SUPPORTING STATEMENT

Part A

Assessing the Feasibility of Disseminating Effective Health Center Products through Mobile Phone Applications

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Agency of Healthcare Research and Quality (AHRQ)

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A. JUSTIFICATION

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see http://www.ahrq.gov/hrqa99.pdf), is 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. AHRQ shall promote health care quality improvement by conducting and supporting:

- 1. research that develops and presents scientific evidence regarding all aspects of health care;
- 2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and
- 3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve under the Paperwork Reduction Act of 1995 this Information Collection request to collect information from users of work products and services initiated by the John M. Eisenberg Clinical Decisions and Communications Science Center (Eisenberg Center).

AHRQ is the lead agency charged with supporting research designed to improve the quality of healthcare, reduce its cost, improve patient safety, decrease medical errors, and broaden access to essential services. AHRQ's Eisenberg Center is aimed at improving communication of findings to a variety of audiences ("customers"), including consumers, clinicians, and health care policy makers. The Eisenberg Center compiles research results into useful formats for customer stakeholders. The Eisenberg Center also conducts investigations into effective communication of research findings in order to improve the usability and rapid incorporation of findings into medical practice. The Eisenberg Center (EC) is one of three components of AHRQ's Effective Health Care (EHC) Program. From 2005 until September 2008, the EC operated through a contract with the Oregon Health and Science University (EC-OHSU), Department of Medicine, located in Portland, Oregon. In September 2008, the contract to operate the EC was awarded to Baylor College of Medicine (EC-BCM), located in Houston Texas.

The collections proposed under this clearance include activities to assess the feasibility of using specific media and awareness-raising processes to encourage consumers who are at risk for selected health problems for which Effective Health Care (EHC) Program materials are available to access information about such materials using mobile phone technologies. The project will specifically focus on promoting awareness of eight consumer guides developed through the EHC Program. The guides are all published in English and Spanish-language versions. All of the guides are designed to help decision makers, including clinicians and health care consumers, use research evidence to maximize the benefits of health care, minimize harm, and optimize the use of health care resources.

The project will test the feasibility of using mobile telephone technology for the dissemination of EHC Program materials to underserved health consumer populations visiting one of five participating health clinics using: a) short message services (SMS), usually referred to as texting, that can be provided to people with basic cell phone service and texting support; and b) mobile Web access that provides access to the Internet via a mobile interface.

Different methods and/or vehicles will be used in the clinics to promote awareness of opportunities to obtain cell phone- or smart phone-based information about the availability of EHC Program materials including: 1) wall posters in patient service areas of the clinics; 2) flyers about the products distributed in magazine racks and through patient kiosks in some areas of the clinics; 3) flyers/announcements given to patients at checkout from the clinic; and 4) health fairs convened to address general health issues, where the information can be provided. See Attachment A for the promotional materials that will be displayed in the form of posters and leaflets. Promotional materials will invite potential users to send a specific text message with the keyword associated with the relevant health condition to the advertised number. Subjects will receive a response text with a brief message about the condition and an invitation to either a) request a printed consumer guide or b) access the mobile Web site to view the guide. See Attachment B for the text messages related to each condition and the standard text messages exchange.

This project has the following goals:

- 1) Summarize marketing efforts in terms of total numbers of posters, flyers, and information sheets distributed through specific venues (e.g., patient waiting areas, patient check-out processes) and numbers of individuals contacted through health fairs and related activities;
- 2) Summarize the extent to which persons in targeted patient populations responded to marketing efforts;
- 3) Assess patient satisfaction with: a) the means by which patients were alerted as to the availability of EHC Program materials; b) the methods patients used to request and access the EHC materials; and c) the value and relevancy of the information that they obtained;
- 4) Characterize perceptions of clinical care providers and clinical staff persons in terms of: a) the value of efforts to promote patient awareness of EHC Program materials using marketing

techniques described in this feasibility project; and b) the effect of these efforts on workflow issues and related aspects of clinic operations.

To achieve the goals of this project the following data collections will be implemented:

