SUPPORTING STATEMENT

Part A

Patient Safety Organization Certification for Initial Listing and Related Forms and a Patient Safety Confidentiality Complaint Form

Version: March 14, 2011

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, Title IX of the Public Health Service (PHS) Act (see in particular section 901 of the PHS Act, Attachment A-1), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of health care; and

2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

The Patient Safety and Quality Improvement Act of 2005 (hereafter the Patient Safety Act, see Attachment A-2 [1]), signed into law on July 29, 2005, was enacted in response to growing concern about patient safety in the United States and the Institute of Medicine's 1999 report, *To Err is Human: Building a Safer Health System.* The goal of the statute is to improve patient safety by providing an incentive for health care providers to work voluntarily with experts in patient safety to reduce risks and hazards to the safety and quality of patient care. When specific statutory requirements are met by organizations seeking to offer expert analytic services regarding patient safety, the information collected and the analyses and deliberations regarding the information, receive Federal confidentiality and privilege protections under this legislation. The Secretary of the Department of Health and Human Services (hereafter the Secretary) delegated authority to the Director of the Office for Civil Rights (OCR) to enforce the confidentiality protections of the patient safety legislation and delegated authority to the Director of

[1] As can be seen in the Attachment A-2, the Patient Safety Act renumbered sections 921-928 of Title IX of the Public Health Service Act (AHRQ's authorizing statute) as sections 931-938, inserted new sections 921-926, and amended section 937. The newly added sections are correspondingly codified as 42 USC .299b-21-299b-26

AHRQ to implement and administer the rest of the statute's provisions (*Federal Register*, Vol. 71, No. 95, May 17, 2006, p. 28701-2).

The Patient Safety Act signifies the Federal Government's commitment to fostering a culture of patient safety among health care providers; it offers a mechanism for creating an environment in which the causes of risks and hazards to patient safety can be thoroughly and honestly examined and discussed without fear of penalties and liabilities. It provides for the voluntary formation of Patient Safety Organizations (PSOs) that can collect, aggregate, and analyze confidential information reported voluntarily by health care providers. By analyzing substantial amounts of patient safety event information across multiple institutions, PSOs will be able to identify patterns of failures and propose measures to eliminate or reduce patient safety risks and hazards. Protected data collections and analyses have been used for years to maintain and improve safety in the airline industry.

In order to implement the Patient Safety Act, the Department of Health and Human Services (HHS) issued the Patient Safety and Quality Improvement Final Rule (hereafter the Patient Safety Rule, see Attachment B), which became effective on January 19, 2009. The Patient Safety Rule establishes a framework by which hospitals, doctors, and other health care providers may voluntarily report information to PSOs, on a privileged and confidential basis, for the aggregation and analysis of patient safety events. In addition, the Patient Safety Rule outlines the requirements that entities must meet to become PSOs and the process by which the Secretary will review and accept certifications and list PSOs.

In addition to the Patient Safety Act and the Patient Safety Rule, HHS issued Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005 (hereafter Guidance, see Attachment C) on December 30, 2010. The Guidance addresses questions that have arisen regarding the obligations of PSOs where they or the organization of which they are a part are legally obligated under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations to report certain information to the Food and Drug Administration (FDA) and to provide FDA with access to its records, including access during an inspection of its facilities. This Guidance applies to all entities that seek to be or are PSOs or component PSOs that have mandatory FDA-reporting obligations under the FDCA and its implementing regulations ("FDA-regulated reporting entities") or are organizationally related to such FDA-regulated reporting entities (e.g., parent organizations, subsidiaries, sibling organizations).

Pursuant to the Patient Safety Rule (see sections 3.102 and 3.112 of the Patient Safety Rule, 42 CFR Part 3, Attachment B), an entity that seeks to be listed as a PSO by the Secretary, must certify that it meets certain requirements and, upon listing, would meet other criteria. To remain listed for renewable three-year periods, a PSO must recertify that it meets these obligations and would continue to meet them while listed. The Patient Safety Act and Patient Safety Rule also impose other obligations discussed below that a PSO must meet to remain listed. In order for the Secretary to carry out statutory obligations to compile and maintain a list of PSOs pursuant to section 42 U.S.C.299b-

24(d), the entities seeking to be listed and to remain listed must complete the proposed forms attached hereto, attesting to compliance with statutory criteria and the corresponding regulatory requirements.

