# SUPPORTING STATEMENT

## Part A

Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats

**Version: October 11, 2011**

Agency of Healthcare Research and Quality (AHRQ)

**Table of contents**

## 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. 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.

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 of HHS (hereafter the Secretary) will review and accept certifications and list PSOs.

[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.

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).

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 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 AHRQ to implement and administer the rest of the statute's provisions (*Federal Register*, Vol. 71, No. 95, May 17, 2006, p. 28701-2). OCR is responsible for enforcing protections regarding patient safety work product (PSWP), which includes: patient-, provider- and reporter-identifying information that is collected, created, or used by PSOs for patient safety and quality activities. Civil money penalties may be imposed for knowing or reckless impermissible disclosures of PSWP.

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.

With this submission, AHRQ is requesting approval of the following proposed administrative forms:

1. PSO Certification for Initial Listing Form (Attachment D). 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 (Attachment E). 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 each successive three year period.

3. PSO Two Bona Fide Contracts Requirement Certification Form (Attachment F). 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 (Attachment G). 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 (Attachment H). This form is to gather information on the type of healthcare providers and settings that PSOs are working with to conduct patient safety activities in order to improve patient safety. 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).

Since the questions concerning the Guidance are now included in both the PSO Certification for Initial Listing and PSO Certification for Continued Listing forms, the previously approved attestation form (June 02, 2011) for the Guidance will no longer be used as a separate form by AHRQ.

OCR is requesting approval of the following administrative form:

Patient Safety Confidentiality Complaint Form (Attachment I). 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.

In addition, AHRQ is requesting approval for a set of common definitions and reporting formats (hereafter Common Formats; see Attachments J and K). As authorized by the Patient Safety Rule, AHRQ coordinates the development of the Common Formats that allow PSOs and health care providers to voluntarily collect and submit standardized information regarding patient safety events.

AHRQ and OCR are seeking OMB approval of the above-described information collection forms and the Common Formats.

**2. Purpose and Use of Information**

***1. Purpose***

a. AHRQ

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

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 initial certification 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. The initial certification form also includes additional questions related to obligations under the Guidance and other requirements for listing related to eligibility and pertinent organizational history. Similarly, the proposed 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 and also includes additional questions related to obligations under the Guidance.

*PSO Two Bona Fide Contracts Requirement Certification Form:*

As specified in 42 CFR Part 3, especially sections 3.102(d)(1) and 3.104(b) of the Patient Safety Rule, a PSO, in order to maintain its listing, will be required to submit a brief attestation, at least once in every 24-month period after its initial date of listing, indicating that it has bona fide contracts with two providers.

*PSO Disclosure Statement Form:*

Section 924(b)(1)(E) of the PHS Act, 42 U.S.C. 299b-24(b)(1)(E), requires a PSO to fully disclose information to the Secretary if the PSO has additional financial, contractual, or reporting relationships with any provider to which the PSO provides services pursuant to the Patient Safety Act under contract or if the PSO is managed or controlled by, or is not operated independently from, any of its contracting providers. Disclosure forms will be collected only when a PSO has such relationships with a contracting provider to report. The Secretary is required to review each disclosure statement and make public findings as to whether a PSO can fairly and accurately carry out its responsibilities.

*PSO Information Form:*

Annual completion of a PSO information form will provide information to HHS on the type of health care settings that PSOs are working with to conduct patient safety activities. This form is designed to collect a minimum level of data for a report of aggregate statistics on the reach of the Patient Safety Act with respect to types of institutions participating and their general location in the United States. The de-identification requirements of the Patient Safety Rule prohibit the release of PSO or provider-specific data. This information will be included in AHRQ's annual quality report, as required under Section 923(c) of the Patient Safety Act.

b. OCR

*Patient Safety Confidentiality Complaint Form:*

Under the Patient Safety Rule, individuals may file written complaints with the OCR when they believe that a person or organization subject to the Patient Safety Act has committed a violation of the statute by disclosing confidential PSWP impermissibly. In order to fulfill its delegated authority to respond to those complaints, OCR must collect a limited set of information sufficient to allow initial processing of such complaints, including contact and identifying information from the complainant.

