Office of Facilities Regulation
OFR@health.ri.gov
3 Capitol Hill, Room 306
Providence, RI 02908-5097

www.health.ri.gov

RI Department of Health

Application and Instructions for:

Patient Safety Organizations (PSO)

Statutory reference – RI General Laws Chapter 23-17.21
Regulatory reference: Rules & Regulations Pertaining to Certification of Patient Safety Organizations (R23-17.21-PSO)

☐ Patient Safety Organization

☐ Component Patient Safety Organization

1. ☐ Initial Licensure
   Licensee Name: ____

2. ☐ Change of Licensee Name Licensee Number: ____________________
3. ☐ Change of address

For Office Use Only

COMMENTS:

Reviewers Initials:

PSO Effective date:______________ PSO License #:_________________

DO NOT REMOVE ANY FULL PAGES FROM THIS BOOKLET

INSTRUCTIONS

- Please answer all questions. Do not leave blanks. Incomplete forms will be returned to you and your Certification will not be issued. Please type or use a ballpoint pen.
- There is no fee for this application.
- Sign the completed application, return it with the required attachments and mail to:

  Rhode Island Department of Health
  Office of Facilities Regulation
  3 Capitol Hill, Room 306
  Providence RI 02908-5097

- Refer any questions concerning this application to the **Office of Facilities Regulations** at (401) 222-2566.
- Certification application materials are public records as mandated by Rhode Island law and may be made available to the public, unless otherwise prohibited by State or Federal law.

Attachments: If you have been requested to submit attachment(s) with this application, please label and staple each separate attachment and securely affix any and all attachments to this application.

Postage: The amount of postage required for mail delivery will vary depending upon the total weight of your attachment(s) and application. Please be careful to include the appropriate postage necessary to mail your completed application.

State of Rhode Island and Providence Plantations
Department of Health

Licensee Name: Please provide the name of the licensee for which certificate is requested.	Name: ______________________________ (As is or will be known to the public)
Ownership Type: Please check ONE	☐ Corporation ☐ Limited Liability Company ☐ Partnership ☐ Limited Partnership ☐ Sole Proprietorship ☐ Governmental Entity
Additional Ownership Information: Ownership information for the 'Ownership Type' as needed.	Name:______________________________ DBA:______________________________
Licensee <u>Contact</u> Information: Please provide the licensee. Phone, Fax and both a general E-mail for the licensee and a contact individual	Licensee Email Address:______________________________ Official Contact Name:______________________________ Phone Number:______________________________ Fax Number:______________________________ Email Address:______________________________
Licensee Official Location: Public information **Used on HEALTH website**	Address Line 1:______________________________ Address Line 2:______________________________ Address Line 3:______________________________ Address City, State, Zip Code:______________________________ Country:______________________________ Phone:______________________________ Fax:______________________________ Email Address:______________________________
Licensee <u>Mailing</u> Information: Please provide the mailing information for all communication regarding this certificate, if different from Licensee Location Information (**Not published on HEALTH website**).	Address Line 1:______________________________ Address Line 2:______________________________ Address Line 3:______________________________ Address City, State, Zip Code:______________________________ Country:______________________________ Phone:______________________________ Fax:______________________________ Email Address:______________________________

Parent Organization, Group Affiliation: Please complete this section if there is any parent organization, group affiliation or other entity that is on the top of the Licensee/agency control	Corporation Type:__________ Name of Organization:__________ Address Line 1:__________ Address Line 2:__________ Address Line 3:__________ Address City, State, Zip Code:__________ Country:__________ Phone:__________ Fax:__________ Email Address:__________
Additional Certifications Required of Component Organizations: If applicable, please certify that the applicant will comply with the additional requirements for a component PSO.	➢ Is the PSO applicant a component of another organization? ☐ ***Yes*** ☐ ***No*** If **YES**, the following three (3) items must also be addressed. ◆ The applicant PSO shall comply with separation of patient safety work product as required under §6.2(c)(1) of *Rules and Regulations Pertaining to Certification of Patient Safety Organizations* [*R23-17.21-PSO*]. ☐ ***Yes*** ☐ ***No*** ◆ The applicant PSO shall comply with nondisclosure of patient safety work product as required under §6.2(c)(2) of *Rules and Regulations Pertaining to Certification of Patient Safety Organizations* [*R23-17.21-PSO*]. ☐ ***Yes*** ☐ ***No*** ◆ The pursuit of the mission of the applicant component PSO shall not create a conflict of interest with the rest of the parent organization(s) of which it is a part as required under §6.2(c)(3) of *Rules and Regulations Pertaining to Certification of Patient Safety Organizations* [*R23-17.21-PSO*]. ☐ ***Yes*** ☐ ***No***
SSN/FEIN: **(Social Security Number/Federal Employer Identification Number)**	**Pursuant to Chapter 76 of Title 5 of the Rhode Island General Laws, as amended, any person applying for or renewing any license, permit, or other authority to conduct a business or occupation within Rhode Island must have filed all required state tax returns and paid all taxes due the state or must have entered into a written installment agreement to pay delinquent state taxes that is satisfactory to the Tax Administrator.** ☐☐☐☐☐☐☐☐☐☐☐☐☐
Federal PSO Certification: Please provide the requested information regarding the applicant's listing as a PSO pursuant to 42 CFR Part 3.	Federal PSO Number:__________ Effective Date of Listing:__________ Listing Expiration Date:__________ **Please provide a copy of the Federal Certification with this Application**
Certification Regarding Patient Safety Activities: Please certify that the applicant has written policies and procedures in place to perform each of the eight (8) designated patient safety activities.	➢ Efforts to improve patient safety and the quality of health care delivery ☐ ***Yes*** ☐ ***No*** ➢ Collection and analysis of patient safety work product ☐ ***Yes*** ☐ ***No*** ➢ Development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices ☐ ***Yes*** ☐ ***No*** ➢ Utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk ☐ ***Yes*** ☐ ***No*** ➢ Maintenance of procedures to preserve confidentiality with respect to patient safety work product ☐ ***Yes*** ☐ ***No*** ➢ Provision of appropriate security measures with respect to patient safety work product ☐ ***Yes*** ☐ ***No*** ➢ Utilization of qualified staff ☐ ***Yes*** ☐ ***No*** ➢ Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system ☐ ***Yes*** ☐ ***No***