The following forms have been previously approved and are unchanged with this submission (see Attachments C-H):

1. PSO Certification for Initial Listing Form. This form, containing certifications of eligibility and a capacity and intention to comply with statutory criteria and regulatory requirements, is to be completed, in accordance with section 924 (a) (1) of the PHS Act, 42 USC 299b-24(a)(1) and the above-cited regulatory certification provisions, by an entity interested in seeking to be listed by the Secretary as a PSO for an initial three year period__

2. PSO Certification for Continued Listing Form. In accordance with section 924(a) (2), 42 USC 299b-24(a)(2) and the above-cited regulatory certification provisions, this form is to be completed by a listed PSO seeking continued listing as a PSO by the Secretary for an additional three years.

3. PSO Two Bona Fide Contracts Requirement Certification Form. To remain listed, a PSO must meet a statutory requirement in 42 USC 299(b)(1)(C) to attest to having contracts with more than one provider, within successive 24 month periods, beginning with the date of its initial listing. This form is to be used by a PSO to certify whether it has met this statutory requirement and the corresponding regulatory provision.

4. PSO Disclosure Statement Form. This form provides detailed instructions to a PSO regarding the disclosure statement it must submit and provides for the required certification by the PSO of the statement's accuracy in accordance with the statute and the section 3.102(d)(2) of the Patient Safety Rule, when it (i) has a contract with a health care provider and (ii) it has financial, reporting, and contractual relationships with that contracting health care provider or does not operate independently from that contracting health care provider. Under the Patient Safety Act and the Patient Safety Rule, the Secretary is required to review each such report and make public findings as to whether a PSO can fairly and accurately carry out its responsibilities.

5. PSO Information Form. This form is to gather information on the type of healthcare settings that PSOs are working with to conduct patient safety activities in order to improve patient safety. Completion of this form is voluntary. It is designed to collect a minimum level of data for a report of aggregate statistics on the reach of the Patient Safety Act, including types of institutions participating and their general location in the US. This information will be included in AHRQ's annual quality report, as required under Section 923(c) of the PHS Act. 42 U.S.C. 299b-23(c). No PSO-specific data will be released without PSO consent.

6. Patient Safety Confidentiality Complaint Form. The purpose of this collection is to allow OCR to collect the minimum information needed from individuals filing patient safety confidentiality complaints with our office so that we have a basis for initial processing of those complaints.

With this submission, AHRQ is requesting approval of the following proposed administrative form which is attached to this request as Attachment I.

7. Supplemental Attestations Regarding FDA Reporting Obligations of PSOs Form (hereafter, attestation form). This form is for entities to certify that they meet the obligations that an entity must meet to be listed and that a PSO must meet to remain listed when the entity or PSO is an FDA-regulated reporting entity or is organizationally related to an FDA-regulated reporting entity. This form will be used for less than one year and will be incorporated into the existing PSO forms with the submission on the renewal clearance later in the year.

2. Purpose and Use of Information

1. Purpose

The Patient Safety Act, in amended section 924 of the PHS Act, 42 U.S.C. 299b-24(a), and the Patient Safety Rule in 45 C.F.R. 3.102 provide that an entity may seek an initial three-year listing as a PSO by submitting an certification form for initial listing that it has policies and procedures in place to perform eight patient safety activities (enumerated in the Patient Safety Act and the Patient Safety Rule), and that it will comply, upon listing, with seven other statutory criteria. Similarly, the certification form for continued listing as a PSO (for each successive three-year period after the initial listing period) would require certifications that the PSO is performing, and will continue to perform, the eight patient safety activities, and is complying with, and will continue to comply with, the seven statutory criteria.

The attestation form, which will be used with both the certification forms for initial and continued listing, includes additional questions that an entity or PSO must certify to related obligations under the Guidance and other requirements for listing related to eligibility and pertinent organizational history.

2. Use of Information

The attestation form will be used by AHRQ to obtain information necessary to carry out its delegated authority to implement the Patient Safety Rule and Guidance, e.g., obtaining initial and subsequent certifications from entities seeking to be listed as PSOs and for making the statutorily-required determinations prior to and during an entity's period of listing as a PSO. This information is used by AHRQ's Center for Quality Improvement and Patient Safety.

3. Use of Improved Information Technology

The attestation form will be available on the Web at www.pso.ahrq.gov and by electronic mail or written request. Electronic submission of the certification forms is an option, in addition to submission via postal mail.

