ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden response (in hours)	Total burden (in hours)
Fellowship applicants	1122	1	40/60	748
Fellowship alumni	454	1	15/60	114
Total	1576			862

Dated: September 23, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–24479 Filed 9–29–10; 8:45 am]

BILLING CODE 4163–18–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: "Reduction of Clostridium difficile Infections in a Regional Collaborative of Inpatient Healthcare Settings through Implementation of Antimicrobial Stewardship." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on July 23, 2010 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 November 1, 2010.

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 e-mail 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 e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Reduction of Clostridium Difficile Infections in a Regional Collaborative of Inpatient Healthcare Settings Through Implementation of Antimicrobial Stewardship

Healthcare Acquired Infections (HAIs) caused almost 100,000 deaths among the 2.1 million people who acquired infections while hospitalized in 2000, and HAI rates have risen relentlessly since then. Alarmingly, 70% of HAIs are due to bacteria that are resistant to commonly used antibiotics (Huang 2007). This project is designed to evaluate the implementation of a program to reduce Clostridium difficile Infection (CDI) in acute care facilities via Antimicrobial Stewardship Programs (ASPs). Working with an already existing collaborative network of acute care facilities in New York that currently collect and report mandatory data on CDI rates and practice strict environmental controls, this project will go beyond environmental strategies in order to attempt to reduce rates of CDI. ASPs seek to promote the appropriate use of antimicrobials via several methods including selecting the appropriate dose, duration and route of administration of antibiotics. Using antibiotics appropriately can potentially improve efficacy, reduce costs, and keep drug-related adverse events to a minimum. The project is a partnership with Boston University School of Public Health (BUSPH), Montefiore Medical Center (MMC), and Greater New York Hospital Association (GNYHA).

The overall aims of the research are to evaluate the implementation of ASPs specific to CDI at 11 participating hospitals (6 intervention sites and 5 control sites) and to create a draft ASP Toolkit. More specifically, the pilot study has been designed to provide information to meet the following objectives:

1. Identify the antimicrobial stewardship activities, both currently in place and those yet to be identified, specific to each site's individual needs, to optimize antimicrobial prescribing practices to reduce CDI.
2. Assess prescriber perceptions related to ASP.
3. Assess barriers and facilitators to ASP implementation.
4. Develop a draft ASP Toolkit to help hospitals optimize their antimicrobial prescribing practices to reduce CDI.

New York (NY) State currently requires ongoing reporting of C-difficile data for both clinical and surveillance purposes. As part of an arrangement with NY State, the Greater New York Hospital Association (GNYHA) also collects and analyzes these data through their CDI collaborative. These data include tracking baseline rates of CDI, including pharmacy data, data related to rates of CDI, patient outcomes, and data about infection control practices (such as hand-washing and other environmental controls to prevent spread of infection). The data are collected on standardized forms that are required by both the state and the Centers for Disease Control and Prevention (CDC). The data collected at these participating hospitals are also collected at multiple hospitals nationwide as part of routine patient care and quality. In addition to new data collections initiated specifically for this project, this routine and ongoing mandatory data collection will serve as the project's knowledge base to allow the assessment of ASP programs.

From the GNYHA data, a three-month sample from the participating hospitals will be analyzed by Montefiore Medical Center (MMC) and GNYHA to obtain baseline information. This data will enable a comparison of the rates of CDI before and after the implementation of an ASP. The ASP will be implemented at 6 hospitals (intervention sites), while 5 other hospitals will serve as control sites and continue with their current practices, including conducting general

infection and environmental controls. The specific elements of the ASPs will vary by hospital based on priorities and what is possible at each facility as well as by the antibiotic(s) targeted and will likely include some of the following:

- Formulary review/changes, restrictions and preauthorization of implicated antimicrobials.
- Feedback to providers of implicated antimicrobials.
- Processes and algorithms for empiric and streamlined regimens for Specific diagnoses/pathogens.
- Antibiotic order form with automatic stop orders.
- Novel combinations of approaches to the use of stewardship staff or technology for stewardship (*e.g.,* software, text paging, pyxis pharmacy machines for tracking and promoting proper antibiotic prescribing), and
- Educational efforts for clinicians and patients upon diagnosis.

While the ongoing mandatory reporting will allow the measurement of change over time in CDI rates, it does not provide the necessary information that hospitals need about the challenges of implementing an ASP.