This complaint form is modeled on the existing Health Information Privacy Complaint Form, HHS-700 (OMB No. 0990-0269).[2] The attached complaint form requests basic information about the individual filing the complaint and about the circumstances surrounding the alleged violation of the Patient Safety Act; it also requests that the individual give or deny consent for OCR to reveal his or her identity to persons at the entity under investigation. The collection of this information is necessary in order for OCR to process complaints.

[2] The OCR has jurisdiction over health plans, health clearinghouses and certain health care providers with respect to enforcement of the standards for privacy of individually identifiable health information under the Privacy Rule issued pursuant to the Health Insurance Portability and Accountability Act (HIPAA). [OCR is also responsible for enforcing Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975 and other statutes that prohibit discrimination by programs or entities that receive Federal financial assistance from HHS. Additionally, OCR has jurisdiction over Federally-conducted programs in cases involving disability-based discrimination under Section 504 of the Rehabilitation Act, and over state and local public entities in cases involving disability-based discrimination under Title II of the Americans with Disabilities Act. Thus, OCR has expertise with respect to what information from a complainant is essential to commence or determine whether to initiate investigations of alleged violations of law.

*c. PSO Common Formats:*

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, and other healthcare providers may voluntarily report information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs, called PSWP, is privileged and confidential. PSWP is used to identify events, patterns of care, and unsafe conditions that increase risks and hazards to patients.

The Patient Safety Act and Patient Safety Rule require PSOs, to the extent practical and appropriate, to collect PSWP from providers in a standardized manner in order to permit valid comparisons of similar cases among similar providers. The collection of PSWP allows the aggregation of sufficient data to identify and address underlying causal factors of patient safety problems.

In order to facilitate standardized data collection, the HHS Secretary authorized AHRQ to develop and maintain the Common Formats to improve the safety and quality of healthcare delivery by allowing health care providers voluntarily collect and submit standardized information regarding patient safety events. Historically, AHRQ issued the initial release of the formats, Version 0.1 Beta, in August 2008, the second release, Version 1.0, in September 2009, a third release Version 1.1, on March 31, 2010, followed by a modification in October 2010 to allow for reporting data on patient safety events related to Health Information Technology. AHRQ received comments on all versions from the public. These public comments, as well as comments from PSOs, encouraged the development of Common Formats for additional healthcare settings

The current Common Formats are designed to support the first stage in the patient safety improvement cycle. For the acute care and skilled nursing facilities, there are two general types of formats, generic and event-specific, that pertain to all patient safety concerns. The three generic formats are: Healthcare Event Reporting Form, Patient Information Form, and Summary of Initial Report. The event-specific Common Formats pertain to frequently occurring and/or serious patient safety events. For the acute care setting, there are eight event-specific formats are: blood or blood product, device or medical/surgical supply including health information technology (HIT), fall, health care-associated infection, medication or other substance, perinatal, pressure ulcer, and surgery or anesthesia. For the skilled nursing facility setting, there are five event-specific formats: device or medical/surgical supply (including HIT), fall, health care-associated infection, medication or other substance and pressure ulcer. The formats include descriptions of patient safety events and unsafe conditions to be reported, specifications for patient safety aggregate reports and individual event summaries, delineation of data elements to be collected for specific types of events, and a user's guide and quick guide. The formats are available through AHRQ's technical assistance center for PSOs, the PSO Privacy Protection Center (PSOPPC).

The Patient Safety Act and the Patient Safety Rule authorize the creation of a Network of Patient Safety Databases (NPSD), to which PSOs, health care providers, and others can voluntarily contribute the nonidentifiable PSWP. The NPSD will be maintained as an interactive, evidence-based management resource for health care providers, PSOs, researchers, and other individuals and organizations.

**2. Use of Information**

a. AHRQ

The forms are revised collection instruments and will be used by AHRQ to obtain information necessary to carry out its delegated authority to implement the Patient Safety Act and Patient Safety Rule, 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.

AHRQ will use data from the NPSD to analyze national and regional statistics, including trends and patterns, regarding patient safety events. As required by the Patient Safety Act and Patient Safety Rule, findings are to be made public and included in AHRQ's annual *National Healthcare Quality Report*.

b. OCR

OCR will use the patient safety confidentiality complaint form to collect information for the initial assessment of an incoming complaint. As noted above, the form is modeled on OCR's form for complaints alleging violation of the privacy of protected health information.[3] Use of the form is voluntary. It may help a complainant provide the essential information. Alternatively, a complainant may choose to submit a complaint in the form of a letter or electronically. An individual who needs help to submit a complaint in writing may call OCR for assistance.

