EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate *	Total cost burden
Total	N/A	N/A	N/A	26,572

* Mean hourly wage of $57.89 for Medical and Health Services Managers (SOC code 11–9111) was obtained from the May 2017 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000—Hospitals, located at *http://www.bls.gov/oes/current/naics3_622000.htm.*

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's 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.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2019–12312 Filed 6–10–19; 8:45 am]

BILLING CODE 4160–90–P

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.*'' In accordance with the Paperwork Reduction Act, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on April 1, 2019 and allowed 60 days for public comment. AHRQ did not receive 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 on or before 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

The AHRQ Safety Program for Improving Antibiotic Use

The Agency for Healthcare Research and Quality (AHRQ) requests to revise and extend the currently approved *AHRQ Safety Program for Improving Antibiotic Use.* The AHRQ Safety Program for Improving Antibiotic Use (the ''AHRQ Safety Program'') aims to help facilities implement antibiotic stewardship programs and to reduce unnecessary antibiotic prescribing. The AHRQ Safety Program has already been implemented in a pilot of integrated delivery systems and a national cohort of 400 acute care hospitals, and is currently being implemented in a national cohort of 500 long-term care facilities. The AHRQ Safety Program was last approved by OMB on September 25, 2017 and will expire on September 30, 2020. The request for extension is to allow for completion of activities and data collection in the AHRQ Safety Program, which are scheduled to occur through March 30, 2021. The OMB control number for the AHRQ Safety Program is 0935–0238. All of the supporting documents for the current AHRQ Safety Program can be downloaded from OMB's website at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201707-0935-003.*

The 2017 OMB clearance included one response for the Structural Assessment and the *Medical Office Survey on Patient Safety Culture (MOSOPS),* but did not include electronic health record (EHR) data or a second response for the Structural Assessment or MOSOPS for the 4th cohort planned for ambulatory settings. This was because the original OMB clearance expiration date fell in the middle of the planned 4th cohort, so the second Structural Assessment and MOSOPS were not within the approved information collection period, and EHR data collection would have been incomplete. In addition, the project team was not certain that the ambulatory care practices would be able to access EHR data. Based on the experience of the pilot cohort, however, it is believed that many ambulatory practices can access these data, and that these practices are more likely to feasibly participate in the AHRQ Safety Program. The revision also updates the estimated annual burden accordingly, and includes changes to the data collection forms which will be used for the ambulatory care cohort based on lessons learned during the pilot cohort.

Background for This Collection

As part of the Department of Health and Human Services (DHHS) Hospital Acquired Infection (HAI) National Action Plan (NAP), AHRQ has supported the implementation and adoption of the Comprehensive Unit-based Safety Program (CUSP) to reduce Central-Line Associated Bloodstream Infections (CLABSI) and Catheter-Associated Urinary Tract Infections (CAUTI), and subsequently applied CUSP to other clinical challenges, including reducing surgical site infections and improving care for mechanically ventilated patients. As part of the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB NAP) to increase antibiotic stewardship (defined as organized efforts to promote the judicious use of

antibiotics) across all healthcare settings, AHRQ is applying the principles and concepts that have been learned from these HAI reduction efforts to antibiotic stewardship (AS).

Antibiotic therapy has saved countless lives over the past several decades. However, bacterial resistance to antibiotics has followed closely on the heels of each new agent's introduction. This has led to an epidemic of antibiotic resistance, with drug choices for some bacterial infections becoming increasingly limited, expensive, and in some cases nonexistent. While antibiotics remain a vital and necessary cornerstone to the treatment of infections, it is estimated that 20–50% of all antibiotics prescribed in U.S. acute care hospitals are either unnecessary or inappropriate. When antibiotics are used inappropriately, bacterial development of resistance is supported in the *absence* of any therapeutic benefit, and patients receiving unnecessary or inappropriate antibiotics are also exposed to the risk of adverse effects such as rash or renal injury as well as the risk of *Clostridioides difficile* infection which can cause a deadly diarrhea. Unlike misuse of other medications, the misuse of antibiotics can adversely impact the health of patients who are not even exposed to them because of the potential for spread of resistant organisms. The Centers for Disease Control and Prevention (CDC) estimates that each year at least two million illnesses and 23,000 deaths are caused by drug-resistant bacteria in the United States alone.