Method of Collection

The following data collection activities will be implemented to achieve the objectives of this project:

1. Focus Groups with no more than 6 staff members at the intervention and control hospitals. The focus groups will be conducted one time only, by telephone and approximately 12 months after the implementation begins. The focus group guides will differ for the intervention and control sites, although there will be a common core of questions. The common core of the focus group protocol will address the following: Issues related to experience with the GNYI–L& environmental and infection control practices they have already been utilizing, strategies they have already used to reduce CDI and perceptions of those strategies, barriers to the environmental practices, particular areas of challenge, facilitators, and factors they think have contributed most to their institution's CDI rates. For the intervention sites, the goal of the focus group will be to understand in a more in-depth and qualitative manner, the experience of actually implementing the ASP. For the control sites, the goal will be to understand what they have learned in being a control site and their plans moving forward. In addition to the core questions, questions will be asked about their interest in starting an ASP program, goals and priorities, expectations of facilitators and barriers and if and when they plan to implement an ASP.

2. ASP Questionnaire will be administered twice, pre and post implementation, to a sample of about 70 hospital staff at both the intervention and control hospitals. Intervention and control facilities will receive the same questionnaire. The purpose of this survey is to measure the staff's perception of the scope of CDI at their facility, current antibiotic prescribing practices, the perceived need for ASPs and how these change over time. The questionnaire also collects some background information such as the staff members' primary work area, time worked in their profession and time worked in this hospital.

While the reporting/surveillance data required by the State of NY and the CDC can measure rates of CDI and compare how hospitals are doing, these data do not capture many important issues. A major reason that most hospitals do not have active, robust ASPs is because they can be incredibly challenging to develop, administer and manage. They require changes in prescribing practices and the active agreement and participation of physicians, pharmacists and administrators. Physicians and pharmacists may challenge restrictions in formularies and determine that a patient may not be given a specific antibiotic. But the severity of CDI makes it very important for hospitals to determine optimal methods for implementing successful ASPs. This pilot study will collect data to allow the comparison of perceptions and experiences between hospitals that do and do not attempt to implement an ASP. Reflections and feedback directly from prescribers and the ASP team using qualitative data collection procedures are needed to fully understand what it means or would mean to implement an ASP. The lessons learned from this project will be useful to health care facilities considering implementing an ASP, and will inform the development of a draft ASP Toolkit; this Toolkit will be evaluated in a separate project before being disseminated.

This study is being conducted by AHRQ through its contractor, BUSPH and their partners Montefiore Medical Center (MMC), and Greater New York Hospital Association (GNYHA), 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).

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this pilot study. Focus Groups will be conducted post-intervention with approximately 6 staff members at each of the 11 study sites (5 control sites and 6 intervention sites) for a total of 66 individuals, approximately 36 at the intervention sites and approximately 30 at the control sites. The control site focus groups will last approximately 45 minutes. The intervention site focus groups will last approximately 60 minutes.

The ASP questionnaire will be administered twice, pre and post-intervention, to about 70 staff members at each of the 11 participating sites and takes about 7 minutes to complete. The total annualized burden is estimated to be 239 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this study. The total cost burden is estimated to be $15,037.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of hospitals	Number of responses per hospital	Hours per response	Total burden hours
Focus groups at intervention sites	6	6	1	36
Focus groups at control sites	5	6	45/60	23
ASP Questionnaire	11	140	7/60	180
Total	22	n/a	n/a	239

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of hospitals	Total burden hours	Average hourly wage rate*	Total cost burden
Focus groups at intervention sites	6	36	$57.38	$2,066
Focus groups at control sites	5	23	57.38	1,320
ASP Questionnaire	11	180	64.73	11,651
Total	22	239	n/a	15,037

* The hourly wage for the focus groups is based upon the mean of the average wages for physicians ($79.33), pharmacists ($50.13), and medical and health services managers ($42.67). The hourly wage for the surveys is based upon the average wages for physicians ($79.33) and pharmacists ($50.13). These data come from the May 2008 National Occupational Employment and Wage Estimates, United States,—U.S. Bureau of Labor Statistics Division of Occupational Employment Statistics, May 2008, National Occupational Employment and Wage Estimates, *http://www.bls.gov/oes/2008/may/oes_nat.htmb#11-0000.*

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the annualized and total cost to the federal government for this two year research project. Project Management includes activities related to coordination between BUSPH staff, contracted staff at MMC and GNYIIA, and monthly phone calls with the task order officer. Project development covers steps taken to revise the research plan and begin implementation. The total cost is estimated to be $999,995.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST TO THE GOVERNMENT

Cost component	Annualized cost	Total cost
Project Management	$28,315	$56,629
Project Development	84,944	169,400
Data Collection and Analysis	169,888	339,776
Technical Assistance and Consultation	60,750	121,500
Confirmatory lab testing	20,000	40,000
Travel	7,500	15,000
Project Supplies and materials	2,450	4,900
Overhead	126,395	252,790
Total	499,998	999,995

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, 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: September 17, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–24423 Filed 9–29–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0374]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 1, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0608. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed