SUPPORTING STATEMENT

Part A

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

Reinstatement with change of a Previously Approved Information Collection, OMB No.0935-0143

Version: 9/24/2024

Agency for Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

About AHRQ:
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 https://www.ahrq.gov/policymakers/hrqa99a.html), 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.

Summary of this Information Collection Request:
This Information Collection Request (ICR) is for a reinstatement with revision of the Patient *Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats*. AHRQ is requesting approval for changes to clarify language on 7 of the forms, and an updated burden statements for all forms within this package. These changes are detailed below on page 6. The OMB control number for this ICR is 0935-0143 and will expire on September 30, 2024. AHRQ is requesting a new expiration date, three years from approval.

Background and Overview of the *Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats*:
The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act, see Attachment A), 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 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 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 (Patient Safety Rule, see Attachment B) which became effective on January 19, 2009. The Patient Safety Rule outlines the requirements that entities must meet to become and remain listed as PSOs, the process by which the Secretary of HHS (Secretary) will accept certifications and list PSOs, and provisions pertaining to the confidentiality and privilege protections for patient safety work product (PSWP).

When specific statutory requirements are met, the information collected and the analyses and deliberations regarding the information receive confidentiality and privilege protections under this legislation. The Secretary delegated authority to the Director of the Office for Civil Rights (OCR) to interpret and enforce the confidentiality protections of the Patient Safety Act (*Federal Register*, Vol. 71, No. 95, May 17, 2006, p. 28701-2). Civil money penalties may be imposed for knowing or reckless impermissible disclosures of PSWP. AHRQ implements and administers the rest of the statute's provisions.

Pursuant to the Patient Safety Rule (42 CFR §3.102), 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 accordance with the requirements of the Patient Safety Rule (see, e.g., 42 CFR §§ 3.102(a)(1), 3.102(b)(2)(i)(E), 3.102(d)(1), and 3.112), the entities seeking to be listed and to remain listed must complete the proposed forms (see Attachments C - J), in order to attest to compliance with statutory criteria and the corresponding regulatory requirements.

The goals of the *Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats* are:

- To encourage individual providers and healthcare organizations to voluntarily report quality and patient safety information to PSOs confidentially and without fear of legal discovery.
- To help healthcare professionals learn from quality and patient safety concerns to prevent similar problems from happening in the future.

To accomplish these goals, the current forms and data collections are approved by OMB:

1. **PSO Certification for Initial Listing Form** (Attachment C). 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 42 U.S.C. 299b-24(a)(1), and the above-cited regulatory certification provisions, by an entity seeking to be listed by the Secretary as a PSO for an initial three-year period. After submitting a PSO Certification for 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.

2. **PSO Certification for Continued Listing Form** (Attachment D). 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 by the Secretary as a PSO for each successive three-year period. This form has been revised to include clarifications on the role of the primary point of contact, more precise language about whether there are any changes to the parent organization or any additional parent organizations and an additional note to clarify how users should determine the response to the standardized way they collect patient safety work product (PSWP). The PSO 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.

3. **PSO Two Bona Fide Contracts Requirement Form** (Attachment E). To remain listed, a PSO must meet a statutory requirement in 42 U.S.C. 299b-24(b)(1)(C) that it has contracts with more than one provider, within successive 24-month periods, beginning with the date of the PSO's 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 and is submitted when the PSO notifies the Secretary that it has entered into contracts with providers.

4. **PSO Disclosure Statement Form** (Attachment F). 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), when it (i) has a contract with a provider and (ii) it has financial, reporting, or contractual relationship(s) with that contracting provider or is not managed, controlled, and operated independently from that contracting 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. This information collection takes place when a PSO first reports having any of the specified types of additional relationships with a provider with which it has a contract to carry out patient safety activities.

