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: *''Developing a Registry of Registries.''* In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on September 21st, 2015 and allowed 60 days for public comment. AHRQ received no substantive comments from the public. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by January 11, 2016.

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 email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION: Proposed Renewal of an Existing Project: OMB Control Number 0935–0203.

The Registry of Patient Registries (RoPR) is a web-based application, and does not require users to submit any type of paper form.

The RoPR collects patient registry data in two (2) ways: Users are able to enter information into the web-based system manually, or use an automated upload feature.

Information being collected in the RoPR Record is visible to the public and patient registries visiting the RoPR Web site, and is available for public use in this capacity.

The RoPR system provides email notification to registry holders informing them on an annual basis of the need to update basic statistics and contact information, but it is the responsibility of the registry holder to update the information.

If a Registry Profile has not been reviewed and updated to the RoPR search site within four (4) years, it is archived.

As of August 8, 2015, the RoPR has 138 patient registries listed.

''Developing a Registry of Registries''

Patient registries have received significant attention and funding in recent years. Similar to controlled studies, patient registries represent some burden to patients (*e.g.,* time to complete patient reported outcome measures, risk of loss of privacy), who often participate voluntarily in hopes of improving knowledge about a disease or condition. Patient registries also represent a substantial investment of health research resources. Despite these factors, patient registries are not required to be registered in ClinicalTrials.gov, presenting the potential for duplication of efforts and insufficient dissemination of findings that are not published in the peer-reviewed literature. To fulfill the obligation of advancing the quality and specificity of patient health care, and to ensure that resources are used in the most efficient manner, patient registries need to be listed in a manner similar to that of trials in ClinicalTrials.gov.

By creating a central point of collection for information about all patient registries in the United States, the RoPR furthers AHRQ's goals by making information regarding quality, appropriateness, and effectiveness of health services (and patient registries in particular) more readily available in a central location.

This research has the following goals:

(1) Maintaining and updating the RoPR database system to be compatible with ClinicalTrials.gov; meeting the following objectives:

a. Providing a searchable database of patient registries in the United States (to promote collaboration, reduce redundancy, and improve transparency);

b. Facilitating the use of common data fields and definitions in similar health conditions (to improve opportunities for sharing, comparing, and linkage) and free-text search field for highlighting information specific to an individual registry;

c. Providing a public repository of searchable summary results (including results from registries that have not yet been published in the peer-reviewed literature);

d. Offering a search tool to locate existing data that researchers can request for use in new studies; and

e. Serving as a recruitment tool for researchers and patients interested in participating in patient registries.

This study is being conducted by AHRQ through its contractor L&M Policy Research and Quintiles, a sub-contractor to L&M, pursuant to AHRQ's statutory authority to conduct and support research and disseminate information on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to database development. 42 U.S.C. 299a(a)(1) and (8).

Method of Collection

To achieve the goals of this project, the following data collections will be implemented:

(1) Collect information from users who populate the RoPR database system, which will achieve all of the above goals.

(2) There are tentative plans for a user satisfaction survey to be enabled within the RoPR system, in the second quarter of 2016. The purpose of this survey is to obtain user/stakeholder feedback to evaluate priorities for future enhancements. Its full nature and design is in the concept stage still and so is not part of the Estimated Annual Respondent Burden. However, for the purpose of full disclosure, plans for the survey are being disclosed in this notice.

The purpose and the use of the RoPR is to provide a readily available public resource strictly for patient registries, following the model of ClinicalTrials.gov, allowing for the increased availability and efficacy of patient registries. The information being collected in the RoPR Record is visible to the public visiting the RoPR Web site, and is readily available for public use. The RoPR is an ongoing data collection initiative.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the RoPR. Between July 2014 and June 2015, 59 new respondents had entered their RoPR record, utilizing either a manual or electronic upload data entry method.

Each respondent need enter his or her new RoPR record only once, and this process is estimated to take 45 minutes. The RoPR system sends an automated reminder to any registry owner who has not updated his or her RoPR record in the past year. An estimated 57.25% (79 records) of all RoPR records were

eligible for updates between July 2014 and June 2015, either by the registry owner's initiative, or when prompted by the automated RoPR reminder. This update process takes about 15 minutes. As the RoPR continues to grow and more patient registry records are added over time, this percentage represents a growing, cumulative number.

In February 2015, Quintiles conducted a knowledge transfer webinar for registry contacts learn how to enter new records into the RoPR. As a result of the knowledge gained during these processes, it is estimated that it takes users 45 minutes to manually enter a new RoPR record; 15 minutes to upload a new RoPR record (an average of 30 minutes using either method). It takes 15 minutes for a person to review and make updates to an existing RoPR record. The total respondent burden is estimated to be a maximum of 64 hours annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Minutes per response	Total burden hours
New RoPR Record (manually—entered or uploaded electronically method)	59	1	45/60	44.25
Review/update existing RoPR Record	79	1	15/60	19.75
Total	138			64.0

Exhibit 2 shows the estimated cost burden associated with the respondent's time to participate in the RoPR. The total cost burden to respondents is estimated at an average of $1,799.60 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate †	Total cost burden
New RoPR Record (manually—entered or uploaded electronically method)	59	44.25	$36.54	$1,617
Review/update existing RoPR Record	79	19.75	36.54	721.67
Total	138	64		2,339

* Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29–0000. National Compensation Survey: Occupational wages in the United States May 2014, ''U.S. Department of Labor, Bureau of Labor Statistics.'' Available at: *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000*.

In order to highlight patient registry concerns about using the RoPR system and turning user feedback into future system maintenance and upgrade initiatives (increasing the usability of the RoPR and lowering the burden of entering patient registry information), plans for a voluntary user satisfaction survey are being considered for 2Q 2016. Its full nature and design is in the concept stage. Therefore, this survey is not part of the Estimated Annualized Respondent Hourly/Cost Burden noted in Exhibits 1 and 2.

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 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.

Sharon Arnold,

Deputy Director.

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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: *''Online Submission Form for Supplemental Evidence and Data for Systematic reviews for the Evidence-based Practice Center Program.''* In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on September 21st, 2015 and allowed 60 days for public comment. AHRQ did not receive any substantive comments. The purpose of this notice is to allow an additional 30 days for public comment.

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