The mandatory fields for the form are: name, contact information, the identity of the person or persons whose information was impermissibly disclosed, the person or entity against whom or which the complaint is being filed, when the incident(s) occurred, and a brief description of what happened. The form also asks the complainant to give or deny consent for OCR to reveal his or her identity to persons at the entity under investigation and requests that the complainant sign the form.

The form requests essentially the same information as the health information privacy complaint form, with the only substantive difference being the basis for the complaint. The wording is modified to reflect the differing authority.

In addition, the form includes several voluntary fields to assist OCR in processing the complaint and to provide appropriate customer service. Those fields are: an alternate person to contact if the complainant cannot be reached; whether this complaint has been filed with other agencies or is the basis of a lawsuit and, if so, to identify where else the complaint has been filed; whether the complainant needs special accommodations for OCR to communicate with them (e.g., Braille, TDD); and the ethnicity, race, and primary language spoken by the complainant (if other than English). We also have included one question, concerning the means by which the complainant learned about filing a complaint with the OCR, to help us provide better service to our complainants. Failure to answer the voluntary questions will *not* affect OCR's decision to process a complaint.

### *3. Use of Improved Information Technology*

a. AHRQ

The forms, except for the Information form, are 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. The Patient Safety Rule states that the Two Bona Fide Contracts Requirement Certification Form may be submitted via electronic mail (pso@ahrq.hhs.gov) until midnight of the last day of the 24-month period. The Information form is available as an electronically fillable form at the PSO PPC Web site at www.PSOPPC.org.

Common Formats Version 1.1, accompanying user information, and technical specifications are available as printable electronic files on the PSO PPC Web site at www.PSOPPC.org.

b. OCR

In addition to paper submission of complaints, OCR facilitates electronic submission of complaints. First, the

[3] The existing health information privacy form was approved by OMB July 6, 2006 (OMB 0990-0269, expiration 07/31/2009).

forms themselves are available to be downloaded electronically to a user's own computer in a form that allows a complainant to fill out the form electronically if they so choose. The form can then be printed and submitted, or submitted electronically via electronic mail. Second, we will be providing the forms in a format that allows completion and submission of the information online. Actual burden time would be reduced only marginally using electronic methods since the bulk of the estimated average effort relates to assembling and recording a set of factual information. Also, while someone with strong keyboarding skills might enter the information more quickly electronically, someone without those skills might take considerably longer than they would using the manual method.

Since access to computers and the internet, as well as computer proficiency, still varies widely, these different methods will allow complainants to use the method with which they are most comfortable without increasing burden on any particular class of individuals.

### *4. Efforts to Identify Duplication*

a. AHRQ
The forms and Common Formats will be the only forms 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.

b. OCR
The information collected by OCR is case-specific and individual-specific and is not otherwise available to OCR. If a person has filed a previous complaint with OCR, a relatively rare occurrence, then data on the individual may be in OCR's records, but confidentiality considerations would restrict our ability to display that information to the complainant, since it might, in fact, relate to another person with the same name. The use of PIN numbers and other methods that allow individuals to return to the same web site without having to re-enter personal information is not likely to be very cost effective given the very limited number of multiple complaint filings by the same individual.

Additionally, there may be situations in which OCR will collect data for multiple purposes. Data collected from a patient safety confidentiality complaint may also be used to investigate possible HIPAA Privacy Rule violations arising from the same event. In those situations, individuals will have the opportunity to fill out either the Patient Safety Confidentiality Complaint Form or the HIPAA Privacy Complaint Form. OCR will then use the data collected from the complaint form submitted to investigate violations of both statutes; therefore, individuals will not be required to submit multiple complaints arising from a single event.

### *5. Involvement of Small Entities*

a. AHRQ
Burden will be kept to a minimum for all entities.

b. OCR
Burden will be kept to a minimum for all complainants.