5. **PSO Profile Form** (Attachment G). This form is designed to collect a minimum level of voluntary data necessary to develop aggregate statistics relating to PSOs, the types of providers they work with, and their general location in the US. The PSO Profile is intended to be completed annually by all PSOs that are "AHRQ-listed" during any part of the previous calendar year. This information is collected by AHRQ's PSO Privacy Protection Center (PSOPPC) and is used to populate the AHRQ PSO selection tool on the AHRQ PSO website, to generate slides presented at the PSO Annual Meeting, and to develop content for AHRQ annual quality report required by 42 U.S.C. 299b-2(b)(2), the National Healthcare Quality and Disparities Report. This collection of information takes place annually with newly listed PSOs first eligible to submit the form in the calendar year after their initial listing by the Secretary.

6. **PSO Change of Listing Information Form** (Attachment H). The Secretary is required under 42 U.S.C. 299b-24(d) to maintain a publicly available list of PSOs. Under the Patient Safety Rule, that list includes, among other information, each PSO's current contact information. The Patient Safety Rule, at 42 CFR 3.102(a)(1)(vi), also requires that, during its period of listing, a PSO must promptly notify the Secretary of any changes in the accuracy of the information submitted for listing. This collection of information takes place on an ongoing basis as needed when there are changes to the PSO's administrative listing information.

7. **PSO Voluntary Relinquishment Form** (Attachment J). A PSO may voluntarily relinquish its status as a PSO for any reason. Pursuant to 42 CFR 3.108(c)(2), for the Secretary to accept a PSO's notification of voluntary relinquishment, the notice must contain certain attestations and future contact information. This form provides an efficient manner for a PSO seeking voluntary relinquishment to provide all the required information.

8. **OCR Consent Form** (Attachment I). The purpose of this collection is to allow the OCR to collect the minimum information needed from individuals filing patient safety confidentiality complaints with OCR so that there is a basis for initial processing of those complaints. 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 and takes place when a member of the public submits a complaint regarding a possible violation of the confidentiality provisions of the Patient Safety Act.

9. **AHRQ Common Formats** (Attachment K). AHRQ is requesting approval for a set of common definitions and reporting formats:

   As authorized by 42 U.S.C. 299b-23(b), AHRQ coordinates the development of the Common Formats that facilitate aggregation of comparable data at local, PSO, regional and national levels. The Common Formats allow PSOs and health care providers to voluntarily collect and submit standardized information regarding patient safety events to fulfill the national learning system envisioned by the Patient Safety Act. The use of the formats by PSOs and other entities is voluntary and is on an ongoing basis.

Proposed revisions to current data collection:

All forms in this package will include updated Burden Statements. The following forms have revisions for clarification which are described below:

1. PSO Certification for Initial Listing (Attachment C) - This form has been revised to include clarification on the role of the primary point of contact.
2. PSO Certification for Continued Listing (Attachment D) - This form has been revised to include clarifications on the role of the primary point of contact, more precise language about whether there are any changes to the parent organization or any additional parent organizations and an additional note to clarify how users should determine the response to the standardized way they collect patient safety work product (PSWP).
3. PSO Profile Form (Attachment G) - The form has been revised to add a new clinical discipline, "Clinical Dialysis Services".
4. PSO Change of Listing Form (Attachment H) - This form has been revised to include note clarification for the parent and the point of contact sections.
5. PSO Voluntary Relinquishment Form (Attachment J) - This form has been revised to include a change from street to mailing address for future contacts of Delisting PSOs.
6. OCR Complaint Consent Form (Attachment I) - The form has two parts, the complaint form and the consent form. The complaint form was updated to conform notice to individuals about confidentiality of identifying information submitted on complaint form with existing approved OCR HIPAA Rules complaint form and to update OCR contact information. The consent form was updated to conform notice to individuals about confidentiality of identifying information submitted on consent form with existing approved OCR HIPAA Rules consent form, to more fully describe OCR authorities allowing collection of information in Privacy Act of 1974 notice, and update OCR contact information.
7. AHRQ Common Formats (Attachment K) – Since the last approval, AHRQ has released Common Formats Event Reporting for Diagnostic Safety, Version 1.0 (CFER-DS V1.0) and is planning on the release of Common Formats for Surveillance- Hospital V1.0 (CFS-H V1.0) in the near future, which is a revision/update from the last version CFS- H V0.3 Beta.

