data collected by PSOs and other entities are comparable. The Common Formats facilitate aggregation of comparable data at local, PSO, regional and national levels.

Since February 2005, AHRQ has convened the Federal Patient Safety Work Group (PSWG) to assist AHRQ in developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS as well as the Departments of Defense and Veterans Affairs. The PSWG helps assure the consistency of definitions/formats with those of relevant government agencies. In addition, AHRQ solicits comments from the private and public sectors regarding proposed versions of the Common Formats through the Patient Safety Organization Privacy Protection Center (PSOPPC). After receiving comments, the PSOPPC solicits review of the formats by its Common Formats Expert Panel. Subsequently, PSOPPC will provide this input to AHRQ who then uses it to refine the Common Formats.

At AHRQ, the Common Formats for Surveillance—Hospitals (CFS–H) are applied in the Quality and Safety Review System (QSRS), a surveillance system designed to detect and calculate patient safety event rates through retrospective in-patient record review. QSRS uses the CFS–H Event Descriptions to create standardized specifications to ensure adverse events are reliability identified across all hospitals and records. For the Common Formats, it should be noted that AHRQ uses the term ''surveillance'' in this context to refer to the improved detection of events and calculation of adverse event rates in populations reviewed that will allow for collection of comparable performance data over time and across populations of patients. These formats are designed to provide, through retrospective review of medical records, information that is complementary to that derived from event reporting systems.

The *Common Formats for Surveillance—Hospital Version 1.0* are categorized into the following topic areas (modules):

- Birth—Maternal
- Birth—Neonatal
- Blood or Blood Product
- Device
- Fall
- Hospital-Acquired Infection (HAI)
- Medication
- Other
- Pressure Injury
- Surgery or Anesthesia
- Venous Thromboembolism

At this time, AHRQ is releasing the CFS–H Version 1.0 Event Descriptions and supporting materials, including an overview and user guide, tabular accounting, and technical release notes.

Comments can be provided on the *Common Formats for Surveillance—Hospital Version 1.0* using the commenting tool at: *https://www.psoppc.org/psoppc_web/publicpages/openforcomment.*

Additional information about the Common Formats can be obtained through AHRQ's PSO website: *https://pso.ahrq.gov/common-formats.*

Dated: August 7, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–17927 Filed 8–9–24; 8:45 am]

BILLING CODE 4160–90–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, 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 a revision of the currently approved information collection project: ''Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats.'' In accordance with the Paperwork Reduction Act of 1995, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by October 11, 2024.

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

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *REPORTSCLEARANCEOFFICER@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 requests that OMB approve a revision to AHRQ's collection of information for the Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats: OMB Control number 0935–0143, expiration September 30th, 2024.

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 is planning on the release of Common Formats for Surveillance—Hospital V1.0 (CFS–H V1.0) in the near future, which is a revision/update from the last version (CFS–H V0.3 Beta).

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 for the PSO Certification for Initial Listing and 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 *pso@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 Form	.33	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.

Mamatha Pancholi,

Deputy Director.

[FR Doc. 2024–17813 Filed 8–9–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3528]

Advancing Rare Disease Therapies Through a Food and Drug Administration Rare Disease Innovation Hub; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting, entitled ''Advancing Rare