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, Department of Health and Human Services.

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) allow information collection related to implementation of the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to 299b–26, in: ''Patient Safety Organization Certification for Initial Listing and Related Forms and a Patient Safety Confidentiality Complaint Form.'' In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on January 27, 2009 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by April 30, 2009.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

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

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ, Reports Clearance Officer, (301) 427–1477.

SUPPLEMENTARY INFORMATION:

Proposed Project

''Patient Safety Organization Certification for Initial Listing and Related Forms and a Patient Safety Confidentiality Complaint Form.''

The Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ) has been delegated the authority to implement the provisions of the Patient Safety and Quality Improvement Act of 2005 (for brevity referenced here as the Patient Safety Act) that call for submission to the Secretary of certifications by entities seeking to become listed by the Secretary as Patient Safety Organizations (PSOs). These entities must certify that they meet or will meet specified statutory criteria and requirements for PSOs as further explained in the final rule to implement the Patient Safety Act, published in the **Federal Register** on November 21, 2008: 73 FR 70732.

The HHS Office for Civil Rights (OCR) has been delegated the authority to enforce the provisions of the Patient Safety Act that mandate confidentiality of ''patient safety work product.'' This term is defined in the statute, at 42 U.S.C. 299b–21(7), and further explained in the final rule (published in the **Federal Register** on November 21, 2008). Individuals may voluntarily submit complaints to OCR if they believe that an individual or organization in possession of patient safety work product unlawfully disclosed it.

Methods of Collection

While there are a number of information collection forms described below, they will be implemented at different times, some near the end of the three year approval period for these standard forms. The forms for certifications of information will collect only the minimum amount of information from entities necessary for the Secretary to determine compliance with statutory requirements for PSOs, i.e., most of the required certification forms will consist of short attestations followed by ''yes'' and ''no'' checkboxes to be checked and initialed.

PSO Certification for Initial Listing and PSO Certification for Continued Listing Forms

The Patient Safety Act, at 42 U.S.C. 299b–24(a), and the final rule at 45 CFR 3.102 provide that an entity may seek an initial three-year listing as a PSO by submitting an initial certification that it has policies and procedures in place to perform eight patient safety activities (enumerated in the statute and the final rule), and that it will comply, upon listing, with seven other statutory criteria. The proposed Certification for Initial Listing Form also includes additional questions related to other requirements for listing related to eligibility and pertinent organizational history. Similarly, the proposed Certification for Continued Listing Form (for each successive three-year period after the initial listing period) would require certifications that the PSO is performing, and will continue to perform, the eight patient safety activities, and is complying with, and will continue to comply with, the seven statutory criteria. The average annual burden in the first three years of 17 hours per year for the collection of information requested by the certification form for initial listing is based upon a total average estimate of 33 respondents per year and an estimated time of 30 minutes per response. Information collection, i.e., collection of initial certification forms, will begin as soon as the forms are approved for use. The average annual burden in the first three years of 8 hours per year for the collection of information requested by the certification form for continued listing is based upon a total average estimate of 17 respondents per year and an estimated time of 30 minutes per response. Collection of forms for continued listing will not begin until several months before November 2011 which is three years after the first PSOs were listed by the Secretary. (See Note after Exhibit 1.)

PSO Two Bona Fide Contracts Requirement Certification

To implement 42 U.S.C. 299b–24(b)(1)(C), the final rule states that, in order to maintain its PSO listing, a PSO will be required to submit a certification, at least once in every 24-month period after its initial date of listing, indicating that it has contracts with two providers (45 CFR 3.102(d)(1)). The annualized burden of 8 hours for the collection of information requested by the two bona fide contracts requirement is based upon an estimate of 33 respondents per year and an estimated 15 minutes per response. This collection of information will begin when the first PSO timely notifies the Secretary that it has entered into two contracts.

