Evaluation of the National DMEPOS Competitive Bidding Program

Revised Supporting Statement for Paperwork Reduction Act Submission

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Contents

Part A: Background

Section 302(b) of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) (MMA) requires the Centers for Medicare and Medicaid Services (CMS) to begin a program of competitive bidding for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) in 10 Competitive Acquisition Areas (CAAs) in 2007. MMA Section 303(d) requires a Report to Congress on the program. This project's purpose is to provide information for this Report to Congress.

To collect this information for CMS, we will use the following three (3) data collection methods: beneficiary and supplier surveys, focus groups with suppliers and referral agents, and key informant discussions with beneficiary groups or advocates, CMS officials or CMS' bidding contract managers, referral agents and suppliers.

Part B: Justification

B.1 Explanation of Circumstances That Make Collection of Data Necessary

Section 302(b) of the MMA requires CMS to begin a program of competitive bidding for DME, supplies, certain orthotics, and enteral nutrients and related equipment and supplies. The bidding program is to be established in 10 CAAs in 2007, an additional 80 CAAs in 2009 and additional CAAs thereafter. The initial CAAs will be based in 10 of the largest Metropolitan Statistical Areas (MSAs).

MMA Section 303(d) requires a Report to Congress on the program, covering program savings, reductions in cost sharing, impacts on access to and quality of affected goods and services, and beneficiary satisfaction. This project's purpose is to provide information for this Report to Congress. Also, interim site visit information and other data collected during this project may be helpful to CMS as it makes plans to implement the second phase (adding 80 large CAAs).

This evaluation's objectives are both summative (is the program having identifiable impacts on costs, access, and quality?) and formative (what early implementation lesson learned can improve the bid and award process as the program expands from 10 competitive acquisition areas (CAAs) in 2007 to 80 or more by 2009?).

Copies of Section 302(b) and 303(d) can be found in Appendix A.

B.2 How the Information Will Be Collected, by Whom, and For What Purpose

The following data will be collected to support a pre-post evaluation design:

- Beneficiary and supplier surveys in three (3) study CAAs and two (2) comparison areas;
- Focus groups with suppliers and referral agents in (3) study CAAs;
- Key informant discussions with beneficiary groups or advocates, CMS officials or CMS' bidding contract managers, referral agents and suppliers in the three (3) CAAs; and

- Key informant discussions over the telephone with beneficiary groups or advocates, referral agents and suppliers in the two (2) comparison areas.

We are requesting Office of Management and Budget (OMB) approval for the beneficiary and supplier surveys, focus groups and key informant discussions in this submission. Please see Exhibit 1 for the research questions each data source will address.

Exhibit 1 Overview of Research Questions and Major Data Sources

Domain	Research Questions	Medicare Claims	Beneficiary Surveys	Supplier Surveys	Focus Groups & Discussions	Program Data
Medicare expenditures & Savings	Unit prices					X
	Utilization	X				
	Program Costs					X
Beneficiary cost-Sharing	Estimated savings in beneficiary out of pocket costs	X	X			
Access	Number and geographic accessibility of suppliers	X	X		X	
	Finding a supplier		X		X	
	Transition issues	X	X		X	
Quality of goods and services	Diversity of products available		X	X	X	
	Access to specific products		X	X	X	
	Quality of service		X		X	
	Product quality		X	X	X	
Consumer satisfaction	Consumer satisfaction		X			
Administrative operations & stakeholder impacts	Program dissemination and outreach				X	
	Bidding process				X	X
	Transition issues				X	
	Quality Standards				X	
Health Outcomes (Oxygen Users)	Health outcomes	X	X			

CMS has planned two kinds of data collections among beneficiaries for purposes of administering the new national DMEPOS competitive bidding program. One data collection mailed by the competitive bidding program intermediary addresses beneficiary satisfaction along several dimensions with a short, one page, survey. This survey will be mailed routinely to new product users. The format of the questions are a rating scale rather than specific response categories and there are no customized questions. While the sample size eventually will be larger, the information gathered will be more general than the program evaluation survey. This is in line with the purpose of the survey, which is quite different from that of the evaluation survey: to monitor regularly the beneficiary experience under the program after it gets

underway, to identify suppliers who may have difficulties serving beneficiaries adequately, and, potentially, to identify overall program issues that may arise from time to time.

In contrast, the evaluation survey uses a pre-post survey design with comparison groups and its purpose is to detect possible changes in beneficiary cost sharing, access, quality of goods and services and customer satisfaction as a result of the new program. Questions are structured with specific sets of response categories that address specific issues in beneficiary cost sharing, access, beneficiary choice of equipment, service quality, training, and customer support.

STATISTICAL DATA COLLECTION

The beneficiary and supplier surveys will focus on oxygen users and users of four other types of DMEPOS. While CMS has not made any final decisions regarding products to select for competitive bidding (pending issuance of the final regulation expected later this year), CMS is required under the Paperwork Reduction Act (PRA) to seek clearance of the data collection forms for the evaluation project at least six (6) months before beginning data collection. An oxygen user survey was designed to allow for the contingency that oxygen would be selected, because oxygen is the highest-volume and highest-expenditure category of durable medical equipment, and because the government's evaluation of the demonstration concluded that oxygen should be monitored if included under future competitive bidding initiatives. A survey of power wheelchair users was also designed and will serve as a prototype for the four "Other DMEPOS" products. After CMS determines the products that will be competitively bid, we will select four products and modify the wheelchair survey to address these products. The majority of the survey will remain intact, however a subset of 14 questions will be modified to accommodate the specific product (beyond substituting the product name throughout the survey). Of the 14 questions, only 6 require changes to the question itself whereas the other 8 only require changes to the answer choices. In the event that oxygen is not part of the competitive bidding program, the customized "Other DMEPOS" users questionnaires will be used.

CMS administrative data sources (including Medicare DMEPOS claims data and other administrative data), National Supplier Clearinghouse (NSC) file data, CMNs for selected beneficiary groups, and supplier bids will be analyzed to address the research questions. A Technical Expert Panel (TEP) convened to provide guidance on some aspects of the evaluation, specifically on how to assess the impact of competitive bidding on beneficiaries who are oxygen users.

NONSTATISTICAL DATA COLLECTION

The referral agent and DMEPOS supplier focus group participants will be asked to assess how the competitive bidding program affected them as well as their perceptions on the impact of competitive bidding on Medicare beneficiaries. The referral agent focus group participants may include discharge planners, case managers, social workers, home health care workers, physical therapists and nurses, among others. The aim is to select referral agents from a diverse array of health care organizations. The supplier focus group participants will include suppliers with a significant part of their business providing at least one of the DMEPOS items chosen for competitive bidding. The different types of referral agents and suppliers selected for the focus groups will provide a greater breadth and diversity of perspectives.

The key informant discussions will be conducted with beneficiary groups/advocates, CMS officials or bidding program managers, referral agents, and suppliers to understand the impact of the program on each of the groups and on Medicare beneficiaries access to and quality of DMEPOS products and services. The

information gathered through the key informant discussions will provide a deeper understanding of program impacts from individuals who are highly engaged with the DMEPOS market and process and have extensive experience in their role.

Trained researchers experienced in moderating focus groups and conducting key informant discussions will collect the nonstatistical data.

B.3 Use of Improved Information Technology to Reduce Burden

Information technology will reduce respondent burden and avoid data duplication for both the beneficiary and supplier surveys in two ways.

First, the self-administered pencil-and-paper beneficiary surveys may alternatively be administered by telephone upon respondent request. Telephone data collection is also used to follow up withnon-respondents. The telephone data collection is supported by a full-featured computer-assisted telephone interviewing (CATI) system with automated case delivery and built-in quality control. We expect 30 percent of beneficiaries will use the CATI system to respond to the survey.

Second, the supplier survey has been developed as a self-administered web-based survey. Respondents are asked to provide information on eight (8) beneficiary claims that were submitted for payment in the previous year (2006). The computer-based format of this survey enables the seamless import of case-specific claims data into the survey to facilitate its administration. Suppliers also have the option of completing this survey via telephone.

B.4 Efforts to Identify and Avoid Duplication

To avoid duplication of beneficiary and supplier data, data collection instruments were developed to ask respondents only about information that cannot be found in extant databases. We have identified the following as sources of extant data that will be used in this evaluation:

- CMS databases, including DMEPOS claims data and other administrative data;
- National Supplier Clearinghouse (NSC) File data; and
- Selected beneficiary group CMNs.

The key informant discussion and focus group recruits (referral agents and suppliers) will be selected to meet different data collection aims. Referral agents included in the key informant discussions will be selected based on extensive experience and their active involvement referring Medicare beneficiaries to DMEPOS suppliers. In contrast, referral agent focus group participants will be selected from different health system types (e.g. urban, rural, public, private) and roles (e.g. discharge planner, physical therapist) to provide a diversity of perspectives from the focus groups. The suppliers for the key informant discussions will be selected for their involvement and familiarity with the local DMEPOS market and years of experience, whereas the focus group suppliers will be selected from a list of suppliers available in the area.

B.5 Efforts to Minimize Burden on Small Business or Other Entities

Small business or other small entities may constitute a large portion of the respondents in the supplier surveys (and qualitative data collection). Therefore, it is critical that burden be minimized for these respondents. As described in Section A.3, the supplier survey is a self-administered web survey requesting the supplier to provide information about eight (8) beneficiary claims pre-selected randomly by the evaluation team from Medicare claims. The TEP and CMS have suggested that eight (8) claims is a number that could be reasonably asked of the supplier to document.

Before initiating baseline data collection, we will conduct cognitive testing with nine (9) DMEPOS suppliers on the survey. The list of potential respondents will be obtained from a convenience sample from the Bethesda metropolitan area and/or drawn from suggestions from the suppliers on the TEP. The cognitive testing will include monitoring ease of navigating efficiently through the instrument, entering responses in the prescribed manner, the appropriateness of claims information requested, the completeness of the drop down menus for product manufacturers and product names/models, burden of completing the survey, and potential wording or administration that increases perceived integrity and diminishes respondents' concerns.

The resulting supplier survey will be provided in a web-based format that enables the seamless import of the supplier's specific and applicable details about the pre-selected claims into the survey. The claims questions will employ drop-down menus for the respondent to select first from the list of manufacturers for the subject claim's coded procedure, and then from that manufacturer choice the applicable products will populate the next question's drop-down menu for the specific product name/model that was supplied to the Medicare beneficiary. The second section of the survey, which asks a few questions about products carried, also uses drop-down menus. Respondents will have the option to complete the survey via telephone. Finally, the supplier survey will provide the option of being completed by a designee whom the identified contact deemed to have enough knowledge about the company's Medicare transactions to be able to accurately respond to the survey.

Small business or other small entities may constitute a portion of the respondents in the supplier focus groups and key informant discussions too. Therefore, it is critical that burden be minimized for these respondents. The supplier focus groups will take up to 90 minutes and the key informant discussions will take up to 60 minutes, and at the supplier's place of business to minimize burden.

B.6 Consequences of Less-Frequent Data Collection

Neither the statistical data (the beneficiary and supplier surveys) nor nonstatistical data (the focus groups and key informant discussions) collected during this evaluation can be collected less frequently. First, the beneficiary and supplier surveys must be administered at two (2) points in time, to allow a measurement of the competitive bidding program's effects in a pre-post analysis. The nonstatistical data collection will be conducted at three (3) time points, the first prior to program implementation, the second three to six (3-6) months after implementation, and the third 12-15 months after program implementation. Nonstatistical data must be collected this frequently to allow sufficient understanding of competitive bidding program impacts from the perspective of the key stakeholders at these important implementation times.

B.7 Special Circumstances Requiring Collection of Information in a Manner Inconsistent with Section 1320.5(d)(2) of the Code of Federal Regulations

There are no special circumstances associated with this data collection.

B.8 Federal Register Comments and Persons Consulted Outside the Agency

In accordance with the Paperwork Reduction Act of 1995, CMS submitted a notice to the *Federal Register* announcing the agency's intention to request an OMB review of data collection activities. The notice was published on June 16, 2006, in Volume 71, Number 116, Page 34928 and provided a 60-day period for public comments. A copy of the *Federal Register* notice for this information is included in Appendix E. Comments were received from Abbott and a response was provided. Modifications to the instruments and evaluation design were incorporated into this re-submission. This resubmission is provided for a 30-day public comment period.

This study's design phase involved convening and consulting with a TEP that provided and continues to provide essential information related to the design of the data collection instruments. The TEP consists of six (6) experts, including:

- A DMERC medical director;
- An individual with expertise in research design;
- A pulmonologist;
- Two (2) oxygen equipment industry representatives; and
- An expert on mobility products.

The first TEP teleconference was held on November 29, 2005, to discuss issues relevant to oxygen therapy, competitive bidding, and the structure of the beneficiary and supplier surveys. The follow up meeting was held on 12/9/05 to review the first draft of the beneficiary survey for oxygen users. Evaluation staff also called several TEP members individually to consult on different components of the data collection and study design. The last teleconference with the TEP was held on January 5, 2006 to review the final versions of the survey and qualitative instruments.

Exhibit 2 contains a complete listing of the TEP members and their affiliations.

Exhibit 2

Technical Expert Panel Members

- Dr. Kent Christopher, PhD, 9086 East Colorado Circle, Denver, CO
- Dr. Doran Edwards, PhD, Palmetto GBA, SADMERC, Columbia, SC
- Laraine Forry, Air Products Healthcare, Lewisberry, PA
- Professor Bruce Friedman, PhD, Dept of Community and Preventative Medicine, University of Rochester, Rochester, NY

- Joseph Lewarski, Inogen, Eastlake, OH
- Jean Minkel, Minkel Consulting, New Windsor, NY

B.9 Payments to Respondents

Honoraria will be provided to the following respondents:

- Pilot cognitive testing of surveys: prior to the start of data collection, nine (9) beneficiaries and nine (9) suppliers will be recruited to pilot test the survey instruments and to provide feedback on the language, ease of administration, and use of the web site (for the supplier survey). Beneficiaries will be offered $35 honorarium and suppliers will be offered a $75 honorarium for their participation.
- Focus groups: at each of three waves of data collection, focus groups will be conducted with referral agents (e.g. discharge planners, rehabilitation therapists, home care staff) and with suppliers and/or supplier group representatives. The focus groups will be held in the evening and participants will be offered dinner and a $75 honorarium.
- Suppliers will be offered a $75 honorarium for their participation in the supplier survey.
- No honoraria will be offered to participants in the in-depth interviews.

B.10 Assurance of Confidentiality

Abt Associates has conducted numerous projects involving sensitive information; consequently, facilities and procedures have been developed to maintain this confidentiality. To begin, all staff assigned to Abt projects sign confidentiality agreements. In addition, access to the data processing areas is controlled, with only authorized personnel allowed in the computer rooms and the computer tape libraries. All databases are password protected, with only the data administrators having write authority over files. Finally, electronic data transferred via diskette or CD-ROM to clients are aggregated, encrypted, and password-protected before shipping via a bonded courier.

Abt will also work with their subcontractor, Pulse Train, for the web survey to ensure secure transmission of the supplier data across the web as it is entered and stored. Abt's Survey Area has been using Bellview by Pulse Train for data collection since 1992. Pulse Train markets and supports the Bellview system and currently hosts and maintains Abt's Survey Department web-based surveys. Pulse Train uses a NetScreen 5GT firewall that integrates several security functions—stateful and Deep Inspection firewall, IPSec VPN (utilizing 168 bit 3DES encryption), Denial of Service protection and Antivirus—with an Asymmetric Digital Subscriber Line (ADSL) interface. Web surveys with sensitive information that require more stringent needs are hosted on a server using Secure Socket Layering (SSL).

The focus groups and key informant discussions will not be audiotaped or videotaped. The written notes collected from the focus groups and discussions will be labeled with a study code and will not include the name of the participant or his/her organization. The materials will be stored in secured locations and electronic materials will be stored in a password–protected computer. Any information presented to outside parties will be presented in summary form. The informed consent forms for the key informant discussions conducted in-person and the informed consent scripts for the key informant discussions conducted over the telephone are provided in Appendix D.

B.11 Questions of a Sensitive Nature

The beneficiary and supplier surveys do not contain any questions concerning sexual behavior and attitudes, or religious beliefs. The beneficiary survey, however, does include key demographic items such as income, race and ethnicity, and health status. Collecting these key demographic data will allow us to determine whether samples in the program and comparison areas are comparable. The supplier survey asks its respondents to provider specific claims data some suppliers may consider to be proprietary business information such as the manufacturers or models of certain HCPCs routinely stocked, estimates of percentage of product share within their business. This information is collected to analyze changes in elements such as product diversity after competitive bidding is implemented.

Respondents to the beneficiary and supplier surveys are explicitly informed that their participation is voluntary, and that they may choose to withdraw from the study or to omit specific items without penalty. No written consent is obtained from the beneficiaries or suppliers; their consent is implied by the completion of their surveys.

Participants in the focus groups and key informant discussions are explicitly informed that their participation is voluntary, and that they may choose to withdraw from the study without penalty. Written consent will be obtained from participants in the in-person discussions and focus groups and verbal consent will be obtained from participants in the telephone discussions (see Appendix D).

B.12 Estimates of Respondent Burden

Exhibit 3 presents estimates of the annual reporting burden for each wave of the data collection process. Time estimates are based on experience with similar instruments used with comparable respondents.

Exhibit 3

Estimates of Annual Burden Hours and Cost

Data Collection Sources	Number of Respondents	Minutes Per Respondent	Response Burden in Hours	Estimated Cost Per Hour [a]	Costs per Respondent	Total Burden (Costs)
STATISTICAL DATA **						
Beneficiary Surveys in Program and Comparison Areas at each wave						
Oxygen	**6,000**	**30**	**3,000**	**0**	**0**	**0**
Other DMEPOS	**6,000**	**30**	**3,000**	**0**	**0**	**0**
Supplier Surveys in Program and Comparison Areas at each wave	**575**	**45**	**431**	**$46.88**	**$35.16**	**$20,217.00**
NONSTATISTICAL DATA ***						
Focus Groups at each wave						

Referral Agent	**30**	**90**	**45**	**$19.23**	**$28.85**	**$865.50**
Suppliers	**30**	**90**	**45**	**$46.88**	**$70.32**	**$2,109.60**
Key Informant Discussion at each wave						
Beneficiary Group/ Advocates	**6**	**60**	**6**	**$16.83**	**$16.83**	**$100.98**
CMS Officials	**6**	**60**	**6**	**$0.00**	**$0**	**$0**
Referral Agent	**6**	**60**	**6**	**$19.23**	**$19.23**	**$115.38**
Suppliers	**6**	**60**	**6**	**$46.88**	**$46.88**	**$281.28**
Comparison Area Key Informant Discussion at each wave						
Beneficiary Group/ Advocates	**4**	**60**	**4**	**$16.83**	**$16.83**	**$67.32**
Referral Agent	**4**	**60**	**4**	**$19.23**	**$19.23**	**$76.92**
Suppliers	**4**	**60**	**4**	**$46.88**	**$46.88**	**$187.52**

[a] Costs for beneficiaries assumed that virtually all would be retired, and thus would incur no loss of wages. Suppliers' hourly wage was estimated based on the targeted population of supply administrators (management level) and supervisors of claims-processing and sales staff. These annual salaries can range from $75,000-$120,00 or an hourly range of $36.06-57.69. Table estimate uses the mean of these two hourly wages.

B.13 Estimates of the Cost Burden to Respondents

Other than their time to participate in the study, which is estimated in Exhibit 3, there are no direct monetary costs to respondents.

B.14 Estimates of Annualized Government Costs

Below are the annual costs for the evaluation of the national DMEPOS competitive bidding program. These costs include labor, other direct costs (printing, postage, travel, telecommunications, etc.) and indirect costs.

Exhibit 4

Annual Costs for the Evaluation of the National DMEPOS Competitive Bidding Program

	Year One	Year Two	Year Three	Year Four	Total
Task 1: Technical Expert Panel	$18,981	$306	$0	$0	$19,287
Task 2: Prepare for Survey	$29,730	$113	$0	$0	$29,843
Task 3: Qualitative Data Collection	$60,002	$154,820	$27,570	$0	$242,392
Task 4: Conduct Surveys	$732,018	$366,175	$0	$0	$1,098,193
Task 5: Assemble and Analyze Secondary Data	$51,571	$168,681	$74,741	$41,534	$336,527
Task 6: Reports	$89,937	$8,002	$21,326	$84,446	$203,711
Tack 7: Project Management	$40,071	$36,126	$34,249	$48,026	$158,472
Task 8: Data Tapes and Documentation	$0	$0	$55	$10,707	$10,762
Task 9: Analysis	--	--	--	$0	$0
All Tasks	$1,022,309	$734,223	$157,942	$184,713	$2,099,187

B.15 Changes in Hour Burden

No change in burden is requested. This submission to OMB is for an initial request for approval.

B.16 Time Schedule, Publication, and Analysis Plan

Described below are the analysis plans and timelines for both the statistical and nonstatistical data collection efforts.

STATISTICAL DATA COLLECTION

Analysis Plan: Beneficiary Surveys

The basic framework for the analysis of the beneficiary survey data will be "differences-in-differences," in which we compare changes in key outcome variables in three (3) study CAAs with changes in the same variables in selected comparison areas.

The report will contain five (5) sets of analyses:

- Analyses of response rates.
- Descriptive tables presenting the survey data.
- Univariate analyses of key independent variables (such as beneficiary demographic characteristics) by program area to determine whether samples in selected program and comparison areas are comparable.
- Univariate analyses of outcome variables and univariate tests of demonstration effects.
- Multivariate analyses of outcome variables and multivariate test of outcome effects. These analyses include the independent variables as control variables and may therefore offer more precise estimates of program effects.

Note that these two (2) types of areas (program and comparison) should be comparable in terms of independent variables because they were selected in a similar way; if they are not comparable in terms of measured variables, then it becomes more important to use multivariate methods to adjust for the underlying differences among samples. In addition, the analysis of survey data will incorporate other variables from the DMEPOS claims, Medicare's enrollment database, and the certificates of medical necessity that will be linked to the survey data. These variables will also be used to establish comparability and will also serve as control variables.

Analysis Plan: Supplier Survey

The following measures, constructed using data from the supplier survey, will be used to estimate program impacts:

- The number of products available within the HCPC and/or the number of products exceeding some threshold level of market share within the HCPC.
- The Herfindahl index (sum of squared market shares of the products or manufacturers within the HCPC), a summary measure of market concentration.
- Concentration ratios (share of market going to the top N products or top N manufacturers).
- Other measures of diversity, for example there may be meaningful ways to group products and re-estimate the Herfindahl index or the concentration ratios based on these groupings.
- Measures of quality, if applicable; these might either be measures based on wholesale acquisition cost or measures based on grouping products according to features associated with product quality.

These measures will be calculated for study CAAs and comparison areas before and after the start of the new payment system. The program effect will be estimated using the difference-in-difference estimator. Comparisons will be conducted between the three (3) study CAAs and the two (2) comparison areas. If necessary, estimates will incorporate appropriate weights to account for varying response rates among different substrata of the sample (such as large and small suppliers).

The report will also contain the following sets of analyses:

- Descriptive statistics on the sample frame, i.e. number and characteristics of suppliers by study HCPC, geographic area, and time period
- Analyses of response rates
- Descriptive tables presenting the survey data

Timelines

Exhibits 5-7 illustrate the timelines for the beneficiary and supplier surveys, as well as for the Data Analysis.

Exhibit 5

Data Collection Overview by Week – Supplier Survey

Date for 2006-2007	Date for 2008	Week of Field Period	Task	Est. Qty. Supplier Survey
12/15/06 – 1/15/07	N/A		Conduct Cognitive Testing of Instrument	9
1/31/07	7/3/08		Finalize web survey for programming	N/A
2/15/07	7/3/08		Testing web survey against programming specifications	N/A
3/1/07	9/1/08	1	Train Research Assistants on study	N/A
3/13/07	9/20/08	1	Launch Web survey	1,000
3/13/07	9/20/08	1	Survey Advance Letter with Link & Password / Inbound calls (800-line) begin	1,000
3/20/07	9/27/08	2	Letter with password & Link Reminder I	1,000
3/27/07	10/6/08	3	Postcard Reminder I	850
4/3/07	10/13/08	4	E-mail Reminder I (link / password provided)	850
7/10/07	10/20/08	5	Postcard Reminder II	750
4/24/07	11/3/08	7	Letter with password & Link Reminder II	750
5/3/07	11/10/08	8	E-mail Reminder II (link / password provided)	700
5/10/07-5/25/07	11/17/08-12/4/08	9-12	Outbound calls to eligible non-responders	700
6/5/07	12/11/08	13	Send incentive checks to all completed cases	N/A
6/20/07	1/17/08	14	Deliver final data set	N/A

Exhibit 6

Data Collection Overview by Week – Beneficiary Survey

Date 2006-2007	Date 2008	Week of Field Period	Task	Est. Qty. Beneficiary Survey
11/30/06	N/A		Finalize test surveys for cognitive testing	N/A
11/15/06-1/15/07	N/A		Conduct Cognitive testing	9
1/25/07	N/A		Finalize Instrument	
1/25/07-2/8/07	12/17/07		Program and Test CATI system	N/A
3/20/07	12/31/07		Train Interviewers	N/A
3/22/07	9/5/08	1	Survey Packet I / Inbound calls (800-line) begin	18,462
3/29/07	9/12/08	2	Post card Reminder I	18,462
4/6/07	9/19/08	3	Survey Packet II	12,920
4/13/07	9/26/08	4	Postcard Reminder II	12,920
4/20/07	10/03/08	5	Survey Packet III	10,193
4/28/07	10/10/08	6	Postcard Reminder III	8,470
5/06/07	10/17/08	7	Survey Packet IV	8,470
5/13/07	10/24/08	8	Postcard Reminder IV	8,000
5/20/07	11/1/08	9	Postcard Reminder V – “Please Call Us”	8,000
5/20/07-6/19/07	11/1/08-12/1/08	9-12	Outbound calls to eligible non-responders	8,000
6/25/07	12/20/08	14	Deliver final data file	

Exhibit 7:

Timeline for Secondary Data Analysis

PROGRAM MILESTONES	Date
NPRM	April 2006
Final rule, containing HCPCs and communities	Nov 2006
Payment under new program begins	Oct 2007
ANALYSIS	
Analysis to refine project design	Jan-Dec 2006
Selection of comparison areas	
Identify likely CAAs and likely HCPCs	Jan-March 2006
Identify likely comparison areas (ARF)	Jan-March 2006
Develop variables and approach for final selection	March-Sept 2006
Final selection	Nov 2006
Sampling frame for beneficiary survey (Wave 1)	Jan-March 2007
Sampling frame for supplier survey (Wave 1)	
Select suppliers	Jan-March 2007
Select claims within supplier	Jan-March 2007
Sampling frame for beneficiary survey (Wave 2)	July-Aug 2008
Sampling frame for supplier survey (Wave 2)	July-Aug 2008
DATA ACQUISITION AND DATABASE CONSTRUCTION	
DUA	Nov 2005
Design Files	
Data acquisition	May-July 2006
Database construction	July-Sept 2006
Sample Files Wave 1	
Data acquisition	Jan-March 2007
Database construction	Jan-March 2007
Sample Files Wave 2	
Data acquisition	July-Aug 2008
Database construction	July-Aug 2008
Program Impact files	
Data acquisition CY 2007	Q1 2008
Initial database construction	Q2-Q3 2008
Data acquisition CY 2008	Q1 2009
Final database construction	Q2-Q3 2009
ANALYSIS OF PROGRAM IMPACTS	Q1-Q3, 2009
DELIVERABLES	
Bene survey Wave 1/ Supplier survey Wave 1	Q2 2007
Bene survey Wave 2 / Supplier survey Wave 2	Q1 2009
Interim Report	Q1 2009
Final Report	Q3 2009

NONSTATISTICAL DATA COLLECTION

Analysis Plan: Nonstatistical Data

The purpose of the nonstatistical data collection is to understand the impact of the competitive bidding program from the perspective of the key stakeholders: beneficiary groups/advocates, CMS officials and bidding program managers, referral agents, and suppliers. The nonstatistical data collected will contribute to the formative and summative evaluation of the competitive bidding program outreach, information dissemination, implementation and impact.

Summaries of key themes or issues that arise in each of the focus groups and key informant discussions will be drafted. From Wave 1 the data will provide a baseline understanding of the DMEPOS environment in that study CAA and will be used as a point of reference from which to compare findings obtained in Waves 2 and 3. The findings from Wave 2 will contribute to a formative evaluation of the program and provide CMS recommendations for improving rollout of competitive bidding in the next CAAs. Additionally, Wave 2 should provide a preliminary understanding of the transition issues and initial impact of the program. Wave 3 should provide an in-depth understanding, from different key stakeholders, of the impact of the competitive bidding program.

The summaries as well as the primary data will be analyzed by the project team with the aim of identifying common themes across the groups and for each of the research domains and questions. A content analysis will be performed for every research question and responses coded. The coded responses will be classified and analyzed for patterns and trends.

The selected comparison area findings will provide a baseline understanding of the environment for DMEPOS, quality and access for Medicare beneficiaries, and the new quality standards. The findings from the comparison areas may also be used to identify any market or DMEPOS changes during and across the three (3) waves that could account for a change identified in the study CAAs. For example, the introduction of a new DMEPOS item that changed the quality of a specific durable medical equipment product may account for the identified change in the CAA.

The analysis plan for the nonstatistical data draws its rigor from 1) the experience of the project team with nonstatistical data collection and analysis and 2) data triangulation. The data is acquired from diverse data sources (four different informant types and documents) and data collection methods (focus groups and key informant discussions). Nonstatistical data triangulation provides a test for consistency (Patton, 2002). This does not necessarily imply demonstrating similar findings across the different data sources, rather it allows for the recognition of inconsistencies or differences that arise from the different data sources. These inconsistencies can be illuminative, particularly when evaluating a new program from the perspective of different stakeholders. This is the strongest design available for use with the observational data that can be generated for the evaluation of the competitive bidding program.

Timeline

Exhibit 8 illustrates the timeline for the nonstatistical data collection and analysis.

Exhibit 8

Nonstatistical Data Collection and Analysis Timeline

SUBTASK	**DATE** (Wave 1, 2, 3)
Preparation for focus groups and key informant discussions	
Collect and create recruitment lists	December 06, 07, 08
Contact and schedule CAA focus groups and key informant discussions	Jan – Mar 07, 08, 09
Make travel arrangements for CAA site visits	Jan – Mar 07, 08, 09
Contact and schedule comparison area key informant discussions	Jan – Mar 07, 08, 09
Conduct focus groups and key informant discussions	
Study CAAs 1-3, comparison areas 1&2	Feb – April 07, 08, 09
Write summaries of focus group and key informant discussions	Feb - April 07, 08, 09
Analysis of Data	
Identify common themes from data collected in that wave	May 07, 08, 09
Conduct content analysis for research domains and questions in that wave	May 07, 08, 09
Code data in that wave	May 07, 08, 09
Synthesize data across the three waves, code data, and conduct analyses	June – July 09

B.17 Display of Expiration Date for OMB Approval

The CMS will display the expiration date for OMB approval on all of the data collection instruments.

B.18 Exceptions to Certification Statement

This submission requires no exceptions to the Certificate for Paperwork Reduction Act (5 CFR 1320.9).

Part C: Collection of Information Employing Statistical Methods

C.1 Respondent Universe and Sampling Methods

Beneficiary Survey

CMS requires a survey of a sample of Medicare beneficiaries in three (3) CAAs and two (2) comparison areas. The three (3) CAAs will be selected based on size, presence of adequate comparison area, and geographic diversity. Furthermore, because payment rates during the baseline period varied by state and because certain other regulations governing suppliers also vary by state, the CAAs selected for primary data collection must not cross state lines. The two (2) comparison areas selected will be similar to the study CAAs with respect to the proportion of the population over 65, number of hospital beds per 1000, user rates, rates of new users and number of suppliers. The survey is to be conducted in two (2) waves,

the first wave in 2006 prior to program launch and the second in 2008 about 15-18 months after program launch.

The target population for the survey is all Medicare beneficiaries in each of the five (5) areas (three (3) study CAAs and two (2) comparison areas) who are users of one of five (5) product categories. These users will be further divided into new and existing users of these products. The product categories will be further defined upon CMS' selection of product lines to include in the bidding process. Essentially, we will be creating 50 strata formed by the cross classification of five (5) geographic areas, five (5) product categories and two (2) types of users (new and existing).

A total sample of 12,000 completed interviews is required per wave. Exhibit 9 shows the number of beneficiaries required in the sample in each stratum.

Exhibit 9

Number of Beneficiaries in Sample by Strata, per Wave

Subgroup	Oxygen	Other DMEPOS	Total
CAA new user	2,800	1,600	4,400
CAA existing user	2,000	800	2,800
Comparison area, new user	1,867	1,067	2,934
Comparison area existing user	1,333	533	1,866
Total	8,000	4,000	12,000

The sample size in each stratum is in terms of number of completed interviews. We assume a 65% response rate overall to the beneficiary survey at each wave—50 % will complete and return a written questionnaire and 15% will complete the questionnaire via telephone. Of the 50% of non-respondents to the written questionnaire, we assume that we will be able to locate telephone numbers for 60% and 50% of those will respond via telephone. Thus, we need to select 18,462 beneficiaries per wave to complete 12,000 surveys per wave.

Supplier Survey

The supplier survey will be conducted in the same five (5) geographic areas as the beneficiary survey (three (3) CAAs and two (2) comparison areas). The target population for this survey is all suppliers who are active with Medicare and have a substantial presence in the selected product categories in the five (5) geographic areas designated for the survey.

In 2007, a sample of approximately 958 suppliers will be selected from the available population in each of the strata shown below. Based on an estimated response rate of 60%, the ultimate sample sizes by strata are also shown. It is possible that in some communities the number of active suppliers will be sufficiently low that the supplier survey will be sent to almost all active suppliers. As in the case of beneficiaries, the survey will be conducted in two (2) waves with an independent sample of suppliers in each wave.

Our sampling plan calls for sampling a large number of suppliers, for this is the only means of achieving statistical significance. It is possible that some areas and product categories may not offer these numbers of suppliers. Other options for achieving statistical significance (namely, expanding the number of study areas) is costly and outside of the resources for this project.

Exhibit 10

Sampling Plan for Supplier Survey: Suppliers (Anticipated Completed Surveys)

Area	Oxygen HCPC1 and HCPC2	Other HCPC 1	Other HCPC 2	Total
CAA	195 (65/site)	75 (25/site)	75 (25/site)	345
Comparison Area	130 (65/site)	50 (25/site)	50 (25/site)	230
Total	325	125	125	575

Each sampled supplier will be asked to provide data on eight (8) claims.

C.2 Information Collection Procedures

Beneficiary Surveys

Oxygen users will be defined based on the presence of a claim within a pre-defined set of oxygen HCPCs. Other DMEPOS users will be defined based on the use of other DMEPOS within product lines selected for competitive bidding. Once those product lines have been chosen, we will sample within product line, i.e., if the products chosen are "wheelchairs" and "hospital beds," we will sample from within the two sub-strata of "wheel chair users," and "hospital bed users." The same number of beneficiaries will be sampled for each of the product categories, regardless of that product categories' market share.

New users of oxygen and "other DMEPOS" will be defined based on the presence of a claim for the product line under study within the last quarter but the lack of a claim in the three quarters before that. .

We will construct sampling frames for the selection of beneficiaries in each stratum using the Medicare claims. All the information required for selecting the beneficiaries will be included in the sampling frame. A systematic sample will be selected in each stratum after sorting the list of beneficiaries by gender and age.

Oxygen users will receive the oxygen survey. Other DMEPOS users will receive one of the other DMEPOS surveys. This survey will ask them to discuss a particular DMEPOS product. For example, those who were sampled as "wheelchair users" will be asked to think about their wheelchair supplier when they complete the survey. Most of the questions asked on each of the different products (oxygen and other DMEPOS) surveys will be the same, i.e., those who were sampled as "wheelchair users" will be asked many of the same questions about their wheelchair supplier as those who were sampled as "hospital

bed users" will be asked about their hospital bed supplier. Since not all questions or answer choices are appropriate for all products, a subset of 14 questions will only address a specific product line.

Supplier Survey

To have adequate statistical power to detect any diversity effects that may exist, we propose to limit the supplier survey to two oxygen HCPCs and two non-oxygen DMEPOS HCPCs that are included in the competitive bidding program. Our criteria for selecting these HCPCs will be the following:

- **The number of HCPC suppliers in each of the study CAAs and comparison areas is large enough to detect statistical significance.** Some areas and product categories may have only a small number of suppliers for certain HCPCs. We will choose the HCPCs for analysis based on which HCPCs have enough suppliers to achieve statistical significance in our analysis.
- **Significance of product diversity from the beneficiary's point of view.** It should be important to beneficiaries' health and quality of life that a range of products exists within the HCPC. These may well be items that must be matched to beneficiary's individual health conditions or lifestyle.
- **Expected sensitivity to competitive bidding.** Items that are sensitive to competitive bidding are those whose Medicare payment is likely to be significantly reduced or those where suppliers might make changes in product lines they carry as a result of lower pricing under competitive bidding.
- **Appropriate number of products within HCPC.** To keep the survey simple and to facilitate the analysis of survey results, we will seek to choose a HCPC in which between two and fifteen different products (or meaningful product groupings) exist.
- **Ease of reporting.** To increase response rates and reduce the effort required for suppliers to respond, we will seek to choose a HCPC in which suppliers are likely to have accessible records that show the make and model of the item supplied. Based on our initial conversations with suppliers, these are likely to be higher-value items, which are typically tracked using serial numbers.
- **A typical as opposed to a one-of-a-kind item.** This survey will pertain to a small number of DMEPOS HCPCs, and it will not be possible to generalize to the wider universe of competitively bid items. Nevertheless, other things equal, we would prefer to choose an item that appears likely to reflect trends among durable medical equipment as a whole, rather than one that is clearly unique or atypical.

Until the specific items are identified in the Final Rule, we will not be able to definitively identify the HCPCs to be used in the survey.

The project team will construct the sampling frame for the supplier survey using DMEPOS claims. This sampling frame will contain a sampling weight that reflects the respondent's share of the total market for the selected HCPC or pair of HCPCs in the geographic area; the sample will be selected so that each supplier's probability of being included will be proportional to its market share.

Each sampled supplier will be asked to provide data on eight (8) claims. The unit of analysis will be the individual claims (not the supplier). The number of claims asked of the suppliers was selected to balance the project's need for statistical precision with the need to manage the response burden. Specifically, this number was chosen to maintain the sizes of the sample of suppliers; to allow us to examine two (2) HCPCs within each supplier category (two (2) oxygen HCPC and two (2) other DMEPOS HCPCs) given finite resources; and to allow us to detect a ten percent change in a binary variable (e.g., whether a given product held the largest share of the HCPC as a whole) with mean of 0.25. Based on our current understanding of suppliers' record keeping, the majority of suppliers could access the data needed to respond to this survey in about 45 minutes, although those with 'paper' systems may take longer. This plan will be discussed with CMS once the CAAs and products are determined, prior to making final decisions.

In this sampling plan, we also assume that it is reasonable to expect oxygen suppliers to offer all of Medicare's units of payment for oxygen, comprising about a dozen HCPCS codes. Under this assumption, we can ask one supplier to provide data regarding four (4) claims in one study oxygen HCPC and four (4) claims in the other study oxygen HCPC in order to maximize statistical power in the presence of design effects. Each of the eight (8) claims will be for a different beneficiary. We assume however that it is not reasonable to expect suppliers of non-oxygen DMEPOS to offer the entire range of non-oxygen DMEPOS products. We thus plan to have two (2) separate samples of suppliers for the two non-oxygen HCPCs and to ask each of those suppliers about eight claims within a single HCPC. We will examine the validity of this assumption using claims data prior to fielding the survey and adjust our plans if necessary.

Based on these sample sizes and the differences-in-differences framework, ranges for detectable differences for each HCPC are shown below in Exhibit 11. These differences are based on a one-sided hypothesis test at a 5 percent level of significance and a binary variable (such as whether the claim reflected the top product) with a mean value of 0.25. For determining the detectable difference we have taken into account the design effect because the sample of claims is not a simple random sample but is sampled from a sample of suppliers. The design effect depends on the size of the variation in the outcome variables between suppliers and within suppliers. For the upper bound on the design effect, we have assumed that ten percent of the variation in the outcome variables stems from between-supplier as opposed to within-supplier effects. With four (4) claims per supplier, we get a design effect of 1.3 for the two oxygen HCPCs whereas with eight (8) claims we get a design effect of 1.7 for the other DMEPOS HCPCs. These design effects produce a smaller effective sample size than the actual sample size. For the lower bound, we have assumed no design effect**.**

Exhibit 11

Sampling Plan for Supplier Survey: Claims

	Oxygen HCPC 1	Oxygen HCPC 2	Other HCPC 1 (e.g. Glucose Monitor)	Other HCPC 2 (e.g. Manual wheelchair)	Total
Claims per supplier	4	4	8	8	
CAA: suppliers (1)	195	195	75	75	
CAA: claims	**780**	**780**	**600**	**600**	**2,760**
Comparison area: suppliers (1)	130	130	50	50	
Comparison area: claims	**520**	**520**	**400**	**400**	**1,840**
Total claims	**1,300**	**1,300**	**1,000**	**1,000**	**4,600**
Detectable difference in a binary variable (percentage points) (2)	8.7-9.9	8.7-9.9	9.9-12.9	9.9-12.9	

Notes: (1) The samples of claims in both oxygen HCPCs are drawn from the same sample of suppliers. The samples of claims in the two non-oxygen HCPCs are drawn from two different samples of suppliers.
(2) Detectable difference calculations are based on pooling the three CAAs together and the two comparison areas together. More information about the detectable difference calculation is provided in the text.

C.3 Methods to Maximize Response Rate

Beneficiary Surveys

The beneficiary surveys (written in English and Spanish) are mailed surveys (one for oxygen-users and four for other DMEPOS users) with phone-follow-up, with the goal of a 65% response rate. We anticipate approximately 50% of the cases will be completed by mail, and 15% by telephone.

In our experience with surveying elderly respondents, we have found a high degree of willingness to participate. However, this population is much more likely than the general population to have physical and cognitive limitations that affect their ability to complete the survey, making it difficult to achieve high response rates. While our goal response rate (65%) is below the target of 80% specified by the Office of Management and Budget (OMB) guidelines, we will seek to minimize the impact of non-response bias by the techniques described below and through statistical measures such as adding weights to our final data.

Instrument Design

We address the challenge of addressing the Medicare population by tailoring the instruments to the needs of this population. The surveys are clearly written, use simple vocabulary, and are printed in large font for respondents who might have visual problems.

The items in each instrument were designed to meet not only the analytical objectives necessary to answer the research questions, but also to be unambiguous, non-threatening, unbiased, non-repetitive and properly sequenced. Response categories are written to be mutually exclusive and collectively exhaustive, where applicable. Each survey will have both a self-administered mail questionnaire and an interviewer-administered telephone survey script in order to offer respondents an option to complete the survey by telephone.

Mail Survey Procedures

Once the sample for the beneficiary survey is drawn, we will send the names and addresses through the National Change of Address (NCOA) system to ensure the address file completeness and accuracy. We will use phone follow-up and other efforts to locate individuals who lack a valid mailing address.

The outer encasement of the mailing materials will convey the importance of the contents. We will use a well-designed, high quality outer envelope with graphics and colored print to convey a clear message about credibility of the source and the importance of a reply. We will mail the beneficiary survey packets using first-class mail and the outer envelope will use the CMS logo and will be designed by a professional graphic artist.

The survey packets mailed to beneficiaries will include a cover letter, study fact sheet, the survey instrument, and a postage-paid reply envelope. The cover letter explains: the purpose of the study and the risks and benefits of participation. In addition, it provides a toll-free number to call with questions, request a Spanish survey, or to complete the interview over the telephone. The materials will be personalized, will clearly identify CMS as the study sponsor, and will depict endorsing professional organizations, in an effort to increase perceived legitimacy.

We will ship a postcard reminder one week after each survey packet to each presumed eligible non-respondent. The follow-up postcard will stress the importance of participation in the study and offer the toll-free number with a request that the recipients call us to complete the interview by phone or let us know why they did not to respond to the mailings.[1] This presents an opportunity for the interviewing staff to conduct refusal conversion efforts, as needed.

Telephone Follow Up

We will minimize non-response by using highly effective sample management techniques by the adherence to strict quality control standards with respect to interviewer monitoring, on-going feedback and training. Highly trained and skilled Abt interviewing staff, including Spanish-speaking interviewers, will conduct phone surveys upon respondent request or as follow up to beneficiaries who have not responded to the mailed surveys.

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[1] Staff will also fulfill re-mail requests, as needed, during the outbound phone follow-up efforts.

Phone follow-up to presumed eligible non-respondents will begin at week nine of the field period and will last through week twelve. First, we will send the list of presumed eligible non-respondents for tele-matching. Dialing for the beneficiary survey will be from 9:00 a.m. to 9:00 p.m., respondent time. Our telephone data collection is supported by a full-featured CATI system with automated case delivery and built-in quality control. The sample management system developed by Abt Associates is extraordinarily sophisticated, providing efficient and effective sample distribution.

Supplier Survey

The strategies for minimizing non-response to the supplier survey draw from standard methods used to attain higher response rates as well as customized approaches aimed at allaying suppliers' concerns and increasing the perceived integrity of the survey. Based on our experience and discussions with our TEP, we anticipate challenges to achieving the targeted response rate because of potential barriers to participation. The potential barriers include suspicion of an ulterior motive for the survey, the similarities of the survey to an audit (using claims), confidentiality and HIPAA concerns, the (unfounded) concern that an already paid claim is being disputed, and other perceptions of past negative experiences with CMS. Therefore recruitment strategies will include the following:

- An advance letter explaining the purpose of the survey;
- Careful attention to the language used in the survey letters;
- Full compliance with all HIPAA regulations and assurances to suppliers that this is the case;
- Assurances that all data will be held in confidence and that the transmission over the Internet will be secure;
- An offer of two modes of survey completion – via the web or on the telephone, both of which will be easily accessible to participants in a corporate setting;
- Endorsement from the relevant professional organizations and associations. These may include the American Association of Homecare (AAHomecare) and other applicable associations/organizations, depending on the products that are chosen for competitive bidding and the supplier survey. Members of the TEP have offered to help us to secure these endorsements;
- Reminder postcards;
- Automated e-mail reminders;
- Telephone follow-ups; and
- A $75 thank you gift upon completing the survey.

Once the DMEPOS products are chosen for competitive bidding there will be a need for a more focused consideration of the concerns unique to those product categories. Besides these strategies, there will be continued discussion on the project team and with the suppliers from the TEP to identify additional ways to encourage participation and dispel concerns.

As part of our ongoing sample management, we will carefully monitor not only the overall completion rates for the surveys but also the completion rates within each of the subgroups (new and existing users of oxygen and other DMEPOS) to ensure that we meet analytical requirements. We will be able to monitor

progress on the Web survey in real time. Specifically, we will be able to track whether a given supplier has logged in and begun the survey, how far he / she has progressed, and whether or not the survey is completed. As a result, we will be targeting and tailoring our phone follow-up to the suppliers who have not yet completed their surveys accordingly, to maximize the results from our efforts and minimize respondent burden.

C.4 Tests of Procedures

Beneficiary Survey Testing

Before we field the beneficiary surveys, we will cognitively test the surveys over the telephone and in person with nine (9) beneficiaries. Through cognitive testing, we hope to determine whether respondents find it easy or hard to complete the survey, identify specific issues or problems with the beneficiary's survey structure and organization, and determine if the wording of specific survey questions could be improved or simplified. Cognitive interviewing is based on the production of verbal reports about each phase of the response process, typically modeled as: comprehension, recall, response formation, and reporting. Cognitive interview protocols will be designed to combine concurrent or retrospective "Think Aloud" techniques with other procedures. Cognitive interviewing can provide possible reasons that a particular question is not performing as intended. Such information will be used for revising instruments.