### *6. Consequences if Information Collected Less Frequently*

a. AHRQ
All of the submissions to be required by AHRQ with the above described forms pursuant to the Patient Safety Rule, 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. Since the use of the Common Formats and submission of PSWP to the NPSD are voluntary, the frequency of the submission of the information will be determined by the PSOs and health care providers.

b. OCR

OCR collects data as necessary. Since OCR needs the mandatory information on these forms to begin an investigation, inability to collect this information would prevent OCR from carrying out our statutorily-mandated authority to conduct complaint investigations and rectify patient safety confidentiality violations. Further, lack of a standardized form would hinder OCR's ability to fully and effectively comply with the requirements of the Government Paperwork Elimination Act to support electronic communication with OCR's stakeholders.

The form also includes a set of voluntary questions: those intended to help us communicate with the complainant in processing the complaint, and one designed to help OCR provide appropriate customer service.

For the first type of voluntary questions (e.g., does the complainant need us to communicate using Braille, is there an alternate person to contact if the complainant cannot be reached), if they were removed from the form, the complaint process could proceed. But there would be a cost in effective customer service in that OCR would not discover special communications needs until contact has been made and the initial contacts may prove to be extremely frustrating for the complainant while increasing the potential for missed communications.

For the question regarding how the complainant learned of OCR, again, if it was removed from the form, the complaint process could proceed. However, over the long-term, OCR's effectiveness in reaching populations in need of our services may be impaired by lack of data on who does, and by implication, does not, avail themselves of OCR's services.

There are no other technical or legal obstacles to reducing burden other than as described in this question or in Question 3.

### *7. Special Circumstances*

Other than the necessity of carrying out the Secretary's responsibilities under the Patient Safety Act, Patient Safety Rule and the Guidance, 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 April, 18, 2011 for 60 days (see Attachment L). No comments were received.

### *8.b. Outside Consultations*

a. AHRQ

In order to develop the Common Formats, AHRQ convened an interagency Federal Patient Safety Work Group (hereafter PSWG) to assist AHRQ with developing and maintaining them. The PSWG includes major health agencies within the HHS - Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the National Library of Medicine, Office of the National Coordinator

for Health Information Technology, the Office of Public Health and Science, the Substance Abuse and Mental Health Services Administration--as well as the Department of Defense and the Department of Veterans Affairs. The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues.

b. OCR

Because OCR is using a complaint-driven information collection form, from which information collected will only be used to process and investigate complaints alleging possible violations of the Patient Safety Act, OCR did not consult with any outside individual or agency with respect to this new information collection. Additionally, as OCR has modeled this new information collection on a comparable complaint form currently used by OCR to collect information regarding possible violations of the HIPAA Privacy Rule, consultation with any outside individuals or agencies regarding the availability of data, the data elements to be recorded, and the reporting format was unnecessary.

After developing the complaint form, OCR did consult with the following individuals in the Office of the Assistant Secretary for Planning and Evaluation regarding the time burden the complaint form may impose on future complainants and the clarity of the form:

**Maya Bernstein**
HHH, Room 434E.2
(202) 690-5896
maya.bernstein@hhs.gov

**Sandra Howard**
HHH, Room 443F.6
(202) 690-7778
sandra.howard@hhs.gov

**Amy Nevel**
HHH, Room 446F.5
(202) 690-7795
amy.nevel@hhs.gov

### *9. Payments/Gifts to Respondents*

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

### *10. Assurance of Confidentiality*

a. AHRQ

The forms from the entities that seek certification as a PSO will be kept in a physically secured area. The AHRQ computer system and related database(s) will be password protected for electronic information. Files containing hardcopies of the actual forms or information from the forms will be safeguarded in a physically secured area. However, the Patient Safety Rule provides that information on the certification forms for initial and continued listing, two bona fide contracts requirement certification, and disclosure statements will be 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.

The PSO Information Form is intended to provide information on the type of health care settings that PSOs are working with to conduct patient safety activities. This form is designed to collect a minimum level of data in order to gather aggregate statistics on the impact of the Patient Safety Act and Patient Safety Rule. The PSOs may submit this information to the PSOPPC using either an online data entry tool or an XML file through the secure area of the PSOPPC.org Web site. In addition, PSOs may submit Common Format data using the secure log in area of the PSOPPC.org Web site.

b. OCR

Pursuant to the Privacy Act, disclosure of information collected from complainants is strictly for investigatory purposes or for a limited set of routine uses consistent with those investigatory purposes. OCR is developing a revision to its approved Privacy Act System of Records (67 Fed Reg. 57011-57014 (September 6, 2002)) to incorporate disclosures that may be made to carry out its Patient Safety Act authorities.

