• Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release to the public;

• Information gathered will not be used for the purpose of substantially informing influential policy decisions; and

• Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections submitted under this generic clearance will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

A **Federal Register** Notice with a 60-day comment period soliciting comments on this information collection was published on May 19, 2021 (86 FR 27088). OGE did not receive any comments in response.

OMB Number: 3209–0010.

Type of Request: Extension.

Affected Public: Individuals; Business or Other For-Profit Institutions; Not-For-Profit Institutions; State, Local, or Tribal Government.

Projected average burden estimates for the next three years:

Estimated Annual Number of Respondents: 91,425.

Average Expected Annual Number of Activities: 39.

Average Number of Respondents per Activity: 2,344.

Responses per Respondent: 1.

Annual Responses: 91,425.

Average Minutes per Response: 3 minutes.

Annual Burden Hours: 3,900 hours.

Frequency: On occasion.

Request for Comments: Agency and public comment is invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). Comments will become a matter of public record.

Approved: July 26, 2021.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2021–16221 Filed 7–29–21; 8:45 am]

BILLING CODE 6345–03–P

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 (AHRQ), Health and Human Services (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) reapprove the proposed information collection project ''*Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats.*'' This proposed information collection was previously published in the **Federal Register** on May 12, 2021 and allowed 60 days for public comment. AHRQ did not receive substantive comments from members of the public. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by August 30, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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*''

AHRQ invites the public to comment on this proposed information collection. 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) 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, 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 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.

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 the 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 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.

5. PSO Profile Form. 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 the annual report required by 42 U.S.C. 299b–2(b)(2), the AHRQ National Healthcare Quality and Disparities Report.

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. 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 100,795.83 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 forms 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 submitted 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 when the PSO notifies the Secretary that it has entered into two contracts with providers, which is required once every 24 months.

PSO Disclosure Statement Form: The overall annual burden for the collection of information requested by the PSO Disclosure Statement Form is based upon an estimate of two 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 72 respondents per year and an estimated three hours per response. The 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.

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.

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 twenty minutes per response.

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.

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.

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

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost
PSO Certification for Continued Listing Form	42	336	40.21	13,510.56
PSO Two Bona Fide Contracts Requirement Form	451	451	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. 3501–3520, 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; (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: July 27, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–16326 Filed 7–29–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10398 #72]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance [1] related to the ''generic'' clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are ''usually voluntary, low-burden, and uncontroversial collections,'' do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. On October 23, 2011, OMB approved our initial request to use the generic clearance process under control number 0938–1148 (CMS–10398). It was last approved on April 26, 2021, via the standard PRA process which included the publication of 60- and 30-day **Federal Register** notices. The scope of the April 2021 umbrella accounts for Medicaid and CHIP State plan amendments, waivers, demonstrations, and reporting. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates or any other aspect of this collection of information, including: The necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by August 13, 2021.

ADDRESSES: When commenting, please reference the applicable form number (see below) and the OMB control number (0938–1148). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may access CMS' website at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information

[1] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/PRA_Gen_ICRs_5-28-2010.pdf.*