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 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.

DATES: Comments on this notice must be received by April 21, 2008.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, 540 Gaither Road, Room #5036; Rockville, MD 20850, or 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 AHRQ's Reports Clearance Officer.

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

SUPPLEMENTARY INFORMATION: ''Patient Safety Organization Certification 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.

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 related Notice of Proposed Rulemaking published in the **Federal Register** on February 12, 2008, 73 FR 8112–8183. 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., each of the required certification forms will consist of short attestations followed by ''yes'' and''no'' checkboxes to be checked and initiated.

Initial PSO Certification and PSO Recertification Forms

The Patient Safety Act, in 42 U.S.C. 299b–24(a) and the proposed rule in 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 proposed regulation), and that it will comply, upon listing, with seven other statutory criteria. The draft initial certification form also includes four questions related to other requirements for listing related to eligibility and pertinent organizational history. Similarly, the proposed certification form for continued listing as a PSO (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 forms for initial and continued 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. Collection of forms for continued listing will not begin until several months before a date that is three years after the first PSOs are listed by the Secretary. (See *Note* after Exhibit 1.)

Two-Contract Certification

To implement 42 U.S.C. 299b–24(b)(1)(C), AHRQ plans to adopt the following procedure, published in the proposed regulation: In order to maintain its PSO listing, a PSO will be required only to submit a brief attestation, at least once in every 24-month period after its initial date of listing, indicating that it has entered into contracts with two providers. The annualized burden of 8 hours for the collection of information requested by the two-contract 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.

Disclosure 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 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 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. 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 toward the end of the calendar year in which 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 safety 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
Patient Safety Organization Certification Form	100/3	1	30/60	17
Recertification Form*	50/3	1	30/60	8
Disclosure Form	50/3	1	30/60	8
Two-Contract Requirement Form**	100/3	1	15/60	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 Recertification Form will be completed by any interested PSO at least 45 days before the end of its current three-year listing period. The three-year period for computing respondent burden begins with the date when the approved forms are officially made available for submission. Thus the burden period does not correspond exactly to the three-year period of listing. The burden period begins shortly (approximately 30 days) before any PSO's listing period. As a result, the burden for the first PSOs to submit certifications for continued listing at least 45 days before their listing lapses is likely to fall just before the three-year anniversary of their first burden, i.e. their completion of their initial certifications and before the end of their third year of listing. We assume completing this form will require 30 minutes, the same time as for the Certification Form. 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-Contract 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 close to the end of the calendar year when PSOs are first listed.

**** A total of 100 PSOs are expected to apply over three years: 50 in year 1; 25 in year 2; and 25 in year 3. Relationship Disclosure, Two-Contract, 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 cost burden
Patient Safety Organization Certification Form	100/3	17	$29.82	$506.94
Recertification Form	50/3	8	29.82	238.56
Disclosure Form	50/3	8	29.82	238.56
Two-Contract Requirement Form	100/3	8	29.82	506.94
Information Form	100/3	17	29.82	506.94
Patient Safety Confidentiality Complaint Form	150/3	17	29.82	506.94
Total	500/3	67	29.82	2,504.88

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 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-contract 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 only approximately 0.05 FTE or $7,500 per year for each agency and virtually no new overhead costs.

Description	Amount
Personnel and 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 only approximately 0.05 FTE or $7,500 per year, with virtually no new overhead costs.

Description	Amount
Personnel and 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 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: February 13, 2008.

Carolyn M. Clancy,

Director, AHRQ.

[FR Doc. 08–757 Filed 2–19–08; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Solicitation for Nominations for New Clinical Preventive Health Topics To Be Considered for Review by the United States Preventive Services Task Force

AGENCY: Agency for Healthcare Research Quality (AHRQ), DHHS.

ACTION: Solicit for new topic nominations.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) invites individuals and organizations to nominate primary and secondary prevention topics pertaining to clinical preventive services that they would like the United States Preventive Services Task Force (USPSTF) to consider for review. All topics previously reviewed by the USPSTF are available on AHRQ's Web site, *http://www.preventiveservices.ahrq.gov*.

The USPSTF is an independent panel of experts that makes evidence-based recommendations regarding the provision of clinical preventive services. Clinical preventive services include screening, counseling and preventive medications associated with primary care. The USPSTF makes recommendations about preventive services for asymptomatic people—people without recognized signs or symptoms of the specific conditions targeted by the preventive service.

Topics can be nominated by individuals, organizations, evidence-based practice centers (EPC) and USPSTF members. The USPSTF will consider nominations in two steps. The USPSTF will first determine if the service is eligible, i.e., constitutes primary or secondary prevention applicable to healthy asymptomatic persons; is primary care feasible or referable from primary care; and addresses a condition with a substantial health burden. As a second step, within eligible topics, the USPSTF will prioritize based on the following set of criteria: public health importance (burden of suffering, potential of preventive service to reduce the burden); and potential for greatest Task Force impact (e.g., clinical controversy, practice does not reflect evidence, inappropriate timing in delivery of services).

Basic Topic Nomination Requirements

Nominations must be no more than 500 words in length and must include the information listed below. Nominations may include supporting documentation; reference lists and other supporting documents are not counted against the 500 word limit, but should not exceed ten pages.

Required information:

1. Name of topic.

2. Rationale for consideration by the USPSTF, describing:

a. Characterization as primary or secondary prevention topic (screening, counseling or preventive medication).

b. Primary care relevance (applicable clinical preventive service must be provided by a primary care provider or initiated in the primary care setting which can be defined as family practice, internal medicine, pediatrics or obstetrics/gynecology).

c. Public health importance (burden of disease/suffering, potential of preventive service to reduce burden, including effective interventions). Citations and supporting documents are recommended.

d. Potential impact of USPSTF's review of the topic, i.e., change in clinical practice, research focus, etc.

DATES: Topic nominations should be submitted by March 21, 2008 in order to be considered for 2008–2010. AHRQ will not reply to submissions in response to the request for nominations, but will consider all topic nominations during the selection process. If a topic is selected for review by the USPSTF, the nominator will be notified by AHRQ.

ADDRESSES: Please submit nominations to: Gloria Washington, ATTN: USPSTF Topic Nominations, Center for Primary Care, Prevention & Clinical Partnerships, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, Fax: 301.427.1595, E-mail: *gloria.washington@ahrq.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: Therese Miller at *therese.miller@ahrq.hhs.gov* or Gloria Washington at *gloria.washington@ahrq.hhs.gov*.

Arrangement for Public Inspection: All nominations will be available for public inspections by appointment at the Center for Primary Care, Prevention & Clinical Partnerships, 301.427.1500, weekdays between 10 a.m. and 5 p.m. (Eastern time).

SUPPLEMENTARY INFORMATION: