TABLE 3—COST TO THE FEDERAL GOVERNMENT—Continued

Cost component	Total cost	Annualized cost
Government Oversight	13,710	4,570
Total	499,877	166,626

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: April 19, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–10007 Filed 4–25–12; 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

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: ''American Recovery and Reinvestment Act ''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 February 23, 2012 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 May 29, 2012.

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).

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 email at *doris.lefkowitz@AHRQ.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

American Recovery and Reinvestment Act ''Developing a Registry of Registries''

The Food and Drug Administration Modernization Act of 1997, Public Law 105–115, provided for the creation of a Clinical Trials Data Bank, known as *ClinicalTrials.gov*. Since its launch in 2000, the *ClinicalTrials.gov* system has registered over 90,500 trials. The large volume of studies currently listed in *ClinicalTrials.gov* and the high usage numbers suggest that the system has been successful at improving access to information about clinical studies. However, while *ClinicalTrials.gov* supports the listing of observational studies, such listing is not required.

Patient registries are a distinct type of observational study. Patient registries may be designed for many purposes, such as to observe the natural history of disease, examine comparative effectiveness, or fulfill post-approval commitments. Patient registries have specific characteristics that are not currently captured on *ClinicalTrials.gov*. To date, some registry sponsors have attempted to leverage the observational study model to post patient registry-type records on *ClinicalTrials.gov*. However, stakeholders have noted that the system does not fully meet their needs.

Patient registries have received significant attention and funding in recent years. Similar to controlled interventional 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, registration of patient registries in *ClinicalTrials.gov* is not currently required, presenting the potential for duplication of efforts and insufficient dissemination of findings that are not published in the peer-reviewed literature. To ensure that resources are used in the most efficient manner, 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 Registry of Patient Registries (RoPR) helps to further AHRQ's goals by making information regarding quality, appropriateness, and effectiveness of health services (and patient registries in particular) more readily available and centralized.

The primary goal of this project is to engage stakeholders in the design and development of a RoPR database system that is compatible with *ClinicalTrials.gov* and meets the following objectives:

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

(2) Facilitates the use of common data fields and definitions in similar health conditions (to improve opportunities for sharing, comparing, and linkage);

(3) Provides a public repository of searchable summary results (including

results from registries that have not yet been published in the peer-reviewed literature);

(4) Offers a search tool to locate existing data that researchers can request for use in new studies; and serves as a recruitment tool for researchers and patients interested in participating in patient registries.

This study is being conducted by AHRQ through its contractor, the Outcome DEcIDE Center, pursuant to the American Recovery and Reinvestment Act, Public Law 111–5, and 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 registry holders, defining a patient registry profile via a web-based interface, to populate the RoPR database system.

The purpose of the RoPR is to create a readily available public resource in the model of ClinicalTrials.gov to share information on existing patient registries to promote collaboration, reduce redundancy, and improve transparency in registry research. Patient registry research has become more prevalent and, based on stakeholder feedback, is not adequately served by ClinicalTrials.gov at present. The information being collected in the RoPR record will be visible to the public visiting the RoPR Web site and will be available for public use in this capacity.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden for the respondents' time to participate in the RoPR. Because the RoPR is a voluntary system available to any entity conducting a patient registry, it is not possible to determine the number of potential respondents. We do know that over 3,800 newly registered records designated as ''observational studies'' were entered into ClinicalTrials.gov in 2010. Only a subset of this number (which we will estimate at a maximum of 40%) would qualify as patient registries and would likely be registered in the RoPR. Therefore, we use 1,520 (3,800*0.40) in Exhibits 1 and 2 below as a very rough, but high, estimation of the potential number of respondents who will enter registries into the RoPR annually. The actual number of respondents will depend on a variety of factors and could vary widely. It should be remembered that mandates could evolve making registration in the RoPR mandatory. Our estimates therefore attempt to factor an upper threshold for volume.

Each respondent will enter a new RoPR record only once and is estimated to take 45 minutes. An estimated 50% (760 records) of RoPR records will be updated once a year and will take about 15 minutes. This estimate is based on a query of ClinicalTrials.gov which showed that about 50% of observational studies registered in ClinicalTrials.gov had been updated in the past year. The total respondent burden is estimated to be 1,330 hours annually.

Exhibit 2 shows the estimated cost burden associated with the respondent's time to participate in the RoPR. The total cost burden is estimated to be $45,579 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
New RoPR Record	1,520	1	45/60	1,140
Review/update RoPR Record	760	1	15/60	190
Total	2,280	na	na	1,330

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form Name	Number of espondents	Total burden hours	Average hourly rate +	Total cost burden
New RoPR Record	1,520	1,140	$34.27	$39,068
Review/update RoPR Record	760	190	34.27	6,511
Total	2,280	1,330	na	$45,579

+ Based upon the mean average wage for Healthcare Practitioners and Technical Occupations, May 2010 National Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics. Available at: *http://www.bls.gov/oes/current/oes_nat.htm#29–0000.*

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to the government to create and maintain the RoPR for 3 years. The total cost is estimated to be $3,184,333.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$2,318,509	$772,836
Project Management	409,149	136,383
Overhead	456,675	152,225

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST—Continued

Cost component	Total cost	Annualized cost
Total	3,184,333	1,061,444

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: April 19, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–10009 Filed 4–25–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Local Therapies for Unresectable Primary Hepatocellular Carcinoma

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

ACTION: Request for scientific information submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from manufacturers of local, minimally invasive, medical devices for unresectable primary hepatocellular carcinoma (e.g., ablation, radiotherapy, or embolization devices). Scientific information is being solicited to inform our Comparative Effectiveness Review of Local Therapies for Unresectable Primary Hepatocellular Carcinoma, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173.

DATES: Submission Deadline on or before May 29, 2012.

ADDRESSES:

Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submitscientific-information-packets/. Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents.

Email submissions: ehcsrc@ohsu.edu (please do not send zipped files—they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239–3098.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: 503–494–0147 or Email: *ehcsrc@ohsu.edu*.

SUPPLEMENTARY INFORMATION:

In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for local therapies for unresectable primary hepatocellular carcinoma.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on local therapies for unresectable primary hepatocellular carcinoma, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/index.cfm/search-for-quides-reviews-and-reports/?productid=1012&pageaction=displayproduct#5056*.

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.