SUPPORTING STATEMENT

Part A

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

Version 21: August 2018

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,[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 promotes health care quality improvement by conducting and supporting:

1. Research that develops and presents scientific evidence on all aspects of health care;

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.

AHRQ conducts and supports research and evaluations, and supports demonstration projects, on (A) the delivery of health care in inner-city areas, and in rural areas; and (B) health care for priority populations, which 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 (Patient Safety Act, see Attachment A[1]), signed into law on July 29, 2005, was enacted in response to growing concern about patient safety and quality 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 create a national learning system by providing for the voluntary formation of Patient Safety Organizations (PSOs). The Patient Safety Act signifies the Federal Government's commitment to fostering and creating an environment in which the causes of health care risks and hazards can be thoroughly and honestly examined and discussed without fear of penalties and liabilities. By analyzing substantial amounts of information across multiple institutions, PSOs are able to identify patterns of failures and propose quality and safety improvements.

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 establishes a framework for the reporting of quality and patient safety information – by hospitals, doctors, nurses, pharmacists, and other providers - to PSOs, on a privileged and confidential basis for the aggregation and analysis. In addition, the Patient Safety Rule outlines the requirements that entities must meet to become and remain listed as PSOs and the process by which the Secretary of HHS (the Secretary) will accept certifications and list PSOs.

In addition to the Patient Safety Act and the Patient Safety Rule, HHS has issued two pieces of guidance regarding reporting obligations. The first guidance was issued on December 30, 2010 - *Patient Safety and Quality Improvement Act of 2005 - HHS Guidance Regarding Patient Safety Organizations' Reporting Obligations to the Food and Drug Administration (FDA)* - addresses questions about the obligations of PSOs that are also required to report certain information to the FDA under the Federal Food, Drug, and Cosmetic Act (FDCA) and its

[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

implementing regulations; (see Attachment C). The second guidance, was issued on May 24, 2016 - *Patient Safety and Quality Improvement Act of 2005 - HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations* - to address questions about patient safety work product (PSWP) and external reporting obligations of providers working with a PSO (see Attachment D).

When specific statutory requirements are met, 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 Act (*Federal Register*, Vol. 71, No. 95, May 17, 2006, p. 28701-2). OCR is responsible for enforcing protections regarding patient safety PSWP which may include: 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. AHRQ implements and administers the rest of the statute's provisions.

Pursuant to the Patient Safety Rule, 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 (42 CFR 3.102). 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 E - L), 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 E). 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 corresponding regulatory provisions, by an entity seeking to be listed by the Secretary as a PSO for an initial three-year period._

2. PSO Certification for Continued Listing Form (Attachment F). In accordance with 42 U.S.C. 299b-24(a)(2) and the corresponding regulatory 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 G). To remain listed, a PSO must meet a statutory requirement in 42 U.S.C. 299b-24(b)(1)(C) that it has bona fide contracts with more than one provider, within successive 24-month periods, beginning with the date of the PSO's initial listing for the purpose of receiving and reviewing PSWP. 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 H). 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 by the PSO in accordance with the 42 U.S.C. 299b-24(b)(1)(E), whereby the entity shall fully disclose: (i) any financial, reporting, or contractual relationship(s) between the entity and any provider that contracts with the PSO and (ii) if applicable, the fact that the PSO is not managed, not controlled, and operated independently from any provider that contracts with the PSO. 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 patient safety activities.

5. PSO Profile Form (Attachment I). This form gathers information on the type of providers and settings with which PSOs are working with to conduct patient safety activities in order to improve quality and safety. It

is designed to collect a minimum level of data necessary to develop aggregate data relating to the Patient Safety Act. This information will be included in AHRQ's *National Healthcare Quality and Disparities Report*, required by required by 42 U.S.C. 299b-2(b)(2).

6. PSO Change of Listing Information Form (Attachment J). 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. During its period of listing, 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.

7. PSO Voluntary Relinquishment Form (Attachment K). A PSO may choose to voluntarily relinquish its status as a PSO for any reason. Pursuant to 42 CFR 3.108(c)(2), in order 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 of the required.

In addition, AHRQ is requesting approval for a set of common definitions and reporting formats (thereafter Common Formats; see Attachment M). As authorized by 42 U.S.C. 299b-23(b), AHRQ coordinates the development of the Common Formats which 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, both clinically and electronically, regarding patient safety events to fulfill the national learning system as envisioned by the Patient Safety Act.

OCR is requesting approval of the following administrative form:

Patient Safety Confidentiality Complaint Form (Attachment L). The purpose of this collection is to allow 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.