2. Purpose and Use of Information

1. Purpose

Patient Safety Organizations (PSOs) collect and analyze data voluntarily reported by healthcare providers to help improve patient safety and healthcare quality. PSOs provide feedback to healthcare providers aimed at promoting learning and preventing future patient safety events. Working with a PSO makes it possible for information from healthcare providers to receive certain legal protections and to be contributed to the Network of Patient Safety Databases (NPSD). Under the Patient Safety and

Quality Improvement Act of 2005 (the Patient Safety Act), AHRQ certifies and lists PSOs. The forms listed above are used to certify and list PSOs are the Certification for Initial Listing, PSO Certification for Continued Listing, PSO Two Bona Fide Contracts Requirement Certification Form, PSO Disclosure Statement Form, PSO Change of Listing Information Form. The PSO Voluntary Relinquishment Form is used by PSOs which no longer wish to remain listed and the PSO Profile Form is a voluntary form PSOs can use to report about themselves and the providers they serve. The Office for Civil Rights (OCR) is responsible for interpretation of the confidentiality provisions of the Patient Safety Act and Rule and has provided the OCR Patient Safety Confidentiality Complaint Form which allows individuals to 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. The information collected on these forms allows the AHRQ and the OCR to administer the Patient Safety Act and Rule.

2. Use of Information

a. AHRQ

AHRQ will use these forms, other than the Patient Safety Confidentiality Complaint Form, to obtain information necessary to carry out its authority to implement the Patient Safety Act and Patient Safety Rule. This includes obtaining initial and subsequent certifications from entities seeking to be or remain listed as PSOs and for making the statutorily required determinations prior to and during an entity's period of listing as a PSO. The PSO Division, housed in AHRQ's Center for Quality Improvement and Patient Safety, uses this information.

b. OCR

OCR will use the Patient Safety Confidentiality Complaint Form to collect information for the initial assessment of an incoming complaint. The form is modeled on OCR's form for complaints alleging violation of the privacy of protected health information.[1] 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 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

[1] .The existing health information privacy form was approved by OMB September 28, 2012 (OMB 0990-0269)

Safety Confidentiality Complaint Form includes one question, concerning how 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 AHRQ PSO website at www.pso.ahrq.gov and by electronic mail or written request. The PSO Profile Form is available in a format that allows completion and submission of the information online at the PSOPPC website at www.PSOPPC.org.

The PSO forms are available in a format that allows completion and submission of the information online. AHRQ has updated the electronic submission of all forms, except for the PSO Certification for Initial Listing and the Patient Safety Confidentiality Complaint Form that is administered by OCR, including the capability of the system to auto populate certain fields based on prior submissions by the PSOs. In addition, paper forms can be downloaded, completed and submitted through electronic mail, to pso@ahrq.hhs.gov, or via postal mail.

The AHRQ Common Formats, accompanying user guide, and technical specifications are available as printable electronic files on the PSOPPC website at www.PSOPPC.org.

b. OCR

In addition to paper submission of complaints, OCR facilitates electronic submission of complaints. First, the Patient Safety Confidentiality Complaint Form is available on the OCR website at https://www.hhs.gov/hipaa/filing-a-complaint/patient-safety-confidentiality/index.html. 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. In addition, while someone with strong keyboarding skills might enter the information more quickly electronically, someone without those skills might take considerably longer than they would if they used 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 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 AHRQ Common Formats data can be submitted by PSOs electronically to the PSOPPC for data non-identification and transmission to the NPSD. This information collection does not duplicate any other effort and the information cannot be obtained 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 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 website 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

Almost all of the submissions to be required by AHRQ with the above-described forms pursuant to the Patient Safety Act and Patient Safety Rule have statutorily based frequency requirements that cannot be reduced, or they have pragmatic foundations that provide AHRQ with the minimum time necessary to take appropriate actions based on the information submitted, including the PSO Change of Listing Information Form which is submitted only for required changes. 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 PSOs and 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 OCR 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. However, 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

There are no special circumstances associated with the above-proposed collections other than the necessity of carrying out the Secretary's responsibilities under the Patient Safety Act and Patient Safety Rule.