### *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 and frequency due to the voluntary nature of seeking listing as a PSO and using the Common Formats. 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 associated with the respondents' time to provide the requested information. The total burden hours are estimated to be 75,764 hours annually and the total cost burden is estimated to be $2,538,852 annually.

*PSO Certification for Initial Listing Form:*

The average annual burden for the collection of information requested by the certification forms for initial listing is based upon a total average estimate of 15 respondents per year and an estimated time of 18 hours per response. This collection of information takes place on an ongoing basis.

*Certification for Continued Listing Form:*

The average annual burden for the collection of information requested by the certification form for continued listing is based upon the estimate that 90% of the projected 80 listed PSOs total, or 24 PSOs annually, will submit forms with an estimated time of eight hours per response. 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.

*Two Bona Fide Contracts Requirement Certification:*

The average annual burden for the collection of information requested by the two-contract requirement is based upon an estimate of 40 respondents per year and an estimated one hour per response. This collection of information takes place when the PSO notifies the Secretary that it has entered into two contracts.

*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 7 respondents annually and thus presumably overestimating respondent burden. The average annual burden estimate of 21 hours for the collection of information requested by the disclosure form is based upon an estimated three hours per response. This information collection takes place 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.

*Information Form:*

The overall annual burden estimate of 240 hours for the collection of information requested by the PSO Information Form is based upon an estimate of 80 respondents per year and an estimated three hours per response. This information collection will begin in 2011; newly listed PSOs will report in the calendar year after their listing by the HHS Secretary.

*Patient Safety Confidentiality Complaint Form:*

The overall annual burden estimate of 1 hour for the collection of information requested by the form is based on an estimate of 3 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 PSWP and there is an allegation of a violation of the statutory protection of PSWP.

*Common Formats:*

AHRQ estimates that 5% FTE of a Patient Safety Manager at a hospital will be spent to administer the Common Formats, which is approximately 100 hours a year. AHRQ estimates the number of hospitals using Common Formats in the first year as 500, then 750 in year 2, and 1000 in year 3, for an annual average of 750 over 3 years.

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 | 15 | 1 | 18 | 270 |
| Certification for Continued Listing Form* | 24 | 1 | 8 | 192 |
| Two Bona Fide Contracts Requirement Form** | 40 | 1 | 1 | 40 |
| Disclosure Statement Form | 7 | 1 | 3 | 21 |
| Information Form*** | 80 | 1 | 3 | 240 |
| Patient Safety Confidentiality Complaint Form | 3 | 1 | 20/60 | 1 |
| Common Formats | 750 | 1 | 100 | 75,000 |
| Total**** | 918 | NA | NA | 75,764 |

* 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. AHRQ expects the number of PSOs to remain stable, with 90% of listed PSOs seeking continued listing. The number of new entities seeking listing will be 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 2011.

**** A total of 45 PSOs are expected to apply over three years at a rate of 15 per year. The Two Bona Fide Contracts Requirement, Disclosure Statement, and even 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 |
|---|---|---|---|---|
| Certification for Initial Listing Form | 15 | 270 | $33.51 | $9,048 |
| Certification for Continued Listing Form | 24 | 192 | $33.51 | $6,434 |
| Two Bona Fide Contracts Requirement Form | 40 | 40 | $33.51 | $1,340 |
| Disclosure Statement Form | 7 | 21 | $33.51 | $704 |
| Information Form | 80 | 240 | $33.51 | $8,042 |
| Patient Safety Confidentiality Complaint Form | 3 | 1 | $33.51 | $34 |
| Common Formats | 750 | 75,000 | $33.51 | $2,513,250 |
| Total | 918 | 75,764 | NA | $2,538,852 |

*Based upon the mean of the hourly wages for healthcare practitioner and technical occupation, National Compensation Survey, May 2009, "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*

a. AHRQ

The total cost to the Federal Government for the PSO forms and Common Formats is $1,737,390 per year, including project management and support for the review and administration of the PSO forms and the development and maintenance of the Common Formats.

b. OCR

Through an interagency agreement (IAA), OCR provides management for and support of the enforcement of the confidentiality protections of the Patient Safety Act and the Patient Safety Rule. The cost of this IAA is approximately $300,000 annually.

