SUPPORTING STATEMENT

Part A

Consumer Research on Public Reporting of Hospital Outpatient Measures

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A. Justification

1. Circumstances that make the collection of information necessary

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.

The Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act (MIEA-TRHCA) of 2006, enacted in December of 2006, made changes in the Outpatient Prospective Payment System (OPPS). Consequently, CMS is now statutorily required to establish a program under which hospitals will report data on the quality of hospital outpatient care using standardized measures to receive the full annual update to the OPPS payment rate. This will be effective for payments beginning in calendar year (CY) 2009. The program established under these amendments is the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The measures will expand as additional priority areas for quality improvement in hospital outpatient settings are identified and will be designed to evaluate the diversity of services and clinical topics provided to adult patients in hospital outpatient settings.

In 2010, CMS plans to publicly report new hospital outpatient quality and efficiency measures on the *Hospital Compare* website depending, in part, on the results of consumer testing. These measures include:

Outpatient Acute Myocardial Infarction (AMI) and Chest Pain/Emergency Department (ED)	
OP-1	Median Time to Fibrinolysis
OP-2	Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
OP-3	Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4	Aspirin at Arrival
OP-5	Median Time to ECG
Outpatient Surgery	
OP-6	Timing of Antibiotic Prophylaxis (Prophylactic Antibiotic Initiated Within One Hour Prior to Surgical Incision)
OP-7	Prophylactic Antibiotic Selection for Surgical Patients
Imaging Efficiency	
OP-8	MRI Lumbar Spine for Low Back Pain
OP-9	Mammography Follow-up Rates
OP-10	Abdomen CT - Use of Contrast Material
OP-11	Thorax CT - Use of Contrast Material

The Centers for Medicare & Medicaid Services (CMS) contracted with L&M Policy Research, LLC (L&M) and its subcontractors, Mathematica Policy Research, Inc. (MPR) and McGee & Evers Consulting (M&E), to conduct exploratory or formative research around the new Hospital Outpatient Measures. Concepts and topics were presented to groups of consumers and caregivers, and to individual physicians. A moderator explored how these subjects cognitively approached the topics, what distinctions they drew or failed to draw, and how they would react to and use new measure types (e.g., efficiency). Specifically, the research team conducted a total of four focus group discussions with consumers and caregivers. The consumer participants ranged in age from 40 to 70 years of age and had a mix of experience with outpatient hospital services; the caregiver participants ranged in age from 18 to 70 years of age and provide care for persons who have had a mix of experience with outpatient hospital services. The team also conducted a total of six in-depth interviews with providers, including three primary care physicians, one emergency room doctor, and two radiologists. The research was conducted in Boston, MA on August 12 and 13, 2009.

Subsequent to this exploratory or formative research, the research team designed mock-ups of the planned measures, utilizing feedback from the measure developers, the website programmers, plain language experts, and other CMS staff and contractors. The goals of the mock-ups were to integrate the measures into an existing website using the display devices similar to those used for extant measures, but presenting the measures clearly and in such a way that consumers and professionals could draw accurate and useful inferences from the data. The research team and CMS remain concerned about a number of issues in the displays and would like to conduct additional website research with consumers, caregivers and professionals to fine tune the recommendations to the website owners and programmers. The team proposes to conduct cognitive interviews with mock-ups and protocols in January 2010 in order to meet Agency deadlines for presentation of the data by June 2010.

The purpose of the cognitive interviews is to gain some 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, so much as to be alerted to “landmines” or dangers to 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. These samples include: patients with prior hospital outpatient experience, patients with medical conditions to the hospital outpatient measures, primary care physicians who refer to hospital outpatient departments for services being measured, radiologists, emergency room physicians, and other specialists with some knowledge of the measures or of the services and procedures underlying the measures.

This project consists of the following data collections:

- Recruitment screening forms to be used by the research facility to match the participant pool to the recruitment goals of the research team (see Attachment B);

- Semi-structured interviews with patients, caregivers, radiology technicians, health plan benefit managers, primary care physicians and specialists (see Attachment C).

This project shall support CMS's efforts to understand how racially and ethnically diverse populations react to and utilize consumer information. The research shall be conducted in a location with different population characteristics from the initial exploratory study location (Boston, MA).

2. Purpose and Use of Information

The information that is collected in the interviews will be used to revise mockups (Attachment D) of measure displays. Areas that are of concern from testing will be presented with options and pros and cons for leadership decision-making. 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 participant will participate in one cognitive 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 subjects. 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 Improved Information Technology

This data collection will utilize digital recording technology to collect, store, and manage the interview data. Participants will respond verbally to guiding questions.

4. Efforts to Identify Duplication

An extensive review of the scientific literature was conducted. Some of the outpatient measures are similar to extant inpatient measures and hence will not be studied as intensively. However, most of the measures are new to public reporting and/or have not been reported as outpatient measures. 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. Some of the imaging efficiency measures remain controversial in some circles, so feedback from radiologists and others with an interest in the measures may be needed to address the concerns of clinicians and professionals as well as the needs of patients and consumers.

5. Involvement of Small Entities

This data collection does not involve or impact small businesses or other small entities.

6. Consequences if Information Collected Less Frequently

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

8.a. Federal Register Notice to be added after FR notice

CMS has committed itself to publicly reporting hospital outpatient measures on *Hospital Compare* when it updates the website in June 2010 depending, in part, on the results of this consumer testing. Workflows for measure developers and website programmers require that consumer testing recommendations be available in January 2010 to meet this deadline. Therefore, CMS requests that OMB waive the CFR 1320.8(d) requirement that a Federal Register notice be published in the Federal Register for 60 days prior to OMB consideration. As required in 5 CFR 1320.13, this request is being made for emergency processing because the collection of information is essential to the mission of the Agency and is needed prior to the expiration of time periods established under 5 CFR 1320.8.

The emergency Federal Register notice is scheduled for publication on or about January 5, 2010.

8.b. Outside Consultations

A stakeholder workgroup will be convened by CMS's contractor to obtain feedback on the research approach from a diverse set of stakeholders. This workgroup consists 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.

9. Payments/Gifts to Respondents

Cognitive interview subjects will receive a stipend, with the amount varying depending on the difficulty of recruiting subjects of different characteristics. For example, radiologists and other medical specialists may be particularly challenging to recruit. Consumers, e.g. beneficiaries or caregivers, will receive approximately $65 and professionals will receive $100.

10. Assurance of 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.

Individuals and organizations contacted will be further assured of the confidentiality of their replies under 42 U.S.C. 1306, and 20 CFR 401 and 4225 U.S.C.552a (Privacy Act of 1974). In instances where respondent identity is needed, the information collection will fully comply with all respects of the Privacy Act.

Information that can directly identify the respondent, such as name and age, will be collected by the research facility. 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.

11. Questions of a Sensitive Nature

Interviews will be conducted in private with an individual interviewer and will focus on soliciting feedback on mock-up 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. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in this project. The screening phone call will be experienced by all participants and is expected to take approximately 5 minutes to complete. It is estimated that one-fourth of those called by the research facility will be selected for the research study. Cognitive interviews will last about 1.5 hours for consumers and 1 hour for physicians. The total burden for all participants is estimated to be 41 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondent's time to participate in the project. The total cost is estimated to be $666.

Exhibit 1. Estimated annualized burden hours

Data Collection Mode	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Initial screening	**80**	**1**	**0.083**	**6.64**
Semi-structured interviews with patients and caregivers	**20**	**1**	**1.5**	**30**
Semi-structured interviews with primary care physicians, specialists and technicians	**4**	**1**	**1.0**	**4**
Total	**104**			**~41**

Exhibit 2. Estimated annualized cost burden

Data Collection Mode	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Screening form	**80**	**6.64**	**$10.30**	**$68**
Semi-structured interviews with patients and caregivers	**20**	**30**	**$10.30**	**$309**
Semi-structured interviews with primary care physicians	**2**	**2**	**$77.64**	**$155**
Semi-structured interviews with specialists	**1**	**1**	**$94.99**	**$95**
Semi-structured interviews with radiology technicians	**1**	**1**	**$38.26**	**$38**
Total	**104**	**41**		**$666**

* Patient/county average hourly wage based on the average per capita income of $21,435 (computed into an hourly wage rate of $10.30). Provider hourly wage based on an average of the following estimates from National Compensation Survey: Occupational wages in the United States May 2008, "U.S. Department of Labor, Bureau of Labor Statistics.)

13. Estimates of Annualized Respondent Capital and Maintenance Costs

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

14. Estimates of Annualized Cost to the Government

Exhibit 3 shows the estimated cost to the Federal government for this one month project. The total cost is $68,000. This amount includes all direct and indirect costs of the design, data collection, analysis, and reporting phase of the study.

Exhibit 3. Estimated Cost

Cost Component	Total Estimated Cost
Project Development	5,000
Data Collection Activities	25,000
Data Processing and Analysis	8,000
Reporting of Results	5,000
Project Management	5,000
Overhead	20,000
Total	**$68,000**

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis, and Public Reporting Plans

	2009			2010					
	Q4			Q1			Q2		
	Oct	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**
CMS submits OMB "Clearance Package" to OMB		**X**							
Federal Register Notice			**X**	**X**					
-- Interviews				**X**					
--Analysis and generation of preliminary reports:				**X**					
Publication of measures on *Hospital Compare*									**X**

17. Exemption for Display of Expiration Date

CMS does not seek this exemption.

Attachments:

Attachment A – CMS Authorizing Legislation

Attachment B – Screening form

Attachment C – Cognitive interview guides

1. For patients/caregivers
2. For professionals (e.g. primary care physicians and specialists)

Attachment D – Mock-ups

Attachment A

Attachment B

Attachment C

Attachment D

Attachment E