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 August 12, 2024, volume 89, page 65629 for 60 days (see Attachment L). AHRQ did not receive substantive comments from members of the public during the 60-day review period.

8.b. Outside Consultations

a. AHRQ

In developing the Common Formats, AHRQ convenes the PSWG to assure consistency with definitions and formats used by other Federal agencies. The PSWG includes offices and agencies within HHS – Office of the Assistant Secretary for Health (OASH), Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, FDA, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration – as well as the Department of Defense and the Department of Veterans Affairs.

In addition, through a contract with AHRQ, the PSOPPC solicits public feedback on each version of the Common Formats. The PSOPPC then convenes an expert panel to review the comments received and provide feedback to AHRQ. Based upon the PSOPPC's review of the expert panel's feedback, AHRQ may further revise 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 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.

9. Payments/Gifts to Respondents

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

10. Assurance of Confidentiality

Data will be kept private to the extent allowed by law. Individuals and organizations will be assured of the confidentiality of their replies under Section 944(c) of the Public Health Service Act. 42 U.S.C. 299c-3(c). That law requires that information collected for activities conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied.

1. AHRQ

The forms from the entities that seek certification as a PSO are kept on the AHRQ computer system and related database(s) that are password protected for electronic information. However, the Patient Safety Rule provides that certain information provided on the PSO forms for Certification for Initial and Continued Listing, PSO Two Bona Fide Contracts Requirement, PSO Disclosure Statement, PSO Change of Listing Information, and PSO Voluntary Relinquishment are made available to the public. In addition, information from the forms is posted on AHRQ's PSO website 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 to characterize PSOs and their health care providers in the conduct of patient safety activities. This form is designed to collect a minimum level of information to gather aggregate data on the impact of the Patient Safety Act. The PSOs may voluntarily submit this information to the PSOPPC using an online data entry tool through the secure area of the PSOPPC.org website.

PSOs that submit Common Formats data to the PSOPPC must use the secure log in area of the PSOPPC.org website. These voluntary data submissions are treated as PSWP and processed pursuant to a data agreement between each PSO and the PSOPPC.

2. 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.

11. Questions of a Sensitive Nature

No questions of a sensitive nature will be asked.

12. Estimates of Annualized Burden Hours and Costs

The PSO information collection forms described below will be implemented at different times and frequencies due to the voluntary nature of seeking listing and remaining listed as a PSO, filing an OCR Patient Safety Confidentiality Complaint Form, and using the Common Formats. For the PSO forms, the burden estimates are based on the average of submissions received over the past three years. For the Common Formats, this estimate is based on the feedback that AHRQ has received during meetings and technical assistance calls from PSOs and other entities that have been utilizing the 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 100,811.58 hours annually and the total cost burden is estimated to be $ 4,946,824.23 annually.

Exhibit 1. Estimated Annualized Burden Hours

Form	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden Hours
1. PSO Certification for Initial Listing Form	11	1	18	198
2. PSO Certification for Continued Listing Form	40	1	8	320
3. PSO Two Bona Fide Contracts Requirement Form	56	1	1	56
4. PSO Disclosure Statement Form	3	1	3	9
5. PSO Profile Form	74	1	3	222
6. PSO Change of Listing Information	51	1	5/60	4.25
7. PSO Voluntary Relinquishment Form	4	1	30/60	2
8. OCR Complaint Consent Form	1	1	20/60	.33
9. AHRQ Common Formats	1,000	1	100	100,000
Total		NA	NA	100,811.58

Exhibit 2. Estimated annualized cost burden

Form	Total burden hours	Average hourly wage rate*	Total cost
1. PSO Certification for Initial Listing Form	198	$49.07	$9,715.86
2. PSO Certification for Continued Listing Form	320	$49.07	$15,702.40
3. PSO Two Bona Fide Contracts Requirement Form	56	$49.07	$2,747.92
4. PSO Disclosure Statement Form	9	$49.07	$441.63
5. PSO Profile Form	222	$49.07	$10,893.54
6. PSO Change of Listing Form	4.25	$49.07	$208.55
7. PSO Voluntary Relinquishment Form	2	$49.07	$98.14
8. OCR Complaint Consent Form	.33	$49.07	$15.35
9. AHRQ Common Formats	100,000	$49.07	$4,907,000
Total			$4,946,824.23

