



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: *“The AHRQ Safety Program for Improving Antibiotic Use.”*

This proposed information collection was previously published in the Federal Register on May 5, 2017, 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.

DATES: Comments on this notice must be received by (INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION).

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 Project

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection. Antibiotics can have serious adverse effects including *Clostridium difficile* infections, organ dysfunction, allergic reactions, and the development of antibiotic resistance on both a patient level and population level. This project will assist acute care, long-term care and ambulatory care settings across the United States in adopting and implementing antibiotic stewardship programs, which are coordinated efforts to improve the use of antibiotics by promoting the selection of the optimal antibiotic regimen, dose, route of administration, and duration of therapy.

More specifically, this project has the following goals:

- Identify best practices in the delivery of antibiotic stewardship in the acute care, long-term care and ambulatory care settings
- Adapt the Comprehensive Unit-Based Safety Program (CUSP) model to enhance antibiotic stewardship efforts in the health care settings
- Assess the adoption of CUSP for antibiotic stewardship and evaluate the effectiveness of the intervention in the participating health care systems
- Develop a bundle of technical and adaptive interventions and associated tools and educational materials designed to support enhanced antibiotic

stewardship efforts

- Provide technical assistance and training to health care organizations nationwide, using a phased approach, to implement effective antibiotic stewardship programs and interventions
- Improve communication and teamwork between health care workers surrounding antibiotic decision-making
- Improve communication between health care workers and patients/families surrounding antibiotic decision-making

This study is being conducted by AHRQ through its contractor Johns Hopkins University, with subcontracted partner NORC. The *AHRQ Safety Program for Improving Antibiotic Use* is being undertaken pursuant to AHRQ's mission to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. 42 U.S.C. 299.

Method of Collection

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

- 1) Structural Assessments: A brief (five to seven questions), online Structural Assessment Tool will be administered in all settings at baseline (pre-intervention) and at the end of the intervention period to obtain general information about facilities and existing stewardship infrastructure and changes in stewardship infrastructure and interventions as a result of the AHRQ Safety Program.
- 2) Team Antibiotic Review Form: The Stewardship Team

- will conduct monthly reviews of at least 10 patients who received antibiotics and fill out an assessment tool in conjunction with frontline staff to determine if the “four moments of antibiotic decision-making” are being considered by providers. The four moments are 1) Is an infection present requiring antibiotics? 2) Were appropriate cultures ordered and best initial choice of antibiotics made? 3) (after at least 24 hours) Are changes in antibiotic orders appropriate? 4) What duration of therapy is appropriate?
- 3) The AHRQ Surveys on Patient Safety Culture will be administered to all participating staff at the beginning and end of the intervention. Each survey asks questions about patient safety issues, medical errors, and event reporting in the respective settings.
- a. The Hospital Survey on Patient Safety Culture will be utilized to evaluate safety culture for acute care hospitals.
 - b. The Nursing Home Survey on Patient Safety Culture will be administered in long term care.
 - c. The Medical Office Survey on Patient Safety Culture will be administered in ambulatory care centers.
- 4) Semi-structured qualitative interviews: In-person and/or telephone discussions will be held before and after implementation with stewardship champions/organizational leaders, physicians, pharmacists, nurse practitioners, physician assistants, nurses, certified nursing assistants and

others deemed relevant, to learn about the facilitators and barriers to a successful antibiotic stewardship program. Specific areas of interest include stakeholder perceptions of implementation process and outcomes, including successes and challenges with carrying out project tasks and perceived utility of the project; staff roles, engagement and support; and antibiotic prescribing etiquette & culture (i.e., social norms and local cultural factors that contribute to prescribing behavior at the facility/unit-level).

- 5) Electronic Health Record (EHR) data: Unit-level antibiotic usage and clinical outcomes will be extracted from the EHRs of participating health care facilities and used to assess the impact of the AHRQ Safety Program for Improving Antibiotic Use.

Estimated Annual Respondent Burden

Exhibit 1. Estimated annualized burden hours

Form Name	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden hours
1. Structural Assessment	500	2	0.2	200
2. Team Antibiotic Review Form	333	90	0.2	5,994

3. Surveys on Patient Safety Culture (SOPS)				
a. HSOPS	4,167	2	.5	4,167
b. NHSOPS	4,167	2	.5	4,167
c. MOSOPS	4,167	2	.5	4,167
4. Semi-structured qualitative interviews (Physicians - line 1; Other Health Practitioners - line 2)	30	2	1	60
	60	2	1	120
5. EHR data	500	12	.5	3,000
Total	13,924	N/A	N/A	21,875

Exhibit 2. Estimated annualized cost burden

Form Name	Number of Respondents	Total Burden hours	Average Hourly Wage Rate*	Total Cost Burden
1. Structural	500	200	\$98.83 ^a	\$19,766

Assessment				
2. Team Antibiotic Review Form	333	5,994	\$98.83 ^a	\$592,387
3. SOPS				
a. HSOPS	4,167	4,167	\$27.87 ^b	\$116,134
b. NHSOPS	4,167	4,167	\$27.87 ^b	\$116,134
c. MOSOPS	4,167	4,167	\$27.87 ^b	\$116,134
4. Semi-structured qualitative interviews (Physicians - line 1; Other Health Practitioners - line 2)	30	60	\$98.83 ^a	\$5,930
	60	120	\$27.87 ^b	\$3,344
5. EHR data	500	3,000	\$27.87 ^b	\$83,610
Total	13,924	21,875	N/A	1,053,439

National Compensation Survey: Occupational wages in the United States May 2016 “U.S. Department of Labor, Bureau of Labor Statistics:” http://www.bls.gov/oes/current/oes_stru.htm

^a Based on the mean wages for 29-1069 Physicians and Surgeons, All Other

^b Based on the mean wages for 29-9099 Miscellaneous Health Practitioners and Technical Workers: Healthcare Practitioners and Technical Workers, All Other

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.

Sharon B. Arnold

Deputy Director

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