SUPPORTING STATEMENT

Part A

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

Version: October 29, 2014; version 29

Agency for 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, The Healthcare Research and Quality Act of 1999 (see http://www.ahrq.gov/hrqa99.pdf), 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[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 are 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

[1] As can be seen in the Attachment A, 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. .These sections are correspondingly codified as 42 USC 299b-21-299b-26

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.

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 legal obligations of PSOs, when they or the organization of which they are a part, to report certain information to the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. This includes providing FDA with access to its records, including access during an inspection of its facilities. This Guidance applies to all entities that seek to be a PSO, or are one currently, either alone or as a component of another organization that have mandatory FDA-reporting obligations under the FDCA and its implementing regulations ("FDA-regulated reporting entities"). It also covers PSOs that 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 re-certify 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 (see Attachments D – I), in order to attest 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 of the 42 U.S.C. 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 42 U.S.C. 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 U.S.C. 299b-24 (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 42 U.S.C. 299b-24(b)(1)(E) 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. In accordance with 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 Profile Form (Attachment H). This form, previously called the PSO Information Form, gathers information on the type of health care 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 necessary to develop aggregate statistics relating to 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, required by 42 U.S.C. 299b-23(c).

6. PSO Change of Listing Information Form (Attachment I). The Secretary is required under 42 U.S.C. 299b-24(d) and the Patient Safety Rule to maintain a publicly available list of PSOs that includes, among other information, each PSO's current contact information. During its period of listing, the Patient Safety Rule, section 3.102(a)(vi), also requires that a PSO must promptly notify the Secretary if there have been any changes in the accuracy of the information submitted for listing, along with the pertinent changes.

OCR is requesting approval of the following administrative form:

Patient Safety Confidentiality Complaint Form (Attachment J). The purpose of this collection is to allow OCR to collect the minimum information needed from individuals filing patient safety confidentiality complaints with OCR to that there is 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 Attachment K). As authorized by the Patient Safety Act and 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)(1), 42 U.S.C. 299b-24(a)(2), 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 attesting 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) requires 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 U.S.C. 299b-24(b)(1)(C) and 42 CFR Part 3, especially sections 3.102(d)(1) and 3.104(b) of the Patient Safety Rule, 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:

As specified in 42 U.S.C. 299b-24(b)(1)(E) and section 3.102(d)(2), a PSO is required 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 Profile Form:

Annual completion of a PSO Profile form (previously the PSO Information Form) will provide information to HHS on PSOs and the type of health care settings that PSOs are working with to conduct patient safety activities in order to improve patient safety. This form is designed to collect a minimum level of data necessary to develop aggregate statistics relating to 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, required by 42 U.S.C. 299b-23(c).

PSO Change of Listing Information Form:

The Secretary is required under 42 U.S.C. 299b-24(d) and the Patient Safety Rule, section 3.102(a)(vi), to maintain a publicly available list of PSOs that includes, among other information, contact information for each entity. During its period of listing, the Patient Safety Rule, section 3.102(a)(vi), a PSO is required to promptly notify the Secretary during its period of listing if there have been any changes in the accuracy of the information submitted for listing, along with the pertinent changes.

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.

The Patient Safety Confidentiality Complaint Form is modeled on the existing Health Information Privacy Complaint Form, HHS-700 (OMB No. 0990-0269).[2] The 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.

c. PSO Common Formats:

The Patient Safety Act establishes a framework by which doctors, hospitals, and other healthcare providers may voluntarily report information regarding patient safety events and quality of care. In order to facilitate standardized data collection, the Secretary authorized AHRQ to develop and maintain the development of common definitions and reporting formats (Common Formats) for health care providers to voluntarily collect and submit information to PSOs and other entities.

In collaboration with an interagency Federal Patient Safety Work Group (hereafter PSWG) and the public, AHRQ has developed Common Formats for two settings of care: acute care hospitals and skilled nursing facilities. The Common Formats include precise definitions of patient safety events that comprise all-cause harm, examples of patient safety population reports, paper forms to guide development of data collection instruments, a user's guide which describes how to use the Common

[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.

Formats, and a metadata registry with data element attributes and technical specifications for use by software developers.

