SUPPORTING STATEMENT

Part A

Consumer Research on Public Reporting of Hospital Quality Measures

Version 4
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Division of Consumer Assessment & Plan Performance (DCAPP)
Centers for Medicare & Medicaid Services (CMS)

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A. Background

One of the primary missions of the Centers for Medicare & Medicaid Services (CMS) is to improve the quality and efficiency of care in the Fee-for-Service (FFS) program. One of the several vehicles used for this mission is the public reporting of quality, efficiency and cost information about hospital care on the *Hospital Compare* website. This vehicle also serves to provide Medicare beneficiaries and other consumers with the type of data needed to make informed decisions about which providers (in this case, hospitals) to use for their care.

Addition of New Quality Information

Organization and Display of New Quality Measures

CMS often adds important new information about quality of care provided in hospitals on the *Hospital Compare* website. As new quality measures are added, the website programmers are faced with deciding how to best integrate the new information into the existing website so that it can be easily accessed and understood by consumers. In 2011, CMS will be adding several new measures to *Hospital Compare.* These new measures will introduce new topics and concepts for consumers and will also use new types of data, than what currently exists on the website. New topics will include: individual measures and composite measures around patient safety, hospital acquired conditions and healthcare associated infections; individual measures around timelines of care provided in the emergency department; and individual and composite measures around the effectiveness of care for heart attack, heart failure, and surgical care. The addition of these new measures raises concern for CMS in how consumers will interpret and be able to use the information. To address these concerns CMS would like to conduct formative research with consumers around the most effective way to incorporate this new information into the website.

Healthcare Associated Infections and Hospital Acquired Conditions

As mentioned above, CMS plans to add new quality information to the *Hospital Compare* in 2011. Some of that information will include patient safety measures in the area of hospital-acquired conditions (HACs). The introduction of this information comes on the heels of recent legislation around Medicare reimbursement for hospital care. Specifically, the Deficit Reduction Act (DRA), which was signed in February of 2006, contains language creating a system for quality adjustment of Medicare payments for inpatient hospital services. The law required the Secretary of Health and Human Services (HHS) to identify at least two hospital-acquired conditions (HAC) which could have reasonably been avoided through the application of evidence based guidelines and would be subject to the adjustment in payment. On July 31, 2008, in the Inpatient Prospective Payment System (IPPS) Fiscal Year (FY) 2009 Final Rule, CMS included 10 categories of conditions that were selected for HAC payment provision. Similarly, based on HHS' priority on reducing Healthcare Associated Infections (HAIs), CMS published its final rule in July 2010 for Medicare reimbursement for hospitals, which included the provision that hospitals would start reporting certain HAIs. This reporting will be a part of the CMS Hospital Inpatient Quality Reporting Program, an initiative

intended to equip consumers with quality of care information to make more informed decisions about their health care, while encouraging hospitals and clinicians to improve the quality of inpatient care provided to all patients.

Consumer Research

Prior to publicly reporting new information in 2011, CMS proposes to conduct consumer research to ensure that the information is presented in a way that is consumer friendly and understandable for consumers to use when making health care decisions. CMS has contracted to conduct exploratory or formative research around how to best organize and display the new quality information, to assist CMS in developing consumer friendly displays of the information and to gather individual feedback about some of the specific measures to be added to *Hospital Compare*, using intensive individual interviews.

Formative/Exploratory Research

Given that the information presents new concepts around healthcare associated infections (HAIs) and hospital acquired conditions (HACs), information which does not currently exist on *Hospital Compare*, CMS proposes to conduct a round of formative research to explore consumers' perceptions, knowledge and understanding of this new topic and to also explore options for effectively integrating the new information into the website, through the existing organizational scheme or potentially through a revised schema. The research team will conduct the exploratory research using focus groups. Focus groups are an effective tool for eliciting individuals' perspectives and examining the differences in their opinions and reactions. Focus groups will allow the research team to gather baseline information from a cross section of potential users, get multiple points of view at one time, and stimulate discussion regarding perceptions and attitudes around the topics, and explore options for language, display, and navigation through group discussion and brainstorming.