PSO Disclosure Statement Form

The Patient Safety statute at 42 U.S.C. 299b–24(b)(1)(E) requires a PSO to fully disclose information to the Secretary if the PSO has additional financial, contractual, or reporting relationships with any provider to which the PSO provides services pursuant to the Patient Safety Act under contract, or if the PSO is managed or controlled by, or is not operated independently from, any of its contracting providers. Disclosure Statement Forms will be collected only when a PSO has such relationships with a contracting provider to report. The Secretary is required to review each disclosure statement and make public findings as to whether a PSO can fairly and accurately carry out its

responsibilities. AHRQ assumes that only a small percentage of entities will need to file such disclosure forms. However, AHRQ is providing a high estimate of 17 respondents annually and thus presumably overestimating respondent burden. In summary, the annual burden of 8 hours for the collection of information requested by the disclosure form is based upon the high estimate of 17 respondents per year and an estimated 30 minutes per response. This information collection will begin when a PSO first reports 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 Information Form

Annual completion of a PSO Information Form will be voluntary and will provide information to HHS on the type of healthcare settings that PSOs are working with to carry out patient safety activities. This form is designed to collect a minimum amount of data in order to gather aggregate statistics on the reach of the Patient Safety Act with respect to types of institutions participating and their general location in the United States. This information will be included in AHRQ's annual quality report, as required under Section 923(c) of the Patient Safety Act (42 U.S.C. 299b–23(c)). No PSO-specific data will be released without PSO consent. The overall annual burden estimate of 17 hours for the collection of information requested by the PSO Information Form is based upon an estimate of 33 respondents per year and an estimated 30 minutes per response. This information collection will begin one year after the first PSOs are listed by the Secretary.

OCR Complaint Form

The complaint form will collect from individuals only the minimum amount of information necessary for OCR to process and assess incoming complaints. The overall annual burden estimate of 17 hours for the collection of information requested by the underlying form is based upon an estimate of 50 respondents per year and an estimated 20 minutes per response. OCR's information collection using this form will not begin until after there is at least one PSO receiving and generating patient safely work product, and there is an allegation of a violation of the statutory protection of patient safety work product.

All Administrative Forms

The overall maximum anticipated annual burden estimate is 75 hours for all the above described collections of information. Because the forms filled out by PSOs vary over each of their first three years, the table below includes three-year total estimates divided by three to arrive at an annual estimate of burden hours. (See below.)

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Certification for Initial Listing Form	100/3	1	30/60	17
Certification for Continued Listing Form*	50/3	1	30/60	8
Two Bona Fide Contracts Requirement Form**	100/3	1	15/60	8
Disclosure Statement Form	50/3	1	30/60	8
Information Form***	100/3	1	30/60	17
Patient Safety Confidentiality Complaint Form	150/3	1	20/60	17
Total****	500/3	na	na	75

Note: * The Certification for Continued Listing Form will be completed by any interested PSO at least 75 days before the end of its then-current three-year listing period. Therefore, we anticipate that only those PSOs that have completed the Certification for Initial Listing Form in the first year that these forms are available will complete the Certification for Continued Listing Form during the three-year approval period for these forms. In the out-years, we expect the number of PSOs to remain stable, with the number of new entrants offset by the number of entities that will relinquish their status or be revoked.

** The Two Bona Fide Contracts Requirement Form will be completed by each PSO within the 24-month period after initial listing by the Secretary.

*** The Information Form will collect data by calendar year, beginning in 2010, at a time when it is anticipated that PSOs will have submitted appreciable data to the Network of Patient Safety Databases.