* Based upon the mean of the hourly average wages for healthcare practitioner and technical occupations, 29-0000, National Compensation Survey, May 2023, "U.S. Department of Labor, Bureau of Labor Statistics." https://www.bls.gov/oes/current/oes290000.htm

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, because 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 $ 1,373,674.97 annually including federal staff and contract costs for the PSO forms and the Common Formats. The previous information collection request (ICR) included an estimate of $2,047,360.31 total annualized cost to the government for personnel and contracting work costs. This reduction can be attributed to efficiencies gained by shifting AHRQ Common Formats work from one of the contractors to the PSO Privacy and Protection Center (PSO PPC) and to the reduction of time needed for AHRQ staff to review the PSO Listing forms and conduct technical assistance related to these forms.

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. The estimates below reflect shifting of tasks among staff and staff changes.

Exhibit 3. Annual Cost for Federal Staff

Personnel	Staff Count	Annual Salary	% of Time	Cost
GS-15, Step 5 average	1	$176,458	65 %	$114,697.70
GS-15, Step 5 average	1	176,458	50%	$88,229.00
GS-14, Step 5 average	2	$150,016	25 %	$75,008.00
GS-13, Step 5 average	1	$126,949	65 %	$82,516.85
GS-13, Step 5 average	1	126,949	25%	$31,737.25
GS-12, Step 5 average	1	$106,759	50 %	$53,379.50
Grand Total				$445,568.30

Average annual salaries are based on the Step 5 for each grade level, 2023 OPM Pay Schedule for Washington/DC area: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/html/DCB.aspx

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
Technical Assistance for Development and Enhancement of the Quality and Safety Review System (QSRS) and enhancement and development of Common Formats	$536,481.67
PSOPPC – PSO Profile Form, Common Formats Development, Maintenance Support, and Common Formats Expert Panel	$391,625.33
Total	$928,106.67

b. OCR

Considering the very limited number of Patient Safety Confidentiality Complaint Forms received by OCR, the estimated annual federal staff for the development, administration, and review of the form is negligible.

Exhibit 5 – Estimated Annualized Costs for the Federal Government

Cost Categories	Annualized Cost
AHRQ Contract support for the development and maintenance of Common Formats	$928,106.67
AHRQ Federal Government Staff support for the review and administration of the PSO forms and development and maintenance of Common Formats	$445,568.30
Total	$1,373,674.97

15. Changes in Hour Burden

The previous information collection request (ICR) included an estimate of 100,795.83 total burden hours for the Common Formats and the following forms: PSO Certification for Initial Listing Form, PSO Certification for Continued Listing Form, PSO Two Bona Fide Contracts Requirement Form, PSO Disclosure Statement Form, PSO Profile Form, PSO Change of Listing Form, the OCR Patient Safety Confidentiality Form, and the PSO Voluntary Relinquishment Form.

The estimated burden hours for the current ICR are 100,811.58 that represent an increase of 15.75 hours.

For this submission, the burden of the forms remains unchanged. A few minor edits for clarity are being made to some of the existing forms which have not affected the burden estimates. The increase of 15.75 burden hours is attributed to the changes in the number of respondents for the PSO forms.

16. Time Schedule, Publication and Analysis Plans

a. AHRQ

Data collected via the PSO forms may be made public by the Secretary. Statistical information about PSOs and data submitted in the Common Formats will be published only as non-identifiable aggregated information.

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.

18. Attachments:

Attachment A: 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: PSO Certification for Initial Listing Form

Attachment D: PSO Certification for Continued Listing Form

Attachment E: PSO Two Bona Fide Contracts Requirement Form

Attachment F: PSO Disclosure Statement Form

Attachment G: PSO Profile Form

Attachment H: PSO Change of Listing Information

Attachment I: OCR Complaint Consent Form

Attachment J: PSO Voluntary Relinquishment Form

Attachment K: AHRQ Common Formats

Attachment L: 60 Day Federal Register Notice