

agencies. The FSCAC will provide advice and recommendations to the Administrator of GSA, the FedRAMP Board, and agencies on technical, financial, programmatic, and operational matters regarding the secure adoption of cloud computing products and services. The FSCAC will ensure effective and ongoing coordination of agency adoption, use, authorization, monitoring, acquisition, and security of cloud computing products and services to enable agency mission and administrative priorities. The purposes of the Committee are:

- To examine the operations of FedRAMP and determine ways that authorization processes can continuously be improved, including the following:
 - Measures to increase agency reuse of FedRAMP authorizations.
 - Proposed actions that can be adopted to reduce the burden, confusion, and cost associated with FedRAMP authorizations for cloud service providers.
 - Measures to increase the number of FedRAMP authorizations for cloud computing products and services offered by small businesses concerns (as defined by section 3(a) of the Small Business Act (15 U.S.C. 632(a)).
 - Proposed actions that can be adopted to reduce the burden and cost of FedRAMP authorizations for agencies.
- Collect information and feedback on agency compliance with, and implementation of, FedRAMP requirements.

- Serve as a forum that facilitates communication and collaboration among the FedRAMP stakeholder community.

The FSCAC will meet no fewer than three (3) times a calendar year. Meetings shall occur as frequently as needed, called, and approved by the DFO.

Purpose of the Meeting and Agenda

The November 14, 2024 public meeting will be dedicated to continued deliberations in order to develop an initial draft of recommendations to the GSA Administrator on their initial two (2) priority initiatives of (1) identifying and documenting top challenges and proposing solutions around the barrier to entry for Cloud Service Providers (CSPs) with a focus on small businesses, third party assessment organizations (3PAOs), and small & large agencies, and (2) identifying and documenting ways to expedite the authorization process for Cloud Service Offerings (CSOs), such as exploring agile authorizations and other potential cost

reductions, both labor and financial, with a focus on small businesses.

Members of the public will have the opportunity to provide oral public comments during this meeting, and may also submit public comments in writing prior to this meeting by completing the public comment form on our website, <https://gsa.gov/fscac>. The meeting agenda will be posted on <https://gsa.gov/fscac> prior to the meeting and can be accessed by selecting the “Federal Secure Cloud Advisory Committee meetings” tab on the left, and then selecting the “November 14, 2024—Virtual” meeting accordion in order to view all meeting materials, agenda, and registration information.

Meeting Attendance

The virtual meeting is open to the public. The meeting materials, registration information, and agenda will be made available prior to the meeting online at <https://gsa.gov/fscac>, by selecting the “Federal Secure Cloud Advisory Committee meetings” tab on the left, and then selecting the “November 14, 2024—Virtual” meeting accordion. Registration for attending the virtual meeting is highly encouraged by 5:00 p.m. EST, on Monday, November 11, 2024. After registration, individuals will receive instructions on how to attend the meeting via email.

For information on services for individuals with disabilities, or to request accommodation for a disability, please email the FSCAC staff at FSCAC@gsa.gov at least 10 days prior to the meeting date. Live captioning may be provided virtually.

Public Comment

Members of the public attending will have the opportunity to provide oral public comment during the FSCAC meeting. Written public comments can be submitted at any time by completing the public comment form on our website, <https://gsa.gov/fscac>, located under the “Get Involved” section. All written public comments will be provided to FSCAC members in advance of the meeting if received by Wednesday, November 6, 2024.

Margaret Dugan

Service-Level Liaison, Federal Acquisition Service, General Services Administration.

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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: In compliance with the *Paperwork Reduction Act of 1995*, 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 reinstatement with change of the information collection project “Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats”, OMB No. 0935–0143 for which approval expired on September 30, 2024. This information collection was previously published in the **Federal Register** on August 12th, 2024 and allowed 60 days for public comment. AHRQ received no 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 November 15, 2024.

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 REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

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

OMB No.: 0935–0143.

OMB Expiration Date: September 30th, 2024.

Type of Request: Reinstatement, with change, of previously approved collection for which approval has expired.

The Patient Safety and Quality Improvement Act of 2005 (the 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 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**, 71 FR 28701–2, May 17, 2006). Civil money penalties may be imposed for knowing or reckless impermissible disclosures of identifiable 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.

Proposed Revisions

The following forms have revisions for clarification which are described below:

1. PSO Certification for Initial Listing—This form has been revised to include clarification on the role of the primary point of contact.
2. PSO Certification for Continued Listing—This form has been revised to include clarifications on the role of the primary point of contact, more precise language about whether there are any changes to the parent organization or any additional parent organizations and an additional note to clarify how users should determine the response to the standardized way they collect patient safety work product (PSWP).
3. PSO Profile form—The form has been revised to add a new clinical discipline, "Clinical Dialysis Services".
4. PSO Change of Listing Form—This form has been revised to note clarifications for the parent and the point of contact sections.
5. PSO Voluntary Relinquishment Form—This form has been revised to include a change from street to mailing address for future contacts with delisted PSOs.
6. Patient Safety Confidentiality Complaint Form—The form has two parts, the complaint form and the consent form. The complaint form was updated (1) to conform the notice to individuals about confidentiality of identifying information submitted on the complaint form with the existing approved OCR HIPAA Rules complaint form and (2) to update OCR contact information. The consent form was updated (1) to conform notice to individuals about confidentiality of identifying information submitted on the consent form with the existing approved OCR HIPAA Rules consent form, (2) to more fully describe OCR authorities allowing collection of information in Privacy Act of 1974 notices, and (3) to update OCR contact information.

7. Common Formats—Since the last approval, AHRQ has released Common Formats Event Reporting for Diagnostic

Safety, Version 1.0 (CFER–DS V1.0) and the Common Formats for Surveillance-Hospital V1.0 (CFS–H V1.0), which is a revision/update from the last version (CFS–H V0.3 Beta).

OMB previously approved the Common Formats and forms described above in 2008, 2011, 2014, 2018, and 2021. 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.

Method of Collection

The PSO forms are available in a format that allows completion and submission of the information online. AHRQ has updated the electronic submission of all forms, except the Patient Safety Confidentiality Complaint Form which is administered by OCR, including the capability of the system to auto populate certain fields based on prior submissions by the PSOs. In addition, paper forms can be downloaded, completed and submitted through electronic mail, to psa@ahrq.hhs.gov, or via postal mail. The Common Formats, accompanying user guide, and technical specifications are available as printable electronic files on the PSOPPC website at www.PSOPPC.org.

In addition to paper submission of complaints, OCR facilitates electronic submission of complaints. First, the Patient Safety Confidentiality Complaint Form is available on the OCR website at <https://www.hhs.gov/hipaa/filing-a-complaint/patient-safety-confidentiality/index.html>. The form is available to be downloaded electronically to a user's own computer in a form that allows a complainant to fill out the form electronically if they so choose. The Patient Safety Confidentiality Complaint Form can then be printed and submitted, or submitted electronically via electronic mail. Second, the form is available in a

format that allows completion and submission of the information online.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent to provide the requested information and Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to provide the requested information. The total burden hours are estimated to be 100,811.58 hours annually and the total cost burden is estimated to be \$4,946,824.23 annually.

1. 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 11 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.

2. 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 40 responses annually.

3. 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 56 respondents per year and an estimated one hour per response.

4. 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 3 respondents per year and estimated 3 hours per response.

5. PSO Profile Form: The overall annual burden for the collection of information requested by the PSO Profile Form is based upon an estimate of 74 respondents per year and an estimated three hours per response.

6. 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 51 respondents per year and an estimated time of five minutes per response.

7. 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.

8. 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.

