

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name/Deliberative method	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
Educational Materials	1685	1685	21.35	35,975
Knowledge and Attitudes Pretest Survey	1685	843	\$21.35	\$17,998
Knowledge and Attitudes Post-test Survey	1685	562	21.35	11,999
Deliberative Experience Survey	1056	264	21.35	5,636
Total	8852	N/A	N/A	248,662

* Based upon the mean of the wages for 00-000 All Occupations (\$21.35), May 2010 National Occupational Employment and Wage Estimates. United States, "U.S. Department of Labor, Bureau of Labor Statistics." http://www.bls.gov/oes/current/oes_nat.htm#00-0000.

Estimated Annual Costs to the Federal Government

Exhibit 3 below breaks down the costs related to this study. These are the costs

associated with the portion of the contract awarded to AIR to conduct the experiment. Since the implementation and evaluation periods will span 24

months, the costs have been annualized by taking the total cost and dividing by 2.

EXHIBIT 3—ESTIMATED ANNUALIZED COST TO THE FEDERAL GOVERNMENT

Cost component	Total cost	Annualized cost
Project Management	\$60,106	\$30,053
Technical Expert Panel	117,793	58,896
Technology Tools	177,580	88,790
Develop Educational Materials	368,624	184,312
Evaluation Plan	214,566	107,283
Implement Methods	1,624,169	812,085
Conceptual Framework	50,195	25,098
Data Processing and Analysis	566,846	283,423
Reporting	135,693	67,847
Overhead	1,281,340	640,670
Total	4,596,914	2,298,457

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: November 16, 2011.

Carolyn Clancy,

Director.

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BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Healthcare Research and Quality****Patient Safety Organizations: Voluntary Relinquishment From HealthWatch, Inc.**

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

ACTION: Notice of delisting.

SUMMARY: AHRQ has accepted a notification of voluntary relinquishment from HealthWatch, Inc. of its status as a Patient Safety Organization (PSO). The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), Public Law 109-41, 42 U.S.C. 299b-21-b-26, provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety and Quality Improvement Final Rule (Patient Safety

Rule), 42 CFR part 3, authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and patient Safety Rule, including when a PSO chooses to voluntarily relinquish its status as a PSO for any reason.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12 Midnight ET (2400) on November 1, 2011.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: <http://www.pso.AHRQ.gov/index.html>.

FOR FURTHER INFORMATION CONTACT: Susan Grinder, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: psa@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is to conduct activities to improve patient safety and the quality of health care delivery. HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule (PDF file, 450 KB. PDF Help) relating to the listing and operation of PSOs. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs. AHRQ has accepted a notification from HealthWatch, Inc., PSO number P0010, which is a component entity of Quality Health Strategies, Inc., to voluntarily relinquish its status as a PSO. Accordingly, HealthWatch, Inc. was delisted effective at 12 Midnight ET (2400) on November 1, 2011.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/index.html>.

Dated: November 16, 2011.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Pressure Ulcer Treatment Medical Devices

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 pressure ulcer treatment medical devices, such as (but not limited to): Ultrasonic wound care systems, negative pressure therapy units, turning & positioning systems, special mattresses, mattress covers, pillows, cushions, etc. Scientific information is being solicited to inform our Pressure Ulcer Treatment Strategies: A Comparative Effectiveness Review, 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 these devices 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 January 3, 2012.

ADDRESSES: Online submissions: <http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-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 pressure ulcer treatment strategies.

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 pressure ulcer treatment strategies, 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://effectivehealthcare.AHRQ.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=838#3870>.

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.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

The Key Questions

A preliminary set of KQs was posted on the Effective Health Care Program Web site of the Agency for Healthcare Research and Quality (AHRQ), and public comments were collected and evaluated.

A Summary of the Public Comments

Most of the public comments addressed specific patient or treatment characteristics and settings. Commenters suggested that the review