**** A total of 100 PSOs are expected to apply over three years: 50 in year one; 25 in year two; and 25 in year three. Disclosure Statement, Two Bona Fide Contracts Requirement, and even voluntary Information Forms may be submitted by individual PSOs in different years. OCR is anticipating considerable variation in the number of complaints per year. Hence we have expressed the total for each year as the average of the expected total over the three year collection period.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form	Number of respondents	Total burden hours	Average hourly wage rate*	Total burden cost
Certification for Initial Listing Form	100/3	17	$31.26	$531.42
Certification for Continued Listing Form	50/3	8	31.26	250.08
Two Bona Fide Contracts Requirement Form	100/3	8	31.26	250.08
Disclosure Statement Form	50/3	8	31.26	250.08
Information Form	100/3	17	31.26	531.42
Patient Safety Confidentiality Complaint Form	150/3	17	31.26	531.42
Total	500/3	75	na	2,344.50

* Based upon the mean of the hourly wages for healthcare practitioner and technical occupation, National Compensation Survey: Occupational wages in the United States 2007, U.S. Department of Labor, Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

a. AHRQ

By statute, AHRQ must collect and review certifications from an entity that seeks listing or continued listing as a PSO under the Patient Safety Act. Additional information collection is also required for entities to remain listed as a PSO (i.e., submissions regarding compliance with the two bona fide contracts requirement and reports of certain relationships between a PSO and each of its contracting providers). The cost to AHRQ of processing the information collected with the above-described forms is minimal: An estimated equivalent of approximately 0.05 FTE or $7,500 per year and virtually no new overhead costs.

Description	Amount
Personnel & Support Staff	$7,500
Consultant (sub-contractor) services	0
Equipment	0
Supplies	0
All other expenses	0
Average Annual Cost	7,500

b. OCR

OCR cannot conduct its work without collecting information through its proposed complaint forms. Even if OCR did not use complaint forms and only took information orally, it would still have to capture the same information in order to begin processing a complaint. Therefore, the incremental cost to OCR of processing the information collected from the complaint form is minimal and is equivalent to approximately 0.05 FTE or $7,500 per year with virtually no new overhead costs.

Description	Amount
Personnel & Support Staff	$7,500
Consultant (sub-contractor) services	0
Equipment	0
Supplies	0
All other expenses	0
Average Annual Cost	7,500

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on the above-described AHRQ and OCR information collection to implement the Patient Safety Act 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, quality improvement and 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: March 18, 2009.

Carolyn M. Clancy,

Director, AHRQ.

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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: 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: ''CAHPS Field Test of Proposed Health Information Technology Questions and Methodology.'' In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by June 1, 2009.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail 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 e-mail at *doris.lefkowitz@ahrq.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

''CAHPS Field Test of Proposed Health Information Technology Questions and Methodology''

The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program is a multi-year initiative of the Agency for Healthcare Research and Quality. AHRQ first launched the program in October 1995 in response to concerns about the lack of good information about the quality of health plans from the enrollees' perspective. Numerous public and private organizations collected information on enrollee and patient satisfaction, but the surveys varied from sponsor to sponsor and often changed from year to year. The CAHPS® program was designed to:

- Make it possible to compare survey results across sponsors and over time; and
- Generate tools and resources that sponsors can use to produce understandable and usable comparative information for consumers.

Over time, the program has expanded beyond its original focus on health plans to address a range of health care services and meet the various needs of health care consumers, purchasers, health plans, providers, and policymakers. Based on the literature review and an assessment of currently available survey instruments, AHRQ identified the need to develop a new health information technology module of the CAHPS® survey. The intent of the planned module is to examine in greater detail than previously patients' perspective on health information technology use by their health care professionals. The intent of the new module is to provide information to clinicians, group practices, health plans, and other interested parties regarding the impact of the use of health information technology on patients' experiences with care. The set of questions about health information technology will be tested as a part of CAHPS® Clinician & Group Survey, Adult Primary Care Questionnaire.

This study, funded through cooperative agreements with RAND and Harvard, is being conducted pursuant to AHRQ's statutory authority to conduct research and evaluations on health care and systems for the delivery of such care, including activities with respect to (1) the quality, effectiveness, efficiency, appropriateness and value of health care services and (2) health care