After completing the cognitive testing interviews, we will conduct a respondent debriefing to determine whether there were any other points of confusion or lack of clarity.

Supplier Survey Testing

The supplier survey has been designed in light of the project's objectives and the desire to maximize response rates and minimize respondent burden. Several members of the TEP, convened for the beneficiary survey, have also advised us on this design.

Prior to the initiation of Wave 1, we will conduct cognitive testing with nine (9) DMEPOS suppliers on the survey. The cognitive testing will include monitoring ease of navigating efficiently through the instrument, entering responses in the prescribed manner, the appropriateness of claims information requested, the completeness of the drop down menus for product manufacturers and product names/models, burden of completing the survey, and potential wording or administration that increases perceived integrity and diminishes perceived barriers to completing the survey.

After completion of the survey, we will conduct a debriefing session with the participants to discuss aforementioned properties of the survey. When possible, we will conduct these testing and debriefing sessions in-person. The cognitive testing participants will receive a $75 honorarium. Additionally, the results of the cognitive testing and subsequent debriefings may be discussed with suppliers of the TEP to explore ideas for further refinement of the instrument before implementation.

C.5 Individuals Consulted on Statistical Aspects of Design

Exhibit 12 contains the names, affiliations, and contact information for the individuals who consulted on statistical aspects of the design. These individuals also assisted in developing the project design and data collection protocols. Abt Associates Inc., Cambridge, Massachusetts is the contractor who will conduct the data collection and analysis for CMS.

Exhibit 12

Statistical Design Consultants

- Dr. Kent Christopher, PhD, Denver, CO, 303-337-8080
- Dr. Doran Edwards, PhD, Palmetto GBA, SADMERC, Columbia, SC, 803-763-4519
- Laraine Forry, Air Products Healthcare, Lewisberry, PA, 717-579-2638
- Professor Bruce Friedman, PhD, University of Rochester, Rochester, NY, 585-273-2618
- Joseph Lewarski, Inogen, Eastlake, OH, 440-269-8046
- Jean Minkel, Minkel Consulting, New Windsor, NY, 845-496-5022
- Jon Christianson, PhD, University of Minnesota, 612-624-3849
- Roger Feldman, PhD, University of Minnesota, 612-624-5669
- Marian Wrobel, PhD, Abt Associates, Cambridge, MA, 617-349-2454
- K.P. Srinath, PhD, Abt Associates, Bethesda, MD, 301-634-1836
- Susan Jureidini, Abt associates, Cambridge, MA, 617-492-7100

APPENDIX A

Medicare Prescription Drug, Improvement and Modernization Act of 2003

Medicare Prescription Drug, Improvement and Modernization Act of 2003

MMA Section 302(b)
H. R. 159-171

One Hundred Eighth Congress
of the
United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday, the seventh day of January, two thousand and three

An Act

To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medi care Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes.

Be it enacted by the Senate and House of Representatives of *the United States of America in Congress assembled*,

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

SEC. 302. PAYMENT FOR DURABLE MEDICAL EQUIPMENT; COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(b) COMPETITIVE ACQUISITION.—
(1) IN GENERAL.—Section 1847 (42 U.S.C. 1395w–3) is amended to read as follows:
''COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES
''SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—
''(1) IMPLEMENTATION OF PROGRAMS.—
''(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.
''(B) PHASED-IN IMPLEMENTATION.—The programs—
''(i) shall be phased in among competitive acquisition areas in a manner so that the competition under the programs occurs in—
''(I) 10 of the largest metropolitan statistical areas in 2007;
''(II) 80 of the largest metropolitan statistical areas in 2009; and
''(III) additional areas after 2009; and
''(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.
''(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.
''(2) ITEMS AND SERVICES DESCRIBED.—The items and services referred to in paragraph (1) are the following:
''(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES.—Covered items (as defined in section 1834(a)(13)) for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.
''(B) OTHER EQUIPMENT AND SUPPLIES.—Items and services described in section 1842(s)(2)(D), other than parenteral nutrients, equipment, and supplies.
''(C) OFF-THE-SHELF ORTHOTICS.—Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) which require minimal selfadjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing

to fit to the individual.
''(3) EXCEPTION AUTHORITY.—In carrying out the programs under this section, the Secretary may exempt—
''(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and
''(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.
''(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF DURABLE MEDICAL EQUIPMENT AND OXYGEN.—In the case of a covered item for which payment is made on a rental basis under section 1834(a) and in the case of payment for oxygen under section 1834(a)(5), the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1834(a).
''(5) PHYSICIAN AUTHORIZATION.—
''(A) IN GENERAL.—With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.
''(B) NO EFFECT ON PAYMENT AMOUNT.—A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.
''(6) APPLICATION.—For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a), section 1834(h), or section 1842(s), as appropriate.
''(b) PROGRAM REQUIREMENTS.—
''(1) IN GENERAL.—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.
''(2) CONDITIONS FOR AWARDING CONTRACT.—
''(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary

finds all of the following:
''(i) The entity meets applicable quality standards specified by the Secretary under section 1834(a)(20).
''(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.
''(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.
''(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.
''(B) TIMELY IMPLEMENTATION OF PROGRAM.—Any delay in the implementation of quality standards under section 1834(a)(20) or delay in the receipt of advice from the program oversight committee established under subsection (c) shall not delay the implementation of the competitive acquisition program under this section.
''(3) CONTENTS OF CONTRACT.—
''(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.
''(B) TERM OF CONTRACTS.—The Secretary shall recompete contracts under this section not less often than once every 3 years.
''(4) LIMIT ON NUMBER OF CONTRACTORS.—
''(A) IN GENERAL.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.
''(B) MULTIPLE WINNERS.—The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.
''(5) PAYMENT.—
''(A) IN GENERAL.—Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.
''(B) REDUCED BENEFICIARY COST-SHARING.—
''(i) APPLICATION OF COINSURANCE.—Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).
''(ii) APPLICATION OF DEDUCTIBLE.—Before applying

clause (i), the individual shall be required to meet the deductible described in section 1833(b).

''(C) PAYMENT ON ASSIGNMENT-RELATED BASIS.—Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

''(D) CONSTRUCTION.—Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

''(6) PARTICIPATING CONTRACTORS.—

''(A) IN GENERAL.—Except as provided in subsection (a)(4), payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

''(i) the contractor has submitted a bid for such items and services under this section; and

''(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

''(B) BID DEFINED.—In this section, the term 'bid' means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

''(C) RULES FOR MERGERS AND ACQUISITIONS.—In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

''(D) PROTECTION OF SMALL SUPPLIERS.—In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

''(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

''(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH, AND COMPLAINT SERVICES.—The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

''(9) AUTHORITY TO CONTRACT FOR IMPLEMENTATION.—The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

''(10) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

''(A) the establishment of payment amounts under paragraph (5);
''(B) the awarding of contracts under this section;
''(C) the designation of competitive acquisition areas under subsection (a)(1)(A);
''(D) the phased-in implementation under subsection (a)(1)(B);
''(E) the selection of items and services for competitive acquisition under subsection (a)(2); or
''(F) the bidding structure and number of contractors selected under this section.
''(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—
''(1) ESTABLISHMENT.—The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the 'Committee').
''(2) MEMBERSHIP; TERMS.—The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.
''(3) DUTIES.—
''(A) ADVICE.—The Committee shall provide advice to the Secretary with respect to the following functions:
''(i) The implementation of the program under this section.
''(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii).
''(iii) The establishment of requirements for collection of data for the efficient management of the program.
''(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d)), and individuals.
''(v) The establishment of quality standards under section 1834(a)(20).
''(B) ADDITIONAL DUTIES.—The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.
''(4) INAPPLICABILITY OF FACA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.
''(5) TERMINATION.—The Committee shall terminate on December 31, 2009.
''(d) REPORT.—Not later than July 1, 2009, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in costsharing, access to and quality of items and services, and satisfaction of individuals.
''(e) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—
''(1) IN GENERAL.—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—
''(A) for which payment would otherwise be made under section 1833(h) (other than for pap smear laboratory tests under paragraph (7) of such section) or section 1834(d)(1) (relating to colorectal cancer screening tests); and

''(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

''(2) TERMS AND CONDITIONS.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2), excluding subsection (b)(5)(B) and other conditions as the Secretary determines to be appropriate.

''(B) APPLICATION OF CLIA QUALITY STANDARDS.—The quality standards established by the Secretary under section 353 of the Public Health Service Act for clinical diagnostic laboratory tests shall apply to such tests under the demonstration project under this section in lieu of quality standards described in subsection (b)(2)(A)(i).

''(3) REPORT.—The Secretary shall submit to Congress—

''(A) an initial report on the project not later than December 31, 2005; and

''(B) such progress and final reports on the project after such date as the Secretary determines appropriate.''.

(2) CONFORMING AMENDMENTS.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended—

(A) by striking ''and (U)'' and inserting ''(U)'';

(B) by inserting before the semicolon at the end the following: '', and (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5)''; and

(C) in clause (D)—

(i) by striking ''or (ii)'' and inserting ''(ii)''; and

(ii) by adding at the end the following: ''or (iii) on the basis of a rate established under a demonstration project under section 1847(e), the amount paid shall be equal to 100 percent of such rate,''.

(3) GAO REPORT ON IMPACT OF COMPETITIVE ACQUISITION ON SUPPLIERS.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study on the impact of competitive acquisition of durable medical equipment under section 1847 of the Social Security Act, as amended by paragraph (1), on suppliers and manufacturers of such equipment and on patients. Such study shall specifically examine the impact of such competitive acquisition on access to, and quality of, such equipment and service related to such equipment.

(B) REPORT.—Not later than January 1, 2009, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A) and shall include in the report such recommendations as the Comptroller General determines appropriate.

(c) TRANSITIONAL FREEZE.—
(1) DME.—
(A) IN GENERAL.—Section 1834(a)(14) (42 U.S.C. 1395m(a)(14)) is amended—
(i) in subparagraph (E), by striking ''and'' at the end;
(ii) in subparagraph (F)—
(I) by striking ''a subsequent year'' and inserting ''2003''; and
(II) by striking ''the previous year.'' and inserting ''2002;''; and
(iii) by adding at the end the following new subparagraphs:
''(G) for 2004 through 2006—
''(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) for the year involved; and
''(ii) in the case of covered items not described in clause (i), 0 percentage points;
''(H) for 2007—
''(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) o f the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and
''(ii) in the case of covered items not described in clause (i), 0 percentage points; and
''(I) for 2008—
''(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and
''(ii) in the case of covered items not described in clause (i), 0 percentage points; and
''(J) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.''.
(B) GAO REPORT ON CLASS III MEDICAL DEVICES.—Not later than March 1, 2006, the Comptroller General of the United States shall submit to Congress, and transmit to the Secretary, a report containing recommendations on the appropriate update percentage under section 1834(a)(14) of the Social Security Act (42 U.S.C. 1395m(a)(14)) for class III medical devices described in section 513(a)(1)(C)

of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C)) furnished to medicare beneficiaries during 2007 and 2008.

(2) PAYMENT RULE FOR SPECIFIED ITEMS.—Section 1834(a) (42 U.S.C. 1395m(a)), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

''(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS AND SUPPLIES.—

''(A) IN GENERAL.—Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

''(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

''(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code, as identified in the column entitled 'Median FEHP Price' in the table entitled 'SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS' included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

''(B) SPECIFIED ITEM OR SUPPLY DESCRIBED.—For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

''(C) APPLICATION OF UPDATE TO SPECIAL PAYMENT AMOUNT.—The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847.''.

(3) PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—Section 1834(h)(4)(A) (42 U.S.C. 1395m(h)(4)(A)) is amended—

(A) in clause (vii), by striking ''and'' at the end;

(B) in clause (viii), by striking ''a subsequent year'' and inserting ''2003''; and

(C) by adding at the end the following new clauses:

''(ix) for 2004, 2005, and 2006, 0 percent; and

''(x) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;''.

(d) CONFORMING AMENDMENTS.—
(1) DURABLE MEDICAL EQUIPMENT; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended—
(A) in paragraph (1)(B), by striking ''The payment basis'' and inserting ''Subject to subparagraph (F)(i), the payment basis'';
(B) in paragraph (1)(C), by striking ''This subsection'' and inserting ''Subject to subparagraph (F)(ii), this subsection'';
(C) by adding at the end of paragraph (1) the following new subparagraph:
''(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of covered items furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—
''(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and
''(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied.''; and
(D) in paragraph (10)(B), by inserting ''in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F)'' after ''under this subsection''.
(2) OFF-THE-SHELF ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(h) (42 U.S.C. 1395m(h)) is amended—
(A) in paragraph (1)(B), by striking ''and (E)'' and inserting '', (E), and (H)(i)'';
(B) in paragraph (1)(D), by striking ''This subsection'' and inserting ''Subject to subparagraph (H)(ii), this subsection'';
and
(C) by adding at the end of paragraph (1) the following new subparagraph:
''(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under such section—
''(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

''(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.''.

(3) OTHER ITEMS AND SERVICES; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1842(s) (42 U.S.C. 1395u(s)) is amended—

(A) in the first sentence of paragraph (1), by striking ''The Secretary'' and inserting ''Subject to paragraph (3), the Secretary''; and

(B) by adding at the end the following new paragraph:

''(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

''(A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

''(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.''.

(e) REPORT ON ACTIVITIES OF SUPPLIERS.—The Inspector General of the Department of Health and Human Services shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act, as amended by subsection (a), are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. Not later than July 1, 2009, the Inspector General shall submit to Congress a report on such study.

MMA Section 303(d)
H. R. 178-179

SEC. 303. PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS.

''(d) MONITORING OF MARKET PRICES.—
''(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.
''(2) COMPARISON OF PRICES.—Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—
''(A) the widely available market price for such drugs and biologicals (if any); and
''(B) the average manufacturer price (as determined under section 1927(k)(1)) for such drugs and biologicals.
''(3) LIMITATION ON AVERAGE SALES PRICE.—
''(A) IN GENERAL.—The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).
''(B) APPLICABLE THRESHOLD PERCENTAGE DEFINED.—In this paragraph, the term 'applicable threshold percentage' means—
''(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and
''(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.
''(C) AUTHORITY TO ADJUST AVERAGE SALES PRICE.—If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—
''(i) the widely available market price for the drug

or biological (if any); or
''(ii) 103 percent of the average manufacturer price (as determined under section 1927(k)(1)) for the drug or biological.
''(4) CIVIL MONEY PENALTY.—
''(A) IN GENERAL.—If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.
''(B) PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (B) in the same manner as they apply to a penalty or proceeding under section 1128A(a).
''(5) WIDELY AVAILABLE MARKET PRICE.—
''(A) IN GENERAL.—In this subsection, the term 'widely available market price' means the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.
''(B) CONSIDERATIONS.—In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:
''(i) Manufacturers.
''(ii) Wholesalers.
''(iii) Distributors.
''(iv) Physician supply houses.
''(v) Specialty pharmacies.
''(vi) Group purchasing arrangements.
''(vii) Surveys of physicians.
''(viii) Surveys of suppliers.
''(ix) Information on such market prices from insurers.
''(x) Information on such market prices from private health plans.

APPENDIX B

Statistical Data Collection Instruments

OMB# 0938-NEW

ABT ID #

CMS Survey of Oxygen Equipment Beneficiaries

If the person this survey was mailed to cannot complete the survey and there is no one else who can do so for him or her, please check the appropriate box below and return the blank survey in the enclosed postage-paid envelope. The person this survey was mailed to is:

- ❑$_1$ In a nursing home or other institution and cannot complete the survey
- ❑$_2$ Deceased
- ❑$_3$ Not able to complete the survey and has no one else who can help
- ❑$_{95}$ Other reason (Specify:) _____

Please return by _____.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-NEW. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Instructions

The questions in this survey ask about your experiences as a person who uses oxygen equipment.

To complete the survey, please answer the questions by checking the box to the left of your answer (as shown below). You are sometimes told to skip over some questions in this survey. When this happens you will see an arrow beside your response with a note that tells you which question to answer next, like this:

- ❒ Yes
- ☑ No → Skip to A5
- ❒ I don't know

If there is no arrow next to your response, please proceed to the next question.

Some people might ask someone else (maybe a spouse, child, or friend) to help them complete this survey. If someone is helping you fill out the survey, remember that the questions always refer to you and your experience with oxygen treatment and equipment.

Confidentiality

All information that would let someone identify you or your family will be kept private. You may choose to answer this survey or not. If you choose not to, this will not affect the Medicare benefits you get. You may notice a number on the cover of this survey. This number is ONLY used to let us know if you returned your survey so we won't send you reminders.

If you have any questions about the survey, please call 1-xxx-xxx-xxxx.

A. INTRODUCTION – ALL USERS

A1. Do you <u>use</u> any type of oxygen system now? This includes using oxygen all of the time, with exercise or walking only, at night only, or using it with another medical device such as a CPAP machine or ventilator.

❑$_1$ Yes **(→ Skip to A2)**

❑$_2$ No

❑$_3$ I have <u>never</u> used Oxygen **(→ Skip to SECTION H)**

A1a. Why did you stop using oxygen? (Please check all that apply and then go to SECTION H)

❑$_1$ I believed that my breathing got better so I didn't need it anymore

❑$_2$ My doctor said I didn't need it

❑$_3$ Oxygen therapy cost too much

❑$_4$ I just didn't like using it

❑$_5$ Equipment was too heavy or cumbersome

❑$_6$ Equipment kept breaking down

❑$_7$ I had a problem getting the supplies from my oxygen supplier

❑$_8$ Other (Please specify:) _____

❑$_{98}$ I don't know

A2. Do you have anyone who regularly helps you use your oxygen equipment (e.g. a relative or a friend)?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

A3. Did your doctor or health care provider (e.g. respiratory therapist) ever explain to you why you needed oxygen?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

A4. Did your doctor or health care provider (e.g. respiratory therapist) ever explain to you how much oxygen you needed?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$I don't know

A5. Did your doctor or health care provider (e.g. respiratory therapist) ever explain to you when you're supposed to use it?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$I don't know

A6. Did your doctor or health care provider (e.g. respiratory therapist) ever explain to you the equipment options that you have?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$I don't know

A7. Did your doctor or health care provider (e.g. respiratory therapist) ever suggest that you contact your supplier about your equipment options?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$I don't know

A8. When you were first prescribed oxygen, how long did you expect to use it?

❑$_1$ Less than 1 month
❑$_2$ 2 to 6 months
❑$_3$ More than 6 months
❑$_4$ Forever
❑$_{98}$ I don't know

A9. When was the last time you saw a doctor or other health care provider (e.g. respiratory therapist) to discuss your need for oxygen?

❑$_1$ Within the last 6 months
❑$_2$ Between 6 months and 1 year ago
❑$_3$ Between 1 and 3 years ago
❑$_4$ More than 3 years ago
❑$_{98}$ I don't know

A10. Do you believe that you have the oxygen equipment that is right for you?

❑$_1$ Yes
❑$_2$ No
❑$_{98}$ I don't know

A11. Are you able to do what you want with your oxygen equipment?

❑$_1$ Yes **(→ Skip to A12)**

❑$_2$ No

❑$_{98}$ I don't know **(→ Skip to A12)**

A11a. What do you want to do that your oxygen equipment <u>does not allow</u> you to do? (Please check all that apply)

❑$_1$ Can't move freely around my home

❑$_2$ Can't go outside of my home to get the mail or for a short walk

❑$_3$ Can't go to the doctor when I need to

❑$_4$ Can't go to church, visit friends, shop, or leave the house for more than a short time

❑$_5$ Something else (Specify):

_____

❑$_{98}$ I don't know

A12. Is using the oxygen equipment difficult or uncomfortable?

❑$_1$ Yes

❑$_2$ No **(→ Skip to A13)**

❑$_{98}$I don't know **(→ Skip to A13)**

A12a. What is it about your oxygen equipment that makes it difficult or uncomfortable for you to use it? (Please check all that apply)

❑$_1$ It is not difficult or uncomfortable to use

❑$_2$ Equipment is too heavy or cumbersome (hard to lift, doesn't fit easily into the car)

❑$_3$ Equipment doesn't supply enough air for the necessary amount of time/ I'm afraid I'll run out of air

❑$_4$ Equipment breaks down a lot

❑$_5$ I don't know how to use the equipment well enough to be away from home

❑$_6$ I am embarrassed to use it

❑$_7$ Other (please tell us what else): _____

❑$_{98}$ I don't know

A14. Does using the equipment make you feel better?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

A15. Are you still using the same oxygen equipment as when you first started oxygen therapy?

❑$_1$ Yes

❑$_2$ No **(→ Skip to SECTION B)**

❑$_{98}$ I don't know **(→ Skip to SECTION B)**

A15a. Why did you make these changes? (Please check all that apply)

❑$_1$ Equipment needed to be replaced because it didn't work

❑$_2$ My condition/breathing changed

❑$_3$ I found new equipment that was better for me

❑$_4$ Equipment no longer available through supplier

❑$_5$ Supplier told me Medicare no longer covered equipment

❑$_6$ Doctor prescribed a different type of equipment

❑$_7$ Other *(Please specify:)* _____

B. STATIONARY OXYGEN – ALL USERS

Stationary oxygen systems are heavy pieces of equipment that you cannot move easily.

These include non-portable oxygen concentrators, liquid oxygen vessels, and large compressed gas oxygen cylinders.

B1. Do you use any type of stationary oxygen system <u>now</u>?

❑$_1$ Yes

❑$_2$ No **(→ Skip to SECTION C)**

B2. What type of stationary oxygen system(s) do you usually use at home? (Please check all that apply)

[Pictures to be provided]

❑1 Oxygen concentrator machine (unit that plugs into the wall and produces oxygen)

❑2 Liquid oxygen vessel (large tank that resembles a large thermos)

❑3 Large compressed oxygen cylinder (resembles a welding tank)

❑4 Oxygen concentrator system that allows me to fill small cylinders

❑5 Small portable concentrator that also serves as a stationary source

❑8 Don't use a stationary oxygen system

❑98 I don't know

[pictures]

B3. What type of oxygen delivery device do you breathe from to get your oxygen? (Please check all that apply)

[Pictures to be provided]

❑1 Nasal cannula (nasal prongs/tubes)

❑2 Transtracheal catheter (very thin tube that goes directly in my throat)

❑3 Reservoir cannula (nasal or pendant)

❑4 Oxygen mask

❑5 Connection to my tracheostomy tube

❑6 Connection to my CPAP machine, bi-level device, or ventilator

❑98 I don't know

[photos]

B4. In general, how often do you use your stationary oxygen system?

❑1 Every day

❑2 A few days a week

❑3 One day per week

❑4 One day or two per month

❑98 I don't know

B5. On the days that you do use stationary oxygen, about how many hours per day do you use it?

_____ hours per day

❑98 I don't know

B6. Are you using less oxygen from your <u>stationary</u> system than was prescribed by your doctor?

❑$_1$ Yes

❑$_2$ No **(→ Skip to B7)**

❑$_{98}$ I don't know **(→ Skip to B7)**

B6a. Please tell us why you are using less oxygen from your <u>stationary</u> system than was prescribed. (Please check all that apply)

❑$_1$ I'm using oxygen as prescribed

❑$_2$ I believe that my breathing got better so I don't need it anymore

❑$_3$ Oxygen therapy costs too much

❑$_4$ I just don't like using it

❑$_5$ Equipment is too heavy or cumbersome

❑$_6$ Equipment keeps breaking down

❑$_7$ I have a problem getting the supplies from my oxygen supplier

❑$_8$ Other (Please specify:) _____

Sometimes people have serious problems with their <u>stationary</u> systems that force them to go without oxygen or to use another source of oxygen, such as a portable tank or emergency back-up tank.

B7.<u>During the past 6 months</u>, did you have any serious problems like these?

