

Settlement Agreement include that Dr. Bois denied that he committed research misconduct but he agreed not to further appeal ORI's findings of research misconduct set forth above. Dr. Bois and HHS further agreed to the following administrative actions beginning on March 14, 2013:

(1) To have his research supervised for a period of three (3) years beginning on the effective date of the Agreement; he agreed that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which his participation is proposed and prior to his participation in any capacity on PHS-supported research, he shall ensure that a plan for supervision of his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of his research contribution; he agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI, with such review and approval to be conducted promptly by ORI and not unreasonably withheld; he agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that for three (3) years beginning with the effective date of the Agreement, any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Dr. Bois is involved, a certification to ORI that the data provided by him are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three years (3) beginning with the effective date of the Agreement.

Dr. Bois further agreed to dismiss his lawsuit with prejudice and to withdraw further proceedings before HHS. Dr. Bois and HHS both agreed to waive or abandon all other claims. This notice supercedes the notice regarding this matter that was previously published in: **Federal Register** 76:111, June 9, 2011.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity,

1101 Wootton Parkway, Suite 750,
Rockville, MD 20852, (240) 453-8800.

David E. Wright,

Director, Office of Research Integrity.

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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, 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: "Pilot Test of the Proposed Value and Efficiency Surveys and Communicating with Patients Checklist." 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 January 7th, 2013 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 20, 2013.

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

Pilot Test of the Proposed Value and Efficiency Surveys and Communicating With Patients Checklist

Maximizing value within the American health care system is an

important priority. Value is often viewed as a combination of high quality, high efficiency care, and there is general agreement by consumers, policy makers, payers, and providers that it is lacking in the U.S. A recent report by the Institute of Medicine estimated that 20 to 30 percent (\$765 billion a year) of U.S. healthcare spending was inefficient and could be reduced without lowering quality.

Multiple overlapping initiatives are currently seeking to improve value using a variety of approaches. Public reporting efforts led by the Centers for Medicare and Medicaid Services (CMS), other payers and consumer groups seek to enable consumers to make more informed choices about the quality, and in some cases, the costs of their care. A variety of demonstration projects and payment reforms initiated by CMS and private insurers are attempting to more closely link care quality with payments to create incentives for higher value care. And national improvement initiatives led by AHRQ (comprehensive unit-based safety programs [CUSP] for central line-associated blood stream infection [CLABSI], catheter-associated urinary tract infections [CAUTI], and surgical units [SUSP]) and CMS (hospital engagement networks, QIO scopes of work) are seeking to raise care quality and reduce readmissions. Results from the CUSP-CLABSI project have demonstrated that central line infections can be reduced and unnecessary costs can be avoided across the health care system by concerted, unit-based improvement efforts.

As a systems level example, Denver Health, with initial funding from AHRQ, has taken major steps towards redesigning clinical and administrative processes so as to reduce staff time, patient waiting, and unnecessary costs. These improvements occurred without harm to quality and in some instances actually improved quality.

In many cases, improving quality improves efficiency naturally. Reducing the number of hospital errors, for example, will reduce costs associated with longer length of stay or error-triggered readmissions. It is more cost-effective to do things right the first time. But higher value may be more likely if organizations doing quality improvement link efforts to improve care quality with efforts to reduce unnecessary costs. AHRQ understands that many of the root causes of inefficiencies that drive up costs are closely linked to root causes of inefficiencies that lead to poor quality, uncoordinated care where redundancies and system failures place patients at risk. Enhancing value in healthcare

requires understanding the contribution that organizational culture makes to value and working to foster a culture where high value is a cultural norm.¹ AHRQ's development of the Hospital Survey on Patient Safety Culture (HSOPS) has contributed greatly to efforts to promote the important role culture plays in providing safe care. HSOPS is used extensively in national improvement campaigns and many hospitals and health systems now regularly assess their safety cultures and use culture scores on organizational dashboards and as parts of variable compensation programs.

If organizations lack cultures committed to value then discrete efforts to raise dimensions of value are likely to yield limited and unsustainable results. And if organizational leaders have no plausible way to know whether their organizational culture is committed to value, then their ability to make value a higher organizational priority will be very limited. Thus, developing value and efficiency survey instruments for hospitals and medical offices fills an important need for many ongoing and planned efforts to foster greater value within American health care.