- 1) Focus Groups/Interviews with Clinicians. A focus group (alternatively, interviews, depending on clinic restrictions) will be conducted at each of the five participating clinics during regularly scheduled internal clinic meetings, to determine how the introduction of marketing materials and related resources influenced, if at all, delivery of care in the clinical settings. Special emphasis will be placed on determining if introduction of the project materials changed the ways in which patients interacted with clinicians. It is expected that each focus group will include no more than 6 clinical professionals (e.g., physicians, physician assistants, nurses and nurse practitioners, pharmacists). See Attachment C for the clinician focus group discussion guide.
- 2) Focus Groups/Interviews with Support Staff. A focus group (alternatively, interviews, depending on clinic restrictions) will be conducted with support staff working in each of the five participating clinics, during regularly scheduled meetings, to determine if the introduction of the project materials altered clinic workflows. It is expected that each focus group will include no more than 10 support staff (e.g., receptionists, nursing assistants, other personnel who interact with patients). See Attachment D for the support staff focus group discussion guide.
- 3) Patient Interviews. In-person interviews conducted immediately after the patient exits the clinic will be used to determine if patients: a) saw and understood the marketing materials (e.g., posters and flyers) in clinic settings; b) were encouraged by the marketing materials to text and request information about their health issue(s); c) could identify specific reasons why they did or did not text; and d) have suggestions about how marketing materials might be changed so that they would be more likely to encourage patients like themselves to text. See Attachment E for the patient interview guide.
- 4) Feedback Questionnaire for Patients Requesting Mailed Guides. All persons that respond to the marketing materials by requesting any of the eight guides to be mailed to them will be asked to complete a brief paper questionnaire included with the guides. The purpose of the questionnaire is to assess the extent to which the guides were easy to read and understand, whether the guides provided the information they sought, and any suggestions for improving and delivering the guides. See Attachment F for the feedback questionnaire for mailed guides.
- 5) Feedback Questionnaire for Patients Visiting the Mobile Web Site. All persons that access the guides via the mobile Web site will be asked to complete a brief online questionnaire. Only subjects exposed to the promotion materials will receive the address of the mobile Web site during the text message conversation, and therefore we expect no other individuals to visit this site. The purpose of the questionnaire is to determine if the guides were useful, the mobile Web site was easy to use, whether they found the information they needed and experienced any difficulty in accessing the guides through their cell phone. See Attachment G for the feedback questionnaire for the mobile Web site.

6) Usage Log Data. Data from automated electronic log systems will be collected from two sources: 1) Mobile Commons, the contractor that manages the cell phone-related message delivery and cell phone-based communication; and 2) the Eisenberg Center at Baylor College of Medicine that manages the EHC Web site visits. Usage log data gathered from the cell phone service contractor will include: 1) counts of text messages received from persons requesting information about consumer guides; 2) the distribution of message counts across originating clinics tracked through the use of distinctive call-in or shortcode numbers assigned to each clinic; and 3) the numbers and originating clinic-specific distributions of follow-up texts Because text communications will be date and time stamped, Eisenberg Center staff will be able to calculate mean durations in time from receipt of the initial messages and follow-ups, which may be useful in determining navigation patterns and suggesting connectivity barriers.

Usage log data gathered from the mobile Web site will allow for identification of: 1) the number of visitors that originate from a specific uniform record locator (URL) associated with each clinic; 2) the duration of visits to the EHC Web site to gather desired information and explore other resources available through the Web site; 3) the number of pages viewed by each visitor; and 4) the number of downloads of the full report associated with each guide, which will also be made available.

This study is being conducted by AHRQ through its contractor, EC-BMC, 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; quality measurement and improvement; and clinical practice. 42 U.S.C. 299a(a)(1),(2) and (4).

2. Purpose and Use of Information

The Eisenberg Center will determine the feasibility of this approach to encouraging patients and anyone else viewing the marketing materials to access information that may be helpful to them in understanding health care choices and engaging more fully in their own health care, and whether this approach should be pursued further.

This information gathered through this exploratory study will provide insights into the feasibility of distributing consumer guides, as well as other Effective Health Care products, using mobile technologies as tools to heighten awareness of these resources by potential users who rely on mobile communication devices for information access. The results will be used to inform future studies on the use of increasingly pervasive communication modalities (e.g., cell phones, smart phones) in communicating with care providers and others and to access information from the Internet and health-related Web sites.

3. Use of Improved Information Technology

Improved electronic technology (e.g., promoting information access via cell phone and smart phone contacts) will be used whenever possible to reduce the burden on the public. Some of the data gathered through this project will be extracted from usage logs. Usage log data gathered by

Mobile Commons will be obtained using automated systems already in place and no special effort will be needed to generate these data. The data will be provided to Eisenberg Center staff in monthly reports provided by Mobile Commons. As with the phone log data, no special data gathering will be required in order to generate Web site usage data. The capabilities required to produce the data are programmed in the Eisenberg Center Web site, and the data will be generated as standard usage reports on a monthly basis

In some instances, however, the most appropriate methodology will involve oral responses to interview queries and/or discussions with groups of people who were engaged in implementation of the project. Paper questionnaires will only be used with patients who request print copies of the EHC guides and will be included in the materials mailed to them; every effort will be made to facilitate ease of responding including provision in the mailed packet of a postage-paid, addressed envelope. Online questionnaires will be administrated to those who access the EHC materials through the mobile Web site; the assessment will consist of a brief set of questions to be distributed only if the user clicks "Yes" to a popup window asking for provision of feedback. No more than a few questions will be asked of any one visitor to minimize respondent burden and thereby improve response rate.

4. Efforts to Identify Duplication

There is a large and growing body of literature on what has become known as mobile health or "mhealth." This literature is contributing to evidence that mobile technologies in general, and the cell phone in particular, can have a measurable impact on health behaviors of individuals, particularly with respect to adherence to recommended health regimens (e.g., blood glucose monitoring, timely medication use). However, to date, nothing has been found in the literature that focuses on strategies that work in prompting patients or other health care consumers to access health resources that may be very important to them through use of a cell phone or other mobile device. The literature is bereft of reports on methods and resources that have been shown to work or not work in motivating the patient or consumer to actually activate phone contact for purposes of accessing information that he or her can use to maintain or improve his or her health.

In preparing for this project, the project staff examined summary information on AHRQ-supported projects related to the Effective Health Care (EHC) Program and related activities. No current projects are exploring the issues described here involving marketing efforts and cell-phone mediated motivational efforts designed to promote action by patients in seeking out and obtaining resources from AHRQ-funded projects that might inform them about important health issues. This is particularly true with regard to low-income and economically disadvantaged patients who are often at increased risk from specific health threats and who often have the fewest resources to manage risk effectively. This project will add new information to understanding the strategies that hold promise for addressing the health information needs of vulnerable populations.

5. Involvement of Small Entities

The survey instruments and procedures for completing the instruments will be designed to minimize the burden on all respondents and will not have a significant impact on small

businesses or other small entities. The clinical service organizations that will be engaged in data gathering have been involved in project development since the early stages, and have provided input on the types of collection that can be implemented with minimal impact work burden for personnel in these care environments.

It should be emphasized that the overall intent of the project is to identify strategies for fostering access to EHC Program products without disruption of clinic workflows. Also, the burden associated with participation in data collection is entirely voluntary and no clinical or support staff person or patient will suffer any penalty if he or she declines to participate.

6. Consequences if Information Collected Less Frequently

These information collections allow for examination of drivers and hindrances to patient access to EHC Program health resources made available through mobile phone text messaging. Inability to collect these data would inhibit efforts to investigate this potential dissemination venue for patient access to accurate, high quality health information resources.

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

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on (date and page number of 60 day notice) for 60 days (see Attachment H).

8.b. Outside Consultations

Collaboration has been established with a marketing company with expertise in mobile phone usage data to assist in documenting cell phone user accessions.

9. Payments/Gifts to Respondents

Clinicians will be reimbursed up to \$250 for participation in the focus groups/interviews, and clinical support staff will be reimbursed up to \$125. These individuals have limited time availability and are accustomed to receiving similar levels of recompense for their valuable input, which is essential to effective product development and testing. Patients participating will be reimbursed in the amount of \$15 for the questionnaires and \$10 for the interviews. Remuneration for interviews and other activities demanding participant time is a recognized standard industry practice, without which it would be difficult to achieve appropriate and adequate participation.

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.

Respondents will be advised that interviews, surveys and/or other data collection activities in which they may be asked to participate are entirely voluntary, and that any information they provide will be combined and summarized with information provided by others and no individually identifiable information will be released. In instances where respondent identifiers may be needed (e.g., for issuance of payment), information collection will fully comply with all requirements of the Privacy Act.

11. Questions of a Sensitive Nature

No questions of a sensitive nature are anticipated under this project-specific clearance. Although some data gathering may deal with specific health conditions, the focus of the query items will be on the method of delivery of the information, rather than on any personal issues around a health condition or how it is managed. All questionnaires to be administered will maintain anonymity.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden for the respondents' time to participate in this research. Focus groups/interviews will be conducted with about 6 clinicians per each of the 5 participating clinics (30 total) and about 10 clinical support staff per clinic (50 total), and will last 45 minutes. Interviews will be conducted with about 60 patients per clinic (300 total) upon exit from the clinical visit, with each interview lasting about 15 minutes. The Feedback Questionnaire for the Mailed Guides will be completed by approximately 200 persons and will take 10 minutes to complete and the Feedback Questionnaire for the Mobile site will be completed by about 200 persons and also requires 10 minutes to complete. The total annual burden is estimated to be 202 hours.

Exhibit 1. Estimated annualized total burden hours

Type of Data Collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Focus Groups/Interviews with Clinicians	30	1	45/60	23
Focus Groups/Interviews with Support Staff	50	1	45/60	38
Patient Interviews	300	1	15/60	75
Feedback Questionnaire for Patients Requesting Mailed Guides	200	1	10/60	33
Feedback Questionnaire for Patients Visiting Mobile Web site	200	1	10/60	33
Total	780	na	na	202

Exhibit 2 shows the estimated annualized cost burden associated with the respondent's time to participate in this research. The total annual cost burden is estimated to be \$5,478.