❑$_1$ Yes

❑$_2$ No **(→ Skip to SECTION C)**

❑$_{98}$ I don't know **(→ Skip to SECTION C)**

B7a. Can you describe the kind of problem(s) that you had? (Please check all that apply)

❑$_1$ Power outage in my home

❑$_2$ Equipment failed or did not work

❑$_3$ Unit ran out of oxygen (liquid or cylinder)

❑$_4$ Other (Please specify:) _____

_____

❑$_{98}$ I don't know

B7b. How many times did you have these kinds of problems?

❑$_1$ One time

❑$_2$ 2 or 3 times

❑$_3$ 4 or more times

❑$_4$ Don't recall the exact number of times

C. PORTABLE OXYGEN – ALL USERS

Portable oxygen systems are made to let you keep using oxygen when you are away from the stationary system. They may be light enough to carry on a strap over your shoulder, or to pull on a wheeled cart.

Your portable oxygen system may be a small gaseous oxygen tank, a small liquid oxygen cylinder, or a small portable oxygen concentrator.

C1. Do you use any type of <u>portable</u> oxygen system <u>now</u>?

❑$_1$ Yes

❑$_2$ No **(→ Skip to SECTION D)**

C2. What type of <u>portable</u> oxygen system(s) do you use? (Please check all that apply)

[Pictures to be provided]

❑$_1$ Mid-sized compressed oxygen tank (E-cylinder, resembles a diving tank)

❑$_2$ Very small and light compressed oxygen tank (can carry on my shoulder)

❑$_3$ Mid-sized or standard portable liquid oxygen unit

❑$_4$ Very small liquid portable unit (i.e., can carry on my shoulder or belt and delivers pulses of oxygen)

❑$_5$ Small portable oxygen concentrator

❑$_6$ Combination of liquid and portable cylinder.

❑$_7$ Don't use a portable oxygen system

[photos]

C3. In general, how often do you use your <u>portable</u> oxygen system?

❑$_1$ Every day
❑$_2$ A few days a week
❑$_3$ One day per week
❑$_4$ One day or two per month
❑$_{98}$ I don't know

C4. On the days that you do use <u>portable</u> oxygen, about how many hours per day do you use it?

_____ hours per day
❑$_{98}$ I don't know

C5. Are you using less oxygen from your <u>portable</u> system than was prescribed by your doctor?

❑$_1$ Yes
❑$_2$ No **(→ Skip to C6)**
❑$_{98}$ I don't know **(→ Skip to C6)**

C5a. Please tell us why you are using less oxygen from your <u>portable</u> system than was prescribed. (Please check all that apply)

❑$_1$ I use my portable oxygen very often
❑$_2$ I think that my breathing is better so I don't need oxygen very much
❑$_3$ I don't want other people to stare at me or know about my condition
❑$_4$ I just don't like using it
❑$_5$ I don't know how to use it very well
❑$_6$ My doctor said not to use it very often
❑$_7$ Equipment is too heavy or cumbersome
❑$_8$ Equipment is too complicated
❑$_9$ Equipment keeps breaking down
❑$_{10}$ I have a problem getting the supplies from the supplier
❑$_{11}$ Other (Please specify:) _____

C6. In general, how often do you get deliveries/refills from your oxygen supplier for your <u>portable</u> oxygen systems? This may include oxygen tank deliveries, liquid oxygen refills, etc.

❑$_1$ 4 times a month
❑$_2$ 2-3 times a month
❑$_3$ Once a month
❑$_4$ Once every year
❑$_5$ Less than once per year
❑$_6$ Don't get refills of any type **(→ Skip to C7)**
❑$_{98}$ I don't know

C6a. If you get tank refills for your <u>portable</u> oxygen system, how many tank refills do you normally get at one time (that is, number of tanks per delivery)?

____ Number of tanks at one time
❑$_{95}$ Don't get refills

An intermittent flow device gives you oxygen only when you breathe in. Examples of these oxygen-conserving devices are pulse-dosing oxygen regulators, small liquid portable units, or portable concentrators.

C7. Do you use any type of <u>intermittent flow devices</u> with your portable system <u>now</u>?

❑$_1$ Yes
❑$_2$ No **(→ Skip to SECTION D)**
❑$_{98}$ I don't know **(→ Skip to SECTION D)**

C7a. When you were first provided with your <u>intermittent flow device</u>, who adjusted the device and tested you while you were using it? (Please check all that apply)

❑$_1$ Home oxygen supplier
❑$_2$ Doctor
❑$_3$ Other medical personnel
❑$_4$ No one
❑$_5$ Not sure who the person was
❑$_6$ Don't remember if anyone did

D. MEDICAL EXPENSES – ALL USERS

D1. In 2006, did you buy any oxygen equipment or supplies with your own money because they were not covered by your insurance? Do not include your Medicare co-pay.

❑$_1$ Yes

❑$_2$ No **(→ Skip to SECTION E)**

❑$_3$ Don't know **(→ Skip to SECTION E)**

D2. What did you buy with your own money in 2006? (Please check all that apply)

❑$_1$ Extra portable oxygen system

❑$_2$ Extra stationary oxygen system

❑$_3$ Oxygen conserving/intermittent device

❑$_4$ Special nasal cannula

❑$_5$ Transtracheal supplies

❑$_6$ Other (specify) _____

❑$_{98}$ I don't know

D3. Think about what you've paid for with your own money for the oxygen equipment and supplies that were not covered by insurance. How much did you spend in 2006? Do not include your Medicare co-pay.

❑$_1$ Less than $100

❑$_2$ $100-$500

❑$_3$ $500 or more

❑$_{98}$ I don't know

E. OXYGEN SUPPLIER – ALL USERS

E1. Do you have more than one supplier for your oxygen equipment, supplies, maintenance and repairs?

❑$_1$ Yes
❑$_2$ No

E2. Overall, how would you rate the supplier that you use most?

❑$_1$ Poor
❑$_2$ Fair
❑$_3$ Good
❑$_4$ Very good
❑$_5$ Excellent
❑$_{98}$ I don't know

E3. Would you recommend this oxygen supplier to a friend who needed similar services?

❑$_1$ Yes
❑$_2$ No
❑$_{98}$ I don't know

E4. How do you get your oxygen refills and supplies? (Please check all that apply)

❑$_1$ Delivered to my home by my supplier
❑$_2$ Mailed to my home by my supplier
❑$_3$ I pick them up from my oxygen supplier
❑$_4$ Some other way (Please tell us how): _____

E5. In general, how much time and energy does it take to get your oxygen equipment, supplies, maintenance and repairs from your supplier?

❑$_1$ No time and energy
❑$_2$ A little time and energy
❑$_3$ Some time and energy
❑$_4$ A lot of time and energy
❑$_{98}$ I don't know

F. YOUR SUPPLIER – NEW USERS ONLY

F1. Have you used oxygen for less than 6 months?

❑$_1$ Yes

❑$_2$ No **(→ Skip to SECTION G)**

❑$_{98}$ I don't know **(→ Skip to SECTION G)**

F2. <u>When you were first prescribed oxygen therapy</u>, were there any problems finding a home oxygen supplier?

❑$_1$ Yes

❑$_2$ No **(→ Skip to F3)**

❑$_{98}$ I don't know **(→ Skip to F3)**

F2a. What kinds of problems were there? (Please check all that apply)

❑$_1$ Hard to find a supplier who covered my area

❑$_2$ Supplier didn't carry what I needed

❑$_3$ Supplier could not deliver equipment when I needed it

❑$_4$ Supplier did not accept Medicare

❑$_5$ Other (describe:) _____

_____

❑$_{98}$ I don't know

F3. <u>When you were first prescribed oxygen therapy</u>, was there a <u>choice</u> of suppliers?

❑$_1$ Yes, many

❑$_2$ Yes, a few

❑$_3$ No, only one supplier available

❑$_{98}$ I don't know

F4. How long after it was ordered did your oxygen supplier deliver your <u>first</u> equipment?

❑$_1$ Same day

❑$_2$ Next day

❑$_3$ Within a week

❑$_4$ More than 1 week later

❑$_{98}$ I don't know

F5. When you were first prescribed oxygen therapy, what kind of training or help did the supplier give you or the person who takes care of you? (Please check all that apply)

Did he/she…

❑$_1$ Give you written instructions on how to use the equipment or supplies

❑$_2$ Show you how to use the equipment or supplies

❑$_3$ Choose a safe and convenient place to store the equipment or supplies

❑$_4$ Show you how to clean and maintain the equipment or supplies

❑$_5$ Show you how to use oxygen safely

❑$_6$ Let you practice how to use and maintain your equipment and supplies while they watched

❑$_7$ Gave me the manufacturer's customer assistance toll-free telephone number

❑$_8$ I didn't get any training or help from my oxygen supplier **(→ Skip to F6)**

❑$_{98}$ I don't know **(→ Skip to F6)**

F5a. As a result of that training, how comfortable do you feel using and maintaining your oxygen equipment?

❑$_1$ Very comfortable

❑$_2$ Comfortable

❑$_3$ Uncomfortable

❑$_4$ Very uncomfortable

❑$_5$ My comfort level has nothing to do with the training that my supplier gave me

F6. When you were first prescribed oxygen therapy and asked your supplier questions about your first equipment, did you get answers that you could understand?

❑$_1$ Yes, completely

❑$_2$ Yes, somewhat

❑$_3$ No

❑$_4$ I didn't ask any questions

❑$_{98}$ I don't know

F7. When you were first prescribed oxygen therapy, did your supplier tell you as much as you wanted to know about the options for your first equipment?

❑$_1$ Yes, completely
❑$_2$ Yes, somewhat
❑$_3$ No
❑$_{98}$ I don't know

F8. When you were first prescribed oxygen therapy, did your supplier spend as much time with you as you wanted?

❑$_1$ Yes
❑$_2$ No
❑$_{98}$ I don't know

G. RECENT EXPERIENCES – ALL USERS

A respiratory therapist is a specially trained professional who helps you improve your breathing.

G1. During the past 3 months, about how often did your oxygen supplier send a respiratory therapist to your home to check on your breathing?

❑$_1$ Never in the 3 months
❑$_2$ Once in the past 3 months
❑$_3$ More than once in the past 3 months
❑$_{98}$ I don't know

G2. During the past 3 months, how often did your supplier send someone to your home to make sure that your oxygen equipment was working right? (Don't include times when they came because you called them).

❑$_1$ Never in the 3 months
❑$_2$ 1-2 times in the 3 months
❑$_3$ More than 2 times in the 3 months
❑$_{98}$ I don't know

G3. <u>During the past 3 months</u>, how reliable was your oxygen supplier in making deliveries?

❑$_1$ Very reliable
❑$_2$ Somewhat reliable
❑$_3$ Not reliable at all
❑$_{98}$ I don't know

G4. <u>During the past 3 months</u>, did you contact your oxygen supplier with a complaint or a problem?

❑$_1$ Yes
❑$_2$ No **(→ Skip to G5)**
❑$_3$ Don't remember **(Go to question G5)**
❑$_4$ Don't know how to contact my oxygen supplier **(→ Skip to G5)**

G4a.Was your complaint or problem settled to your satisfaction?

❑$_1$ Yes
❑$_2$ No
❑$_3$ I am waiting for it to be settled
❑$_{98}$ I don't know

G5. <u>During the past 3 months</u>, did you contact your oxygen supplier to get emergency service or advice ?

❑$_1$ Yes

❑$_2$ No **(→ Skip to G6)**

❑$_{98}$ I don't know **(→ Skip to G6)**

G5a. In general, how fast did they respond to your needs, either by phone or in person? Would you say…

❑$_1$ Within 1 day

❑$_2$ Within 2 days

❑$_3$ Within 1 week

❑$_4$ Longer than 1 week

❑$_5$ Don't remember

❑$_6$ Don't know how to contact my oxygen supplier **(→ Skip to G6)**

G5b.Were you able to get the emergency service or advice you needed?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

G6. <u>During the past 3 months</u>, did you need to contact your supplier after regular business hours?

❑$_1$ Yes

❑$_2$ No (→ **Skip to G7)**

❑$_{98}$ I don't know **(→ Skip to G7)**

G6a.During the past 3 months when you contacted your supplier after business hours in general, were you able to get the service or advice you needed?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

G7. During the past 3 months, how reliable has your oxygen equipment been? Would you say…

❑$_1$ Very reliable
❑$_2$ Somewhat reliable
❑$_3$ Somewhat unreliable
❑$_4$ Very unreliable
❑$_{98}$ I don't know

G8. During the past 3 months, have you changed your oxygen supplier?

❑$_1$ Yes
❑$_2$ No **(→ Skip to SECTION H)**
❑$_{98}$ I don't know **(→ Skip to SECTION H)**

G8a. Why did you change your oxygen supplier? (Please check all that apply)

❑$_1$ I moved
❑$_2$ Supplier no longer accepted Medicare for oxygen equipment and supplies
❑$_3$ Supplier went out of business
❑$_4$ Not happy with the quality of service
❑$_5$ Not happy with equipment
❑$_6$ Not happy with the choices of oxygen equipment I could get
❑$_7$ Changed to an HMO and had to use a different supplier
❑$_8$ Other *(Please describe:)* ____

_____

H. ABOUT YOU – ALL

Section H is about you, the person whose name is on the mailing label of this survey.

H1. In general, how would you rate <u>your overall health</u>?

- ❑$_1$ Excellent
- ❑$_2$ Very good
- ❑$_3$ Good
- ❑$_4$ Fair
- ❑$_5$ Poor

H2. <u>Compared to 1 year ago</u>, how would you rate your health now? Would you say…

- ❑$_1$ Much better now
- ❑$_2$ Somewhat better now
- ❑$_3$ About the same
- ❑$_4$ Somewhat worse now
- ❑$_5$ Much worse now
- ❑$_{98}$ I don't know

H3. Which best describes your living situation <u>now</u>? (Please check all that apply)

- ❑$_1$ I live alone
- ❑$_2$ Spouse/partner
- ❑$_3$ Parent/step-parent
- ❑$_4$ Child/children
- ❑$_5$ Other relative(s)
- ❑$_6$ Friend
- ❑$_7$ Other person(s) not related to me

H4. What is the highest grade or level of school that you have <u>completed</u>?

- ❑$_1$ 8th grade or less
- ❑$_2$ Some high school but did not graduate
- ❑$_3$ High school graduate or GED
- ❑$_4$ Some college or technical school
- ❑$_5$ College graduate
- ❑$_6$ More than a 4-year college degree

H5. What was your household's annual income during 2006 before taxes?

❑$_1$ Less than $5,000 ($416 per month)
❑$_2$ Between $5,001 and $10,000 ($417–$833 per month)
❑$_3$ Between $10,001 and $20,000 ($834–$1,666 per month)
❑$_4$ Between $20,001 and $30,000 ($1,667–2,500 per month)
❑$_5$ Over $30,001 (More than $2,500 per month)
❑$_{98}$ I don't know

H6. Are you of Hispanic or Latino heritage?

❑$_1$ Yes
❑$_2$ No

H7. How would you describe your race? (Please check all that apply)

❑$_1$ American Indian or Alaskan Native
❑$_2$ Asian
❑$_3$ Black or African American
❑$_4$ Native Hawaiian or other Pacific Islander
❑$_5$ White or Caucasian
❑$_6$ Other *(Please tell us:)* _____

_____

I. Other Information

I1. Please check the correct statement:

❑$_1$ I am the person to whom this survey was addressed **(→ Skip to END)**

❑$_2$ I filled this survey out or helped fill it out for someone else

I2. Which of these comes closest to how you helped the person with this survey?

❑$_1$ I wrote the answers that the person told me

❑$_2$ I answered the questions myself based on my knowledge of the person's condition

❑$_3$ Both of the above

END

Thank you for completing the survey. Please return the completed survey in the postage-paid envelope addressed to:

Todd Robbins
CMS Survey of Beneficiaries Using Oxygen
55 Wheeler Street,
Cambridge, MA 02138

If you have any **questions about the survey**, please call toll-free 1-xxx-xxx-xxxx.

If you have any **questions about Medicare**, please visit the website of the Center for Medicare Services at: http://www.medicare.gov/, or call 1-800-MEDICARE.

OMB# 0938-NEW

ABT ID #

CMS Survey of Beneficiaries Using Power Wheelchairs

If the person this survey was mailed to cannot complete the survey and there is no one else who can do so for him or her, please check the appropriate box below and return the blank survey in the enclosed postage-paid envelope. The person this survey was mailed to is:

- ❑$_1$ In a nursing home or other institution and cannot complete the survey
- ❑$_2$ Deceased
- ❑$_3$ Not able to complete the survey and has no one else who can help
- ❑$_{95}$ Other reason (Specify:) _____

Please return by _____.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-NEW. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Instructions

The questions in this survey ask about your experiences as a person who uses a power wheelchair.

To complete the survey, please answer the questions by checking the box to the left of your answer (as shown below). You are sometimes told to skip over some questions in this survey. When this happens you will see an arrow beside your response with a note that tells you which question to answer next, like this:

- ❒ Yes
- ☑ No → Skip to A5
- ❒ I don't know

If there is no arrow next to your response, please proceed to the next question.

Some people might ask someone else (maybe a spouse, child, or friend) to help them complete this survey. If someone is helping you fill out the survey, remember that the questions always refer to you and your experience with your power wheelchair.

Confidentiality

All information that would let someone identify you or your family will be kept private. You may choose to answer this survey or not. If you choose not to, this will not affect the Medicare benefits you get. You may notice a number on the cover of this survey. This number is ONLY used to let us know if you returned your survey so we won't send you reminders.

If you have any questions about the survey, please call 1-xxx-xxx-xxxx

A. INTRODUCTION – ALL USERS

A1. Do you <u>use</u> your power wheelchair now? This includes using a power wheelchair all of the time or just occasionally.

❑$_1$ Yes **(→ Skip to A2)**

❑$_2$ No

❑$_3$ I have <u>never</u> used a power wheelchair **(→ Skip to SECTION F)**

A1a. Why did you stop using your power wheelchair? (Please check all that apply and then skip to SECTION F)

❑$_1$ My condition got better so I didn't need it anymore

❑$_2$ My condition got worse so I couldn't use it anymore

❑$_3$ I was embarrassed to use it

❑$_4$ I was not comfortable sitting in it

❑$_5$ I did not feel safe driving it

❑$_6$ I just didn't like using it

❑$_7$ It was too difficult to use

❑$_8$ It kept breaking down

❑$_9$ I had no place to charge it and/or store it

❑$_{10}$ It did not have the features I needed

❑$_{11}$ Other (Please specify:) _____

❑$_{98}$ I don't know

A2. Do you have anyone who regularly helps you use your power wheelchair (e.g. a relative or a friend)?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

A3. Did your doctor or health care provider (e.g. physical therapist) ever explain to you why you needed to use a power wheelchair?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

A4. Did your doctor or health care provider (e.g. physical therapist) ever explain to you the different types of power wheelchairs, controls options and accessories that exist?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

A5. Did your doctor or health care provider (e.g. physical therapist) ever suggest that you contact your supplier about your options?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

A6. When you were first prescribed your power wheelchair, how long did you expect to use it?

❑$_1$ Less than 1 month

❑$_2$ 2 to 6 months

❑$_3$ More than 6 months

❑$_4$ Forever

❑$_{98}$ I don't know

A7. When was the <u>last time</u> you saw a <u>doctor or health care provider</u> (e.g. physical therapist) to discuss your mobility needs or issues related to your wheelchair?

❑$_1$ Within the last 6 months
❑$_2$ Between 6 months and 1 year ago
❑$_3$ Between 1 and 3 years ago
❑$_4$ More than 3 years ago
❑$_{98}$ I don't know

A8. Do you believe that you have the power wheelchair that is right for you?

❑$_1$ Yes
❑$_2$ No
❑$_{98}$ I don't know

A9. Are you able to do what you want with your power wheelchair?

❑$_1$ Yes **(→ Skip to A10)**
❑$_2$ No
❑$_{98}$ I don't know **(→ Skip to A10)**

A9a. What do you want to do that your current power wheelchair <u>does not allow</u> you to do? (Please check all that apply)

❑$_1$ Nothing
❑$_2$ Maneuver the chair more easily inside my home
❑$_3$ Maneuver the chair more easily outside of my home
❑$_4$ Put the chair in a car/taxi to go places
❑$_5$ Sit comfortably in it for a longer time
❑$_6$ Be able to transfer in and out of the wheelchair easily
❑$_6$ Other (please tell us what else):

_____
_____

❑$_{98}$ I don't know

A10. Is using the power wheelchair difficult or uncomfortable?

❑$_1$ Yes

❑$_2$ No **(→Skip to A11)**

❑$_{98}$ I don't know **(→Skip to A11)**

A10a.What is it about your power wheelchair that makes it difficult or uncomfortable for you to use it? (Please check all that apply)

❑$_1$ It is not difficult or uncomfortable

❑$_2$ I cannot sit comfortably in it

❑$_3$ I cannot maneuver it well

❑$_4$ I can't transfer in and out of it easily

❑$_5$ I can't put it in the car or taxi

❑$_6$ It goes too slow or too fast

❑$_7$ It is too heavy and cumbersome to use

❑$_8$ I have trouble charging it

❑$_{98}$ I don't know

A11.In general, how often do you use your power wheelchair?

❑$_1$ Less than once a day

❑$_2$ Every day

❑$_3$ A few days a week

❑$_4$ One day per week

❑$_5$ One day or two per month

❑$_{98}$ I don't know

A12.On the days that you do use your power wheelchair how much do you us it?

_____ hours per day

❑$_{98}$ I don't know

A13.<u>During the past 6 months</u>, did you have any problems with your power wheelchair that made you go without it or made you use an unsuitable wheelchair instead?

❑$_1$ Yes

❑$_2$ No **(→ Skip to A13)**

❑$_{98}$ I don't know **(→ Skip to A13)**

A13a. How many times did you have these kinds of problems?

❑$_1$ One time

❑$_2$ 2 or 3 times

❑$_3$ 4 or more times

❑$_4$ Don't recall the exact number of times

A13b. Can you describe the kind of problem(s) that you had? (Please check all that apply)

❑$_1$ Wheelchair failed/did not work

❑$_2$ Other (Please specify:) _____

❑$_{98}$ I don't know

A14.Are you still using the same wheelchair and accessories (e.g. controls, cushion) as when it (they) was originally prescribed?

❑$_1$ Yes **(→ Skip to B1)**

❑$_2$ No, I have a different wheelchair

❑$_3$ No, I have different accessories

❑$_{98}$ I don't know **(→ Skip to B1)**

A14a. Why did you make this (these) change(s)? (Please check all that apply)

❑$_1$ Wheelchair needed to be replaced because the original one didn't work

❑$_2$ My medical condition changed, so I needed something different

❑$_3$ Found a new wheelchair that was better for me

❑$_4$ Found new features/accessories that were better for me

❑$_5$ Doctor/ health care provider prescribed a different type of wheelchair

❑$_6$ Supplier changed

❑$_7$ Other (Please specify:) _____

_____

B. MEDICAL EXPENSES – ALL USERS

B1. In 2006, did you buy any accessories or parts for your power wheelchair or have maintenance or repairs done with your own money because they were not covered by your insurance? Do not include your Medicare co-pay.

❑$_1$ Yes

❑$_2$ No **(→ Skip to SECTION C)**

❑$_{98}$ I don't know **(→ Skip to SECTION C)**

B2. What did you buy with your own money in 2006? (Please check all that apply)

❑$_1$ Seat or back cushions

❑$_2$ Tires

❑$_3$ Crutch holder

❑$_4$ Lap tray

❑$_5$ Repairs

❑$_6$ Routine maintenance

❑$_7$ Other (specify) _____

B3. Think about what you've paid for with your own money for your accessories, parts, maintenance or repairs not covered by insurance. How much did you spend in 2006? Do not include your Medicare co-pay.

❑$_1$ Less than $100

❑$_2$ $100-$500

❑$_3$ $500 or more

❑$_{98}$ I don't know

C. YOUR SUPPLIER – ALL USERS

C1. Do you have more than one supplier for your power wheelchair, accessories, parts, maintenance and repairs?

❑$_1$ Yes
❑$_2$ No

C2. Overall, how would you rate the supplier that you use most?