### *15. Changes in Hour Burden*

The previous information collection request (ICR), which was a new collection, included an estimate of 101 total burden hours for the following forms: Certification for Initial Listing Form, Certification for Continued Listing Form, Two Bona Fide Contracts Requirement Form, Disclosure Statement Form, the Information Form, the OCR Patient Safety Confidentiality Complaint Form, and the Attestation Form. The estimated burden hours for the current ICR are 75,764 which represents an increase of 75,663 hours. The implementation of the Common Formats accounts for 75,000 burden hours. An additional increase of 663 burden hours is attributed to changes in the number of respondents and changes in the burden estimates for the PSO forms; these changes are described below.

The burden estimates in the previous submission were developed prior to the full implementation of the PSO program. Now that the PSO program is fully implemented and AHRQ has received feedback from program participants, the burden estimates have been increased significantly for all of the PSO forms, except for the Patient Safety Confidentiality Complaint form, which is unchanged. The new estimates were revised to reflect input on the forms and Common Formats received from PSOs, healthcare organizations, and providers at the AHRQ annual meetings, PSO annual meetings, and technical assistance calls with PSOs.

Certification for Initial Listing Form -- the estimated response time has increased from 30 minutes to 18 hours with a decrease of the number of responses from 33 to 15 per year. Thus, the total burden hours from this form have increased to 270 from 17 in the original submission which represents an increase of 253 hours. The decrease in responses represents a steady state for the PSO program now that it has been fully implemented.

Certification for Continued Listing -- the estimated response time has increased from 30 minutes to 8 hours with an increase in the number of responses from 17 to 24, 90% of the listed PSOs. The total burden hours has increased from 9 to 192 which represents an increase of 183 hours.

Two Bona Fide Contracts Requirement Form – the estimated response time has increased from 15 minutes to 60 minutes with an increase of responses from 33 to 40; the total burden hours are now 40 instead of 8 which represents an increase of 32 hours.

Disclosure Statement Form -- the estimated response time has increased from 30 minutes to 3 hours with a decrease in the number of responses from 17 to 7; the total burden hours has increased from 9 to 21 which represents an increase of 12 hours.

Information Form -- the estimated response time has increased from 30 minutes to 3 hours with an increase in the number of responses from 33 to 80; the total burden hours have increased from 17 to 240 which represents an increase of 223 burden hours.

Patient Safety Confidentiality Complaint Form -- the estimated response time remains unchanged at 20 minutes per form. However, the number of responses has decreased from 50 responses to 3 responses. Since no complaints have been received to date, this estimate has been adjusted accordingly. The total number of burden hours has decreased from 17 to 1 which represents a decrease of 16 total burden hours.

Attestation Form -- this form is no longer being used separately; the questions from this form are now included in both the Certification for Initial Listing and Certification for Continued Listing Forms. The 24 burden hours for this form are now included in the Certification for Initial Listing and Certification for Continued Listing Forms.

### *16. Time Schedule, Publication and Analysis Plans*

a. AHRQ

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.

b. OCR

The information on alleged violations of statutory confidentiality requirements collected under this data collection request will not be published. The data collection will begin after the effective date of the Patient Safety Rule with the first reported violation under the Patient Safety Act. (See 42 U.S.C. 299b-22(b).)

### *17. Exemption for Display of Expiration Date*

Neither AHRQ nor OCR seeks 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 (Patient Safety Act)

Attachment B: Patient Safety and Quality Improvement Final Rule (Patient Safety Rule)

Attachment C: Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005 (Guidance)

Attachment D: PSO Certification for Initial Listing Form

Attachment E: PSO Certification for Continued Listing Form

Attachment F: PSO Two Bona Fide Contracts Requirement Form

Attachment G: PSO Disclosure Statement Form

Attachment H: PSO Information Form

Attachment I: Patient Safety Confidentiality Complaint Form

Attachment J: Common Formats Details

Attachment K: Common Formats Complete Set of Forms

Attachment L: Federal Register Notice