

publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number,

and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be received within 30 days of this notice directly to the OS OMB Desk Officer all comments must be faxed to OMB at 202-395-6974.

*Proposed Project:* SF-424 Grants Application Form—OMB No. 4040-0004—Revision—Grants.gov.

The SF-424 form is an OMB approved collection (4040-0004). Proposed revisions of the SF-424 include global changes created by the Federal Funding Accountability and Transparency Act (Transparency Act). The Transparency Act was signed into law on September 26, 2006 (Pub. L. 109-282). The legislation requires the Office of Management and Budget (OMB) to establish a publicly available, online

database containing information about entities that are awarded federal grants, loans, and contracts. The revised form will assist agencies in collecting some of the required data elements for the database through the SF-424 grant applications. This form will be utilized by up to 26 federal grant making agencies.

The SF-424 form revisions incorporate standard data elements required by the Transparency Act such as a nine-digit zip code, the addition of "Parish" to the "County" field, and common language in the form instructions to "Areas Affected by Project" and the "Congressional District of." We are requesting a three year clearance of this form. The affected public may include: Federal, State, local, or tribal governments, business or other for profit, and not for profit institutions.

ESTIMATED ANNUALIZED BURDEN TABLE

Agency	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
DOC .....	16,460	1	30/60	8,230
DOE .....	2,700	1	60/60	2,700
ED .....	10,235	1	60/60	10,235
EPA .....	3,816	1	240/60	15,264
HHS .....	5,800	1.1551	270/60	30,148
SSA .....	1,000	2	20/60	667
USAID .....	200	2	15/60	100
USDA .....	229,946	1	60/60	229,946
DOI .....	11,604	1.8156	26/60	9,130
DOD .....	172	1.2	60/60	206
DOL .....	1,000	1	30/60	500
TOTAL .....				307,126

**Seleda Perryman,**  
*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. E9-1650 Filed 1-26-09; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Solicitation of Written Comments on Draft Centers for Disease Control and Prevention's Immunization Safety Office Scientific Agenda**

**AGENCY:** Department of Health and Human Services, Office of the Secretary.  
**ACTION:** Notice; correction.

**SUMMARY:** The Department of Health and Human Services published a document in the **Federal Register** of January 2, 2009 soliciting comments on the draft Centers for Disease Control and Prevention's Immunization Safety Office Scientific Agenda. Within the

instructions for submitting comments electronically there was a typographical error in the e-mail address. The National Vaccine Program Office (NVPO) is requesting resubmission of any public comments sent prior to January 16, 2009 in response to the previously published Request for Information on the Immunization Safety Office Scientific Agenda.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kirsten Vannice, (202) 690-5566; e-mail *vaccinesafetyRFI@hhs.gov*.

**Correction**

In the **Federal Register** of January 2, 2009, Vol. 74, No. 1, on page 107, in the 3rd column, correct the **ADDRESSES** caption to read:

**ADDRESSES:** Electronic responses are preferred and may be addressed to *vaccinesafetyRFI@hhs.gov*. Written responses should be addressed to the National Vaccine Program Office, U.S. Department of Health and Human

Services, 200 Independence Avenue, SW., Washington, DC 20201, *Attention:* Vaccine Safety RFI.

Dated: January 22, 2009.

**Bruce Gellin,**  
*Deputy Assistant Secretary for Health, Director, National Vaccine Program Office, U.S. Department of Health and Human Services.*

[FR Doc. E9-1692 Filed 1-26-09; 8:45 am]

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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, 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.

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

**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](mailto: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 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 1,

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 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
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.

\*\*\* 1A 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 cost burden
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

Description	Amount
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: January 11, 2009.

**Carolyn M. Clancy,**

*Director, AHRQ.*

[FR Doc. E9-1009 Filed 1-26-09; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Agency for Toxic Substances and Disease Registry

[ATSDR-251]

##### Availability of the Report "ATSDR Studies on Chemical Releases in the Great Lakes Region"

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

**ACTION:** Notification of publication.

**SUMMARY:** This report responds to a request from the International Joint Commission (IJC), the binational organization that works to implement the Great Lakes Water Quality Agreement (GLWQA) between the U.S. and Canada. The GLWQA calls for the two nations to define "the threat to human health from critical pollutants" found in the Great Lakes basin.

This notice announces the availability of the report entitled "ATSDR Studies on Chemical Releases in the Great Lakes Region". This report summarizes previously-published public health assessment products and chemical release information for the 26 U.S. AOCs and 54 counties that are in close geographic proximity to those AOCs. This is a descriptive report that does not make associations between health outcomes and chemical exposures. The compilation of environmental data, gathered by ATSDR and the Environmental Protection Agency (EPA), is intended to help decision-makers set future priorities.

**ADDRESSES:** Address all comments concerning this notice to Ms. Olga Dawkins, ATSDR, Division of Toxicology and Environmental Medicine, 1600 Clifton Road, NE., MS F-32, Atlanta, Georgia 30333.

**FOR FURTHER INFORMATION CONTACT:** Bruce Fowler, PhD, Division of Toxicology and Environmental Medicine, Agency for Toxic Substances and Disease Registry, Mailstop F-32, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (770) 488-7250. Electronic access to these documents is also available at the ATSDR Web site: <http://www.atsdr.cdc.gov/>.

**SUPPLEMENTARY INFORMATION:** The geographic focus of this report is a set

of 26 "Areas of Concern" (AOCs) along Great Lakes streams, rivers, and lakes. These AOCs are defined under the Agreement as ecologically degraded geographic areas requiring remediation. Much of the available data pertain to counties, and not to AOCs. Some AOCs occupy small parts of a single county, while others may reach across more than one county. The data come from publicly available data sets provided by ATSDR and the U.S. EPA.

The GLWQA defines "critical pollutants" as substances that persist in the environment, bioaccumulate in fish and wildlife, and are toxic to humans and animals. There are 12 categories of critical pollutants. This report emphasizes the critical pollutants (within the constraints imposed by using existing data) but also presents information on other pollutants, when such information is available and relevant.

*This report compiles and presents previously collected environmental data from four sources:*

- Data on hazardous waste sites in AOC counties, from evaluations prepared by the Agency for Toxic Substances and Disease Registry (ATSDR);
- Chemical release data from the U.S. Environmental Protection Agency's (EPA) Toxic Release Inventory (TRI);
- Data on pollutant discharges into water, from EPA's National Pollutant Discharge Elimination System (NPDES);
- Data on "beneficial use impairments" such as wildlife and drinking water advisories, from each of the Great Lakes states.

*These data are presented in three ways:* In text, in tables, and in Geographic Information System-based (GIS) maps created by ATSDR for each of the 26 U.S. AOCs.

This is a descriptive report that does not make associations between health outcomes and chemical exposures. The compilation of environmental data, gathered by ATSDR and EPA, is intended to help decision-makers set future priorities.

Dated: January 20, 2009.

**Ken Rose,**

*Director, Office of Policy, Planning, and Evaluation National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.*

[FR Doc. E9-1597 Filed 1-26-09; 8:45 am]

**BILLING CODE 4163-70-P**