❑$_1$ Poor
❑$_2$ Fair
❑$_3$ Good
❑$_4$ Very good
❑$_5$ Excellent
❑$_{98}$ I don't know

C3. Would you recommend this power wheelchair supplier to a friend who needed similar equipment and services?

❑$_1$ Yes
❑$_2$ No
❑$_{98}$ I don't know

C4. How did you get your power wheelchair?

❑$_1$ Delivered to my home by my supplier
❑$_2$ Mailed to my home by my supplier
❑$_3$ I picked it up from my supplier
❑$_4$ I picked it up at a seating clinic or rehabilitation center
❑$_5$ Some other way (Specify): _____

C5. In general, how much time and energy did it take to get the power wheelchair, accessories, parts, maintenance and repairs from your supplier?

❑$_1$ No time and energy
❑$_2$ A little time and energy
❑$_3$ Some time and energy
❑$_4$ A lot of time and energy
❑$_{98}$ I don't know

D. YOUR SUPPLIER – NEW USERS ONLY

D1. Have you used your power wheelchair for less than 6 months?

❑$_1$ Yes

❑$_2$ No **(→ Skip to SECTION E)**

❑$_{98}$ I don't know **(→ Skip to SECTION E)**

D2. <u>When you were first prescribed your power wheelchair</u>, were there any problems finding a supplier?

❑$_1$ Yes

❑$_2$ No **(→ Skip to D3)**

❑$_{98}$ I don't know **(→ Skip to D3)**

D2a. What kinds of problems were there? (Please check all that apply)

❑$_1$ Hard to find a supplier who covered my area

❑$_2$ Supplier did not carry what I needed

❑$_3$ Supplier could not deliver equipment when I needed it

❑$_4$ Supplier did not accept Medicare

❑$_5$ Other (describe:) _____

❑$_{98}$ I don't know

D3. <u>When you were first prescribed your power wheelchair</u>, was there a <u>choice</u> of suppliers?

❑$_1$ Yes, many

❑$_2$ Yes, a few

❑$_3$ No, only one supplier available

❑$_{98}$ I don't know

D4. How long after it was ordered did you receive your <u>first</u> power wheelchair?

❑$_1$ Same day

❑$_2$ Next day

❑$_3$ Within a week

❑$_4$ More than 1 week later

❑$_{98}$ I don't know

D5. When you were first prescribed your power wheelchair, what kind of training or help did the supplier give you or the person who takes care of you? Did he/she… (Please check all that apply)

- ❑1 Give you written instructions on how to use the power wheelchair
- ❑2 Show you how to use the power wheelchair
- ❑3 Choose a safe and convenient place to store and charge the power wheelchair
- ❑4 Show you how to clean and maintain the power wheelchair
- ❑5 Show you how to use the power wheelchair safely
- ❑6 Let you practice how to use and maintain your power wheelchair while they watched
- ❑7 Gave me the manufacturer's customer assistance toll-free telephone number
- ❑8 I didn't get any training or help from my supplier **(→ Skip to D5)**
- ❑98 I don't know **(→ Skip to D5)**

D5a. As a result of that training, how comfortable do you feel using and maintaining your power wheelchair?

- ❑1 Very comfortable
- ❑2 Comfortable
- ❑3 Uncomfortable
- ❑4 Very uncomfortable
- ❑5 My comfort level has nothing to do with the training that my supplier gave me

D6. When you first got your power wheelchair and asked your supplier questions, did you get answers that you could understand?

- ❑1 Yes, completely
- ❑2 Yes, somewhat
- ❑3 No
- ❑4 I didn't ask any questions
- ❑98 I don't know

D7. When you first got your power wheelchair, did your supplier tell you as much as you wanted to know about the options for your power wheelchair?

- ❑1 Yes, completely
- ❑2 Yes, somewhat
- ❑3 No
- ❑98 I don't know

D8. When you first got your power wheelchair, did your supplier spend as much time with you as you wanted?

❑$_1$ Yes

❑$_3$ No

❑$_{98}$I don't know

E. RECENT EXPERIENCES – ALL USERS

E1. During the past 3 months, how often did your supplier send someone to your home to make sure that your power wheelchair was working right? (Don't include times when they came because you called them).

❑$_1$ Never

❑$_2$ Once in the 3 months

❑$_3$ More than once in the 3 months

❑$_{98}$I don't know

E2. During the past 3 months, how reliable was your supplier in making deliveries or repairs?

❑$_1$ Very reliable

❑$_2$ Somewhat reliable

❑$_3$ Not reliable at all

❑$_{98}$ I don't know

E3. <u>During the past 3 months</u>, did you contact your supplier with a complaint or a problem?

❑$_1$ Yes

❑$_2$ No **(→ Skip to E4)**

❑$_{98}$I don't know **(→ Skip to E4)**

❑$_4$ Don't know how to contact my supplier **(→ Skip to E4)**

E3a.When you contacted your supplier, was your complaint or problem settled to your satisfaction?

❑$_1$ Yes

❑$_2$ No

❑$_3$ I am waiting for it to be settled

❑$_{98}$ I don't know

E4. <u>During the past 3 months</u>, did you contact your supplier to get emergency service or advice?

❑$_1$ Yes

❑$_2$ No (→ **Skip to E5)**

❑$_{98}$I don't know **(→ Skip to E5)**

E4a. In general, how fast did they respond to your needs, either by phone or in person? Would you say…

❑$_1$ Within 1 day

❑$_2$ Within 2 days

❑$_3$ Within 1 week

❑$_4$ Longer than 1 week

❑$_{98}$ I don't know

E4b. Were you able to get the emergency service or advice you needed?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

E5. During the past 3 months, did you need to contact your supplier after regular business hours?

❑$_1$ Yes

❑$_2$ No (→ **Skip to E6)**

❑$_{98}$ I don't know **(→ Skip to E6)**

E5a. During the past 3 months when you contacted your supplier after business hours in general, were you able to get the service or advice you needed?

❑$_1$ Yes

❑$_2$ No

❑$_{98}$ I don't know

E6. During the past 3 months, how reliable has your power wheelchair been? Would you say…

❑$_1$ Very reliable

❑$_2$ Somewhat reliable

❑$_3$ Somewhat unreliable

❑$_4$ Very unreliable

❑$_{98}$ I don't know

E7. During the past 3 months, have you changed your power wheelchair supplier?

❑$_1$ Yes

❑$_2$ No **(→ Skip to SECTION F)**

❑$_{98}$ I don't know **(→ Skip to SECTION F)**

E7a. Why did you change your power wheelchair supplier? (Please check all that apply)

❑$_1$ I moved

❑$_2$ Supplier no longer accepted Medicare for the equipment

❑$_3$ Supplier went out of business

❑$_4$ Not happy with the quality of service

❑$_5$ Not happy with equipment

❑$_6$ Not happy with the choices of equipment/service I could get

❑$_7$ Supplier did not provide power wheelchair, accessories or repair service I needed

❑$_8$ Changed to an HMO and had to use a different supplier

❑$_9$ Other (Please describe):_____

F. ABOUT YOU - ALL

Section F is about you, the person whose name is on the mailing label of this survey.

F1. In general, how would you rate your overall health?

❑$_1$ Excellent

❑$_2$ Very good

❑$_3$ Good

❑$_4$ Fair

❑$_5$ Poor

F2. <u>Compared to 1 year ago</u>, how would you rate your health now? Would you say…

❑$_1$ Much better now
❑$_2$ Somewhat better now
❑$_3$ About the same
❑$_4$ Somewhat worse now
❑$_5$ Much worse now
❑$_{98}$ I don't know

F3. Which best describes your living situation <u>now</u>? (Please check all that apply)

I live….

❑$_1$ Alone
❑$_2$ With spouse/partner
❑$_3$ With parent/step-parent
❑$_4$ With child/children
❑$_5$ With other relative(s)
❑$_6$ With friend
❑$_7$ With other person(s) not related to me

F4. What is the highest grade or level of school that you have <u>completed</u>?

❑$_1$ 8th grade or less
❑$_2$ Some high school but did not graduate
❑$_3$ High school graduate or GED
❑$_4$ Some college or technical school
❑$_5$ College graduate
❑$_6$ More than a 4-year college degree

F5. What was your household's annual income during 2006 before taxes?

❑$_1$ Less than $5,000 ($416 per month)

❑$_2$ Between $5,001 and $10,000 ($417–$833 per month)

❑$_3$ Between $10,001 and $20,000 ($834–$1,666 per month)

❑$_4$ Between $20,001 and $30,000 ($1,667–2,500 per month)

❑$_5$ Over $30,001 (More than $2,500 per month)

❑$_{98}$ I don't know

F6. Are you of Hispanic or Latino decent?

❑$_1$ Yes

❑$_2$ No

F7. How would you describe your race? (Please check all that apply)

❑$_1$ American Indian or Alaskan Native

❑$_2$ Asian

❑$_3$ Black or African American

❑$_4$ Native Hawaiian or other Pacific Islander

❑$_5$ White or Caucasian

❑$_6$ Other (Please tell us:) _____

G. Other Information

G1. Please check the correct statement:

❑$_1$ I am the person to whom this survey was addressed **(→ Skip to END)**

❑$_2$ I filled this survey out or helped fill it out for someone else

G2. Which of these comes closest to describing how you helped the person with this survey?

❑$_1$ I wrote the answers that the person told me

❑$_2$ I answered the questions myself based on my knowledge of the person's condition

❑$_3$ Both of the above

END

Thank you for completing the survey. Please return the completed survey in the postage-paid envelope addressed to:

Todd Robbins
CMS Survey of Beneficiaries Using [Medical Equipment and Supplies]
55 Wheeler Street,
Cambridge, MA 02138

If you have any **questions about the survey**, please call toll-free 1-xxx-xxx-xxxx.

If you have any **questions about Medicare**, please visit the website of the Center for Medicare Services at: http://www.medicare.gov/, or call 1-800-MEDICARE.

CMS letterhead

COVER LETTER FOR SURVEY PACKET I

[Date]

«AbtID»
«FName» «MI» «LName»
«Addr1», «Addr2»
«City», «State» «Zip»

Dear «FName» «MI» «LName»:

I am writing to ask your help with a voluntary research survey that the Centers for Medicare and Medicaid Services (CMS) is conducting about your experiences as a person who uses medical equipment and supplies. CMS is the federal agency that runs Medicare.

Your name was selected at random from a list of people who have recently obtained medical equipment and supplies that were paid for by Medicare. The enclosed questionnaire contains questions about your experiences with your equipment and your equipment supplier. Please take a few minutes to complete the questionnaire and return it in the postage-paid envelope to Abt Associates, the research company helping CMS with the survey. If you would prefer to complete the survey by telephone, please call NUMBER, toll-free- Monday-Friday between TIME and TIME Eastern Time.

Your answers to the questions will be grouped together with everyone else who completes the survey. We do not foresee any possible risks to you from participating in this survey, other than the minimal risk that your confidentiality might not be preserved. All the information you provide will be held in strict confidence by CMS and Abt Associates and will be protected by the Federal Privacy Act and the full extent provided by law. You may choose to answer this survey or not. Your participation is voluntary and will not affect any benefits you receive, now or in the future. However, the answers you provide will help CMS help Medicare make sure that beneficiaries have access to the medical equipment and services they need. This study has been endorsed by (INSERT NAME OF AGENCIES). They encourage your participation. Enclosed is a fact sheet that provides more information about the study.

Your participation is critical to the success of the study.
We hope to receive your completed survey by [FILL DATE].

If you have questions about the survey or to complete the survey by telephone or to request a questionnaire in Spanish, please call NUMBER.

Thank you in advance for your participation.

Sincerely,

_____Privacy Officer
The Centers for Medicare & Medicaid Services

CMS letterhead

COVER LETTER FOR SURVEY PACKET 2

[Date]

«AbtID»
«FName» «MI» «LName»
«Addr1», «Addr2»
«City», «State» «Zip»

Dear «FName» «MI» «LName»:

I am writing to ask your help with a voluntary research survey that the Centers for Medicare and Medicaid Services (CMS) is conducting about your experiences as a person who uses medical equipment and supplies. CMS is the federal agency that runs Medicare. Enclosed is a fact sheet that provides more information about the study.

Your name was selected at random from a list of people who have recently obtained medical equipment and supplies that were paid for by Medicare. A few weeks ago, we sent you a letter and a questionnaire in the mail. If you have already completed it, we thank you for your participation. Since we have not yet received your survey, we have enclosed another copy for your convenience and extended our submission deadline to **[DATE]**.

The survey contains questions about your experiences with your equipment and your equipment supplier. Please take a few minutes to complete and return the questionnaire in the postage-paid envelope to Abt Associates, the research company helping CMS with the survey. If you would prefer to complete the survey by telephone, please call NUMBER, toll-free Monday-Friday between TIME and TIME Eastern Time.

Your answers to the questions will be grouped together with everyone else who completes the survey. We do not foresee any possible risks to you from participating in this survey, other than the minimal risk that your confidentiality might not be preserved. All the information you provide will be held in strict confidence by CMS and Abt Associates and will be protected by the Federal Privacy Act and the full extent provided by law. You may choose to answer this survey or not. Your participation is voluntary and will not affect any benefits you receive, now or in the future. However, the answers you provide will help CMS help Medicare make sure that beneficiaries have access to the medical equipment and services they need. Your participation is critical to the success of the study! This study has been endorsed by (INSERT NAME OF AGENCIES). They encourage your participation.

If you have questions about the survey or to complete the survey by telephone or to request a questionnaire in Spanish, please call NUMBER.

Thank you in advance for your participation.

Sincerely,

_____Privacy Officer, The Centers for Medicare & Medicaid Services

Study Fact Sheet:
Centers for Medicare and Medicaid Services (CMS)
Survey of Oxygen Users

Purpose of the Study

The purpose of the study is to learn more about your satisfaction with the equipment, supplies, and service you receive from your oxygen (or other durable medical equipment) supplier. We also hope to better understand your experiences in obtaining and using this equipment.

Study Sponsor

The study is funded by the Centers for Medicaid and Medicare Services (CMS), the federal agency that runs the Medicare program. CMS has arranged for Abt Associates, a research company, to conduct the study.

Who Else is Participating?

We have sent this survey to approximately thousands of other Medicare Beneficiaries like you, who use Oxygen or other durable Medical Equipment. Each person selected at random for the study will represent others like him or herself across the United States, so CMS can better understand your experiences in obtaining and using this equipment.

Will My Information Be Kept Confidential?

All of your study information will be stored securely by staff at Abt Associates Inc., who are trained to protect your privacy and confidentiality. Your answers to the questions will be grouped together with everyone else who completes the survey and presented in summary format. Your name or contact information will not be linked to your answers provided to CMS. Your name will not be used in any study publication or presentation.

Options for Completing the Survey

You may complete this survey by filling out the enclosed questionnaire and returning it in the postage-paid envelope provided. Or, if you prefer, you may call our toll-free number and complete the survey over the telephone. If you feel you are unable to answer these questions, you may also choose someone to answer these questions on your behalf. This person should be knowledgeable about your health and your experiences with this equipment. However, please do not ask personnel from your oxygen supplier to help you complete this survey.

Contact Information for Questions

If you have any questions about the study procedures, you may call Todd Robbins, Survey Director at Abt Associates Inc., toll-free at 1-800-xxx-xxxx. If you have any questions about your rights as a study participant, you may call Marianne Beauregard, the person in charge of the committee at Abt Associates that is responsible for making sure that study subjects are treated fairly and properly. She may be reached at 617-349-2852.

Study Fact Sheet:
Centers for Medicare and Medicaid Services (CMS)
Survey of Durable Medical Equipment Users

Purpose of the Study

The purpose of the study is to learn more about your satisfaction with the equipment, supplies, and service you receive from your oxygen (or other durable medical equipment) supplier. We also hope to better understand your experiences in obtaining and using this equipment.

Study Sponsor

The study is funded by the Centers for Medicaid and Medicare Services (CMS), the federal agency that runs the Medicare program. CMS has arranged for Abt Associates, a research company, to conduct the study.

Who Else is Participating?

We have sent this survey to approximately thousands of other Medicare Beneficiaries like you, who use Oxygen or other durable Medical Equipment. Each person selected at random for the study will represent others like him or herself across the United States, so CMS can better understand your experiences in obtaining and using this equipment.

Will My Information Be Kept Confidential?

All of your study information will be stored securely by staff at Abt Associates Inc., who are trained to protect your privacy and confidentiality. Your answers to the questions will be grouped together with everyone else who completes the survey and presented in summary format. Your name or contact information will not be linked to your answers provided to CMS. Your name will not be used in any study publication or presentation.

Options for Completing the Survey

You may complete this survey by filling out the enclosed questionnaire and returning it in the postage-paid envelope provided. Or, if you prefer, you may call our toll-free number and complete the survey over the telephone. If you feel you are unable to answer these questions, you may also choose someone to answer these questions on your behalf. This person should be knowledgeable about your health and your experiences with this equipment. However, please do not ask personnel from your oxygen supplier to help you complete this survey.

Contact Information for Questions

If you have any questions about the study procedures, you may call Todd Robbins, Survey Director at Abt Associates Inc., toll-free at 1-800-xxx-xxxx. If you have any questions about your rights as a study participant, you may call Marianne Beauregard, the person in charge of the committee at Abt Associates that is responsible for making sure that study subjects are treated fairly and properly. She may be reached at 617-349-2852.

BENEFICIARY SURVEY POSTCARD REMINDER

Dear Sir or Madam:

We recently sent you a survey. The purpose of the survey is to learn about your experiences with obtaining medical equipment and supplies. Your participation is voluntary, but it is important that we hear from you because only you can tell us about your unique experience.

If you have already completed the survey, we thank you for your participation. If you have any questions, or if you prefer to complete the survey over the telephone, please call us, toll-free at xxxxxx. Thank you for taking part in this important study.

Sincerely,

Todd Robbins, Senior Survey Director
Abt Associates Inc.

Durable Medical Equipment and Prosthetics, Orthotics and Supplies (DMEPOS)

Supplier Survey

(OMB# 0938-NEW)

A Study of Medical Equipment Suppliers

Sponsored by:
The Centers for Medicare & Medicaid Services (CMS)

NOTES FOR WEB PROGRAMMER:

THROUGHOUT THE SURVEY – WEB PROGRAMMING SPECS WILL BE IN ALL CAPS WITH THE INTRO OF "**CATI: XXXX**".

DATA FOR THE SURVEY WILL BE SUPPLIED (FOR THE FILLS) BY THE SAMPLE INFORMATION. FOR EACH CASE, WE WILL LOAD CLAIMS DATA FOR 8 CLAIMS, CORRESPONDING TO THE CASE BY THE ABT ID PROVIDED.

IN THE LOGIN SCREEN:

- WE WOULD LIKE TO CONFIRM THE CONTACT INFORMATION FOR THE USER, WITH THE SAMPLE INFORMATION PROVIDED (COMPANY AFFILIATION).
- LINK TO A PDF OF THE STUDY FACT SHEET.

DISPLAY THE ABT AND CMS LOGOS AT THE BOTTOM OF EACH SCREEN IN THE SURVEY (LOGOS WILL BE PROVIDED ELECTRONICALLY).

LOAD ONLY 1-2 SURVEY ITEMS PER PAGE. IF AN ITEM IS LEFT BLANK, DO NOT REQUEST CONFIRMATION THAT THE ITEM WAS INTENDED TO BE BLANK (UNLESS SPECIFIED IN PROGRAMMING SPECIFICATIONS).

USE RADIO BUTTONS FOR THE ANSWER OPTIONS, UNLESS THEY ARE ENTERING TEXT. PLACE THE BUTTONS TO THE LEFT OF THE ANSWER CHOICES, AS SHOWN IN ATTACHED SPECIFICATIONS.

USE ARIAL FONT, SIZE 12 FOR TEXT ON THE SCREENS. USE COLOR OR SHADING WHEN SPECIFIED. BACKGROUND OF SCREEN SHOULD BE LIGHT BLUE, TEXT SHOULD BE BLACK.

SUPPLIER SURVEY
SCREEN LAYOUT AND QUESTIONS

ENTRY SCREEN A

(CMS LOGO)
(ABT ASSOCIATES INC. LOGO)

The Centers for Medicare & Medicaid Services (CMS) Survey of Suppliers of Durable Medical Equipment

PASSWORD:	XXXXX

CATI: IF POSSIBLE, PASSWORDS ARE NOT TO EXCEED A 5 DIGIT / LETTERS COMBINATION.

ENTRY SCREEN B

The Centers for Medicare & Medicaid Services (CMS) Survey of Suppliers of Durable Medical Equipment

Thank you for your participation in this important study. Please confirm you are completing this survey on behalf of [INSERT SUPPLIER NAME].

□1	Yes, that is correct → SKIP TO SCREEN 1
□2	No, that is not the company I represent → SKIP TO TERMINATE

CATI: NEW SCREEN: <TERMINATE>: It appears the password you provided does not match the company you represent. Please call us, toll-free, at 1-800-xxx-xxxx to receive the correct password for your company.

INTRO SCREEN 1

The purpose of this study is to help CMS better understand the types of products beneficiaries receive under the broad HCPCs categories provided in the claims. In addition, we are examining if and how these products change over time, particularly in the environment of competitive bidding. Your participation is critical to the success of this study.

The questions in this survey will take approximately 45 minutes to answer. We will be asking you to provide detailed information on eight DMEPOS claims submitted to CMS on behalf of Medicare beneficiaries who recently obtained products from your company. Therefore, you may need to access records in your computer system or from your patient files. Additionally, the survey will end with a few general, non-claim questions about the types of products you provide to Medicare beneficiaries. We do not request any identifying patient information.

Supplying these data will not violate any HIPAA regulations. All the information you provide will remain confidential. The findings from this survey will be presented in summary format, – with everyone's answers grouped together. This survey is not an audit. Your responses to this survey will not affect any claims that have been paid by CMS.

The American Association for Respiratory Care and [INSERT NAME OF ORGANIZATION] have endorsed and strongly encourage your participation in this survey.

CATI: Insert logos of endorsing organization

We have attached the Study Fact Sheet in the link below to provide you with additional information about the study.

□1	Continue to begin survey

[AFFIX LINK TO STUDY FACT SHEET (.pdf) ON THIS SCREEN]

INTRO SCREEN 2 (Oxygen supplier Sample only)

On the screens that follow are 8 different claims you have submitted for [INSERT PRODUCT CATEGORY]. Of these 8 claims, 4 will pertain to HCPC [INSERT HCPC] and 4 claims will pertain to HCPC [INSERT HCPC].

Each question will provide the claim number, HCPC, and date of service to facilitate the retrieval of the claim in order to provide the specific information about the product that was provided to the Medicare beneficiary.

INTRO SCREEN 3 (Wheelchair or hospital bed Sample only)

On the screens that follow are 8 different claims you have submitted for [INSERT PRODUCT CATEGORY].

Each question will provide the claim number, HCPC, and date of service to facilitate the retrieval of the claim in order to provide the specific information about the product that was provided to the Medicare beneficiary.

CATI: Only one manufacturer or drop down item can be selected for each claim.

CLAIM 1 NEW SCREEN

1. The first claim we would like you to provide information about is:

   Beneficiary Name (INSERT BENE NAME)
   Beneficiary HIC#
   Claim number [INSERT CLAIM NUMBER]
   HCPCS code [INSERT HCPC]
   Date of Service [INSERT DATE OF SERVICE]

   Please retrieve your records for this claim and tell us what specific product was provided.

   1A. Select the product manufacturer [INSERT DROP DOWN MENU]

   1B. Select the product name and/or model [INSERT DROP DOWN MENU, UPDATED FROM MANUFACTURER SELECTED]

CLAIM 2 NEW SCREEN

2. For the second claim, please retrieve your records for:

   Beneficiary Name (INSERT BENE NAME)
   Beneficiary HIC#
   Claim number [INSERT CLAIM NUMBER]
   HCPCS code [INSERT HCPC]
   Date of Service [INSERT DATE OF SERVICE]

For this claim, what specific/exact product was provided?

2A. Select the product manufacturer [INSERT DROP DOWN MENU]

2B. Select the product name and/or model [INSERT DROP DOWN MENU, UPDATED FROM MANUFACTURER SELECTED]

CLAIM 3 NEW SCREEN

3. Please retrieve your records for the following claim:

Beneficiary Name (INSERT BENE NAME)
Beneficiary HIC#
Claim number [INSERT CLAIM NUMBER]
HCPCS code [INSERT HCPC]
Date of Service [INSERT DATE OF SERVICE]

For this claim, what specific/exact product was provided?

3A. Select the product manufacturer [INSERT DROP DOWN MENU]

3B. Select the product name and/or model [INSERT DROP DOWN MENU, UPDATED FROM MANUFACTURER SELECTED]

CLAIM 4 NEW SCREEN

4. Please retrieve your records for the following claim:

Beneficiary Name (INSERT BENE NAME)
Beneficiary HIC#
Claim number [INSERT CLAIM NUMBER]
HCPCS code [INSERT HCPC]
Date of Service [INSERT DATE OF SERVICE]

For this claim, what specific/exact product was provided?

4A. Select the product manufacturer [INSERT DROP DOWN MENU]

4B. Select the product name and/or model [INSERT DROP DOWN MENU, UPDATED FROM MANUFACTURER SELECTED]

CLAIM 5 SCREEN

5. Please retrieve your records for the following claim:

   Beneficiary Name (INSERT BENE NAME)
   Beneficiary HIC#
   Claim number [INSERT CLAIM NUMBER]
   HCPCS code [INSERT HCPC]
   Date of Service [INSERT DATE OF SERVICE]

   For this claim, what specific/exact product was provided?

   5A. Select the product manufacturer [INSERT DROP DOWN MENU]

   5B. Select the product name and/or model [INSERT DROP DOWN MENU, UPDATED FROM MANUFACTURER SELECTED]

CLAIM 6 NEW SCREEN

6. Please retrieve your records for the following claim:

   Beneficiary Name (INSERT BENE NAME)
   Beneficiary HIC#
   Claim number [INSERT CLAIM NUMBER]
   HCPCS code [INSERT HCPC]
   Date of Service [INSERT DATE OF SERVICE]

   For this claim, what specific/exact product was provided?

   6A. Select the product manufacturer [INSERT DROP DOWN MENU]

   6B. Select the product name and/or model [INSERT DROP DOWN MENU, UPDATED FROM MANUFACTURER SELECTED]

CLAIM 7 NEW SCREEN

7. Please retrieve your records for the following claim:

   Beneficiary Name (INSERT BENE NAME)
   Beneficiary HIC#
   Claim number [INSERT CLAIM NUMBER]
   HCPCS code [INSERT HCPC]
   Date of Service [INSERT DATE OF SERVICE]

   For this claim, what specific/exact product was provided?

   7A. Select the product manufacturer [INSERT DROP DOWN MENU]

7B. Select the product name and/or model [INSERT DROP DOWN MENU, UPDATED FROM MANUFACTURER SELECTED]

CLAIM 8 NEW SCREEN

8. Please retrieve your records for the following claim:

Beneficiary Name (INSERT BENE NAME)
Beneficiary HIC#
Claim number [INSERT CLAIM NUMBER]
HCPCS code [INSERT HCPC]
Date of Service [INSERT DATE OF SERVICE]

For this claim, what specific/exact product was provided?

8A. Select the product manufacturer [INSERT DROP DOWN MENU]

8B. Select the product name and/or model [INSERT DROP DOWN MENU, UPDATED FROM MANUFACTURER SELECTED]

GENERAL QUESTIONS NEW SCREEN

In this last set of questions, we would like to know the types of products you most commonly provide to Medicare beneficiaries. Please provide us your best estimates for the following questions.

9. From the menus of products listed below, please select the different types (models) of [INSERT DMEPOS PRODUCT], that you regularly offer Medicare beneficiaries. [INSERT DROP DOWN MENU OF ALL MODELS FROM ALL MANUFACTURERS ALPHABETICALLY]

9a. Of the ones you selected above, which are the two models that you tend to provide Medicare beneficiaries most often? [INSERT DROP DOWN MENU OF ALL MODELS SELECTED IN QUESTION #9)

10. Approximately what percentage of your total [INSERT DMEPOS PRODUCT] business for Medicare beneficiaries does each of these makeup? (Please refer to # number of items sold and not % of dollar volume)

___ %	Manufacturer/Model 1 [POPULATE FIELD FROM QUESTION 9A]

___ %	Manufacturer/Model 2 [POPULATE FIELD FROM QUESTION 9A]

(**PROGRAMMER'S NOTE: ASK 12, 12a, AND 13 ONLY IF OXYGEN SUPPLER SAMPLE)—IF WHEELCHAIR OR HOSPITAL BED SAMPLE SKIP TO FINAL NEW SCREEN)**

12. From the menus of products listed below, please select the different types (models) of [INSERT DMEPOS PRODUCT], that you regularly offer Medicare beneficiaries. [INSERT DROP DOWN MENU OF ALL MODELS FROM ALL MANUFACTURERS ALPHABETICALLY]

12a. Of the ones you selected above, which are the two models that you tend to provide Medicare beneficiaries most often? [INSERT DROP DOWN MENU OF ALL MODELS SELECTED IN QUESTION #12)

13. Of these two, approximately what percentage of your total [INSERT DMEPOS PRODUCT] business for Medicare beneficiaries does each of these make up? Please refer to # number of items sold and not dollar volume.

___ %	Manufacturer/Model 1 [POPULATE FIELD FROM QUESTION 12A]
___ %	Manufacturer/Model 2 [POPULATE FIELD FROM QUESTION 12A]

FINAL NEW SCREEN

Thank you for your participation in the Centers for Medicare & Medicaid Services (CMS) Survey of Suppliers of Durable Medical Equipment and Supplies. Your participation has been critical to the success of the study.

We would like to thank you by offering you a check for $75.00. Please tell us how you would like us to make out the check:
__ Please make the check payable to the company--(INSERT NAME OF COMPANY)
__ Please make the check payable to me _____ (Please insert your name)
__ No, thank you. I do not wish to receive a check.

If you have any questions about the study, or need more information, please call Todd Robbins, Survey Director at Abt Associates, toll-free at 1-800-xxx-xxxx.

Supplier Survey Illustrative Example

Supplier Survey Illustrative Example

EXAMPLE DMEPOS ITEM: Manual Wheelchair, Standard; HCPC Code: K0001

1. Please retrieve your records for the following claim:

Claim number: 123456
HCPCS code: K0001
Date of Service: 11-11-1111

For this claim, what specific/exact product was provided?

1A. Select the product manufacturer

Manufacturer Drop Down Menu
Access Point Medical, Inc.
Alum Creek Wheelchair, Inc.
American Bantex Corporation
Dalton Medical Corporation
Damaco
Dr. K Healthcare Products
Drive Medical Design & Manufacturing
Everest & Jennings
Evermed
Freedom Designs, Inc.
Gendron
Graham-Field
Guardian
HME Providers
Hoveround Corporation
Invacare
Kareco
Karman Healthcare Inc.
Labac
Levo USA, Inc.
Lumex
Major Mobility Products, Inc.
Maple Leaf Wheelchairs
Medline Industries, Inc.
Merits
New Solutions, LLC
Nova Ortho-Med, Inc.
PMI Incorporated
Summit Durable Medical Equipment
Theradyne
Tuffcare
Other

1B. Select the product name and/or model

Models
9000 Recliner
CareGuard
Futuro 4800
Futuro 4130
Invacare MG
IVC 900 (Formerly Rolss 900)
IVC Tracer EX2 Fixed Frame Builder Wheelchair (Model TREXFF)
Rolls 400
Rolls 900 (Name Changed to IVC 900)
Tracer
Tracer EX
Tracer LX - Standard Adult Frame
Tracer Plus
Other

9. From the menus of products listed below, please select the <u>different</u> types (models) of [INSERT DMEPOS PRODUCT], that you <u>regularly offer</u> Medicare beneficiaries. [INSERT DROP DOWN MENU OF ALL MODELS FROM ALL MANUFACTURERS ALPHABETICALLY]

Manufacturer Drop Down Menu
Access Point Medical, Inc.
Alum Creek Wheelchair, Inc.
American Bantex Corporation
Dalton Medical Corporation
Damaco
Dr. K Healthcare Products
Drive Medical Design & Manufacturing
Everest & Jennings
Evermed
Freedom Designs, Inc.
Gendron
Graham-Field
Guardian
HME Providers
Hoveround Corporation
Invacare
Kareco
Karman Healthcare Inc.
Labac
Levo USA, Inc.
Lumex

Major Mobility Products, Inc.
Maple Leaf Wheelchairs
Medline Industries, Inc.
Merits
New Solutions, LLC
Nova Ortho-Med, Inc.
PMI Incorporated
Summit Durable Medical Equipment
Theradyne
Tuffcare
Other

FOR EACH MANUFACTURER SELECTED THE RANGE OF MODELS OFFERED BY THE MANUFACTURER WILL APPEAR FOR THE SUPPLIER TO SELECT. FOR EXAMPLE:

Invacare Models
9000 Recliner
CareGuard
Futuro 4800
Futuro 4130
Invacare MG
IVC 900 (Formerly Rolss 900)
IVC Tracer EX2 Fixed Frame Builder Wheelchair (Model TREXFF)
Rolls 400
Rolls 900 (Name Changed to IVC 900)
Tracer
Tracer EX
Tracer LX - Standard Adult Frame
Tracer Plus
Other

10. Of the ones you selected above, which are the two models that you tend to provide Medicare beneficiaries most often? [insert drop down menu of al models selected in question #9)

Selected Manufacturers: Drop Down Menu
Access Point Medical, Inc.
Damaco
Everest & Jennings
Invacare
Medline Industries, Inc.
Tuffcare

11. Of these two, approximately what percentage of your total [insert DMEPOS product] business for Medicare beneficiaries does each of these makeup? Please refer to # number of items sold and not dollar volume.

25 %	Everest & Jennings
30 %	Invacare

SUPPLIER SURVEY -- COVER LETTER FOR SURVEY PACKET I

[Date]

«AbtID»
«FName» «MI» «LName»
«Addr1», «Addr2»
«City», «State» «Zip»

Dear «FName» «MI» «LName»:

As a supplier of [INSERT PRODUCT NAME CHOSEN], you play an important role in providing Medicare beneficiaries with equipment and services they need to maintain their health and well-being. At the Centers for Medicare & Medicaid Services (CMS), we are interested in information about how the national competitive bidding program might impact the types of products available to Medicare beneficiaries. To provide data for a formal study of the new program, we have hired a research firm, Abt Associates, which is conducting a survey of DMEPOS suppliers.

Your company was selected at random from suppliers working with Medicare. To participate in this study, simply log on to the web link provided and enter your unique password. It should take about 45 minutes to complete. Your participation is voluntary, but critical to the success of this study. As a token of appreciation for your time and effort in assisting us with this survey, we will send you a thank-you gift of $75; details are available at the bottom of the computerized survey form.

The website for the survey is: www.xxxxxxxx.com
Your unique password is: xxxxxx

We hope to receive your completed survey by [INSERT DATE]

Your answers to the questions will be grouped together with everyone else who completes the survey. We do not foresee any possible risks to you from participating in this survey, other than the minimal risk that your confidentiality might not be preserved. All the information you provide will be held in strict confidence by CMS and Abt Associates and will be protected by the Federal Privacy Act and the full extent provided by law. This survey is not an audit. Your responses to this survey will not affect any claims that have been paid by CMS.

The American Association for Respiratory Care and [INSERT NAME HERE] have endorsed and strongly encourage your participation in this survey.

We have also enclosed a study fact sheet for your review. If you have any questions about the study, or if you prefer to complete the survey over the telephone, please call Todd Robbins, Survey Director at Abt Associates Inc., toll-free at: 1-800-xxx-xxxx. Thank you for taking part in this important study.

Sincerely,

_____, Title
The Centers for Medicare & Medicaid Services

SUPPLIER SURVEY -- COVER LETTER FOR SURVEY PACKET II

[Date]

«AbtID»
«FName» «MI» «LName»
<<Company Name>>«Addr1», «Addr2»
«City», «State» «Zip»

Dear «FName» «LName»:

A few weeks ago, we sent you a letter inviting you to participate in an important study conducted by the Centers for Medicare & Medicaid Services (CMS). As a supplier of oxygen or other durable medical equipment, you play an important role in providing Medicare beneficiaries with products and services they need to maintain their health and well-being.

At CMS, we are responsible for understanding how the competitive bidding program might impact you and the types of products available to Medicare beneficiaries. So we have hired a research firm, Abt Associates, to conduct a survey of suppliers from across the country. Your company was selected at random from suppliers working with Medicare. If you are willing to be part of this study, simply log in to the web link provided and enter your unique password. It should take you about 45 minutes to complete. Your participation is voluntary, but critical to the success of this study. You will receive a thank you gift of $75 upon completion of the survey.

This survey is not an audit. Your responses to this survey will not affect any claims that have been paid by CMS.

The American Association for Respiratory Care and [INSERT NAME HERE] have endorsed and strongly encourage your participation in this survey.

Because your participation is so important to the success of the study – we have extended our submission deadline. We hope to receive your completed survey by [INSERT DATE]

The website for the survey is: www.xxxxxxxx.com
Your unique password is: xxxxxx

Your answers to the questions will be grouped together with everyone else who completes the survey. We do not foresee any possible risks to you from participating in this survey, other than the minimal risk that your confidentiality might not be preserved. All the information you provide will be held in strict confidence by CMS and Abt Associates and will be protected by the Federal Privacy Act and the full extent provided by law.

We have also enclosed a study fact sheet for your review. If you have any questions about the study, or if you prefer to complete the survey over the telephone, please call Todd Robbins, Survey Director at Abt Associates Inc., toll-free at: 1-800-xxx-xxxx. Thank you for taking part in this important study.

Sincerely,

_____, Title
The Centers for Medicare & Medicaid Services

Study Fact Sheet: Centers for Medicare & Medicaid Services (CMS) Survey of Durable Medical Equipment Suppliers

Purpose of the Study
The purpose of this study is to better understand the impacts of the national competitive bidding program being launched by Medicare this year. The survey of suppliers is one part of a multi-faceted research project to provide information to the Congress, the Executive Branch, and the public about the new program. Your participation in the supplier survey will provide information about the new program's impact on the types of products available to Medicare beneficiaries.

This survey is not an audit or any other type of payment investigation. Your responses to this survey will not affect any claims that have been paid by Medicare. The survey's sole purpose is to collect information in a scientific manner to enable researchers to understand whether and how product offerings might change under competitive bidding.

Study Sponsor
The study is funded by the Centers for Medicaid and Medicare Services (CMS), the government agency that runs the Medicare program. CMS has asked Abt Associates, a research company, to conduct the study.

Study Endorsements
The study has been endorsed by American Association for Respiratory Care and the [INSERT NAME HERE]. These organizations encourage your participation and recognize that this study is an important research effort.

Who Else is Participating?
This survey is being sent to hundreds of suppliers, like yourself, who provide oxygen or other durable medical equipment to Medicare beneficiaries. Each supplier was scientifically selected at random to represent other companies like yours. Each payment record about which we ask in this survey was also selected at random.

Will My Information Be Kept Confidential?
Yes. All the information you provide will be kept confidential. Your answers will be grouped together with those of the other participants and presented in summary format. All of your study information will be stored securely at Abt Associates Inc. Staff at Abt Associates is trained to protect your privacy and confidentiality. Your name or contact information will not be linked to your answers provided to CMS. Your answers to the questions will not be linked to your company's contact information in any report or publication.

HIPAA Regulations on Providing Information about Beneficiaries
The questions in the survey pertain to information on beneficiary claims. We do not ask you to provide any names or contact information for the beneficiaries associated with these claims. Providing these data will not be in violation of any HIPAA regulations.

Options for Completing the Survey
The survey can be completed on-line at www.xxxxxxx.xxxx. Your password is provided in the enclosed cover letter. Alternatively, you can reach us, toll-free, at 1-800-xxx-xxxx to complete the survey via telephone. Use this toll free number to confirm your password, or with any questions you may have about the study. You will receive a thank you gift of $75 after completing the survey.

Contact Information for Questions

If you have any questions about the study procedures, you may call Todd Robbins, Survey Director at Abt Associates Inc., toll-free at 1-800-xxx-xxxx. If you have any questions about your rights as a study participant, you may call Marianne Beauregard, the person in charge of the committee at Abt Associates that is responsible for making sure that study subjects are treated fairly and properly. She may be reached at 617-349-2852.

SUPPLIER POSTCARD/EMAIL REMINDER

Dear Supplier:

We recently sent you a survey. The purpose of the survey is to learn about how the competitive bidding program might affect the types of products available to Medicare beneficiaries. Your participation is voluntary but vital to decision-makers who oversee the program. The survey is not an audit and it will not affect your relationship with CMS.

The American Association of Respiratory Care and [INSERT NAME HERE] have endorsed and strongly support participation in this survey.

If you have already completed the survey on-line, we thank you for your participation. If you need the link and password provided again, if you have any questions, or if you prefer to complete the survey over the telephone, please call us, toll-free at 1-800-xxx-xxxx. As a token of our appreciation, we will send you a gift of $75 after you complete the survey. Thank you for taking part in this important study.

Sincerely,

_____, Title
The Centers for Medicare & Medicaid Services

APPENDIX C

Nonstatistical Data Collection Instruments

Focus Group Guide

Referral Agents (Wave 1)

Introduction (5 minutes)

Welcome. Thank you for joining us today. I am _____ [Insert your name] from Abt Associates Inc. We do research on health care. I will be moderating our discussion and _____ [Insert co-moderator] will be assisting and taking notes.

The topic we'll be discussing today is the changes in Medicare with regard to durable medical equipment and the fee schedule they use to pay suppliers of these products. This "competitive bidding program" has recently been implemented in your area. Each of you has been asked to participate because you are a referral agent that works with Medicare beneficiaries. We are particularly interested in your perspective on the current durable medical equipment market and suppliers available to Medicare beneficiaries. Over the next year and a half, two more focus groups will be held in your area as a part of this study. Focus groups are also being held in other areas and these will help the Centers for Medicare & Medicaid Services (CMS) understand the impact of the program.

Informed Consent (5 minutes)

Before we begin, I need to read aloud some of the key points of the consent form you just signed. Did everyone sign the form?

- Today we will ask you to discuss your experiences with Medicare beneficiaries and durable medical equipment
- Your participation is voluntary
- The focus groups will last approximately 1.5 hours
- The discussion will be confidential
- You can refuse to take part in this focus group if you wish without affecting your professional relationship with CMS
- You do not have to answer any questions you do not wish to answer
- You can quit the study at any time

- We do not foresee any possible risks from participating in this focus group, other than the minimal risk that confidentiality might not be preserved
- There are no costs to you for participating in the focus group
- You will receive $75 today for participating and dinner is provided
- This discussion will not be video or audiotaped, rather _____ [Insert co-moderator] will be taking notes. The notes from tonight will be labeled with a study code, not your names, and they will be kept in a locked file and/or a password-protected computer at Abt Associates Inc. in Cambridge, Massachusetts. A summary of the notes will be shared with CMS
- Your comments, and those of others in the focus group, will be used in reports to the government, in summary form and your name will not be included in the report
- **Does anyone have any questions?**

How the focus group will work (3 minutes)

- Want to keep the discussion informal and relaxed
- Eat and use the restrooms as you like
- During the discussion, please feel free to ask me or each other if something is unclear
- There are no right or wrong answers
- If you disagree with what someone else says, or have a different experience, please say so or I'll think that you all agree
- Some of you may have strong opinions, so please be respectful of other's
- Be careful not to talk all at once; I don't want to miss anything that is said
- My job is to make sure we hear from everyone. Some people talk more than others, and I'll be encouraging everyone to speak up.

Participant Introductions (7 minutes)

Let's go around the room and quickly introduce ourselves. [Write on the flip chart the following items]

- First name
- Title (for example social worker, discharge planner, etc)
- Organization you represent
- Clients you serve
- Role with durable medical equipment

BASELINE ENVIRONMENT

1. **Could you describe the referral process as it happens in your role? Let's go around the room.**

    - *From beginning to end*
    - *What do you do for your patients? (e.g. file the certificate of medical necessity – CMN)*
    - *How is it different as a discharge planner, Physical Therapist, social worker, home health worker, etc?*

2. **How do you determine which supplier you refer your clients to?**

    a. Do you have a list of suppliers? Where does it come from?
    b. Do you have a preferred supplier?
    c. Are you satisfied with your interactions with suppliers? Why or why not?
    d. Do you find any significant problems related to accessing suppliers at present?

3. **How is the DMEPOS market in this area?**

    a. Are there enough suppliers?
    b. Is there a dominant supplier?

i. For oxygen?

ii. Product X, Y, Z?

c. How do suppliers compete for referrals?

d. Do suppliers market their services?

i. How do they market? (pamphlets, visits, etc.)

ii. To whom do they market? (you, patients, etc.)

4. **What do you think of the current level of <u>access</u> and <u>quality</u> of DMEPOS products and services that suppliers provide your clients?**

COMPETITIVE BIDDING PROGRAM

5. **How many of you have heard about Medicare's change in the durable medical equipment fee schedule for suppliers, also known as "competitive bidding"?**

COUNT NUMBER OF RAISED HANDS _____

PROGRAM DESCRIPTION: The competitive bidding program for durable medical equipment, prosthetic, orthotic supplies (DMEPOS) is a program administered by the Center for Medicare and Medicaid Services (CMS), part of the Department of Health and Human Services (DHS), to control the costs of DMEPOS by requiring suppliers to bid for a contract to provide DMEPOS products and services to Medicare beneficiaries. This will result in a new fee schedule for specific DMEPOS items, which could reduce the number of suppliers available to beneficiaries and potentially change the suppliers with whom you work. Currently the

suppliers are submitting their bids and CMS is beginning to provide information to referral agents and beneficiaries.

6. **How did you hear about the program?**

7. **What are your initial thoughts about it?**

8. **How do you think the program will affect <u>your role</u>?**

   - *The referral process? (e.g. if suppliers you previously used are not winning bidders)*

9. **How do you think the program will affect <u>suppliers</u> in your area?**

   - *Reduce the numbers?*
   - *More marketing?*
   - *Change in level of service provided?*

10. **How do you think the program will affect <u>Medicare beneficiaries</u>?**

QUALITY STANDARDS

11. **How many of you have heard about the "quality standards" required of DMEPOS suppliers for items & services provided Medicare beneficiaries?**

COUNT NUMBER OF RAISED HANDS _____

QUALITY STANDARDS DESCRIPTION: As a part of the Medicare Modernization Act 2003, the Center for Medicare and Medicaid Services (CMS) requires Durable Medical Equipment, Prosthetic, Orthotic Supplies (DMEPOS) Suppliers to comply with newly established quality standards in order to receive payment for items or services provided to Medicare beneficiaries.

12. What do you think of the quality standards?

a. Are they needed?
b. Is there a problem with them?
c. Will they change your role?
d. How will they affect beneficiaries?

ENDING QUESTION

13. Do you have any final thoughts about the current state of DMEPOS in this area or the competitive bidding program?

Those are all the questions that I have today. I want to thank you for participating in this discussion.

Focus Group Guide
Referral Agents (Wave 2)

Introduction (5 minutes)

Welcome. Thank you for joining us today. I am _____ [Insert your name] from Abt Associates Inc. We do research on health care. I will be moderating our discussion and _____ [Insert co-moderator] will be assisting and taking notes.

The topic we'll be discussing today is the changes in Medicare with regard to durable medical equipment and the fee schedule they use to pay suppliers of these products. This "competitive bidding program" has recently been implemented in your area. Each of you has been asked to participate because you are a referral agent that works with Medicare beneficiaries. We are particularly interested in your perspective on the current durable medical equipment market and suppliers available to Medicare beneficiaries. Over the next year and a half, two more focus groups will be held as a part of this study. Focus groups are also being held in other areas and these will help the Centers for Medicare & Medicaid Services (CMS) understand the impact of the program.

