EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate ($)	Total cost burden ($)
Grand Total	155,895	86,073	na	1,934,860

* Mean hourly wage for All Occupations (00–0000).
** Mean hourly wage for Medical Secretaries (43–6013).
*** Mean hourly wage for Pharmacy Technicians (29–2052). Occupational Employment Statistics, May 2016 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.*

Request for Comments

In accordance with the Paperwork Reduction Act, 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 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.

Karen J. Migdail,

Chief of Staff.

[FR Doc. 2018–03855 Filed 2–23–18; 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 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 April 27, 2018.

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 emails 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.*''

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, 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 PSO 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, see Attachment B) which became effective on January 19, 2009. The Patient Safety Rule establishes a framework by which hospitals, doctors, and other health care providers may voluntarily report information to PSOs, on a privileged and confidential basis, for the aggregation and analysis of patient safety events. 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 (Secretary) will accept certifications and list PSOs.

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 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 confidentiality protections regarding patient safety work product (PSWP), which may include: Patient-, provider-, and reporter-identifying information that is collected, created, or used for or 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 (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 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) attests 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 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 between the entity and any provider that contracts with the entity; and (ii) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity. 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.* This form, previously called the PSO Information Form, gathers information on the type of health care providers and settings with which PSOs are working to conduct patient safety activities in order to improve patient safety. It is designed to collect a minimum level of data necessary to develop aggregate statistics relating to the Patient Safety Act, including types of institutions participating and their general location in the US. This information will be included in AHRQ's 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 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 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 (hereafter Common Formats). As authorized by 42 U.S.C. 299b–23(b) and the Patient Safety Rule, AHRQ coordinates the development of the Common Formats that allow PSOs and health care providers to voluntarily collect and submit standardized information regarding patient safety events to fulfill the national learning system as envisioned by the Patient Safety Act.

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, 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. This information is used by the PSO Program Office housed in AHRQ's Center for Quality Improvement and Patient Safety.

OCR

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 violation 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 information collection forms that are the subject of this notice 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 100,724.88 hours annually and the total cost burden is estimated to be $3,833,588.92 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 16 respondents per year and an estimated time of 18 hours per response. The estimated response number not only includes submissions by entities subsequently listed as 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 at least every 24 months 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 entities 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 within 45 days of when a PSO begins having any of the specified types of additional relationships with a health care 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 initially requested to submit the form in the calendar year after their listing by the Secretary.

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 third of an 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. OCR's information collection using this form will not begin until after there is an allegation of a violation of the confidentiality protections 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 of the number of 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. As the network for patient safety databases (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	05/60	5.08
OCR Patient Safety Confidentiality Complaint Form	1	1	20/60	0.33
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

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form	Number of respondents	Total burden hours	Average hourly wage rate * ($)	Total cost ($)
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	0.33	38.06	12.55
PSO Voluntary Relinquishment Form	5	2.50	38.06	95.15
Common Formats	1,000	100,000	38.06	3,806,000.00
Total				3,833,590.06

* Based upon the mean of the hourly average wages for health care practitioner and technical occupations, 29–0000, National Compensation Survey, May 2016, ''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, 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 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.

Karen J. Migdail,

Chief of Staff.

[FR Doc. 2018–03854 Filed 2–23–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–1053]

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 Monitoring and Reporting System for the Division of Community Health's Cooperative Agreement Programs 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 September 16, 2017 to obtain comments from the public and affected agencies. CDC received three comments related to the previous notice. 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 or send an email to *omb@cdc.gov.* 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

Monitoring and Reporting System for the Division of Community Health's Cooperative Agreement Programs (OMB No. 0920–1053, expiration March 31, 2018)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In September 2014, the Division of Community Health (DCH), CDC, announced a new cooperative agreement program, *Racial and Ethnic Approaches to Community Health (REACH)* program, authorized by the Public Health Service Act and the Prevention and Public Health Fund of the Affordable Care Act (Funding Opportunity Announcement (FOA) FOA DP14–1419PPHF14).

REACH awardees include 18 state, local and tribal governmental agencies, and 31 non-governmental organizations. CDC designed the *REACH* program to address chronic diseases and risk factors for chronic diseases, including physical inactivity, poor diet, obesity, and tobacco use. The program provides support for implementation of broad, evidence- and practice-based policy and environmental improvements in large and small cities, urban rural areas, tribes, multi-sectorial community coalitions, and racial and ethnic communities experiencing chronic disease disparities.

CDC seeks OMB approval to collect information from the 49 *REACH* awardees during a supplemental fourth year of funding utilizing an electronic management information system, the