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the National Quality Form (NQF), a non-profit organization focused on health care quality, to solicit comments and advice to guide the further refinement of the Common Formats. The NQF then convenes an expert panel to review the comments received and provide feedback. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, revises and refines the Common Formats.

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 non-identifiable PSWP. The NPSD will be maintained as an interactive, evidence-based management resource for health care providers, PSOs, researchers, and other individuals and organizations. Common Formats data can be submitted by PSOs electronically to the PSO Privacy Protection Center (PSOPPC) for data de-identification and transmission to the NPSD.

Additional information on the Common Formats, including the scope of and the development process, is provided in Attachment K.

2. Use of Information

a. AHRQ

The forms described above, other than the PSO Change of Listing Information Form, are revised collection instruments that were previously approved by OMB in 2008 and 2011. These forms, along with the new PSO Change of Listing Information Form, 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 the PSO Program Office housed in 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

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

complaint is being filed, when the incident(s) occurred, and a brief description of what happened. The Patient Safety Confidentiality Complaint 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 Patient Safety Confidentiality Complaint 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). The Patient Safety Confidentiality Complaint Form includes one question, concerning the means by which the complainant learned about filing a complaint with the OCR, which helps OCR provide better service to 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 PSO Profile Form, are available on the Web at www.pso.ahrq.gov and by electronic mail or written request. The PSO Profile form is available as an electronically fillable form at the PSOPPC Web site at www.PSOPPC.org.

The PSO forms are available in a format that allows completion and submission of the information online. In addition, paper forms can be downloaded, completed and submitted through electronic submission or via postal mail. The Patient Safety Rule states that the Two Bona Fide Contracts Requirement Certification Form may be submitted through online submission or via electronic mail (pso@ahrq.hhs.gov) until midnight of the last day of the 24-month period.

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

b. OCR

In addition to paper submission of complaints, OCR facilitates electronic submission of complaints. First, the form is 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 Patient Safety Confidentiality Complaint Form can then be printed and submitted, or submitted electronically via electronic mail. Second, the form is available in a format that allows completion and submission of the information online. Actual burden time is 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 PSO forms are the only collection tools used by AHRQ to collect data from entities seeking listing as PSOs and from PSOs. The Common Formats data can be submitted by PSOs electronically to the PSOPPC for data de-identification and transmission to the NPSD. 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 Patient Safety Confidentiality Complaint 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 July 18, 2014for 60 days (see Attachment L). No comments were received.

8.b. Outside Consultations

a. AHRQ

In order to develop the Common Formats, AHRQ convened the 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 and Medicaid Services, FDA, 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.

Through a contract with AHRQ, NQF solicits feedback on each version of the Common Formats from private sector organizations and individuals. The NQF then convenes an expert panel to review the comments received and provide feedback. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, further revises the Common Formats.

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 Patient Safety Confidentiality 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 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 provides that information provided by PSOs

on the certification forms for Initial and Continued Listing, Two Bona Fide Contracts Requirement, Disclosure Statement, and Change of Listing Information 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.

The PSO Profile 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 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, the forms will be implemented at different times and frequency due to the voluntary nature of seeking listing and remaining listed as a PSO, filing a Patient Safety Confidentiality Complaint Form, 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 100,704 hours annually and the total cost burden is estimated to be $3,618,294.72 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 17 respondents per year and an estimated time of 18 hours per response. The estimated response number not only includes submissions by entities listed PSOs, but also entities that submit an initial listing form that do not become a PSO. During the past three years, AHRQ has provided substantial technical assistance about the PSO Program, including to entities seeking initial listing. After submitting an initial listing form, an entity may withdraw its form or submit a revised form, particularly after receiving technical assistance from AHRQ. In addition, AHRQ, on behalf of the Secretary, may deny listing if an entity does not meet the requirements of the Patient Safety Act and Patient Safety Rule. 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 has an estimated time of eight hours per response and 16 responses annually. The Certification for Continued Listing Form must be completed by any interested PSO at least 75 days before the end of its current three-year listing period. The number of respondents is based upon the estimate that 65% of the projected 77 listed PSOs total will submit forms for continued listing. The estimated number of responses reflects the fact that a PSO can choose to voluntarily relinquish its status as a PSO for any reason or that a PSO can choose to not seek continued listing and allow it's listing to expire. In addition, AHRQ, on behalf of the Secretary, can revoke the listing of a PSO if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule. Therefore, AHRQ estimates that approximately two thirds of PSOs will seek continued listing and submit the form.