Given the widespread impact of cost and waste in health care, AHRQ will develop the Value and Efficiency (VE) Surveys for hospitals and medical offices. These surveys will measure staff perceptions about what is important in their organization and what attitudes and behaviors related to value and efficiency are supported, rewarded, and expected. The surveys will help hospitals and medical offices to identify and discuss strengths and weaknesses within their individual organizations. They can then use that knowledge to develop appropriate action plans to improve their value and efficiency. To develop these tools AHRQ will recruit medical staff from 42 hospitals and 96 medical offices to participate in cognitive testing and pretesting.

In addition to the VE surveys, AHRQ also intends to develop and test the feasibility and utility of a Patient Communication Checklist. Patients are demanding greater clarity into the costs of health care and what they can do about affordability problems. While there is recent interest in making health care prices more transparent for

consumers (e.g., the Health Care Price Transparency Promotion Act of 2013 (H.R. 1326)), physician communication with patients about the cost of care will be a key component to attaining high-value, high-quality care from a patient perspective. To aid physicians, this proposal will develop a consumer value (CV) checklist. Physician checklists have been instrumental in many quality improvements, such as with AHRQ's reduction in central line-associated blood stream infections [CLABSI] (See Atul Gawande's Checklist Manifesto, Metropolitan Books, 2009). Checklists have also reduced surgical complications by preventing miscommunication during complex procedures. Similarly, checklists could potentially facilitate communication between clinicians and patients in complex discussions about patient preferences, quality, value, and out-of-pocket costs. The objective of the CV checklist is to facilitate shared decision-making, and also engage physician and patients in joint problem solving. For example, if discussions emanating from use of a checklist show that the patient is not likely to fill a critical prescription for financial reasons, this could trigger a discussion of generic substitutes or state or other subsidies available. Since the proper goal for any health care delivery system is to improve the quality and value of care delivered to patients, such a tool will bring the patient perspective on value into the decision-making about their care.

The CV checklist will address three major topics: who should talk with patients about preferences and value issues (e.g., nurses, physicians, etc.), when should these conversations occur (e.g., when patients may incur costs, when they express financial concerns, etc.), and how can clinicians prepare for and effectively facilitate such discussions.

This research has the following goals:

- (1) Develop, cognitively test and modify as necessary the VE surveys (one for hospitals and one for medical offices);
- (2) Pretest the VE surveys in hospitals and medical offices and modify as necessary based on the results;
- (3) Develop, cognitively test and modify as necessary the checklist;
- (4) Seek consumer/patient input on the potential value of the checklist;
- (5) Pretest the checklist in hospitals and medical offices and either drop or modify as necessary based on patient and clinician views of the results;
- (6) Make the final VE surveys and checklist available for use by the public.

This study is being conducted by AHRQ through its contractor, Health

Research & Educational Trust (HRET), and subcontractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve these goals the following activities and data collections will be implemented:

(1) Cognitive interviews for the VE surveys. One round of interviews on the VE surveys will be conducted by telephone with 9 respondents from hospitals and 9 respondents from medical offices. The purpose of these interviews is to understand the cognitive processes the respondent engages in when answering a question on the VE survey and to refine the survey's items and composites. These interviews will be conducted with a mix of senior leaders and clinical staff (i.e., unit/department managers, practitioners, nurses, technicians, and medical assistants) from hospitals and medical offices throughout the U.S. with varying characteristics (e.g., size, geographic location, type of medical office practice/hospital, and possibly extent of experience with waste-reduction efforts).

(2) Pretest for the VE surveys. The surveys will be pretested with senior leaders and clinical staff from 42 hospitals and 96 medical offices. The purpose of the pretest is to collect data for an assessment of the reliability and construct validity of the surveys' items and composites, allowing for their further refinement. A site-level point-of-contact (POC) will be recruited in each medical office and hospital to manage the data collection at that organization (compiles sample information, distribute surveys, promote survey response, etc.). Exhibit 1 includes a burden estimate for the POC's time to manage the data collection.

(3) Medical office information form. This form will be completed by the medical office manager in each of the 96 medical office pretest sites to provide background characteristics, such as type of specialty(s) and majority ownership. A hospital information form will not be needed because characteristics on pretest hospitals will be obtained from the American Hospital Association's (AHA) data set based on a hospital's AHA ID number.