Specifically, the research team conducted a series of focus group discussions with consumers and informal caregivers (in particular, family members or friends who help care for Medicare beneficiaries). The consumer participants will range in age from 40 to 70 years of age and will include persons with a mix of hospital experience (persons who have had a recent hospital stay and persons who anticipate a hospital stay in the near future); the informal caregiver participants will range in age from 18 to 70 years of age and help care for persons who have had a mix of hospital experience.

Intensive Individual Interviews

Subsequent to the exploratory or formative research, the research team proposes to design and gather feedback about mock data displays and explanatory language for the new quality and safety measures using intensive individual interviews. The interviewer, for example, will show subjects one of the new HAC and HAI measures, such as Central Line-Associated Bloodstream Infections (CLABSI). The interviewer will explore how the research subjects cognitively approach the topic of HAIs/HACs, how salient the information is to their healthcare decisions, and how they react to the new information. In particular, the

interviewer will look for misinterpretations, unintended reactions or confusion, and changes to the display or language that might improve them.

The goal of gathering such individual feedback about the mock-ups will be to determine how to best integrate the new information into the existing website using the display devices similar to those used for extant measures, while presenting the information clearly and in such a way that consumers can draw accurate and useful inferences from the data.

The team proposes using one-on-one intensive interviews for this research, in order to gain more in-depth feedback from individuals. Intensive individual interviews can yield detailed, more nuanced information because of the focused time and rapport established with an individual. Our team often uses intensive individual interviews to understand how individuals understand, process, and respond to specific materials. We have found that issues related to comprehension or interpretation of complex technical information is better probed in one-on-one settings, as the dynamics of focus groups can make it difficult to tease out variations among individuals. The team will conduct two rounds of intensive individual interviews on the new information, utilizing a second round to fine tune the mock displays and to make useful recommendations to the website programmers.

Specifically, the research team will conduct intensive individual interviews with hospital patient consumers, informal family caregiver consumers and physicians. The hospital patient consumer participants will range in age from 40 to 70 years of age and will include persons with a mix of hospital experience (persons who have had a recent hospital stay and persons who anticipate a hospital stay in the near future); the informal family caregiver consumer participants will range in age from 18 to 70 years of age and help care for persons who have had a mix of hospital experience; and the physician participants will include surgeons, hospital internists, and primary care physicians who commonly refer patients to hospitals. The consumer and physician interviews are considered to be separate information collections, as there will be two separate interview guides.

The purpose of the consumer research will be to gain feedback from subjects who may reflect the population of users of the website, without attempting to definitively determine how any particular population of users would react to and use the site. That is, the team is not attempting to achieve an understanding that can be generalized, but to identify particular issues or concerns that should be avoided in the presentation of the data. Because this study is qualitative, the data collection will employ convenience samples of individuals from different segments of the population. An estimated breakdown of research participants is displayed in exhibit 1.

Exhibit 1.

Research Round/Participant Type	Formative/Exploratory Focus Groups	Intensive Individual Interviews	Follow-up Intensive Individual Interviews
Patient consumers who have	20	6-8	6-8

Research Round/Participant Type	Formative/Exploratory Focus Groups	Intensive Individual Interviews	Follow-up Intensive Individual Interviews
had/anticipate having a hospital stay within the next six months			
Informal family caregivers of patients who have had/anticipate having a hospital stay within the next six months	20	6-8	6-8
Physicians with some knowledge and/or experience with these types of infections	0	6	6
Total Research Participants	40	20	20

We will work with established, reliable market research firms to enlist the necessary participants, providing them tailored screeners for the recruitment process. We have learned from previous experience that engaging the assistance of research firms is advantageous not only for ensuring access to a reliable pool of potential research participants but also for the added benefit of access to facilities designed for conducting qualitative research. We have developed ongoing relationships with several market firms that staff skilled recruiters and project managers, experienced in identifying appropriate research participants, coordinating the research schedule, and providing overall management of the research logistics. These firms maintain large databases of various populations, including healthcare consumers, patients, informal caregivers, and medical professionals. The firms also provide access to in-depth interview and focus group rooms, including one-way mirrors for observing the research. We have developed recruitment screeners that include a detailed script along with specific criteria to use when contacting potential participants. The scripts include screening questions designed to target the specific audience required for this research, including such criteria as gender, age, race and ethnicity, and level of education. Our screening tools also take into account certain exclusion criteria, screening out, for example, individuals who work in the health care industry, to avoid response bias.