4. Efforts to Identify Duplication

The attestation form will be the only form used by AHRQ to collect such data from entities seeking listing as PSOs and from PSOs. This information collection does not duplicate any other effort and the information cannot be obtained as reliably from any other source.

5. Involvement of Small Entities

Burden will be kept to a minimum for all entities.

6. Consequences if Information Collected Less Frequently

The submissions to be required by AHRQ with the above described form pursuant to the Patient Safety Rule and Guidance, have statutorily based frequency requirements that cannot be reduced or pragmatic foundations that provide AHRQ with the minimum time necessary to take appropriate actions based on the information submitted.

7. Special Circumstances

Other than the necessity of carrying out the Secretary's responsibilities under the Patient Safety Act, there are no special circumstances associated with the above-proposed collections.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on February 28, 2011 for 30 days (see Attachment J).

8.b. Outside Consultations

In order to develop the attestation form, AHRQ worked with representatives within the Office of the Secretary, the Office for General Counsel and FDA to assist AHRQ with developing the Guidance and attestation form.

9. Payments/Gifts to Respondents

No payment, gift or remuneration will be provided to respondents.

10. Assurance of Confidentiality

The forms from the entities that seek certification as a PSO are kept in a physically secured area. The AHRQ computer system and related database(s) are password protected for electronic information. Files containing hardcopies of the actual forms or information from the forms are safeguarded in a physically secured area. However, the Patient Safety Rule and Guidance provides that information on the certification forms for initial and continued listing that are made available to the public and posted on AHRQ's PSO Web site unless a completed form contains information that it is determined by the Secretary to be confidential commercial information or personal information that should be protected. Generally, AHRQ is not seeking to collect any individual-specific information on the forms.

11. Questions of a Sensitive Nature

No questions of a sensitive nature will be asked.

12. Estimates of Annualized Burden Hours and Costs

While there are a number of information collection forms described below, they will be implemented at different times, some near the end of the three year approval period for these standard forms. All of these forms are currently approved except for the attestation form. Exhibit 1 shows the estimated annualized burden hours for the respondent to provide the requested information, and Exhibit 2 shows the estimated annualized cost burden for the respondents' time to provide the requested information.

PSO Certification for Initial Listing and PSO Certification for Continued Listing Forms:

The average annual burden in the first three years of 17 hours per year for the collection of information requested by the certification forms for initial and continued listing is based upon a total average estimate of 33 respondents per year and an estimated time of 30 minutes per response. Information collection, i.e., collection of initial certification forms, will begin as soon as the forms are approved for use. Collection of forms for continued listing will not begin until several months before November 2011 which is three years after the first PSOs were listed by the Secretary. (See *Note* after Exhibit 1.)

PSO Two Bona Fide Contracts Requirement Certification:

The annualized burden of 8 hours for the collection of information requested by the two-contract requirement is based upon an estimate of 33 respondents per year and an estimated 15 minutes per response. This collection of information will begin when the first PSO timely notifies the Secretary that it has entered into two contracts.

PSO Disclosure Statement Form:

AHRQ assumes that only a small percentage of entities will need to file a disclosure form. However, AHRQ is providing a high estimate of 17 respondents annually and thus presumably overestimating respondent burden. In summary, the annual burden of 8 hours for the collection of information requested by the disclosure form is based upon the high estimate of 17 respondents per year and an estimated 30 minutes per response. This information collection will begin when a PSO first reports having any of the specified types of additional relationships with a health care provider with which it has a contract to carry out patient safety activities.

PSO Information Form:

The overall annual burden estimate of 17 hours for the collection of information requested by the PSO Information Form is based upon an estimate of 33 respondents per year and an estimated 30 minutes per response. This information collection will begin one year after the first PSOs are listed by the Secretary.

OCR Complaint Form:

The overall annual burden estimate of 17 hours for the collection of information requested by the underlying form is based upon an estimate of 50 respondents per year and an estimated 20 minutes per response. OCR's information collection using this form will not begin until after there is at least one PSO receiving and generating *patient safety work product* and there is an allegation of a violation of the statutory protection of *patient safety work product*.

Attestation Form:

The Attestation Form will be used for only approximately six months and will be merged into the other PSO forms when the OMB clearance for the PSOs is renewed later this year. The Attestation Form will be completed by approximately 76 existing PSOs and approximately 5 entities expected to seek listing by AHRQ as a PSO in 2011 and takes about 15 minutes to complete.

All Administrative Forms:

The overall maximum anticipated annual burden estimate is 96 hours for all the above-described collections of information. Because the forms filled out by PSOs vary over

each of their first three years, the table below includes three-year total estimates divided by three to arrive at an annual estimate of burden hours. (See below.)

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to complete the required forms. The total cost burden is estimated to be $3,000 annually.

Exhibit 1. Estimated Annualized Burden Hours

Form	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden Hours
Patient Safety Organization Certification for Initial Listing Form	100/3	1	30/60	17
Certification for Continued Listing Form*	50/3	1	30/60	8
Two Bona Fide Contracts Requirement Form**	100/3	1	15/60	8
Disclosure Statement Form	50/3	1	30/60	8
Information Form***	100/3	1	30/60	17
Patient Safety Confidentiality Complaint Form	150/3	1	20/60	17
Attestation Form	81/1	1	15/60	21
Total****	264	Na	na	96

Note: * The Certification for Continued Listing Form will be completed by any interested PSO at least 75 days before the end of its current three-year listing period. The three-year period for computing respondent burden begins with the date when the approved forms are officially made available for submission. Thus, the burden period does not correspond exactly to the three-year period of listing. The burden period begins shortly (approximately 30 days) before any PSO's listing period. As a result, the burden for the first PSOs to submit certifications for continued listing at least 45 days before their listing lapses is likely to fall just before the three-year anniversary of their first burden, i.e. their completion of their initial certifications and before the end of their third year of listing. We assume completing this form will require 30 minutes, the same time as for the Certification Form. In the out-years, we expect the number of PSOs to remain stable, with the number of new entrants offset by the number of entities that will relinquish their status or be revoked.

** The Two Bona Fide Contracts Requirement Form will be completed by each PSO within the 24-month period after initial listing by the Secretary.

*** The Information Form will collect data by calendar year, beginning in 2010, at a time when it is anticipated that PSOs will have submitted appreciable data to the Network of Patient Safety Databases.

**** A total of 100 PSOs are expected to apply over three years: 50 in year one; 25 in year two; and 25 in year three. The Two Bona Fide Contracts Requirement, Disclosure Statement, and even voluntary Information Forms may be submitted by individual PSOs in different years. OCR is anticipating considerable variation in the number of complaints per year. Hence, we have expressed the total for each year as the average of the expected total over the three year collection period.

Exhibit 2. Estimated annualized cost burden

Form	Number of Respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Certification for Initial Listing Form	100/3	17	$31.26	$531
Certification for Continued Listing Form	50/3	8	$31.26	$250
Two Bona Fide Contracts Requirement Form	100/3	8	$31.26	$250
Disclosure Statement Form	50/3	8	$31.26	$250
Information Form	100/3	17	$31.26	$531
Patient Safety Confidentiality Complaint Form	150/3	17	$31.26	$531
Attestation Form	81/1	21	$31.26	$657
Total	264	96	na	$3,000

*Based upon the mean of the hourly wages for healthcare practitioner and technical occupation, National Compensation Survey: Occupational wages in the United States 2007, "U.S. Department of Labor, Bureau of Labor Statistics."

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Cost to the Government

By statute, AHRQ must collect and review certifications from an entity that seeks listing or continued listing as a PSO under the Patient Safety Act. The cost to AHRQ of processing the information collected with the above-described form is minimal; an

estimated equivalent of only approximately 0.05 FTE or $7,500 per year for each agency and virtually no new overhead costs

Description	Amount
Personnel & Support Staff	$7,500
Consultant (sub-contractor) services	$0
Equipment	$0
Supplies	$0
All other expenses	$0
Average Annual Cost	**$7,500**

15. Changes in Hour Burden

This is a no change from the prior information collection.

16. Time Schedule, Publication and Analysis Plans

Data collected may be made public by the Secretary. In particular, statistical information about PSOs will be published as part of the process of preparing a mandatory report to Congress on effective measures for improving patient safety.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments:

Attachment A-1: Section 901 of the Public Health Service Act

Attachment A-2: P.L. 109-41, Patient Safety and Quality Improvement Act of 2005

Attachment B: Patient Safety Rule

Attachment C: PSO Certification for Initial Listing Form

Attachment D: PSO Certification for Continued Listing Form

Attachment E: PSO Two Bona Fide Contracts Requirement Form

Attachment F: PSO Disclosure Statement Form

Attachment G: PSO Information Form

Attachment H: Patient Safety Confidentiality Complaint Form

Attachment I: Attestation Form

Attachment J: Federal Register Notice