Informed Consent (5 minutes)

Before we begin, I need to read aloud some of the key points of the consent form you just signed. Did everyone sign the form?

- Today we will ask you to discuss your experiences with Medicare beneficiaries and durable medical equipment
- Your participation is voluntary
- The focus groups will last approximately 1.5 hours
- The discussion will be confidential
- You can refuse to take part in this focus group if you wish without affecting your professional relationship with CMS
- You do not have to answer any questions you do not wish to answer
- You can quit the study at any time

- We do not foresee any possible risks from participating in this focus group, other than the minimal risk that confidentiality might not be preserved
- There are no costs to you for participating in the focus group
- You will receive $75 today for participating and dinner is provided
- This discussion will not be video or audiotaped, rather _____ [Insert co-moderator] will be taking notes. The notes from tonight will be labeled with a study code, not your names, and they will be kept in a locked file and/or a password-protected computer at Abt Associates Inc. in Cambridge, Massachusetts. A summary of the notes will be shared with CMS
- Your comments, and those of others in the focus group, will be used in reports to the government, in summary form and your name will not be included in the report
- **Does anyone have any questions?**

How the focus group will work (3 minutes)

- Want to keep the discussion informal and relaxed
- Eat and use the restrooms as you like
- During the discussion, please feel free to ask me or each other if something is unclear
- There are no right or wrong answers
- If you disagree with what someone else says, or have a different experience, please say so or I'll think that you all agree
- Some of you may have strong opinions, so please be respectful of other's
- Be careful not to talk all at once; I don't want to miss anything that is said
- My job is to make sure we hear from everyone. Some people talk more than others, and I'll be encouraging everyone to speak up.

Participant Introductions (7 minutes)

Let's go around the room and quickly introduce ourselves. [Write on the flip chart the following items]

- First name
- Title (for example social worker, discharge planner, etc)
- Organization you represent
- Clients you serve
- Role with durable medical equipment

COMPETITIVE BIDDING PROGRAM

1. **The DMEPOS competitive bidding program began a few months ago, how was the <u>information</u> you were provided regarding the program?**
    a. General information about the program
        i. What information did you receive? In what form? From whom did you receive this information?
        ii. Information regarding what (which supplies) is covered?
        iii. Did you find it helpful? Why or why not?
        iv. CMS' availability or contractors?
        v. From who else did you receive information?
        vi. What other information would you have wanted?

    b. List (directory) of "winning" suppliers?
        i. Received in a timely manner?
        ii. From whom?
        iii. In what form? (email, paper, etc.)

2. **How has the <u>transition</u> to the competitive bidding program been?**

    a. For example transition to new suppliers?

    b. What other transitions have you had to make?

3. **What <u>changes</u> have you noticed in your <u>role/work</u>? Be specific.**
    a. Changes in the referral process
    b. New relationships with suppliers
    c. Difficulties

4. **What <u>changes</u> have you noticed in the <u>quality</u> and <u>access</u> of DMEPOS products provided Medicare beneficiaries?**
    a. Quantity of suppliers?
        i. Are there an adequate number of suppliers in the area? For oxygen? Products X, Y, Z?
    b. Quality of products?
        i. Changes in products provided?

5. **What <u>changes</u> have you noticed in the DMEPOS market?**
    a. Are there enough suppliers?
    b. Is there a new dominant supplier?
        i. For oxygen?
        ii. Product X, Y, Z?
    c. How do suppliers compete for referrals?
    d. Do suppliers market their services?
        i. How do they market? (pamphlets, visits, etc.)
        ii. To whom do they market? (you, patients, etc.)

6. **Are beneficiaries aware of the program? What do they know about it?**

a. Have they noticed changes? What?

b. Have they been able to get information when they have had problems or questions?

c. What questions have your clients/patients been asking with regard to this program?

d. What could be done to better inform beneficiaries?

7. What do you see as the successes and failures of the program?

QUALITY STANDARDS

8. This program included a requirement that suppliers meet certain quality standards, have you noticed any changes?

IF PARTICIPANTS AREN'T FAMILIAR WITH THE STANDARDS, READ DESCRIPTION BELOW

QUALITY STANDARDS DESCRIPTION: As a part of the Medicare Modernization Act 2003, the Center for Medicare and Medicaid Services (CMS) requires Durable Medical Equipment, Prosthetic, Orthotic Supplies (DMEPOS) Suppliers to comply with newly established quality standards in order to receive payment for items or services provided to Medicare beneficiaries.

9. What do you think of the quality standards?

a. Are they needed?

b. Is there a problem with them?

c. Will they change your role?

d. How will they affect beneficiaries?

ENDING QUESTIONS

10. What questions or concerns about the program do you have as it continues forward?

11. Do you have any final thoughts about the Medicare DMEPOS competitive bidding program?

Those are all the questions that I have today. I want to thank you for participating in this discussion.

Focus Group Guide
Referral Agents (Wave 3)

Introduction (5 minutes)

Welcome. Thank you for joining us today. I am _____ [Insert your name] from Abt Associates Inc. We do research on health care. I will be moderating our discussion and _____ [Insert co-moderator] will be assisting and taking notes.

The topic we'll be discussing today is the changes in Medicare with regard to durable medical equipment and the fee schedule they use to pay suppliers of these products. This "competitive bidding program" has recently been implemented in your area. Each of you has been asked to participate because you are a referral agent that works with Medicare beneficiaries. We are particularly interested in your perspective on the current durable medical equipment market and suppliers available to Medicare beneficiaries. Over the next year and a half, two more focus groups will be held in your area as a part of this study. Focus groups are also being held in other areas and these will help the Centers for Medicare & Medicaid Services (CMS) understand the impact of the program.

Informed Consent (5 minutes)

Before we begin, I need to read aloud some of the key points of the consent form you just signed. Did everyone sign the form?

- Today we will ask you to discuss your experiences with Medicare beneficiaries and durable medical equipment
- Your participation is voluntary
- The focus groups will last approximately 1.5 hours
- The discussion will be confidential
- You can refuse to take part in this focus group if you wish without affecting your professional relationship with CMS
- You do not have to answer any questions you do not wish to answer

- You can quit the study at any time
- We do not foresee any possible risks from participating in this focus group, other than the minimal risk that confidentiality might not be preserved
- There are no costs to you for participating in the focus group
- You will receive $75 today for participating and dinner is provided
- This discussion will not be video or audiotaped, rather _____ [Insert co-moderator] will be taking notes. The notes from tonight will be labeled with a study code, not your names, and they will be kept in a locked file and/or a password-protected computer at Abt Associates Inc. in Cambridge, Massachusetts. A summary of the notes will be shared with CMS
- Your comments, and those of others in the focus group, will be used in reports to the government, in summary form and your name will not be included in the report
- **Does anyone have any questions?**

How the focus group will work (3 minutes)

- Want to keep the discussion informal and relaxed
- Eat and use the restrooms as you like
- During the discussion, please feel free to ask me or each other if something is unclear
- There are no right or wrong answers
- If you disagree with what someone else says, or have a different experience, please say so or I'll think that you all agree
- Some of you may have strong opinions, so please be respectful of other's
- Be careful not to talk all at once; I don't want to miss anything that is said
- My job is to make sure we hear from everyone. Some people talk more than others, and I'll be encouraging everyone to speak up.

Participant Introductions (7 minutes)

Let's go around the room and quickly introduce ourselves. [Write on the flip chart the following items]

- First name
- Title (for example social worker, discharge planner, etc)
- Organization you represent
- Clients you serve
- Role with durable medical equipment

QUESTIONS

1. **We spoke with some of you a few months after the program began, in the midst of transition. Now a year later does it seem that the transition is complete (for you, suppliers, beneficiaries)?**

    - *Transitioning to new suppliers?*
    - *Other aspects?*

2. **What <u>changes</u> have you noticed since the program began a year ago?**
    a. Changes in the referral process
    b. Suppliers
        i. Quantity of suppliers?
        ii. Quality of suppliers?
        iii. How and to whom they market?
        iv. Product changes?

3. **How has the program affected your work and role?**
    - *Changes in the referral process*
    - *New relationships with suppliers*
    - *Extra or different responsibilities*
    - *Difficulties/Challenges*

4. **How has the competitive bidding program affected beneficiary care?**
    a. In terms of access
        i. Are there adequate numbers of suppliers in the area?
            - For oxygen
            - For products X, Y, Z
        ii. Convenience?
    b. In terms of facility
        i. Changes in products provided?
        ii. Diverse array of products?
        iii. Quality of services provided?
    c. Have patients been able to get information when they have problems or questions?

5. **What <u>changes</u> have you noticed in the DMEPOS market?**
    a. Are there enough suppliers?
    b. Is there a new dominant supplier?
        i. For oxygen?
        ii. Product X, Y, Z?
    c. How do suppliers compete for referrals?
    d. Do suppliers market their services?
        i. How do they market? (pamphlets, visits, etc.)
        ii. To whom do they market? (you, patients, etc.)

6. **This program included a requirement that suppliers meet certain quality standards, have you noticed any changes?**

IF PARTICIPANTS AREN'T FAMILIAR WITH THE STANDARDS, READ DESCRIPTION BELOW

QUALITY STANDARDS DESCRIPTION: As a part of the Medicare Modernization Act 2003, the Center for Medicare and Medicaid Services (CMS) requires Durable Medical Equipment, Prosthetic, Orthotic Supplies (DMEPOS) Suppliers to comply with newly established quality standards in order to receive payment for items or services provided to Medicare beneficiaries.

7. **What do you think of the quality standards?**
    a. Are they needed?
    b. Is there a problem with them?
    c. Will they change your role?
    d. How will they affect beneficiaries?

8. **What do you see as the successes and failures of the program?**
    - *Poorer suppliers have left the market*

9. **What questions or concerns about the program do you have as it continues forward?**

10. **Do you have any final thoughts about the Medicare competitive bidding program?**

Those are all the questions that I have today. I want to thank you for participating in this interview.

Focus Group Guide
Suppliers (Wave 1)

Introduction (5 minutes)

Welcome. Thank you for joining us today. I am _____ [Insert your name] from Abt Associates Inc. We do research on health care. I will be moderating our discussion and _____ [Insert co-moderator] will be assisting and taking notes.

The topic we'll be discussing today is the changes in Medicare durable medical equipment, prosthetic, orthotic, supplies (DMEPOS) fee schedule for suppliers. Your area has been chosen as a site for implementation. Each of you has been asked to participate because you are a supplier or supplier group representative that provides DMEPOS products and services to Medicare beneficiaries. We are particularly interested in your experiences and perspectives on this new program. Over the next year and a half, two more focus groups will be held in your area as a part of this study. Focus groups are also being held in other areas and these will help the Centers for Medicare & Medicaid Services (CMS) understand the impact of the program.

Informed Consent (5 minutes)

Before we begin, I need to read aloud some of the key points of the consent form you just signed. Did everyone sign the form?

- Today we will ask you to discuss your experiences with preparing for this new fee schedule and providing DMEPOS to Medicare beneficiaries
- Your participation is voluntary
- The focus groups will last approximately 1.5 hours
- The discussion will be confidential
- You can refuse to take part in this focus group if you wish without affecting your professional relationship with CMS
- You do not have to answer any questions you do not wish to answer
- You can quit the study at any time

- We do not foresee any possible risks from participating in this focus group, other than the minimal risk that confidentiality might not be preserved
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- Your comments, and those of others in the focus group, will be used in reports to the government, in summary form and your name will not be included in the report
- **Does anyone have any questions?**

How the focus group will work (3 minutes)

- Want to keep the discussion informal and relaxed
- Eat and use the restrooms as you like
- During the discussion, please feel free to ask me or each other if something is unclear
- There are no right or wrong answers
- If you disagree with what someone else says, or have a different experience, please say so or I'll think that you all agree
- Some of you may have strong opinions, so please be respectful of other's
- Be careful not to talk all at once; I don't want to miss anything that is said
- My job is to make sure we hear from everyone. Some people talk more than others, and I'll be encouraging everyone to speak up.

Participant Introductions (7 minutes)

Let's go around the room and quickly introduce ourselves. [Write on the flip chart the following items]

- First name
- Supplier or organization you represent
- Types of DMEPOS you provide

BASELINE ENVIRONMENT

1. **How do Medicare beneficiaries get to each of you as a supplier?**

    a. Discharged from hospital? Referred from clinics? Walk-ins?
    b. Who refers them to you?
    c. Are you satisfied with your referral patterns?

2. **Do you think that there are an adequate number of suppliers in this area? Why or why not?**

COUNT # OF RAISED HANDS

3. **How many of you think beneficiaries are generally satisfied with their choices of DMEPOS suppliers in this area? Why?**

COUNT # OF RAISED HANDS

BIDDING PROGRAM

4. **How many of you are aware of the Medicare DMEPOS competitive bidding program?**

COUNT # OF RAISED HANDS

    a. When did you first hear about it?
    b. How did you hear about the program?
        - *Informational meeting by CMS?*
        - *Trade organization?*

5. **When you first heard about the competitive bidding program, what did you think?**

6. **Do you think your area (MSA) is a good market for competitive bidding? Why or why not?**

7. **One goal of competitive bidding is to reduce the prices that Medicare pays for DMEPOS. Medicare has included products Z,Y,Z in the competitive bidding program: X, Y, and Z.**

    a. Which of these product groups has the greatest potential of obtaining lower prices from competitive bidding?
        - X
        - Y
        - Z

    b. Which has the least potential?
    c. Are there any excluded product groups that should be in the program?

8. **What did you hear from CMS about the program and Requests for Bids (RFBs)?**
    a. Were you officially notified?
    b. What materials did you receive?
    c. What did you think of the materials?
        - Were they clear?
        - Straightforward?
        - Complete?
    d. Do you feel that you were adequately informed?
    e. Was a Medicare representative available for questions? Who was it? Were they helpful?

    f.

9. **How many of you submitted the bid?**

COUNT # OF RAISED HANDS

    a. Why did you decide to bid?
    b. How did you decide which products to bid on? Why?

10. What do you think of the bidding process?

- *Does it seem appropriate?*
- *Is it too much?*
- *Confusing?*
- *How is it compared to private bids you have made?*
- *Did it take long time to complete the bidding process? How long?*
- *CMS (or bidding program manager) available?*

11. Do you have a good sense of how they are going to evaluate the bids and pick the winners?

PROGRAM IMPACT

12. How do you anticipate the program will affect you as a supplier?

a. If you lose a bid(s), how will it affect you? Why?

b. If you win a bid(s), how will it affect you? Why?

13. How do you think the program will impact Medicare beneficiaries?

14. How might the program affect the quality of DMEPOS supplies and services you are able to provide? Can you give me an example?

15. **What do you think of the DMEPOS quality standards?**

16. **What challenges/issues do you anticipate arising with this program?**

ENDING QUESTION

17. **Do you have any final thoughts about the Medicare competitive bidding program as it gets underway?**

Those are all the questions that I have today. I want to thank you for participating in this interview.

Focus Group Guide
Suppliers (Wave 2)

Introduction (5 minutes)

Welcome. Thank you for joining us today. I am _____ [Insert your name] from Abt Associates Inc. We do research on health care. I will be moderating our discussion and _____ [Insert co-moderator] will be assisting and taking notes.

The topic we'll be discussing today is the changes in Medicare durable medical equipment, prosthetic, orthotic, supplies (DMEPOS) fee schedule for suppliers. Your area has been chosen as a site for implementation. Each of you has been asked to participate because you are a supplier or supplier group representative that provides DMEPOS products and services to Medicare beneficiaries. We are particularly interested in your experiences and perspectives on this new program. Over the next year and a half, two more focus groups will be held in your area as a part of this study. Focus groups are also being held in other areas and these will help the Centers for Medicare & Medicaid Services (CMS) understand the impact of the program.

Informed Consent (5 minutes)

Before we begin, I need to read aloud some of the key points of the consent form you just signed. Did everyone sign the form?

- Today we will ask you to discuss your experiences with preparing for this new fee schedule and providing DMEPOS to Medicare beneficiaries
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- The focus groups will last approximately 1.5 hours
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- Your comments, and those of others in the focus group, will be used in reports to the government, in summary form and your name will not be included in the report
- **Does anyone have any questions?**

How the focus group will work (3 minutes)

- Want to keep the discussion informal and relaxed
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- Be careful not to talk all at once; I don't want to miss anything that is said
- My job is to make sure we hear from everyone. Some people talk more than others, and I'll be encouraging everyone to speak up.

Participant Introductions (7 minutes)

Let's go around the room and quickly introduce ourselves. [Write on the flip chart the following items]

- First name
- Supplier or organization you represent
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THE BIDDING PROCESS

1. **All of you completed the bidding process for the DMEPOS competitive bid program, what did you think?**

    - *Length of time to complete RFBs?*
    - *CMS availability?*
    - *Any problems?*
    - *Any concerns? (e.g. did the process raise any concerns about the bid Medicare would receive in terms of quality?)*

WINNING BIDS

2. **Were you informed in a timely manner that you won the bid(s)?**

3. **Do you feel that the bid decisions were fair? Why or why not?**

4. **What effect do you think winning will have on your business?**

    - *Relationships with referral agents?*
    - *Personnel or staffing?*
    - *Finances?*
    - *Billing system?*
    - *Clients?*
    - Products and services provided?

PROGRAM IMPACT

5. **The Medicare competitive bidding program has begun – we would like to hear your thoughts about it.**

- *How has the transition gone?*

- *Have there been any problems or issues from the transition to competitive bidding?*

  Does it seem that there are enough winners?

6. What effect, if any, has the provision in place for beneficiaries to transition to different suppliers had?

- *On you as a supplier?*

- *On beneficiaries?*

7. How has the program affected you as a supplier?

- *How has the competitive bidding program affected the products you provide?*

- *Do you anticipate that the program will narrow or limit the services you are able to provide?*

  - *For example would you conduct follow-up visits less frequently?*

  - *Instruction / Training?*

8. How has the program affected beneficiaries?

9. What do you think of the DMEPOS quality standards that are also a requirement of the program?

- *Appropriate?*

<u>Ending Question</u>

10. Do you have any final thoughts about the Medicare competitive bidding program?

Those are all the questions that I have today. I want to thank you for participating in this discussion.

Focus Group Guide
Suppliers (Wave 3)

Introduction (5 minutes)

Welcome. Thank you for joining us today. I am _____ [Insert your name] from Abt Associates Inc. We do research on health care. I will be moderating our discussion and _____ [Insert co-moderator] will be assisting and taking notes.

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Participant Introductions (7 minutes)

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- First name
- Supplier or organization you represent
- Types of DMEPOS you provide

PROGRAM IMPACT

1. **It has been a year since the Medicare competitive bidding program began.**

    a. What has been successful about the program?
    b. What has been unsuccessful?

2. **How has the program affected you as a supplier?**

3. **Can you provide examples of "tough" choices you have had to make as a result of the program?**

    - *Have you had to cut back on staff/employees?*
    - *Have you decreased the frequency of f/u visits?*

4. **How has the competitive bidding program affected the products and services you are able to provide?**

5. **How has the program affected beneficiaries?**

6. **Do you have any final comments about the Medicare competitive bidding program?**

7. **Has your relationship with CMS or the DMEPOS changed in anyway because of the competitive bidding? How?**

Those are all the questions that I have today. I want to thank you for participating in this interview.

Key Informant Discussion Guide

Beneficiary Groups/Advocates (WAVE 1)

Questions:

1. **What is the name of your organization?**

2. **What type of organization are you? What role do you serve?**
    a. Are you a local/national organization?
    b. Does your local organization use resources, activities, etc. designed or distributed by a parent organization?
    c. Is your organization part of a community level coalition? Working with other organizations? Please describe.
    d. Who are your clients/constituents?
    e. Are any of your clients Medicare beneficiaries? What percent?

3. **Do you work with Medicare beneficiaries? With DMEPOS?**
    a. What do you do for Medicare beneficiaries regarding DMEPOS? Please provide examples?
        i. Educational services?
        ii. Outreach?
        iii. Advocacy?
        iv. Lobbying?
        v. Referral?
        vi. Financial Assistance?

4. **How is the DMEPOS supplier market in this area currently structured?**

    a. Are the available suppliers spread out or are they concentrated in a particular geographic area?

b. Is there a dominant supplier?
c. Are there both large and small suppliers?
d. Do you perceive that there are an adequate number of suppliers in this area? IF NOT, for what products is supply inadequate?
e. Do suppliers have to compete? Based on what?
   - *Quality?*
   - *Price?*
   - *Service?*
   - *Referral agents?*

f. How do suppliers market their products and services?
g. Do the suppliers compete with mail-order suppliers**?**

5. Do you refer beneficiaries to suppliers?

a. Which ones?
b. How do you decide which suppliers to refer people to? Do you have a list?
c. How did you develop the referral list?

6. What do you think of the current level of DMEPOS products and services provided Medicare beneficiaries? Please provide examples.

a. Access?
b. Quality?
c. Diversity of products? Choice?
d. Ancillary services – education, maintenance, etc.

7. **Have you heard of the Medicare plan to use Competitive Bidding to modify the DMEPOS fee schedule for reimbursing suppliers?**

INTERVIEWER: If they have not heard of the program, read the description below.

PROGRAM DESCRIPTION: The competitive bidding program for durable medical equipment, prosthetic, orthotic supplies (DMEPOS) is a program administered by the Center for Medicare and Medicaid Services (CMS), part of the Department of Health and Human Services (DHS), to control the costs of DMEPOS by requiring suppliers to bid for a contract to provide DMEPOS products and services to Medicare beneficiaries. This will result in a new fee schedule for specific DMEPOS items and could reduce the number of suppliers available to beneficiaries. Currently the suppliers are submitting their bids and CMS is beginning to provide information to referral agents and beneficiaries.

a. What do you think about it?
b. How do you think it might affect (positively and negatively) your clients?

8. **Does your organization have a policy or position statement on Medicare's competitive bidding program?**

9. **Do you have any final comments about the current environment of DMEPOS for Medicare beneficiaries in your area (and the competitive bidding program)?**

Key Informant Discussion Guide

Beneficiary Groups/Advocates (WAVE 2)

Questions:

1. What information has your organization received regarding the DMEPOS Competitive Bidding Program?

a. What did you receive?
b. When?
c. From whom?
d. Did you find the information helpful?
e. What questions are remaining for you?
f. What additional information would have been helpful?

2. What, if anything, has your organization been doing with regard to Medicare beneficiaries, DMEPOS and this relatively new program?

- *Educational activities*
- *Outreach*

3. Have members/clients asked about the program?

a. What types of questions or comments are you getting?
b. What are the primary concerns or issues being raised?

4. Have any suppliers contacted you regarding the program?

a. What was the purpose of the contact?
b. What was your response?

5. **Did CMS conduct any outreach efforts to educate beneficiaries about the program *through your organization?* Describe.**

6. **How do you think DMEPOS suppliers have changed over the past few months (under the competitive bidding program)?**
    a. Number of suppliers? Is it adequate?
    b. Has there been a change in suppliers? (Those not part of the program)
    c. Has there been a change in how suppliers compete? Based on what?
        - *Quality?*
        - *Price?*
        - *Service?*
        - *Referral agents?*

    d. Suppliers marketing their products and services?

7. **Have you noticed any impact of the program on beneficiaries?**
    a. Access to DMEPOS?
    b. Quality of DMEPOS?
    c. Diversity of products? Choice?
    d. Ancillary services – education, maintenance, etc.

8. **Do you think the program will ultimately be successful? Why or why not?"**

9. **Do you have any final comments about the relatively new competitive bidding program for Medicare beneficiaries and DMEPOS?**

Key Informant Discussion Guide

Beneficiary Groups/Advocates (WAVE 3)

Questions:

1. **It has been a year since the inception of the competitive bidding program. What do think of the program at this point?**

    a. Successes of the program
    b. Failures or limitations
    c. Significant changes

2. **What has your organization done with or for beneficiaries with regard to DMEPOS over the past year related to the program? (e.g. education)**

    a. How does that differ from your activities prior to the program?

