Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Benefit Plan; *Use:* Section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added sections 1860D–1 through D–42 to establish this new program. Part D plans use the information discussed to comply with the eligibility and associated Part D participating requirements. CMS will use this information to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and to ensure that correct information is disclosed to enrollees, both potential enrollees and enrollees. *Form Number:* CMS–10141 (OMB#: 0938–0964); *Frequency:* Yearly; *Affected Public:* Individuals and households, and business or other for-profit and not-for-profit institutions; *Number of Respondents:* 19,937,660; *Total Annual Responses:* 43,153,271; *Total Annual Hours:* 36,520,101. (For policy questions regarding this collection contact Christine Hinds at 410–786–4578. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Consumer Assessment of Health Care Providers and Systems (CAHPS); *Use:* CMS is required to collect and report information on the quality of health care services and prescription drug coverage available to persons enrolled in a Medicare health or prescription drug plan under provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Specifically, the MMA under Sec. 1860D–4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding Medicare prescription drug plans and Medicare Advantage plans and report this information to Medicare beneficiaries prior to the Medicare annual enrollment period. The Medicare CAHPS survey meets the requirement of collecting and publicly reporting consumer satisfaction information. Refer to the supporting documents to review the current collection changes. *Form Number:* CMS–R–246 (OMB#: 0938–0732); *Frequency:* Yearly; *Affected Public:* Individuals and households, and business or other for-profit and not-for-profit institutions; *Number of Respondents:* 567,324; *Total Annual Responses:* 567,324; *Total Annual Hours:* 242,376. (For policy questions regarding this collection contact Elizabeth Goldstein at 410–786–6665. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage: *Use:* Section 1860D–4(g)(1) of the Social Security Act requires Part D plan sponsors that deny prescription drug coverage to provide a written notice of the denial to the enrollee. The purpose of this notice is to provide information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process. For a list of changes, refer to the summary of changes document. *Form Number:* CMS–10146 (OMB#: 0938–0976); *Frequency:* Daily; *Affected Public:* Business or other for-profits; *Number of Respondents:* 456; *Total Annual Responses:* 290,344; *Total Annual Hours:* 145,172. (For policy questions regarding this collection contact Kathryn M. Smith at 410–786–7623. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Detailed Explanation of Non-Coverage (42 CFR 422.626(e)(1)), and Notice of Medicare Non-Coverage (42 CFR 422.624(b)(1)); *Use:* Under section 42 CFR 422.624 (b)(1), skilled nursing facilities (SNFs), home health agencies (HHAs), and comprehensive outpatient rehabilitation facilities (CORFs) must deliver to Medicare health plan enrollees a 2-day advance notice of termination of services. Per requirements at 42 CFR 422.626(e)(1), plans must deliver detailed notices to the Quality Improvement Organization (QIO) and enrollees whenever an enrollee appeals a termination of services. The Notice of Medicare Non-Coverage (NOMNC) and the Detailed Explanation of Non-Coverage (DENC) fulfill these regulatory requirements. Additionally, 42 CFR 417.600(b) provides that cost plans must follow these same fast track appeal notification procedures for their enrollees in SNFs, HHAs and CORFs. Refer to the crosswalk document for a list of changes. *Form Number:* CMS–10095 (OMB#: 0938–0910); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 25,655; *Total Annual Responses:* 100,785; *Total Annual Hours:* 45,353.25 (For policy questions regarding this collection contact Stephanie Simons at 206–615–2420. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *August 23, 2010.* OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer; Fax Number: (202) 395–6974; E-mail: *OIRA_submission@omb.eop.gov.*

Dated: July 19, 2010.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–17898 Filed 7–22–10; 8:45 am]

BILLING CODE 4120–01–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.

DATES: Comments on this notice must be received by September 21, 2010.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports clearance Officer, AHRQ, by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

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-[A] 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	237	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.htm#b11–0000.*

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 GNYHA, 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: July 9, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–17796 Filed 7–22–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease

Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (BSC, NCEH/ATSDR): Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry, of the Department of Health and Human Services, has been renewed for a 2-year period extending through May 21, 2012.

For further information, contact Paula Burgess, M.D., Ph.D., Designated Federal Officer, BSC, NCEH/ATSDR, 1600 Clifton Road, NE, Mailstop E–28, Atlanta, Georgia 30333, telephone 404/488–0574, e-mail.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 15, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–18063 Filed 7–22–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0347]

International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 13 on Bulk Density and Tapped Density of Powders General Chapter; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 14, 2010 (75 FR 40843). The document announced the availability of a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 13: Bulk Density and Tapped Density of Powders General Chapter." The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Planning and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3208, Silver Spring, MD 20993–0002, 301–796–9148.

SUPPLEMENTARY INFORMATION: In FR Doc. 2010–17055, appearing on page 40843 in the **Federal Register** of Wednesday, July 14, 2010, the following correction is made:

On page 40843, in the first column, in the headings section of the document, "[Docket No. FDA–2010–N–0344]" is corrected to read "[Docket No. FDA–2010–D–0347]".

Dated: July 20, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–18119 Filed 7–22–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Administration for Children and Families

Maternal, Infant, and Early Childhood Home Visiting Program

AGENCY: Health Resources and Services Administration and Administration for Children and Families, HHS.

ACTION: Request for public comment on criteria for evidence of effectiveness of home visiting program models for pregnant women, expectant fathers, and caregivers of children birth through kindergarten entry.

SUMMARY: The Health Resources and Services Administration and