety work product to any person in the rest of the parent organization(s)? *Note: 45 CFR § 3.102(c)(2) limits use of shared personnel.*	☐ YES	☐ NO
18.	Is there any conflict of interest between the component entity's mission and the rest of its parent organization(s)?	☐ YES	☐ NO

PART IV: CERTIFICATION OF ATTESTATIONS

I am authorized to complete this form on behalf of the entity seeking listing as a PSO. The statements on this form, and any submitted attachments or supplements to it, are true, complete, and correct to the best of my knowledge and belief and are made in good faith. If I have attached an optional narrative, I certify that it is true, correct and complete. I understand that a knowing and willful false statement on this form, including any attachments, can be punished by fine or imprisonment or both (United States Code, Title 18, Section 1001). I also understand that the regulation, at 42 CFR 3.102(a), requires that if any change takes place that would render any attestation inaccurate or incomplete, or if there is a change in the PSO contact information, the entity seeking listing must notify the Secretary within 45 days of any such change.

Authorized Official Signature: _____

Date: _____

uthorized Official Printed Name: _____

Authorized Official Title: _____

Telephone:_____

Fax: _____

E-mail: _____

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