While approaches including development of new antibiotic agents, increased surveillance for antibiotic resistance, prevention of HAIs, and prevention of transmission of resistant infections are important efforts to combat antibiotic resistance, it is critical to curb the inappropriate use of antibiotics to slow the emergence of antibiotic resistance and to preserve efficacy of existing antibiotics and those under development.

As of January 1st, 2017, The Joint Commission (TJC)'s new Antimicrobial Stewardship Standard requires that all acute care hospitals have robust antibiotic stewardship programs. In addition, starting on November 28, 2017, the Centers for Medicare & Medicaid Services (CMS) required that all long-term care facilities that receive reimbursement from CMS have antibiotic stewardship programs in place.

The Comprehensive Unit-Based Safety Program (CUSP), developed at the Armstrong Institute at Johns Hopkins University, combines improvement in patient safety culture, teamwork, and communication together with a technical bundle of interventions to improve patient safety. CUSP is a powerful culture change tool, which has been successfully utilized to reduce CLABSI in ICUs in Michigan and Rhode Island and subsequently to reduce CLABSI by 41% in more than 1,000 ICUs in 44 states, Puerto Rico and the District of Columbia. Although evidence-based recommendations for prevention of CLABSI had existed for years, the combination of safety culture change on units and implementation of technical interventions resulted in significant reductions in CLABSI and introduced the concept that a rate of zero CLABSIs is achievable. CUSP is also being used to reduce other HAIs in multiple settings (*http://www.ahrq.gov/professionals/quality-patient-safety/hais/index.html*).

This project will assist hospitals, nursing homes, and ambulatory care sites across the United States in adopting and implementing AS programs and interventions.

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 CUSP model to enhance antibiotic stewardship efforts in the health care settings
- 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 and families surrounding antibiotic decision-making
- Conduct a comprehensive evaluation to assess the adoption of the CUSP for AS in acute care, long-term care and ambulatory care settings to identify the effectiveness of the program, process outcomes, and lessons learned

The project will be implemented in four cohorts; (1) Cohort 1 is a pilot limited to 10 facilities each in three integrated delivery systems spanning acute care, long-term care, and ambulatory settings; (2) Cohort 2 will expand to include 250–500 acute care hospitals; (3) Cohort 3 will include 250–500 long-term care facilities; and (4) Cohort 4 will include 250–500 ambulatory care facilities.

The AHRQ Safety Program 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 the AHRQ Safety Program, the following data collections will be implemented:

(1) *Structural Assessments:* A brief, eight question, online Structural Assessment Tool will be administered at baseline (pre-intervention) and at the end of the intervention period to obtain general information about facilities and stewardship infrastructure and changes to stewardship infrastructure and interventions that are anticipated to be sustained as a result of the AHRQ Safety Program *(one response per facility for the 4th cohort in ambulatory settings was included in the original OMB review, this revision adds an additional response per facility, relevant changes made to line 1.b. in Exhibits A.1. and A.2.).*

(2) *Team Antibiotic Review Form:* The Stewardship Team in hospitals and nursing homes 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 can be summarized as: (1) Is an infection present requiring antibiotics? (2) Are appropriate cultures being ordered and is the most optimal initial choice of antibiotics being prescribed? (3) (after at least 24 hours) Is it appropriate to make changes to the antibiotic regimen (*e.g.,* stop therapy, narrow therapy, change from intravenous to oral therapy)? (4) What duration of therapy is appropriate?

(3) *The AHRQ Surveys on Patient Safety Culture:* The appropriate versions of these surveys and the MOSOPS 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. The surveys will be administered to all participating staff at

the beginning and end of the intervention. *(One response per respondent for the 4th cohort in ambulatory settings was included in the original OMB review, this revision adds an additional response per respondent, relevant changes made to line 3.d. in Exhibits A.1. and A.2.).*

a. The *Hospital Survey on Patient Safety Culture (HSOPS)* will be utilized to evaluate safety culture for acute care hospitals.

b. The *Nursing Home Survey on Patient Safety Culture (NHSOPS)* will be administered in long-term care.

c. The *Medical Office Survey on Patient Safety Culture (MOSOPS)* will be administered in ambulatory care centers.