Exhibit 2. Estimated annualized total cost burden

Type of Data Collection	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Focus Groups/Interviews with Clinicians	30	23	\$83.59	\$1,923
Focus Groups/Interviews with Support Staff	50	38	\$14.31	\$544
Patient Interviews	300	75	\$21.35	\$1,601
Feedback Questionnaire for Patients Requesting Mailed Guides	200	33	\$21.35	\$705
Feedback Questionnaire for Patients Visiting Mobile Web site	200	33	\$21.35	\$705
Total	780	202	na	\$5,478

^{*}Based upon the mean wages for clinicians (29-1062 family and general practitioners), clinical team members (31-9092 medical assistants) and consumers (00-0000 all occupations), National Compensation Survey: Occupational wages in the United States May 2010, "U.S. Department of Labor, Bureau of Labor Statistics."

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Cost to the Government

The maximum cost to the Federal Government is estimated to be \$204,406 annually over the two years of this clearance. Exhibit 3 shows the total and annualized cost by the major cost components.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	\$146,175	\$73,088
Data Collection Activities	\$85,425	\$42,713
Data Processing and Analysis	\$67,125	\$33,563
Project Management	\$47,588	\$23,794
Overhead	\$62,500	\$31,250
Total	\$408,813	\$204,406

15. Changes in Hour Burden

This is a new information collection request.

16. Time Schedule, Publication and Analysis Plans

Timeline for Data Gathering to Assess the Feasibility of Marketing the Availability of Effective Health Cat (EHC) Program Products Using Text Messaging and Mobile Web Access Via Cell Phone to Promote Consumer Awareness and Prompt Product Inquiries*																		
Major Data Cathoring Tasks		2010-2011 2011-20								1-2012								
Major Data Gathering Tasks to Be Completed								e-O		_					Post-OMB Approval			
Create the marketing materials and prepare cell phone messaging capabilities to support product promotion with targeted patient groups																•		
Complete stakeholder buy-in processes, including multi-organizational clearances to implement project is selected settings																		
Submit initial OMB clearance request to gather data as indicated in this document																		
Work with OMB representatives in revising and refining clearance request																		
Begin implementation of marketing initiatives (e.g., posters, flyers, cell phone enabled prompting messages)																		
Complete the public comment period required for OMB clearance																		
Obtain OMB clearance and begin data collection																		
Administer and monitor responses to patient questionnaires included with mailed Guides and via mobile Web site																		
Conduct focus groups/interviews with clinicians and clinical support staff in participating clinics																		
Conduct telephone interviews with patients who volunteer to participate in clinics																		

*NOTE: The project timeline was extended with approval from the AHRQ contracting officer to allow time to obtain approvals from multiple organizations and multiple groups within organizations that had authority related to data gathering; a process that extended longer than anticipated, reducing opportunities for adequate data collection.

Analyze data from feedback questionnaires and from clinician, clinical support staff, and patient interviews and focus groups

Prepare the final report on the feasibility of marketing efforts in fostering cell-phone based prompting to access EHC Program guides Publish results via the Effective Health Care Program Web site and in journal article(s)

Most data will be analyzed using descriptive statistics, and it is unlikely that the results can be generalized to the larger population. Some quantitative data are being collected in the form of the questionnaire surveys and usage logs. These data will be summarized primarily using descriptive statistics. Limited inferential statistics could be applied if we see a large numbers of responses to the questionnaires; and these would likely consist of comparisons across demographic categories on various indices of satisfaction. Because many of the data points will be measured using a 5-point Likert-type scale, nonparametric techniques will likely be warranted.

The analyses of focus groups and interviews will be qualitative and consist mostly of narrative summaries of the discussions. The results of these findings are primarily for internal use but may be shared with key government policy and management officials, AHRQ staff, public and private health providers, and members of the general public.

It is expected that at least two types of publications will be developed from results of this project. The first will be a summary that will be prepared for publication on the Effective Health Care Program Web Site. This summary will describe the work done on the project, including the methods employed in conducting the projected, the types of data collection completed, and the analyses done with the data. This may be published as research brief or short report in an appropriate area of the EHC Program Web site. In addition, data from follow-up activities carried out within parameters indicated in this OMB clearance request will be prepared as in manuscript format for submission to at least one peer-reviewed professional journal A likely candidate journal for publication of the project results is the *Journal of Communication*, but other journals will also be considered.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Promotional Materials

Attachment B: User Tested Cell Phone Messages

Attachment C: Clinician Focus Group Discussion Guide

Attachment D: Support Staff Focus Group Discussion Guide

Attachment E: Patient Interview Questions

Attachment F: Feedback Questionnaire for Patients Requesting Mailed Guides

Attachment G: Feedback Questionnaire for Patients Visiting the Mobile Web site

Attachment H: [Federal Register]