SUPPORTING STATEMENT

Part A

Patient Safety Organization Certification and Related Forms and a Patient Safety Confidentiality Complaint Form

Version: February 27th, 2008

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

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

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

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

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

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

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

[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

safety legislation and delegated authority to the Director of the Agency for Healthcare Research and Quality (AHRQ) to implement and administer the rest of the statute's provisions (*Federal Register*, Vol. 71, No. 95, May 17, 2006, p. 28701-2).

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

Pursuant to the proposed regulation implementing the Patient Safety Act, (see draft sections 3.102 and 3.112 of the proposed rule, 42 CFR Part 3, Attachment B), an entity that seeks to be listed as a PSO by the Secretary of the Department of Health and Human Services, must certify that it meets certain statutory requirements and, upon listing, would meet other statutory 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 also imposes other obligations discussed below that a PSO must meet to remain listed. In order for the Secretary to carry out his 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 (SFxx - SFxx) which are attached to this request as Attachments C-G.

1. Patient Safety Organization Certification Form. This form, containing certifications of eligibility and a capacity and intention to comply with statutory criteria and 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. Recertification Form. In accordance with section 924(a)(2), 42 USC 299b-24(a) (2) and the above-cited regulatory certification provisions, this form is to be completed by a listed PSO seeking continued listing as a PSO by the Secretary for an additional three years.

3. Disclosure Form. This form provides detailed instructions to a PSO regarding the narrative 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 draft NPRM, proposed section 3.102(d)(2), 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 proposed NPRM, 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.

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

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

OCR is requesting approval of the following administrative form (SFxx) (see Attachment H):

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

AHRQ and OCR are seeking OMB approval of the above-described information collection forms at the same time that the information collection requirements contained in a draft NPRM to implement the Patient Safety Act are at OMB for review.

2. Purpose and Use of Information

1. Purpose

a. AHRQ

Initial PSO Certification and PSO Recertification Forms:

The Patient Safety Act, in amended section 924 of the PHS Act, 42 U.S.C. 299b-24(a), and the proposed 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 statute and the proposed regulation), and that it will comply, upon listing, with seven other statutory criteria. The draft initial certification form also includes four questions related to 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.

Disclosure 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.

Two-Contract Certification:

To implement section 924(b)(1)(C) of the PHS Act, 42 U.S.C. 299b-24(b)(1)(C), AHRQ plans to adopt the following procedure, published in the proposed regulation: in order to maintain its PSO listing, a PSO will be required only to submit a brief attestation, at least once in every 24-month period after its initial date of listing, indicating that it has entered into contracts with two providers.

PSO Information Form:

Annual completion of a PSO information form will be voluntary and will provide information to HHS on the type of healthcare settings that PSOs are working with to carry out patient safety activities. This form is designed to collect a minimum amount of data in order to gather 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. This information will be included in AHRQ's annual quality report, as required under Section 923(c) of the Patient Safety Act. No PSO-specific data will be released without PSO consent.

b. OCR

Patient Safety Confidentiality Complaint Form:

Under the NPRM, individuals may file written complaints with the Office for Civil Rights when they believe that a person or organization subject to the Patient Safety Act has committed a violation of the statute by disclosing confidential patient safety work product 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. Use of Information

a. AHRQ

SFxx Forms are new collection instruments and will be used by AHRQ to obtain information necessary to carry out its delegated authority to implement the Patient Safety Act, 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 will be used by AHRQ's Center for Quality Improvement and Patient Safety.

b. OCR

OCR will use this new 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.

[2] The Office for Civil Rights (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.

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

The mandatory fields for the proposed 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 Office for Civil Rights, 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

SFxx Form will be available on the Web at www.pso.ahrq.gov and by email or written request. Electronic submission of the certification forms is expected to be an option, in addition to submission via postal mail or fax. The proposed rules state that the Two-Contract Requirement Form may be submitted via email (psoforms@ahrq.hhs.gov) until midnight of the last day of the 24-month period.

b. OCR

In addition to paper submission of complaints, OCR facilitates electronic submission of complaints. First, the 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. In the future, we expect to provide full web-based electronic submission of complaints.

4. Efforts to Identify Duplication

a. AHRQ
SFxx Form will be the only forms used by AHRQ to collect such data 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 draft NRPM, 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.

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, there are no special circumstances associated with the above-proposed collections.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on February 20th, 2008 for 60 days (see Attachment I).

8.b. Outside Consultations

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 (ASPE) 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

SFxx 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 SFxx Forms or information from the SFxx Forms will be safeguarded in a physically secured area. However, the information on the certification forms for initial and continued listing, disclosure statements, and the two-contract requirement generally will be made available to the public and may be posted on AHRQ's website unless 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 SFxx Forms.

The PSO Information Form is intended to provide information to the Department of Health and Human Services on the type of healthcare settings that Patient Safety Organizations (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; no PSO-specific data from this collection is expected to be released to the public and would only be done with the consent of the identifiable entities.

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, some near the end of the three year approval period for these standard forms. Exhibit 1 shows the estimated annualized burden hours for the respondent to provide the requested information, and Exhibit 2 shows the estimated annualized cost burden for the respondents' time to provide the requested information.

Initial PSO Certification and PSO Recertification Forms:

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

Two-Contract Certification:

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

Disclosure Form:

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

PSO Information Form:

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

OCR Complaint Form:

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

All Administrative Forms:

The overall maximum anticipated annual burden estimate is 75 hours for all the above-described collections of information. Because the forms filled out by PSOs vary over each of their first three years, the table below includes three-year total estimates divided by three to arrive at an annual estimate of burden hours. (See below.)

Exhibit 1. Estimated Annualized Burden Hours

Form	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden Hours
Patient Safety Organization	100/3	1	30/60	17

Certification Form				
Recertification Form*	50/3	1	30/60	8
Disclosure Form	50/3	1	30/60	8
Two-Contract Requirement Form**	100/3	1	15/60	8
Information Form***	100/3	1	30/60	17
Patient Safety Confidentiality Complaint Form	150/3	1	20/60	17
Total****	550/3	na	na	75

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

** The Two-Contract 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 close to the end of the calendar year when PSOs are first listed.

**** A total of 100 PSOs are expected to apply over three years: 50 in year 1; 25 in year 2; and 25 in year 3. Relationship Disclosure, Two-Contract, and even voluntary Information Forms may be submitted by individual PSOs in different years. OCR is anticipating considerable variation in the number of complaints per year. Hence we have expressed the total for each year as the average of the expected total over the three year collection period.

Exhibit 2. Estimated Annualized Cost Burden

Form	Number of Respondents	Total burden hours	Average hourly wage rate	Total cost burden

Patient Safety Organization Certification Form	100/3	17	$29.82	$506.94
Recertification Form	50/3	8	$29.82	$238.56
Disclosure Form	50/3	8	$29.82	$238.56
Two-Contract Requirement Form	100/3	8	$29.82	$238.56
Information Form	100/3	17	$29.82	$506.94
Patient Safety Confidentiality Complaint Form	150/3	17	$29.82	$506.94
Total	550/3	75	$29.82	$2,236.50

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

By statute, AHRQ must collect and review certifications from an entity that seeks listing or continued listing as a PSO under the Patient Safety Act. Additional information collection is also required for entities to remain listed as a PSO (i.e., submissions regarding compliance with the two-contract requirement and reports of certain relationships between a PSO and each of its contracting providers). The cost to AHRQ of processing the information collected with the above-described forms is minimal; an estimated equivalent of only approximately 0.05 FTE or $7,500 per year for each agency and virtually no new overhead costs

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

b. OCR

OCR cannot conduct its work without collecting information through its proposed complaint forms. Even if OCR did not use complaint forms and only took information orally, it would still have to capture the same information in order to begin processing a complaint. Therefore, the incremental cost to OCR of processing the information collected from the complaint form is minimal and is equivalent to only approximately 0.05 FTE or $7,500 per year with, with virtually no new overhead costs.

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

15. Changes in Hour Burden

This is a new information collection.

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 final 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

Attachment B: Excerpts from the Notice of Proposed Rulemaking

Attachment C: Patient Safety Organization Certification Form

Attachment D: Recertification Form

Attachment E: Disclosure Form

Attachment F: Two-Contract Requirement Form

Attachment G: PSO Information Form

Attachment H: Patient Safety Confidentiality Complaint Form

Attachment I: 60 Day Federal Register Notice