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 Forms

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

The proposed 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 corresponding regulatory provisions provides 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 and that it will comply, upon listing, with seven other statutory criteria. Similarly, the proposed certification form for continued listing as a PSO, and for each successive three-year period after the initial listing period, in accordance with 42 U.S.C. 299b-24(a)(2) and the corresponding regulatory provisions, 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. Both the initial and continued

listing forms include additional questions related to other requirements for listing related to eligibility and pertinent organizational history.

PSO Two Bona Fide Contracts Requirement Certification Form:

As specified in 42 U.S.C. 299b-24(b)(1)(C), a PSO, in order to maintain its listing, will be required to submit a brief attestation, at least once in every 24-month period after its initial date of listing, indicating that it has bona fide contracts with more than one provider for the purpose of receiving and reviewing PSWP.

PSO Disclosure Statement Form:

As specified in 42 U.S.C. 299b-24(b)(1)(E), 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 and the Patient Safety Rule 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 Change of Listing Information Form:

The Secretary is required under 42 U.S.C. 299b-2(b)(2) to maintain a publicly available list of PSOs that includes, among other information, contact information for each entity. On this form, a PSO provides any revisions or additions to the listing information. During its period of listing, the Patient Safety Rule, at 42 CFR 3.102(a)(1)(vi), requires a PSO to promptly notify the Secretary of any changes to information submitted for listing.

PSO Voluntary Relinquishment Form:

A PSO may choose to voluntarily relinquish its status as a PSO at any time. Pursuant to 42 CFR 3.108(c)(2), in order for the Secretary to accept a PSO's notification of voluntary relinquishment, a PSO provides the reasons for requesting voluntary relinquishment, notifications to providers about and disposition of PSWP (if applicable), and appropriate contact for further communications from the Secretary.

PSO Profile Form:

Voluntary annual completion of this form will provide information to HHS on PSOs and the type of providers 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 information necessary to develop aggregate data relating to PSOs and the providers who work with PSOs.

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. AHRQ Common Formats:

As authorized by 42 U.S.C. 299b-23(b), AHRQ develops and maintains the development of Common Formats (also known as formats) for providers to voluntarily collect and submit information to PSOs and other entities. These formats establish a framework by which doctors, hospitals, and other providers may voluntarily report information regarding patient safety events and quality of care.

In collaboration with an interagency Federal Patient Safety Work Group (hereafter PSWG) and the public, AHRQ has developed Common Formats for Event Reporting for three settings of care – hospitals, community pharmacies, and nursing homes. The 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 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 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 authorizes the creation of a Network of Patient Safety Databases (NPSD), to which PSOs, providers, and others can voluntarily contribute the non-identifiable PSWP. The NPSD will be maintained as an interactive, evidence-based management resource for 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 non-identification and transmission to the NPSD. Use of the Common Formats and submission of data to the PSOPPC/NPSD are voluntary.

The Common Formats are also part of AHRQ's efforts to support patient safety event surveillance. Common Formats for Surveillance-Hospital (beta version) will be made available electronically in the Quality and Safety Review System (QSRS) which relies on clinical information recorded in medical records thus making use of structured data where it is or may become available. Overall, the QSRS will generate adverse event rates and trend performance over time. While it is still under development, the QSRS is designed to serve as a local hospital and health system tool to identify and measure adverse events.

Additional information on the Common Formats - including scope, development process, and the current releases - is provided in Attachment M.

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[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.

2. Use of Information

a. AHRQ

The forms described above, other than the PSO Voluntary Relinquishment Form, are revised collection instruments that were previously approved by OMB in 2008, 2011, and 2014.

AHRQ will use these forms to obtain information necessary to carry out its delegated authority to implement the Patient Safety Act and Patient Safety Rule, including 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. This information is used by the PSO Program Office housed in AHRQ's Center for Quality Improvement and Patient Safety.

b. OCR

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

The mandatory fields for the form are: name, contact information, the identity of the person or persons whose information was impermissibly disclosed, the person or entity against whom or which the complaint is being filed, when the incident(s) occurred, and a brief description of what happened. The 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 AHRQ PSO website 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 website at www.PSOPPC.org.

The PSO forms are available in a format that allows completion and submission of the information online. Since the last submission to OMB, AHRQ has modernized and automated the electronic submission of all forms, except

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

for the PSO Certification for Initial Listing, 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 Patient Safety Rule states that the PSO Two Bona Fide Contracts Requirement Certification Form may be submitted through online submission or via electronic mail 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 website 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 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 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 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 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 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 the 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 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 February 26, 2018 for 60 days on page 8274 (see Attachment N).

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. In addition, 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 on the AHRQ computer system and related database(s) which are password protected for electronic information. However, the Patient Safety Rule provides that 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 and 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 in order to gather aggregate data on the impact of the Patient Safety Act. The PSOs may voluntarily 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 website.

