

- Fax: 202-501-4067.
- Mail: General Services

Administration, Regulatory Secretariat (MVCB), 1275 First Street, NE., Washington, DC 20417. Attn: Hada Flowers/IC 3090-0200.

Instructions: Please submit comments only and cite Information Collection 3090-0200, in all correspondence related to this collection. All comments received will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided.

SUPPLEMENTARY INFORMATION:

A. Purpose

The General Services Administration is requesting that the Office of Management and Budget (OMB) review and approve information collection, 3090-0200, Sealed Bidding. The information requested regarding an offeror's monthly production capability is needed to make progressive awards to ensure coverage of stock items.

B. Annual Reporting Burden

Respondents: 10.

Responses per Respondent: 1.

Hours per Response: .5.

Total Burden Hours: 5.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street, NE., Washington, DC 20417, telephone (202) 501-4755. Please cite OMB Control No. 3090-0200, Sealed Bidding, in all correspondence.

Dated: April 11, 2011.

Millisa Gary,

Acting Director, Office of Governmentwide Acquisition Policy.

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BILLING CODE 6820-61-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. In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by June 17, 2011.

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 dorislefkowitz@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

The Patient Safety and Quality Improvement Act of 2005 (hereafter the Patient Safety Act), 42 U.S.C. 299b-21 to 299b-26, 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 improve patient safety 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 will be able to identify patterns of failures and propose measures to eliminate or reduce patient safety 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 (hereafter the Patient Safety Rule), 42 CFR part 3, 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 PSOs and the process by which the Secretary of HHS (hereafter the Secretary) will review and accept certifications and list PSOs.

In addition to the Patient Safety Act and the Patient Safety Rule, HHS issued Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005 (hereafter Guidance) on December 30, 2010. The Guidance addresses questions that have arisen regarding the obligations of PSOs where they or the organization of which they are a part are legally obligated under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations to report certain information to the Food and Drug Administration (FDA) and to provide FDA with access to its records, including access during an inspection of its facilities. This Guidance applies to all entities that seek to be or are PSOs or component PSOs that have mandatory FDA-reporting obligations under the FDCA and its implementing regulations ("FDA-regulated reporting entities") or are organizationally related to such FDA-regulated reporting entities (e.g., parent organizations, subsidiaries, sibling organizations).

When PSOs meet the requirements of the Patient Safety Act, the information collected and the analyses and deliberations regarding the information receive Federal 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. 71 **Federal Register** 28701-28702 (May 17, 2006). OCR is responsible for enforcing protections regarding patient safety work product (PSWP), which generally includes information that could improve patient safety, health care quality, or health care outcomes and (1) is assembled or developed by a provider for reporting to a PSO and is reported to a PSO or (2) is developed by a PSO for the conduct of patient safety activities. Civil money penalties may be imposed for knowing or reckless impermissible disclosures of

PSWP. AHRQ implements and administers the rest of the Patient Safety Act's provisions.

Pursuant to 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, will meet other criteria. To remain listed for renewable three-year periods, a PSO must recertify that it meets these obligations and will 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 order for the Secretary to administer the Patient Safety Act and Rule, the entities seeking to be listed and to remain listed must complete the proposed forms attached hereto.

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, which is to be completed by an entity seeking to be listed by the Secretary as a PSO for an initial three-year period, contains certifications that the entity meets the requirements for listing as a PSO, in accordance with 42 U.S.C. 299b-24(a)(1) and 42 CFR 3.102.
2. **PSO Certification for Continued Listing Form.** In accordance with 42 U.S.C. 299b-24(a)(2) and the Patient Safety Rule, this form is to be completed by a listed PSO seeking continued listing as a PSO by the Secretary for an additional three year period.
3. **PSO Two Bona Fide Contracts Requirement Certification Form.** To remain listed, a PSO must have contracts with more than one provider, within successive 24 month periods, beginning with the date of its initial listing. 42 U.S.C. 299(b)(1)(C). This form is to be used by a PSO to certify whether it has met this requirement.
4. **PSO Disclosure Statement Form.** A PSO must submit this form when it (i) has a Patient Safety Act contract with a health care provider and (ii) it has financial, reporting, and contractual relationships with that contracting provider or is not independent of that contracting provider. 42 U.S.C. 299b-24; 42 CFR 3.102(d)(2).
5. **PSO Information Form.** This form gathers information on PSOs and the type of healthcare providers and settings that they are working with 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, as required by 42 U.S.C. 299b-23(c).