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 30 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 two respondents and an estimate of six 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.

Profile Form:

The overall annual burden estimate of 231 hours for the collection of information requested by the PSO Profile Form is based upon an estimate of 77 respondents per year and an estimated three hours per response. Newly listed PSOs report in the calendar year after their listing by the Secretary.

Patient Safety Confidentiality Complaint Form:

The overall annual burden estimate of one hour for the collection of information requested by the form is based on an estimate of three 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.

PSO Change of Listing Information Form:

The average annual burden for the collection of information requested by the change of listing information forms is based upon a total average estimate of 24 respondents per year and an estimated time of five minutes per response. This collection of information takes place on an ongoing basis.

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. In the previous submission, AHRQ estimated that 1,000 hospitals would be using the Common Formats once the PSO program was fully implemented. As the NPSD becomes operational, AHRQ estimates the number of hospitals using Common Formats will remain level for the next three years at 1,000 hospitals.

Exhibit 1. Estimated Annualized Burden Hours

Form	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden Hours
Certification for Initial Listing Form*	17	1	18	306
Certification for Continued Listing Form*	16	1	8	128
Two Bona Fide Contracts Requirement Form**	30	1	1	30
Disclosure Statement Form***	2	1	3	6
Profile Form****	77	1	3	231
Patient Safety Confidentiality Complaint Form***	3	1	20/60	1
Change of Listing Information***	24	1	05/60	2
Common Formats	1,000	1	100	100,000
Total***	1,169	NA	NA	100,704

*AHRQ expects the number of PSOs to remain relatively stable, with 65% of listed PSOs seeking continued listing. The number of new entities seeking listing will be offset by the number of entities that will voluntarily relinquish their status as a PSO, allow the initial listing to expire, or have their listing revoked for cause by AHRQ.

** 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 Two Bona Fide Contracts Requirement and Disclosure Statement forms may be submitted by individual PSOs in different years. Due to changes in their operations, a PSO can submit more than one Change of Listing Information in a year. OCR is anticipating considerable variation in the number of complaints per year. Hence, the total for each year is expressed as an average of the expected total over the three year collection period.

**** Beginning in 2011, the Profile Form collects data from listed PSOs each calendar year.

Exhibit 2. Estimated annualized cost burden

Form	Number of Respondents	Total burden hours	Average hourly wage rate*	Total cost
Certification for Initial Listing Form	17	306	$ 35.93	$ 10,994.58
Certification for Continued Listing Form	16	128	$ 35.93	$ 4,599.04
Two Bona Fide Contracts Requirement Form	30	30	$ 35.93	$ 1,077.90
Disclosure Statement Form	2	6	$ 35.93	$ 215.58
Profile Form	77	231	$ 35.93	$ 8,299.83
Patient Safety Confidentiality Complaint Form	3	1	$ 35.93	$ 35.93
Change of Listing Information	24	2	$ 35.93	$ 71.86
Common Formats	1,000	100,000	$ 35.93	$ 3,593,000.00
Total	1,169	100,704	NA	$ 3,618,294.72

* Based upon the mean of the hourly wages for healthcare practitioner and technical occupations, 29-0000, National Compensation Survey, May 2013, "U.S. Department of Labor, Bureau of Labor Statistics." (http://www.bls.gov/oes/current/oes_nat.htm#29-0000)

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 $5,443,220.00 $ 5,443,220.00annually including federal staff and contract costs for the PSO forms and the Common Formats.

Exhibit 3 shows the estimated annualized federal staff for project management and support for the development, administration, and review of the PSO forms and development and maintenance of the Common Formats.

Exhibit 3: Annual Cost for Federal Staff

Personnel	Staff Count	Annual Salary	% of Time	Cost
GS-15, Step 5 average	3	$141,660	65.0%	$276,237.00
GS-15, Step 5 average	1	$141,660	50.0%	$70,830.00
GS-14, Step 5 average	2	$120,429	25.0%	$60,244.00
GS-13, Step 5 average	1	$101,914	25.0%	$25,479.00
Grand Total				$432,790.00

Average annual salaries are based on the Step 5 for each grade level, 2014 OPM Pay Schedule for Washington/DC area: http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/DCB.pdf

Exhibit 4 shows the estimated annualized contract costs for the PSO forms and development and maintenance of the Common Formats.