Certification Regarding PSO Criteria: Please certify that the applicant will comply with each of the six (6) designated criteria.	➢ The mission and primary activity of the applicant PSO shall be to conduct activities that are to improve patient safety and the quality of health care delivery.	☐ ***Yes***	☐ ***No***
	➢ The applicant PSO shall have appropriately qualified workforce members, including licensed or certified medical professionals.	☐ ***Yes***	☐ ***No***
	➢ The applicant PSO is not a health insurance issuer, and is not a component of a health insurance issuer.	☐ ***Yes***	☐ ***No***
	➢ The applicant PSO shall make disclosures to the Director of Health as required under §5.4 of Rules and Regulations Pertaining to Certification of Patient Safety Organizations [R23-17.21-PSO].	☐ ***Yes***	☐ ***No***
	➢ To the extent practical and appropriate, the applicant PSO shall collect patient safety work product from reporting entities in a standardized manner that permits valid comparisons of similar cases among similar reporting entities.	☐ ***Yes***	☐ ***No***
	➢ The applicant PSO shall utilize patient safety work product for the purpose of providing direct feedback and assistance to reporting entities to effectively minimize patient risk.	☐ ***Yes***	☐ ***No***
Additional Certification Regarding PSO Contract Criteria: Please certify that the applicant will comply with specified contract criteria.	*The applicant PSO, within the initial two (2) year certification period, must enter into at least two (2) bona fide contracts, each of a reasonable period of time, each with a different reporting entity for the purpose of receiving and reviewing patient safety work product.* ➔ Does the applicant PSO already have at least two (2) bona fide contracts which meet the criteria specified §6.2(b)(1)(iii) of *Rules and Regulations Pertaining to Certification of Patient Safety Organizations* [*R23-17.21-PSO*]?	☐ ***Yes***	☐ ***No***
	If "Yes" or for certification renewal, please attach documentation or information regarding contracts marked "Confidential" ➔ If **NO**, A PSO shall be required to submit a supplemental certification and explanation to the Director of Health pursuant to §5.4(a) of *Rules and Regulations Pertaining to Certification of Patient Safety Organizations* [*R23-17.21-PSO*].		
Affidavit of Applicant Please read, sign and date this affidavit.	AFFIDAVIT AND SIGNATURE **This Application Must be Signed** I certify that the applicant complies with the prohibition regarding an ineligible entity as defined in §2.2 of *Rules and Regulations Pertaining to Certification of Patient Safety Organizations* [*R23-17.21-PSO*]. I have read carefully the questions in the foregoing application and have answered them completely, without reservations of any kind, and I declare under penalty of perjury that my answers and all statements made by me herein are true and correct. Should I furnish any false information in this application, I hereby agree that such act shall constitute cause for denial, suspension or revocation of this Certification in the State of Rhode Island. I understand that this is a continuing application and that I have an affirmative duty to inform the Rhode Island Department of Health of any change in the answers to these questions after this application and this Affidavit is signed. I hereby declare, under penalty of perjury, that I have filed all required state tax returns and have either paid all taxes due the state or have entered into a written installment agreement with the Rhode Island Division of Taxation.		
	Signature of Authorized Person ____________ **Printed Name of Authorized Person** ____________ **Date of Signature (MM/DD/YY)** ____________ **Title of Authorized Person** ____________ Furnishing the FEIN is mandatory. The FEIN will be transmitted to the Rhode Island Division of Taxation pursuant to Chapter 76 of Title 5 of the Rhode Island General Laws, as amended.		