In addition, PSOs may submit Common Format data using the secure log in area of the PSOPPC.org website. These voluntary data submission are treated as PSWP and processed pursuant to a data agreement between each PSO and the PSOPPC.

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

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. The burden estimates are based on the average of the forms submissions received over the past three years.

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 100,724.91hours annually and the total cost burden is estimated to be $3,833,685.21annually.

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 16 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. 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.

PSO 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 21 responses annually. 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.

PSO Two Bona Fide Contracts Requirement Certification Form:

The average annual burden for the collection of information requested by the PSO Two Bona Fide Contract Certification Form is based upon an estimate of 42 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 with providers.

PSO Disclosure Statement Form:

Because only a small percentage of PSOs will need to file a Disclosure Statement Form, the average burden for the collection of information requested by the disclosure form is based upon an estimate of three respondents per year and 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 provider with which it has a contract to carry out patient safety activities.

PSO Profile Form:

The overall annual burden for the collection of information requested by the PSO Profile Form is based upon an estimate of 70 respondents per year and an estimated three hours per response. The collection of information takes place annually with newly listed PSOs submitting the form in the calendar year after their listing by the Secretary.

PSO Change of Listing Information Form:

The average annual burden for the collection of information requested by the PSO Change of Listing Information Form is based upon an estimate of 61 respondents per year and an estimated time of five minutes per response. This collection of information takes place on an ongoing basis as needed when there are changes to the PSO’s listing information.

OCR 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 one respondent per year and an estimated 20 minutes per response; the estimate of one form is provided due to the fact that no submissions have been received until this point. 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 Voluntary Relinquishment Form:

The average annual burden for the collection of information requested by the PSO Voluntary Relinquishment Form is based upon a total average estimate of five respondents per year and an estimated time of five minutes per response.

Common Formats:

AHRQ estimates that 5% FTE of a patient safety manager at a facility will be spent to administer the Common Formats, which is approximately 100 hours a year. The use of the formats by PSOs and other entities is voluntary and is on an ongoing basis. 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. As the NPSD becomes operational, AHRQ will revise the estimate based on actual submissions.

Exhibit 1. Estimated Annualized Burden Hours

Form	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden Hours
PSO Certification for Initial Listing Form	16	1	18	288
PSO Certification for Continued Listing Form	21	1	8	168
PSO Two Bona Fide Contracts Requirement Form	42	1	1	42
PSO Disclosure Statement Form	3	1	3	9
PSO Profile Form	70	1	3	210
PSO Change of Listing Information	61	1	5/60	5.08
OCR Patient Safety Confidentiality Complaint Form	1	1	20/60	.33
PSO Voluntary Relinquishment Form	5	1	30/60	2.50
Common Formats	1,000	1	100	100,000
Total		NA	NA	100,724.91

Exhibit 2. Estimated annualized cost burden

Form	Number of Respondents	Total burden hours	Average hourly wage rate*	Total cost
PSO Certification for Initial Listing Form	16	288	$38.06	$10,961.28
PSO Certification for Continued Listing Form	21	168	$38.06	$6,394.08
PSO Two Bona Fide Contracts Requirement Form	42	42	$38.06	$1,598.52
PSO Disclosure Statement Form	3	9	$38.06	$342.54
PSO Profile Form	70	210	$38.06	$7,992.60
PSO Change of Listing Form	61	5.08	$38.06	$193.34
OCR Patient Safety Confidentiality Complaint Form	1	.33	$38.06	$12.55
PSO Voluntary Relinquishment Form	5	2.50	$38.06	$190.30
Common Formats	1,000	100,000	$38.06	$3,806,000.00
Total				$3,833,685.21

* Based upon the mean of the hourly average wages for healthcare practitioner and technical occupations, 29,000, National Compensation Survey, May 2015, "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, 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 $4,198,560.15 annually 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. The estimates below reflect shifting of tasks among staff such as the shifting of contract management from the GS 15 to GS 14; the addition of new staff; the decrease in contract management tasks resulting from consolidation of contracts to support the PSO program; and the reduced level of effort to produce new Common Formats due to staff vacancies.

Exhibit 3: Annual Cost for Federal Staff

Personnel	Staff Count	Annual Salary	% of Time	Cost
GS-15, Step 5 average	1	$149,377	40 %	$59,750.80
GS-14, Step 5 average	3	$126,958	15 %	$57,131.10
GS-13, Step 5 average	1	$107,435	85 %	$91,319.75
GS-13, Step 5 average	1	$107,435	50 %	$53,717.50
GS-13, Step 5 average	1	$107,435	20 %	$21,487.00
Grand Total				$283,406.15

Average annual salaries are based on the Step 5 for each grade level, 2017 OPM Pay Schedule for Washington/DC area: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/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
SSS - PSO Operations and Common Formats Support	$800,000.00
PSOPPC – PSO Profile Form, Common Formats Development and Maintenance Support	$2,759,109.00
NQF – Common Formats Expert Panel	$228,175.33
Total	$3,787,284.33

b. OCR

Through an interagency agreement (IAA), OCR provides management for and support of technical assistance and the enforcement of the confidentiality protections of the Patient Safety Act and the Patient Safety Rule.