(4) *Semi-structured qualitative interviews:* During the project pilot period with Cohort 1, 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 therapy prescriptions and antibiotic use for diagnosed respiratory conditions will be extracted from the Electronic Health Records (EHRs) of participating units and used to assess the impact of the AHRQ Safety Program. *(4th cohort in ambulatory settings portion is new from original OMB review, noted in line 6 in Exhibits A.1. and A.2.).*

Estimated Annual Respondent Burden

Exhibit A.1 shows the estimated annualized burden hours for the respondents' time to complete the Structural Assessments, Team Antibiotic Review Forms, AHRQ Patient Safety Culture Surveys, semi-structured qualitative interviews, and EHR data extractions. Data will be collected from 30 acute care, long-term care, and ambulatory care sites during the Cohort 1 one-year pilot period; up to 500 acute care hospitals in Cohort 2; up to 500 long-term care facilities in Cohort 3; and up to 500 ambulatory care sites in Cohort 4. With this revision, the total estimated annualized burden hours for the data collection activities are 27,064.

EXHIBIT A.1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
1. Structural Assessments:				
a. Structural Assessments—Cohorts 1, 2 and 3 (baseline, post-intervention)	343	2	0.2	137
b. Structural Assessments—Cohort 4 (baseline and endline)	167	2	0.2	67
2. Team Antibiotic Review Form (Cohorts 1, 2, and 3)	337	90	0.25	7,583
3. AHRQ Patient Safety Culture Surveys:				
a. HSOPS, NHSOPS, MOSOPS (Cohort 1)	83	2	0.5	83
b. HSOPS (Cohort 2)	4,167	2	0.5	4,167
c. NHSOPS (Cohort 3)	4,167	2	0.5	4,167
d. MOSOPS (Cohort 4)	4,167	2	0.5	4,167
4. Semi-structured qualitative interviews (Cohort 1):				
a. Physicians	30	2	1	60
b. Other Health Practitioners	60	2	1	120
5. EHR data (Cohorts 1, 2, and 3)	334	12	1	4,008
6. EHR data (Cohort 4)	167	15	1	2,505
Total	14,022	.....	.....	27,030

Exhibit A.2 shows the estimated annualized cost burden based on the respondents' time to complete the data collection forms. The total cost burden is estimated to be $1,311,096.

EXHIBIT A.2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
1. Structural Assessments:				
a. Structural Assessments—Cohorts 1, 2 and 3 (baseline, post-intervention)	343	137	[a] $98.83	$13,540
b. Structural Assessments—Cohort 4 (baseline and endline)	167	67	[a] 98.83	6,622
2. Team Antibiotic Review Form (Cohorts 1, 2, and 3)	337	7,583	[a] 98.83	749,428
3. AHRQ Patient Safety Culture Surveys:				
a. HSOPS, NHSOPS, MOSOPS (Cohort 1)	83	83	[b] 27.87	2,313
b. HSOPS (Cohort 2)	4,167	4,167	[b] 27.87	116,134
c. NHSOPS (Cohort 3)	4,167	4,167	[b] 27.87	116,134
d. MOSOPS (Cohort 4)	4,167	4,167	[b] 27.87	116,134
4. Semi-structured qualitative interviews (Cohort 1):				
a. Physicians	30	60	[a] 98.83	5,930

EXHIBIT A.2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
b. Other Health Practitioners	60	120	[b] 27.87	3,344
5. EHR data (Cohorts 1, 2, and 3)	334	4,008	[b] 27.87	111,703
6. EHR data (Cohort 4)	167	2,505	[b] 27.87	69,814
Total	14,022	27,064		1,311,096

* 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's 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.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2019–12306 Filed 6–10–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–E–6741 and FDA–2018–E–0046]

Determination of Regulatory Review Period for Purposes of Patent Extension; BAXDELA IV INJECTION—NDA 208611

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for BAXDELA IV INJECTION under new drug application (NDA) 208611 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 12, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 9, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 12, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 12, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2017–E–6741 and FDA–2018–E–0046 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; BAXDELA IV INJECTION.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9