



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project “*Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats.*”

DATES: Comments on this notice must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

“*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), 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 create a national learning system. By providing incentives of nation-wide confidentiality and legal privilege, the Patient Safety Act learning system improves patient safety and quality by providing an incentive for health care providers to work voluntarily with experts in patient safety to reduce risks and hazards to the safety and quality of patient care. The Patient Safety Act signifies the Federal Government's commitment to fostering a culture of patient safety among health care providers; it offers a mechanism for creating an environment in which the causes of risks and hazards to patient safety can be thoroughly and honestly examined and discussed without fear of penalties and liabilities. It provides for the voluntary formation of Patient Safety Organizations (PSOs) that can collect, aggregate, and analyze confidential information reported voluntarily by health care providers. By analyzing substantial amounts of patient safety event information across multiple institutions, PSOs are able to identify patterns of failures and propose measures to eliminate or reduce 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, 42 CFR Part 3) 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).

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, in order to attest to compliance with statutory criteria and the corresponding regulatory requirements.

Method of Collection

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

1. PSO Certification for Initial Listing Form. 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.
2. PSO Certification for Continued Listing Form. 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.
3. PSO Two Bona Fide Contracts Requirement Certification Form. To remain listed, a PSO must meet the 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.

4. PSO Disclosure Statement Form. 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 42 U.S.C. 299b-24(b)(1)(E), when it (i) has a contract with a provider to carry out patient safety activities, and (ii) it has other financial, reporting, or contractual relationship(s) with that contracting provider, or it 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.
5. PSO Profile Form. This form is designed to collect voluntarily a minimum level of 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 the AHRQ National Healthcare Quality and Disparities Report, an annual quality report required by 42 U.S.C. 299b-2(b)(2).
6. PSO Change of Listing Information Form. 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.

7. PSO Voluntary Relinquishment Form. A PSO may 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 information.

OCR is requesting approval of the following administrative form:

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 OCR so that there is a basis for initial processing of those complaints.

In addition, AHRQ is requesting approval for a set of common definitions and reporting formats (Common 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.

OMB previously approved the Common Formats and forms described above in 2008, 2011, 2014, and 2018. 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.

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 violations of the privacy of protected health information. 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.

Estimated Annual Respondent Burden

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 form 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 100,795.83 hours annually and the total cost burden is estimated to be \$4,053,000.33 annually.

PSO Certification for Initial Listing Form: The average annual burden for the collection of information requested by the certification form for initial listing is based upon a total average estimate of 10 respondents per year and an estimated time of 18 hours per response. The estimated response number includes submissions by not only entities listed as PSOs, but also entities that submit initial listing forms that do not become PSOs. 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 42 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 51 respondents per year and an estimated one hour per response. This collection of information takes place once per 24-month period when the PSO notifies the Secretary that it has two contracts with providers that meet the requirements.

PSO Disclosure Statement Form: The average burden for the collection of information requested by the Disclosure Statement Form is based upon an estimate of two respondents per year and estimated three hours per response. This information collection takes place within 45 days of when a PSO begins 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 72 respondents per year and an estimated three hours per response. The collection of information takes place annually; newly listed PSOs may first submit the form in the calendar year after their initial 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 54 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.

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 four respondents per year and an estimated time of thirty minutes per response.

OCR Patient Safety Confidentiality Complaint Form: The overall annual burden estimate for the collection of information requested by the OCR Patient Safety Confidentiality Complaint Form is based on an estimate of one respondent per year and an estimated twenty minutes per response. The voluntary use of the form may occur when an allegation of a violation of the confidentiality protections of the Patient Safety Act is made.

Common Formats: AHRQ estimates that 5% full time equivalent (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 of the 1,000 respondents 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. 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	10	1	18	180
PSO Certification for Continued Listing Form	42	1	8	336
PSO Two Bona Fide Contracts Requirement Form	51	1	1	51
PSO Disclosure Statement Form	2	1	3	6
PSO Profile Form	72	1	3	216
PSO Change of Listing Information	54	1	05/60	4.50
PSO Voluntary Relinquishment Form	4	1	30/60	2
OCR Patient Safety Confidentiality Complaint Form	1	1	20/60	.33
Common Formats	1,000	1	100	100,000
Total		NA	NA	100,795.83

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	10	180	\$40.21	\$7,237.80
PSO Certification for Continued Listing Form	42	336	\$40.21	\$13,510.56
PSO Two Bona Fide Contracts Requirement Form	51	51	\$40.21	\$2,050.71
PSO Disclosure Statement Form	2	6	\$40.21	\$241.26
PSO Profile Form	72	216	\$40.21	\$8,685.36
PSO Change of Listing Form	54	4.50	\$40.21	\$180.95
PSO Voluntary Relinquishment Form	4	2	\$40.21	\$80.42
OCR Patient Safety Confidentiality Complaint Form	1	.33	\$40.21	\$13.27
Common Formats	1,000	100,000	\$40.21	\$4,021,000.00
Total				\$4,053,000.33

* Based upon the mean of the hourly average wages for healthcare practitioner and technical occupations, 29-0000, National Compensation Survey, May 2019, "U.S. Department of Labor, Bureau of Labor Statistics."

<https://www.bls.gov/oes/current/oes290000.htm>

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; and, for OCR's enforcement of confidentiality; (b) the

accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: May 6, 2021.

Marquita Cullom,

Associate Director.