(4) Survey to identify items for CV checklist. In order to identify items to

¹ (refers to 2nd paragraph in page 3) According to Pronovost and Sexton (Assessing Safety Culture: Guidelines and Recommendations, Qual Saf Health Care 2005; 14:231-23), "Definitions of culture commonly refer to values, attitudes, norms, beliefs, practices, policies, and behaviors of personnel. In essence, culture is 'the way we do things around here'."

put on the checklist, a survey will be developed and sent to 160 representative participants (40 Physicians, 40 Registered Nurses, 20 Social Workers, 20 Health Educators, and 40 Patients). Once the survey responses have been collected, responses will be analyzed to help inform the development of the CV checklist. Checklist items will be chosen based on what is learned. For example, if clinicians strongly believe that it is inappropriate to discuss costs and value with patients, the checklist may require different items than if clinicians recognize the importance of such conversations but believe they lack required information to facilitate them.

(5) Cognitive Interviews for the CV checklist. Once checklist items have been identified, cognitive interviews will be conducted with 9 respondents in hospitals and 9 respondents in medical offices to understand the cognitive processes the respondent engages in when using the CV checklist. Cognitive interviewing will allow checklist developers to identify and classify difficulties respondents may have regarding checklist items. To get different perspectives, interviews will be conducted with a mix of physicians, nurses, social workers, health educators, and patients in hospitals and medical offices.

(6) Pretest the CV checklist. The checklist will then be pretested to solicit feedback from 50 physicians in hospitals and 50 physicians in medical offices. The pilot testing process will help identify areas where users of the checklist have trouble understanding, learning, and using the checklist. It also provides the opportunity to identify

issues that can prevent successful deployment of the checklist.

(7) Dissemination activities. The final VE Surveys and CV checklist will be made available to the public through the AHRQ Web site. This activity does not impose a burden on the public and is therefore not included in the burden estimates in Exhibit 1.

The information collected will be used to test and improve the draft survey items in the VE Surveys and CV checklist.

The final VE instruments will be made available to the public for use in hospitals and medical offices to assess value and efficiency from the perspectives of their staff. The survey can be used by hospitals and medical offices to identify areas for improvement. Researchers are also likely to use the surveys to assess the impact of hospitals' and medical offices' value and efficiency improvement initiatives.

The final CV checklist will be made available to hospital and medical office clinicians to aid in having conversations with patients about value.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research. Cognitive interviews for the Hospital VE survey will be conducted with 9 hospital staff (approximately 3 managers, 3 nurses, and 3 technicians) and will take about one hour and 30 minutes to complete. Cognitive interviews for the Medical Office VE survey will be conducted with 9 medical office staff (approximately 4 physicians and 5 medical assistants)

and will take about one hour and 30 minutes to complete. The Hospital VE survey will be administered to about 4,032 individuals from 42 hospitals (about 96 surveys per hospital) and requires 15 minutes to complete. A site-level POC will spend approximately 16 hours administering the Hospital VE survey. The Medical Office VE survey will be administered to about 504 individuals from 96 medical offices (about 5 surveys per medical office) and requires 15 minutes to complete. A site-level POC will spend approximately 6 hours administering the Medical Office VE survey. The medical office information form survey will be completed by a medical office manager at each of the 96 medical offices participating in the pretest and takes 10 minutes to complete.

One-hundred and sixty individuals (40 physicians, 40 nurses, 20 social workers, 20 health educators, and 40 patients) will participate in the survey to identify items for the CV checklist and will take 15 minutes to complete. Cognitive interviews for the CV checklist will be conducted with 18 individuals (9 in hospitals and 9 in medical offices, consisting of approximately 4 physicians, 4 nurses, 2 social workers, 2 health educators, and 6 patients) and will take about one hour to complete. One hundred physicians will participate in the pretest of the CV checklist (50 in hospitals and 50 in medical offices). The total burden is estimated to be 2,534 hours annually.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be \$115,559 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Number of respondents | Number of responses per respondent | Hours per response | Total burden hours |
|---|-----------------------|------------------------------------|--------------------|--------------------|
| Cognitive interviews for the Hospital VE survey | 9 | 1 | 1.5 | 14 |
| Cognitive interviews for the Medical Office VE survey | 9 | 1 | 1.5 | 14 |
| Pretest for the Hospital VE survey | 4,032 | 1 | 15/60 | 1,008 |
| Pretest for the Medical Office VE survey | 504 | 1 | 15/60 | 126 |
| POC Administration of the Hospital VE survey | 42 | 1 | 16 | 672 |
| POC Administration of the Medical Office VE survey | 96 | 1 | 6 | 576 |
| Medical office information form | 96 | 1 | 10/60 | 16 |
| Survey to identify items for CV checklist | 160 | 1 | 15/60 | 40 |
| Cognitive interviews for the CV checklist | 18 | 1 | 1 | 18 |
| Pretest for the CV checklist | 100 | 1 | 30/60 | 50 |
| Total | 5,066 | na | na | 2,534 |