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 our office so that we have 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). Pursuant to 42 U.S.C. 299b-23(b), 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.

Estimated Annual Respondent Burden

While there are a number of information collection forms described below, they will be implemented at different times and frequency due to the voluntary nature of seeking listing as a PSO and using the Common Formats. 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 75,764 hours annually and the total cost burden is estimated to be \$2,538,852 annually.

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 15 respondents per year and an estimated time of 18 hours per response. This collection of information takes place on an ongoing basis.

Certification for Continued Listing Form

The average annual burden for the collection of information requested by the certification form for continued listing is based upon the estimate that 90% of the listed PSOs during the 3 years of this clearance, or 24 PSOs annually, will submit forms with an estimated time of eight hours per response. The Certification for Continued Listing Form will be completed by any interested PSO at least 75 days before the end of its current three-year listing period.

Two Bona Fide Contracts Requirement Certification

The average annual burden for the collection of information requested by the two-contract requirement is based upon an estimate of 40 respondents per year and an estimated one hour per response. This collection of information takes place when the PSO notifies the Secretary that it has entered into two contracts.

Disclosure Statement Form

AHRQ assumes that only a small percentage of entities will need to file a disclosure form. However, AHRQ is providing a high estimate of 7 respondents annually and thus presumably overestimating respondent burden. The average annual burden estimate of 21 hours for the collection of information requested by the disclosure form is based upon an estimated three hours per response. This information collection takes place 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.

Information Form

The overall annual burden estimate of 240 hours for the collection of information requested by the PSO Information Form is based upon an estimate of 80 respondents per year and an estimated three hours per response. This information collection will begin in 2011; newly listed PSOs will first report in the calendar year after their listing by the HHS Secretary.

Patient Safety Confidentiality Complaint Form

The overall annual burden estimate of 1 hour for the collection of information requested by the form is based on an estimate of two 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 PSWP and there is an allegation of a violation of the statutory protection of PSWP.

Common Formats

AHRQ estimates that 5% FTE of a Patient Safety Manager at a hospital will be spent to administer the Common Formats, which is approximately 100 hours a year. AHRQ estimates the number of hospitals using Common Formats in the first year as 500, then 750 in year 2, and 1000 in year 3, for an annual average of 750 over 3 years.

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 for Initial Listing Form	15	1	18	270
Certification for Continued Listing Form	24	1	8	192
Two Bona Fide Contracts Requirement Form	40	1	1	40
Disclosure Statement Form	7	1	3	21
Information Form	80	1	3	240
Patient Safety Confidentiality Complaint Form	2	1	20/60	1
Common Formats	750	1	100	75,000
Total	918	NA	NA	75,764

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	15	270	\$33.51	\$9,048
Certification for Continued Listing Form	24	192	33.51	6,434
Two Bona Fide Contracts Requirement Form	40	40	33.51	1,340
Disclosure Statement Form	7	21	33.51	704
Information Form	80	240	33.51	8,042
Patient Safety Confidentiality Complaint Form	2	1	33.51	34
Common Formats	750	75,000	33.51	2,513,250
Total	918	75,764	NA	2,538,852

* Based upon the mean of the hourly wages for healthcare practitioner and technical occupation, National Compensation Survey, May 2009, "U.S. Department of Labor, Bureau of Labor Statistics."

Estimated Annual Costs to the Federal Government

a. AHRQ

The total cost to the Federal Government for the PSO forms and Common Formats is \$1,737,390 per year, including project management and support for the review and administration of the PSO forms and the development and maintenance of the Common Formats.

b. OCR

Through an interagency agreement (IAA), OCR provides management for and support of the enforcement of the confidentiality protections of the Patient Safety Act and the Patient Safety Rule. The cost of this IAA is approximately \$300,000 annually.

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 healthcare research and healthcare 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 29, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011-9252 Filed 4-15-11; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

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

ACTION: Notice.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, AHRQ [has submitted a Generic Information Collection Request (Generic ICR): "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*).

This proposed information collection was previously published in the **Federal Register** on December 22nd, 2010 (75 FR 80542) 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 must be submitted May 18, 2011.

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

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at doris.lefkowitz@AHRO.hhs.gov.