Rhode Island Department of Health

Instructions For Disclosure Statement – PSO Relationship With a Reporting Entity

When Must a Disclosure Statement Be Submitted?

§5.4(b) of the *Rules and Regulations Pertaining to Certification of Patient Safety Organizations* [*R23-17.21-PSO*] requires that a Patient Safety Organization (PSO) fully disclose to the Director of Health any financial, contractual or reporting relationships the PSO has with a reporting entity and, if applicable, the extent to which the PSO is not independently managed or controlled, or if it does not operate independently from, the reporting entity.

[**NOTE**: *A revised disclosure statement may be voluntarily submitted when a relationship or form of control described in a previous statement submitted to the Director of Health terminates. It is not required.*]

Deadline for Filing a Disclosure Statement

A PSO is required to submit a disclosure statement to the Director of Health within forty five (45) days of the date that the PSO entered each relationship where the circumstances described in either §5.4(b)(1) or §5.4(b)(2) of the *Rules and Regulations Pertaining to Certification of Patient Safety Organizations* [*R23-17.21-PSO*] are applicable.

Content of a Disclosure Statement

(a) A PSO shall fully disclose any contractual, financial or reporting relationships described below that it has with a reporting entity.

    (1) Contractual relationships which are not limited to relationships based on formal contracts but also encompass relationships based on any oral or written agreement or any arrangement that imposes responsibilities on the PSO.

    (2) Financial relationships including any direct or indirect ownership or investment relationship between the PSO and the contracting reporting entity, shared or common financial interests or direct or indirect compensation arrangement, whether in cash or in-kind.

    (3) Reporting relationships including any relationship that gives the reporting entity access to information or control, directly or indirectly, over the work of the PSO that is not available to other contracting reporting entities.

(b) A PSO shall fully disclose if it is not independently managed or controlled, or if it does not operate independently from, the contracting reporting entity. In particular, the PSO shall further disclose whether the contracting reporting entity has exercised or imposed any type of management control that could limit the PSO's ability to fairly and accurately perform patient safety activities and fully describe such control(s).

(c) PSOs may also describe or include in their disclosure statements, as applicable, any agreements, stipulations, or procedural safeguards that have been created to protect the ability of the PSO to operate independently or information that indicates the limited impact or insignificance of its financial, reporting or contractual relationships with a contracting reporting entity

Revised: March 2009

Rhode Island Department of Health

Disclosure Statement – PSO Relationship With a Reporting Entity

PSO Name: ______________________________ **PSO #:** __________

Name of Reporting Entity: ______________________________

Disclosure (check one): ☐ New ☐ Revision to disclosure statement of: __________

AFFIDAVIT AND SIGNATURE

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 reporting entities. I certify, under penalty of perjury, that all 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 also certify that I will submit a revised disclosure statement to the Director of Health within forty-five (45) days of any change that renders this attestation (including descriptive disclosures in attached documents) inaccurate or incomplete.

______________________________	______________________________
Signature of Authorized Person	Printed Name of Authorized Person
______________________________	______________________________
Date of Signature (MM/DD/YYYY)	Title of Authorized Person

Revised: March 2009

Rhode Island Department of Health

PSO Attestation Regarding The Two Bona Fide Contracts Requirement

Before completing this form, review the requirements of the *Rules and Regulations Pertaining to Certification of Patient Safety Organizations* [*R23-17.21-PSO*], especially §5.4(a) & §6.2(b)(1)(iii).

§5.4(a) requires that, no later than forty five (45) calendar days prior to expiration of a Patient Safety Organization's (PSO) certification, as specified in §6.3(a), the PSO shall submit to the Director of Health an attestation as to whether it has met the requirement of §6.2(b)(1)(iii) regarding two (2) bona fide contracts.

§6.2(b)(1)(iii) further requires a PSO to have entered into at least two (2) bona fide contracts, each of a reasonable period of time, each with a different reporting entity for the purpose of receiving and reviewing patient safety work product.

PSO Name: ______________________________ **PSO #:** __________

The above named PSO has entered into at least two (2) bona fide contracts, each of a reasonable period of time, each with a different reporting entity for the purpose of receiving and reviewing patient safety work product, pursuant to §6.2(c)(1) of *Rules and Regulations Pertaining to Certification of Patient Safety Organizations* [*R23-17.21-PSO*].

AFFIDAVIT AND SIGNATURE

I am authorized to complete this form and to certify, under penalty of perjury, that all statements are true, complete and correct to the best of my knowledge and belief, and are made in good faith.

______________________________	______________________________
Signature of Authorized Person	Printed Name of Authorized Person
______________________________	______________________________
Date of Signature (MM/DD/YYYY)	Title of Authorized Person

Revised: March 2009