For each information collection request, the following data collection tools will be submitted:

1) Recruitment screening forms to be used by the research facilities to match the participant pool to the recruitment goals of the research team (Attachment A);

2) Semi-structured interview protocols for patient consumers, informal family caregivers, and physicians (Attachments B);

3) Mock ups of data displays and narrative content for public reporting of quality and safety measures (Attachment C); and

4) Consent form (Attachment D

This project will support CMS's efforts to understand how diverse populations react to and utilize consumer information. The research shall be conducted in three different sites, to include locations with diverse population characteristics and varying levels of hospital choice. The first information collection will occur in June/July 2011, in order to meet Agency deadlines for adding the new information to *Hospital Compare* by December 2011.

B. Justification

1. Need and Legal Basis

As noted above, CMS is committed to being transparent and to making publicly reported information useful to consumers. The work under this collection of information is needed to insure the new rates of hospital acquired conditions and healthcare-associated infections and other information meet those goals.

2. Information Users

The information that is gathered during the formative research will be used to develop draft displays of the new quality information and accompanying explanatory information for consumer use. The research team will create paper-based mockups of the information to be tested with research participants, during the second and third rounds of research. The information that is collected from those interviews will be used to revise mockups of displays and explanatory language for a final round of consumer testing. Areas of concern identified during consumer testing will be presented with options and pros and cons for leadership decision-making in a research report. For example, if two different display options have both advantages and disadvantages, the report describing results of this research shall attempt to provide leadership with a basis for making a decision. The format of the report will include screenshots and detailed instructions to help website programmers accurately implement the recommendations.

Each research participant will participate in one focus group or one intensive individual interview session. Once the interview data are collected, they will be transcribed. A process of qualitative analysis will be used to identify common themes across multiple audiences. Transcripts, video and audio recordings will be reviewed to insure that no biases were introduced (e.g., from leading questions) and that alternate interpretations of the data are considered.

3. Use of Information Technology

This data collection will utilize digital recording technology to collect, store, and manage the interview data. The research team has established procedures for ensuring the protection of confidentiality for participants who have contributed personal information to a study, including removing all names from the interview notes and assigning each participant a code or pseudonym and removing major identifying details, such as participants' surnames and

addresses, from any notes or records obtained from the screening process. Also, all of the data will be destroyed within a period of one year after the research team has completed the final report.

4. Duplication of Efforts

An extensive review of the literature will be conducted prior to commencing the consumer research. Most of the information is new to public reporting and/or has not been reported as quality information. Hence, while prior research provides some guidance on how to present these data, additional research is needed to insure the data are accurately interpreted and effectively used.

5. Small Businesses

There may be a limited number of physician participants who may own or work for a small physician practice. Overall, however, this information collection does not involve or impact small businesses or other small entities.

6. Less Frequent Collection

This is a one-time data collection.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

A Federal Register Notice was posted in November, 2010. CMS has committed itself to publicly reporting new hospital quality information on *Hospital Compare* when it updates the website in January 2012. Workflows for measure developers and website programmers require that consumer testing recommendations be available in July 2011 to meet this deadline.

Therefore, CMS published the Federal Register notice in November 2010, for a 60-day comment period, prior to submission to OMB. The team did not receive public comments in response to that notice. The team then completed a revised signature package, based on updates from internal measurement and policy experts. The team published the revised package in the Federal Register in February 2011, for a 30-day comment period. The team did not receive any additional comments received during the 30-day comment period.

A stakeholder workgroup was convened by the contractor research team in March 2011 to obtain feedback on the research approach from a diverse set of stakeholders. This workgroup consisted of representatives of consumer advocacy organizations, hospital associations, physicians, foundations that support public reporting of healthcare quality and quality improvement, business associations, insurers and other purchasers. The contractor research

team will consider feedback received from the workgroup as they provide CMS with feedback.

9. Payments/Gifts to Respondents

Intensive individual interview subjects will receive a stipend, based on the rates set by OMB. These rates are currently set at 40 dollars for an hour long interview with consumers and 75 dollars for professionals. As the professionals being sought are physicians representative of clinicians in a community, CMS may request a higher stipend rate from OMB to avoid recruiting a biased sample.

10. Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose.

Information that can directly identify the respondent, such as name and age, will be collected by the research facilities. However, only the age and first name of each participant shall be passed on to the CMS research contractor. Participant confidentiality will be protected by de-identifying audio data upon transcription. All data will be stored on encrypted and password protected files. Data will only be presented in aggregate and de-identified format. Only the principal investigator and research staff necessary to conduct research will have access to the data. All research data is maintained in locked cabinets within a locked data storage area. All electronic files are password and encryption protected. All activities stated in this project will be performed in concordance with the Health Insurance Portability and Accountability Act (HIPPA) Privacy Rule, 45 CFR Parts 160 and 164. Informed consent will be obtained from all who participate in the semi-structured interviews. (See Attachment D).

11. Sensitive Questions

Interviews will be conducted in private with an individual focus group moderator or interviewer and will focus on soliciting feedback on the quality information and measure displays, rather than on any personal or sensitive information. However, interviewees appearing distressed or confused by the interview shall be provided any additional information or a referral to medical or counseling help as needed. Interviewees who wish to investigate CMS consumer information further will be given links and/or phone numbers as necessary.

12. Burden Estimates (Hours & Wages)

Over the course of the project, CMS anticipates screening 120 individual for 5 minutes with phone calls to schedule 60 individuals for interviews and focus groups. Forty (40) consumer individuals will participate in 1 ½ hour focus groups, 14 consumers and 6 physicians will participate in 1 ½ hour intensive individual interviews. The burden estimates in terms of

hours and costs that are anticipated over the course of the project are listed below. Detailed estimates for each information collection will be provided at the time each is submitted.

Exhibit on estimated annualized burden hours

Data Collection Mode	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Screening form	**80**	**1**	**0.083**	**6.64**
***Focus group discussions**	**40**	**1**	**3**	**120**
***Intensive Individual Interviews**	**20**	**1**	**3**	**60**
Total	**140**			**186.64**

* Includes 1.5 hours for research and 1.5 hours assumed time required to travel to and from focus group facility.

Exhibit on estimated annualized cost burden

Data Collection Mode	Number of respondents	Total burden hours	Hourly Stipend	Total cost burden
Screening form	**80**	**6.64**	**$20.90***	**$139**
Focus Group Discussions	**40**	**120**	**$20.90***	**$2508**
Intensive Individual Interviews	**20**	**60**	**$20.90/$105.66***	**$878 + 1902= 2780**
Total	**60**	**186.64**		**$5427**

* Hourly wage based on the mean hourly wage estimates from the *May 2009 National Occupational Employment and Wage Estimates*, U. S. Bureau of Labor Statistics. Provider hourly wage based on mean wage estimates for surgeons from the May 2009 Occupational Employment and Wages, Occupational Employment Statistics, U.S. Department of Labor, Bureau of Labor Statistics.

13. Capital Costs

There are no direct costs to respondents other than their time to participate in the study.

14. Cost to Federal Government

Exhibit 4 shows the estimated cost to the Federal government for this six month project. The total cost is $204,000. This amount includes all direct and indirect costs of the design, data collection, analysis, and reporting phase of the study.

Exhibit 4. Estimated Cost

Cost Component	Estimated Total Cost
Project Development	15,000
Data Collection Activities	75,000
Data Processing and Analysis	24,000
Reporting of Results	15,000
Project Management	15,000

Overhead	60,000
Total	**204,000**

15. Changes in Hour Burden

This is a new collection of information.

16. Publication/Tabulation Dates

Timeline	2010		2011												2012
	Q4		Q1			Q2			Q3			Q4			Q1
	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	
CMS submits OMB "Clearance Package" to OMB	X														
Federal Register Notice (60 day comment period)	X														
CMS revises OMB "Clearance Package" t o OMB			X												
Federal Register Notice (30 day comment period)				X											
Consumers Research									X	X		X			
Publication of data on *Hospital Compare*															X

17. Expiration Date

CMS would like to display the expiration date. It does not seek an exemption.

18. Certification Statement

Not applicable.

ATTACHMENTS that will be provided for each IC

Attachment A – Screening forms

Attachment B – Intensive Individual interview guides

Attachment C – Testing Materials/Mockups

Attachment D – Consent form