9. 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.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents	Number of responses per respondent	Hours per response	Total burden Hours
1. PSO Certification for Initial Listing Form	11	1	18	198
2. PSO Certification for Continued Listing Form	40	1	8	320
3. PSO Two Bona Fide Contracts Requirement Form	56	1	1	56
4. PSO Disclosure Statement Form	3	1	3	9
5. PSO Profile Form	74	1	3	222
6. PSO Change of Listing Information	51	1	05/60	4.25
7. PSO Voluntary Relinquishment Form	4	1	30/60	2
8. OCR Patient Safety Confidentiality Complaint Form	1	1	20/60	.33
9. Common Formats	1,000	1	100	100,000
Total		NA	NA	100,811.58

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form	Total burden hours	Average hourly wage rate *	Total cost
1. PSO Certification for Initial Listing Form	198	\$49.07	\$9,715.86
2. PSO Certification for Continued Listing Form	320	49.07	15,702.40
3. PSO Two Bona Fide Contracts Requirement Form	56	49.07	2,747.92
4. PSO Disclosure Statement Form	9	49.07	441.63
5. PSO Profile Form	222	49.07	10,893.54
6. PSO Change of Listing Form	4.25	49.07	208.55
7. PSO Voluntary Relinquishment Form	2	49.07	98.14
8. OCR Patient Safety Confidentiality Complaint Form33	49.07	15.35
9. Common Formats	100,000	49.07	4,907,000
Total			4,946,824.23

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

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: October 3, 2024.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-25-0572]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "CDC and ATSDR Health Message Testing System (HMTS)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on June 4, 2024 to obtain comments from the public and affected agencies. CDC received one non-substantive comment. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

CDC and ATSDR Health Message Testing System (HMTS) (OMB Control No. 0920-0572, Exp. 10/31/2024)—Extension—Office of Communications (OC), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

Before CDC disseminates a health message to the public, the message always undergoes scientific review. However, even though the message is based on sound scientific content, there is no guarantee that the public will understand a health message or that the message will move people to take recommended action. Communication theorists and researchers agree that for health messages to be as clear and influential as possible, target audience members or representatives must be involved in developing the messages and provisional versions of the messages must be tested with members of the target audience. Increasingly, there are circumstances when CDC must move swiftly to protect life, prevent disease, or calm public anxiety. Health message testing is even more important

in these instances, because of the critical nature of the information need.

In the interest of timely health message dissemination, many programs forgo the important step of testing messages on dimensions such as clarity, salience, appeal, and persuasiveness (*i.e.*, the ability to influence behavioral intention). Skipping this step avoids the delay involved in the standard OMB review process, but at a high potential cost. Untested messages can waste communication resources and opportunities because the messages can be perceived as unclear or irrelevant. Untested messages can also have unintended consequences, such as jeopardizing the credibility of federal health officials.

The CDC/ATSDR Health Message Testing System (HMTS), a Generic information collection, enables programs across CDC and ATSDR to collect the information they require in a timely manner to:

- Ensure quality and prevent waste in the dissemination of health information by CDC to the public;
- Refine message concepts and test draft materials for clarity, salience, appeal, and persuasiveness to target audiences;
- Guide the action of health communication officials who are responding to health emergencies, Congressionally-mandated campaigns with short timeframes, media-generated public concern, time-limited communication opportunities, trends, and the need to refresh materials or dissemination strategies in an ongoing campaign.

Each testing instrument will be based on specific health issues or topics. Although it is not possible to develop one instrument for use in all instances, the same kinds of questions are asked in most message testing. This package includes generic questions and formats that can be used to develop health message testing data collection instruments. These include a list of screening questions, comprised of demographic and introductory questions, along with other questions that can be used to create a mix of relevant questions for each proposed message testing data collection method. However, programs may request to use additional questions if needed. Message testing questions will focus on issues such as comprehension, impressions, personal relevance, content and wording, efficacy of response, channels, and spokesperson/sponsor. Such information will enable message developers to enhance the effectiveness of messages for intended audiences. Data collection methods proposed for