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

| Form name | Number of respondents | Total burden hours | Average hourly wage rate* | Total cost burden |
|---|-----------------------|--------------------|---------------------------|-------------------|
| Cognitive interviews for the Hospital VE survey | 9 | 14 | ^a \$36.16 | \$506 |
| Cognitive interviews for the Medical Office VE survey | 9 | 14 | ^b 46.87 | 656 |
| Pretest for the Hospital VE survey | 4,032 | 1,008 | ^c 36.02 | 36,308 |
| Pretest for the Medical Office VE survey | 504 | 126 | ^d 27.73 | 3,494 |
| Administration of the Hospital VE survey | 42 | 672 | ^e 55.80 | 37,498 |
| Administration of the Medical Office VE survey | 96 | 576 | ^f 50.98 | 29,364 |
| Medical office information form | 96 | 16 | ^f 50.98 | 816 |
| Survey to identify items for CV checklist | 160 | 40 | ^g 45.02 | 1,801 |
| Cognitive interviews for the CV checklist | 18 | 18 | ^h 39.84 | 717 |
| Pretest for the CV checklist | 100 | 50 | ⁱ 87.98 | 399 |
| Total | 5,066 | 2,534 | na | 115,559 |

* National Occupational Employment and Wage Estimates in the United States, May 2011, "U.S. Department of Labor, Bureau of Labor Statistics" (available at http://www.bls.gov/oes/current/naics4_621100.htm [for medical office setting] and http://www.bls.gov/oes/current/naics4_622100.htm [for hospital setting]).

^aBased on the weighted average wages for 3 Registered Nurses (29–1111, \$33.56), 3 Medical and Clinical Laboratory Technicians (29–2012, \$19.11), and 3 General and Operational Managers (11–1021, \$55.80) in the hospital setting;

^bBased on the weighted average wages for 4 Family and General Practitioners (29–1062; \$87.18) and 5 Medical Assistants (31–9092, \$14.63) in the medical office setting;

^cBased on the weighted average wages for 1,937 Registered Nurses, 1,131 Medical and Clinical Laboratory Technicians, 526 General and Operational Managers and 446 Physicians (29–1069; \$66.23) in the hospital setting;

^dBased on the weighted average wages for 91 Family and General Practitioners and 413 Medical Assistants in the medical office setting;

^eBased on the average wages for General and Operational Managers in the hospital setting;

^fBased on the average wages for General and Operational Managers in the medical office setting;

^gBased on the weighted average wages for 40 Physician and Surgeons (29–10692; \$88.78), 40 Registered Nurses (29–1111; \$33.23), 20 Social Workers (21–1022; \$24.28), 20 Health Educators (21–1091, \$25.07), and 20 Patients (00–0000; \$21.74);

^hBased on the weighted average wages for 4 Physician and Surgeons, 4 Registered Nurses, 2 Social Workers, 2 Health Educators, and 6 Patients;

ⁱBased on the weighted average wages for 50 Physician and Surgeons in the hospital setting and 50 Family and General Practitioners in the medical office setting;

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to the government

for this data collection. Although data collection will last for less than one year, the entire project will take about

2 years. The total cost for the three surveys is approximately is \$1,001,202.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

| Cost component | Total cost | Annualized cost |
|------------------------------------|------------|-----------------|
| Project Development | \$273,838 | \$136,919 |
| Data Collection Activities | 153,119 | 76,560 |
| Data Processing and Analysis | 171,764 | 85,882 |
| Publication of Results | 14,753 | 7,377 |
| Project Management | 10,032 | 5,016 |
| Overhead | 377,696 | 188,848 |
| Total | 1,001,202 | 500,601 |

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 health care 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 8, 2013.

Carolyn M. Clancy,
Director.

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