The cost of this IAA is approximately $127,869.66 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	$3,787,284.33
AHRQ Federal Government Staff support for the review and administration of the PSO forms and development and maintenance of Common Formats	$283,406.15
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	$127,869.66
Total	$4,198,560.15

15. Changes in Hour Burden

The previous information collection request (ICR) included an estimate of 100,704 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, and the OCR Patient Safety Confidentiality Form.

The estimated burden hours for the current ICR, which now includes the new PSO Voluntary Relinquishment Form, are 100,722.88 which represent an increase of 18.88 hours.

For this submission, the burden of the forms remains unchanged. The increase of 18.88 burden hours is attributed to the changes in the number of respondents for the PSO forms, which are described below, and the addition of the new form.

PSO Certification for Initial Listing Form -- the estimated response time remains unchanged at 18 hours with a decrease in the number of responses from 17 to 16 per year. Thus, the total burden hours from this form have decreased from 306 in the previous submission to 288 which represents a decrease of 18 hours. The estimated response rate is based on the average of forms submitted by listed PSOs and entities that submitted forms, but withdrew the forms or AHRQ inactivated the form or denied listing.

PSO Certification for Continued Listing -- the estimated response time remains unchanged at eight hours with an increase in the number of responses from 16 to 21 per year. The total burden hours per year have increased from 128 to 168 which represents an increase of 40 hours. The estimated response rate is based on the average of forms submitted by listed PSOs. In order to remain listed, a PSO must submit a PSO Certification for Continued Listing form in its third year after initial listing and then every three years as long as they remain listed.

PSO Two Bona Fide Contracts Requirement Form -- the estimated response time remains unchanged at 60 minutes with an increase in the number of responses from 30 to 42; the total burden hours are now 42 instead of 30 which represents an increase of 12 hours. The estimated response rate is based on the average of PSO Two Bona Fide Requirements Forms submitted by listed PSOs. In order to remain listed, a PSO is 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 -- the estimated response time has remains unchanged at three hours with an increase in the number of responses from two to three; the total burden hours are now nine instead of six which represents an increase of three hours. The estimated response rate is based on the average of PSO Disclosure Statement Forms submitted by listed PSOs which are required to maintain listing.

PSO Profile Form -- the estimated response time remains unchanged at three hours with a decrease in the number of responses from 77 to 70; the total burden hours have decreased from 231 to 210 which represent an increase of 21 hours. The estimated response rate is based on the average of number of listed PSOs that submit PSO Profile Forms at the end of each year.

PSO Change of Listing Information Form - the estimated response time has remains unchanged at five minutes with an increase in the number of responses from 24 to 61; the total burden hours have increased from two hours to three hours and five minutes which represents an increase of two hours and five minutes. The estimated response rate is based on the average of PSO Change of Listing Information Forms submitted by listed PSOs which are submitted as necessary to maintain listing.

OCR Patient Safety Confidentiality Complaint Form-- the estimated response time remains unchanged at 30 minutes with a decrease in the number of responses from three to one; the total burden hours have decreased from one hour to 33 minutes which represents a decrease of 27 minutes. The estimated response rate is based on the fact that there has not been a submission of this form to OCR during the PSO program.

Common Formats -- the estimated response time and responses remains unchanged at 100 hours per facility and 1,000 facilities. The use of the Common Formats by PSOs and other entities is voluntary and is on an ongoing basis.

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:	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:	*2010 Patient Safety and Quality Improvement Act of 2005 - HHS Guidance Regarding Patient Safety Organizations' Reporting Obligations to the Food and Drug Administration (FDA)*
Attachment D:	*2016 Patient Safety and Quality Improvement Act of 2005 - HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations.*
Attachment E:	PSO Certification for Initial Listing Form
Attachment F:	PSO Certification for Continued Listing Form
Attachment G:	PSO Two Bona Fide Contracts Requirement Form
Attachment H:	PSO Disclosure Statement Form
Attachment I	PSO Profile Form
Attachment J:	PSO Change of Listing Information

Attachment K: OCR Patient Safety Confidentiality Complaint Form

Attachment L: PSO Voluntary Relinquishment Form

Attachment M: Common Formats Details

Attachment N: Federal Register Notice

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