Exhibit 4 - Estimated Total Contract Costs

Contract	Annualized Cost
USHIK – Common Formats Metadata Registry	$153,524.00
SSS - PSO Operations and Common Formats Support	$599,895.00
PSOPPC – PSO Profile Form and Common Formats Development and Maintenance Support	$2,037,522.00
NPSD – Analysis of Common Formats Data	$1,009,969.00
NQF – Common Formats Expert Panel	$265,059.00
QSRS – Common Formats Development	$582,981.00
IOM – Report on NPSD	$83,333.00
Total	$4,732,283.00

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 $ 278,147.00 annually.

With the costs for AHRQ and OCR, the annualized costs for the federal government are the sum of the cost categories outlined below in Exhibit 5:

Exhibit 5 - Estimated Annualized Costs for the Federal Government

Cost Categories	Annualized Cost
AHRQ Contract support for the development and maintenance of Common Formats	$ 4,732,283.00
AHRQ Federal Government Staff support for the review and administration of the PSO forms and development and maintenance of Common Formats	$ 432,790.00
OCR Federal Government Staff support for management for and the enforcement of the confidentiality protections of the Patient Safety Act and the Patient Safety Rule	$ 278,147.00
Total	$ 5,443,220.00

15. Changes in Hour Burden

The previous information collection request (ICR) included an estimate of 75,764 total burden hours for the Common Formats and the following forms: Certification for Initial Listing Form, Certification for Continued Listing Form, Two Bona Fide Contracts Requirement Form, Disclosure Statement Form, the PSO Profile Form, and the OCR Patient Safety Confidentiality Complaint Form. The estimated burden hours for the current ICR are 100,704 which represent an increase of 24,940 hours.

The new estimates were revised to reflect input on the PSO 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. For this submission, the burden of the OCR Patient Safety Confidentiality Complaint Form remains unchanged. With the addition of the Change of PSO Listing Information form, the burden hours are increased by only two hours due to new form. The additional increase of 24,938 burden hours is attributed to changes in the number of respondents for the PSO forms and the Common Formats which are described below.

Certification for Initial Listing Form -- the estimated response time remains unchanged at 18 hours with an increase of the number of responses from 15 to 17 per year. Thus, the total burden hours from this form have increased to 306 from 270 in the previous submission which represents an increase of 36 hours. The estimated response rate is based on the average of initial listing forms submitted by listed PSOs and entities that submitted forms, but withdrew the forms or AHRQ inactivated the form or denied listing.

Certification for Continued Listing -- the estimated response time remains unchanged at eight hours with a decrease in the number of responses from 24 to16, which is 65% of the estimated 77 listed PSOs. The total burden hours have decreased 192 to 128 which represents a decrease of 64 hours. The estimated response rate is based on the average of continued listing forms submitted by listed PSOs with approximately two thirds of PSOs seeking continued listing.

Two Bona Fide Contracts Requirement Form -- the estimated response time remains unchanged at 60 minutes with a decrease in the number of responses from 40 to 30; the total burden hours are now 30 instead of 40 which represents a decrease of 10 hours. The estimated response rate is based on the average of two bona fide contracts requirement forms submitted by listed PSOs.

Disclosure Statement Form -- the estimated response time has remains unchanged at three hours with a decrease in the number of responses from seven to two; the total burden hours have decreased from 21 to 6 which represents a decrease of 15 hours. The estimated response rate is based on the average of disclosure statement forms submitted by listed PSOs.

PSO Profile Form -- the estimated response time remains unchanged at three hours with a decrease in the number of responses from 80 to 77; the total burden hours have decreased from 240 to 231 which represents a decrease of nine hours. The estimated response rate is based on the average of number of listed PSOs.

Common Formats -- the estimated response time remains unchanged at 100 hours per hospital with an increase of the number of responses from 750 to 1,000; the total burden hours have increased from 75,000 to 100,000 which represents an increase of 25,000 hours.

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: 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 Profile Form

Attachment I: PSO Change of Listing Information

Attachment J: Patient Safety Confidentiality Complaint Form

Attachment K: Common Formats Details

Attachment L: Federal Register Notice