3. **How has the program affected you as an organization in any way, or your role?**

4. **How do you think the DMEPOS suppliers available to beneficiaries have changed over the past year (under the competitive bidding program)?**

    a. Number of suppliers? Is it adequate?
    b. Competition among suppliers?
        - *Quality?*
        - *Price?*
        - *Service?*

- *Referral agents' preferences?*

c. The way that suppliers market?

5. **From what you have seen and heard, how has the program affected beneficiaries?**
    a. Access to DMEPOS?
    b. Quality of DMEPOS?
    c. Diversity of products? Choice?
    d. Ancillary services – training, maintenance, etc.
    e. Assistance with insurance?

6. **Do you have any final comments about the competitive bidding program for Medicare beneficiaries and their DMEPOS? Suggestions to make the program better?**

Key Informant Discussion Guide

CMS Officials or CMS' Bidding Program Managers (Wave 1)

Researcher Note: Some questions may be more appropriate for the CMS official than for the bidding program manager and vice versa. Inform the participant at the beginning that they can defer if he/she is not the appropriate individual to answer that question.

Questions:

1. **Responsibility for Program Administration**
    a. What are the responsibilities of CMS officials versus the bidding program managers?
    b. How will the competitive bidding program be administered in this MSA?
    c. Who is responsible for administration?
    d. What responsibilities reside at the local level?
    e. How is oversight of local program administration to be carried out?
    f. When will (was) the program be initiated at this site?

2. **Process for Selecting Suppliers** *(Ask questions only if it is unknown from available materials)*?
    a. How were suppliers and the potential bidders informed about the program?
        i. bidders conferences/meetings?
        ii. written materials?
        iii. other means of education
    b. How was the RFB distributed?
    c. What information was required of bidders in the RFB?
        --quality (customer service, facilities, inventory, etc)
        --service capacity
        --finances
        --geographic coverage

d. What support was provided to suppliers in constructing their bids?

e. How are suppliers being selected?

3. How do you anticipate this program will affect the referral process?

a. For referral agents?

b. Suppliers?

c. Beneficiaries?

d. Beneficiary advocates

4. Program Outreach and Dissemination

a. How and when will referral agents be notified that the program has begun?

b. How and when will beneficiaries be notified?

c. What vehicles of communication will be used for outreach?

d. When were (will) materials sent out? What was sent? (can we get copies)

5. Assessment of the Market

a. What process will be used to assess overall supplier capacity in the market?

b. How will the ability of suppliers to increase capacity be assessed?

c. How will geographic coverage in the market be assessed?

d. Are any changes projected in the physician authorization process expected as part of the program? If so, what are they?

e. Is an exemption process for small suppliers anticipated? If so, what are the key features of this process likely to be?

6. Plans for Program Monitoring

a. What type of complaint reporting system is envisioned for the program? How will it differ from the system now in place?

b. What ombudsman services will be available for consumers?

c. What data will the ombudsman collect? Are the data available?

d. How will the program be monitored locally?

e. What rules are likely to be implemented or steps taken to create a level playing field for small suppliers?
f. What

7. General Observations

a. What do you see as the biggest obstacles to program implementation in this MSA? Why?
b. What are your biggest concerns about your ability to monitor supplier performance?
c. How long do you think it will be before some form of steady state under the program will be achieved?
d. Overall, in your opinion. What is the biggest threat to the success of the program in this MSA?

Key Informant Discussion Guide

CMS Officials or CMS' Bidding Program Managers (Wave 2)

Researcher Note: Some questions may be more appropriate for the CMS official than for the bidding program manager and vice versa. Inform the participant at the beginning that they can defer if he/she is not the appropriate individual to answer that question.

Questions:

1. **Program Administration**
    a. How has the administration of the program gone?
    b. What has been successful? Unsuccessful?
    c. After the program was begun, what were the most important issues that arose requiring decisions or policy refinement? How were they resolved?

2. **Selecting Suppliers**
    a. How and when were the RFBs distributed?
    b. What support was provided to suppliers in constructing their bids?
    c. How did the selection process go? What problems arose?
    d. How were winners selected?
    e. How were winners informed about the program?

3. **Supplier market**
    a. Are there enough suppliers?
    b. Have the suppliers been able to maintain the capacity they proposed?
    c. Are suppliers meeting the needs of beneficiaries?

4. **How has the program affected the referral process?**
    a. For referral agents?
    b. Suppliers?
    c. Beneficiaries?

5. **Program Outreach and Dissemination**
    a. Was the program outreach successful? Unsuccessful?
    b. How and when were referral agents and beneficiaries notified about the program?
    c. What vehicles of communication were used for outreach?
    d. When were materials sent out? What was sent?

6. **Program Monitoring**
    a. How is the program monitored?
    b. Is there a complaint reporting system?
        i. What types of complaints have you received?
    c. How is quality being monitored or assessed as the program rolls out?

7. **What have been the reactions to the program from each of these stakeholders?**
    a. Suppliers
    b. Referral agents
    c. Beneficiaries
    d. Beneficiary advocacy organizations
    e. Congress

8. **General Observations**
    a. What do you think were the biggest obstacles? Why? Can they be corrected?
    b. What are your biggest concerns as the program moves forward?
    c. What areas to you see as needing improvement and can they be addressed within the coming ½ year?
    d. What changes, if any, do you anticipate for the remainder of this initial year of the program?

Key Informant Discussion Guide

CMS Officials or CMS' Bidding Program Managers (Wave 3)

Researcher Note: Some questions may be more appropriate for the CMS official than for the bidding program manager and vice versa. Inform the participant at the beginning that they can defer if he/she is not the appropriate individual to answer that question.

Questions:

1. **Program Administration**
    a. How has the administration of the program gone?
    b. What has been successful? Unsuccessful?
    c. After the program was begun, what were the most important issues that arose requiring decisions or policy refinement? How were they resolved?

2. **Supplier market**
    a. Are there enough suppliers?
    b. Have the suppliers been able to maintain the capacity they proposed?
    c. Are suppliers meeting the needs of beneficiaries? How is that being determined?

3. **How has the program affected the referral process?**
    a. For referral agents?
    b. Suppliers?
    c. Beneficiaries?

4. **Program Outreach and Dissemination**
    a. Was the program outreach successful? Unsuccessful?
    b. How and when were referral agents and beneficiaries notified?
    c. What vehicles of communication were used for outreach?
        i. Were they effective?
    d. When were materials sent out? What was sent?

e. How has the ongoing communication gone compared to the initial communication?

5. **Program Monitoring**
    a. How is the program monitored?
    b. Is there a complaint reporting system?
        i. What types of complaints have you received?
        ii. What are the most common complaints?
        iii. What is the process for resolving – for example?
    c. How is quality being monitored or assessed as the program is being implemented?

6. **What has been the impact of the program on each of these stakeholders?**
    a. Suppliers
    b. Referral agents
    c. Beneficiaries
    d. Beneficiary advocacy organizations

7. **General Observations**
    a. Did the problems or concerns with the program in the first months improve over the subsequent 9 months?
    b. What do you think were the biggest obstacles? Why? Can they be corrected?
    c. What have been the big problems with the program?
    d. What areas do you see as needing improvement?
    e. What changes do you think would better meet the goals of this competitive bidding program?

Key Informant Discussion Guide

Referral Agents (Wave 1)

Questions:

Background Information

1. **What is your title and training?**

2. **What organization are you affiliated with and what type of an organization is it?**

3. **What is your role in working with clients generally and Medicare beneficiaries specifically?**

4. **Which DMEPOS products do your clients most frequently use?**

Referral Process

5. **Could you describe your referral process from beginning to end?**

    a. How or when do you get involved with patients/clients?
        - *Discharged from hospital?*
        - *Referral from doctor's office*?

b. What do you do for patients?
   - *File the certificate of medical necessity (CMN)?*

c. Do you feel satisfied with the outcomes you can achieve? Why or why not?

6. How do you determine which supplier you refer your clients to?

a. Do you have a list of suppliers? Where does it come from?

b. Do you have a preferred supplier?

c. Are you satisfied with your interactions with suppliers? Why or why not?

d. Do you find any significant problems related to accessing suppliers at present?

7. **How is the DMEPOS market in this area?**

a. Are there enough suppliers?

b. Is there a dominant supplier?
   i. For oxygen?
   ii. Product X, Y, Z?

c. How do suppliers compete for referrals?

d. Do suppliers market their services?
   i. How do they market? (pamphlets, visits, etc.)
   ii. To whom do they market? (you, patients, etc.)

8. **What do you think of the current level of <u>access</u> and <u>quality</u> of DMEPOS products and services that suppliers provide your clients?**

<u>BIDDING PROGRAM</u>

9. **Have you heard about Medicare's change in the durable medical equipment fee schedule for suppliers, also known as "competitive bidding"?**

PROGRAM DESCRIPTION: The competitive bidding program for durable medical equipment, prosthetic, orthotic supplies (DMEPOS) is a program administered by the Center for Medicare and Medicaid Services (CMS), part of the Department of Health and Human Services (DHS), to control the costs of DMEPOS by requiring suppliers to bid for a contract to provide DMEPOS products and services to Medicare beneficiaries. This will result in a new fee schedule for specific DMEPOS items, which could reduce the number of suppliers available to beneficiaries and potentially change the suppliers with whom you work. Currently the suppliers are submitting their bids and CMS is beginning to provide information to referral agents and beneficiaries.

10. How did you hear about it?

11. What are your initial thoughts about it?

12. How do you think competitive bidding will affect <u>your role</u>?

- *Referral process*
- *To whom you refer patients*
- *Suppliers you prefer or do not prefer*

13. How do you think the program will affect <u>suppliers</u> in your area?

14. How do you think competitive bidding could affect <u>Medicare beneficiaries</u>?

- *Access to products*
- *Quality of services*

QUALITY STANDARDS

15. Have you heard about the "quality standards" required of DMEPOS suppliers for items & services provided Medicare beneficiaries?

QUALITY STANDARDS DESCRIPTION: As a part of the Medicare Modernization Act 2003, the Center for Medicare and Medicaid Services (CMS) requires Durable Medical Equipment, Prosthetic, Orthotic Supplies (DMEPOS) Suppliers to comply with newly established quality standards in order to receive payment for items or services provided to Medicare beneficiaries.

16. **What do you think of the quality standards?**

a. Are they needed?
b. Is there a problem with them?
c. Will they change your role?
d. How will they affect beneficiaries?

Closing Question

17. **Do you have any final thoughts about the current state of DMEPOS and the new Medicare competitive bidding program?**

Key Informant Discussion Guide
Referral Agents (Wave 2)

Questions:

Skip questions 1 to 4 if the referral agent was a participant in Wave 1.

Background Information

1. **What is your title and training?**

2. **What organization are you affiliated with and what type of an organization is it?**

3. **What is your role in working with clients generally and Medicare beneficiaries specifically?**

4. **Which DMEPOS products do your clients most frequently use?**

5. **The DMEPOS competitive bidding program began a few months ago. How was the <u>information</u> you were provided regarding the program?**
   a. General information about the program
      i. From whom?
      ii. What form?

   b. List (directory) of "winning" suppliers?

iii. Received in a timely manner?

iv. From whom?

v. In what form? (email, paper, etc.)

b. Information regarding what (which supplies) is covered

c. Information received

i. Did you find it helpful? Why or why not?

ii. Has CMS or its representatives been available to respond to concerns?"

iii. From whom else did you receive information?

iv. What other information would you like?

6. **The Medicare competitive bidding program has been underway the past few months. How has the <u>transition</u> been?**

a. Have you had to transition to new suppliers? For what services?

b. Have there been any significant issues relating to suppliers that did not exist prior to this program?

i. How did they arise?

ii. Why do you believe they are related to the new program?

7. **What <u>changes</u> have you noticed in <u>your role/work</u> since the program began?**

a. Referral process?

b. Your professional relationships? (e.g. with suppliers)

c. Difficulties?

8. **What <u>changes</u> have you noticed in the <u>quality and access</u> of DMEPOS products provided Medicare beneficiaries?**

a. Are there an adequate number of suppliers?

i. For oxygen?

ii. For product X, Y, Z?

b. Have the specific products provided changed? (e.g. brand of a product)

c. How has the quality of services provided changed? (e.g. instruction provided, follow-up visits, timeliness, etc.)

9. What changes have you noticed in the DMEPOS supplier market, with regard to the following?

a. Number of suppliers available?

b. Dominance of certain suppliers?

   i. For oxygen?

   ii. Product X, Y, Z?

c. How suppliers compete for referrals?

d. How suppliers market their services?

   i. How they market? (pamphlets, visits, etc.)

   ii. To whom they market? (you, patients, etc.)

10. What do beneficiaries know about this program?

- *Are they aware of the program?*
- *Have they noticed changes? What?*
- *What questions, if any, have your clients/patients been asking with regard to this program?*
- *Have they been able to get help when they have problems or questions?*
- *What could be done to better inform beneficiaries?*

11. The change in Medicare DMEPOS included a requirement that suppliers meet certain quality standards. Are you familiar with these standards?

IF THE INFORMANT ISN'T FAMILIAR WITH THE STANDARDS, READ DESCRIPTION BELOW, THEN ASK QUESTION 8.

QUALITY STANDARDS DESCRIPTION: As a part of the Medicare Modernization Act 2003, the Center for Medicare and Medicaid Services (CMS) requires Durable Medical Equipment, Prosthetic, Orthotic Supplies (DMEPOS) Suppliers to comply with newly established quality standards in order to receive payment for items or services provided to Medicare beneficiaries.

12. What do you think of the quality standards?

a. Are they needed?
b. Is there a problem with them?
c. Have they changed your role at all?
d. Have they affected the products and services provided beneficiaries?

13. What questions or concerns about the program do you have as it continues forward?

14. Do you have any final thoughts about the Medicare competitive bidding program?

Key Informant Discussion Guide

Referral Agents (Wave 3)

Questions:

Skip questions 1 to 4 if the referral agent was a participant in Wave 1.

Background Information

1. **What is your title and training?**

2. **What organization are you affiliated with and what type of an organization is it?**

3. **What is your role in working with clients generally and Medicare beneficiaries specifically?**

4. **Which DMEPOS products do your clients most frequently use?**

5. **We spoke a few months after the program began, still in the midst of transition. Now a year later, what <u>changes</u> have you noticed since the program began?**

6. **Has your work or role changed since the program was implemented?**
   - *New challenges?*

- *Extra or different responsibilities?*
- *Relationships*

7. **What changes have you noticed in the DMEPOS supplier market?**

    a. Changes in the referral process?

    b. Suppliers

        i. Adequate number of suppliers?

        ii. Quality of suppliers available to beneficiaries?

        iii. Product changes?

8. **How has the competitive bidding program affected beneficiary care?**

    a. Access to DMEPOS products and services?

    b. Diverse array of products?

    c. Quality or level of products and services provided?

    d. Have patients been able to get information when they have problems or questions?

    e. How and to whom suppliers market?

    f. Timeliness of DMEPOS product provision and services?

    g. Communication with suppliers?

9. What do you see as the successes and failures of the program?

- *Poorer suppliers have left the market*
- *Supplier response to service requests is not as quick*

10. What questions or concerns about the program do you have as it continues forward?

11. Do you have any suggestions for how it could be improved?

12. Do you have any final thoughts about the Medicare competitive bidding program?

Key Informant Discussion Guide

Suppliers (Wave 1)

Questions:

1. **What DMEPOS do you provide?**
    - *Oxygen*
    - *Wheelchairs*
    - *Hospital beds*
    - *Orthotics*
    - *Prosthetics*

2. **Are you accredited? By whom?**

3. **How would you describe yourself as a supplier?**
    a. How long have you been supplying DMEPOS?
    - *Large vs. small*
    - *Niche vs. full service*
    - *Geographic limitations*

4. **How do Medicare beneficiaries get to you as a supplier?**
    a. Discharged from hospital? Referred from clinic? Walk-in? Most common? Variation by service type?
    b. Who refers them to you?

5. **Are you satisfied with your referral network at present?**
    a. How do referral agents know about your services?
    b. How do you market your products and services?
    c. What types of referrals do you get?
    d. How are your relationships with referral agents?

6. **What services are beneficiaries typically provided as a part of the DMEPOS? (***If you provide a lot of DMEPOS, describe the services provided with one of your highest volume products?)*
    a. Delivery and set-up
        i. Who does it? What is their background or training?
    b. Equipment maintenance
    c. Level of training or instruction provided
    d. Type and frequency of follow-up

DMEPOS Market

7. **How would you describe the DMEPOS supplier market in this area?**
    - *Are suppliers spread out or concentrated in a particular geographic here?*
    - *Is there a dominant company?*
        - *How does this vary, if at all, by product type?*
    - *Do you perceive that there are an adequate number of suppliers?*
        - *How does this vary by product type?*

8. **Where do you fit as a supplier in this market?**
    a. How do you compete with other suppliers?
        - *Price*
        - *Service / Quality*
        - *Referral agents' preferences*
    b. To what extent do you compete with mail-order suppliers**?**

Competitive Bidding

9. **What have you heard from CMS (or CMS' bidding program managers) about the competitive bidding program and Request for Bids (RFBs)?**
    a. Were you officially notified?
    b. What materials did you receive?

c. What did you think of the materials?
   - Were they clear?
   - Straightforward?
   - Complete?

d. Do you feel that you were adequately informed?

e. Was a Medicare representative available for questions? Who was it? Were they helpful?

10. Did you submit a bid(s)?

a. Why did you decide to bid?

b. How did you choose products you bid on?

11. What did you think of the bidding process?

a. Do you have a good understanding of how bids will be evaluated and chosen?

b. Do you feel that adequate consideration has been given to ensuring that small suppliers can participate in the program (are you a small/large supplier)?

Program Impact

12. If you win, how will it affect your company?

a. What will you gain?

b. Will you supply fewer (more) brands of products?

c. How you market your products and services?

13. If you lose, how will it affect your company?

a. What will you gain/lose?

b. Will you supply fewer (more) brands of products?

c. How you market your products and services?

14. How do you anticipate the program will affect Medicare beneficiaries?

a. Will beneficiaries be able to get the same products and services they had before this program?
b. Will suppliers experience any pressure to shift to lower-quality products? If so, how will that happen (e.g. lower profit margins)?
c. What other influences will affect the products and services used by patients you work with?

15. What do you think will be the changes both positive and negative on quality?

- *Consulting with prescribers*
- *Assessing appropriateness of the equipment*
- *Develop service plan*
- *Equipment management? Repairs? Adjustments?*
- *Replacing equipment*
- *Procedure for equipment delivery and set-up? Who sets up? Their background?*
- *Provide training or instruction? Who does this?*
- *What information or training is provided? Operation? Safety? Repair? Written or oral?*
- *Follow-up*

16. Any other thoughts about the program or its likely impact?

Key Informant Discussion Guide
Suppliers (Wave 2)

Questions:

Skip questions 1 to 6 if supplier participated in wave 1.

1. **What DMEPOS do you provide?**
    - *Oxygen*
    - *Wheelchairs*
    - *Hospital beds*
    - *Orthotics*
    - *Prosthetics*

2. **Are you accredited? By whom?**

3. **How would you describe yourself as a supplier?**
    - **a.** How long have you been supplying DMEPOS?
        - *Large vs. small*
        - *Niche vs. full service*
        - *Geographic limitations*

4. **How do Medicare beneficiaries get to you as a supplier?**
    a. Discharged from hospital? Referred from clinic? Walk-in? Most common? Variation by service type?
    b. Who refers them to you?

5. **Are you satisfied with your referral network at present?**
    a. How do referral agents know about your services?
    b. How do you market your products and services?
    c. What types of referrals do you get?

d. How are your relationships with referral agents?

6. What services are beneficiaries typically provided as a part of the DMEPOS?

- *If you provide a lot of DMEPOS, describe the services provided with one of your highest volume products?*

a. Delivery and set-up
    i. Who does it? What is their background or training?
b. Equipment maintenance
c. Level of training or instruction provided
d. Type and frequency of follow-up

The Bidding Process

7. Overall, how was the bidding process?

- *Did you have the resources you needed to submit a bid?*
- *Was the receipt of the information timely?*
- *Was the process described in the information you received?*

8. Did you have outside assistance formulating your bid(s)?

9. Have you had experience formulating bids for the private sector and was the process similar? In what respect was it different?

10. How was the notification process?

- *Timeliness*
- *Fairness*

11. Did you win any of the bid(s) you submitted? Lose any of the bid(s)?

INTERVIEWER:

If the supplier <u>lost</u> a bid asks questions 6-8,17,then stop.

If they <u>won</u> a bid skip to question 9.

If they <u>won & lost</u> a bid ask all questions.

Losing Bids

12. Were you informed in a timely manner that you lost the bid(s)?

13. Do you think the decision was fair, in light of what you know about other suppliers' bids?

- *What do you believe were the most important factors in losing the bid?*

14. What effect will losing have on your business?

- *Relationships with referral agents?*
- *Relationships with equipment distributors/suppliers?*
- *Changes in personnel or staffing?*
- *Effect on other aspects of your work?*
- *Convert part of the store?*
- *Merge? Sell?*
- *Write your congressman?*

Winning Bids

15. Were you informed in a timely manner that you won the bid(s)?

16. Do you feel that the bid decisions were fair? Why or why not?

17. What effect do you think winning is having and will continue to have on your business?

- *Relationships with referral agents?*
- *Personnel or staffing?*
- *Finances*
- *Billing system*
- *Number of clients*
- *Products and services provided*

Transition

18. Do you think enough suppliers won contracts in this area to provide for the Medicare beneficiaries? Why or why not?

19. How has the transition to this new contractual relationship with CMS gone?

20. Has CMS or its representatives been available to respond to concerns or issues?"

21. What effect, if any, has the provision in place for beneficiaries to transition to different suppliers had?

The Program Impact

22. With changes in reimbursement have you had to make tough choices about the provision of DMEPOS product and services? If yes, what were they?

a. What factors were important in reaching these decisions?

23. How have beneficiaries been affected by this program?

- *Access to products*
- *Level of services provided*

24. What do you think of the quality standards required with the program?

- *Burdensome / Helpful?*
- *Applicable / Appropriate?*
- *Suggestion for how they could be improved?*

25. What concerns do you anticipate will arise as the program roles out over the next year?

26. Is there anything else that you would like to tell us about the program?

Key Informant Discussion Guide
Suppliers (Wave 3)

Questions:

Skip questions 1 to 6 if supplier participated in wave 1.

BACKGROUND INFORMATION:

1. **What DMEPOS do you provide?**
   - *Oxygen*
   - *Wheelchairs*
   - *Hospital beds*
   - *Orthotics*
   - *Prosthetics*

2. **Are you accredited? By whom?**

3. **How would you describe yourself as a supplier?**
   - **a.** How long have you been supplying DMEPOS?
     - *Large vs. small*
     - *Niche vs. full service*
     - *Geographic limitations*

4. **How do Medicare beneficiaries get to you as a supplier?**
   a. Discharged from hospital? Referred from clinic? Walk-in? Most common? Variation by service type?
   b. Who refers them to you?

5. **Are you satisfied with your referral network at present?**

a. How do referral agents know about your services?
b. How do you market your products and services?
c. What types of referrals do you get?
d. How are your relationships with referral agents?

6. What services are beneficiaries typically provided as a part of the DMEPOS?

- *If you provide a lot of DMEPOS, describe the services provided with one of your highest volume products?*

a. Delivery and set-up
    i. Who does it? What is their background or training?
b. Equipment maintenance
c. Level of training or instruction provided
d. Type and frequency of follow-up

PROGRAM IMPACT

7. How has the competitive bidding program changed your business?

a. Number of clients
b. Products and services provided
c. Personnel / staffing
d. Financially / Billing system
    i. Prices for non-Medicare clients
    ii. Private pay clients
e. Marketing

8. Since the institution of the competitive bidding program (~12 months ago) what have you had to change (and why) in terms of the following:

a. Products provided
b. Delivery and set-up
    i. Who does it? Their background or training?
c. Equipment maintenance
d. Level of training or instruction provided

e. Frequency of follow-ups

9. Overall, what have been the consequent changes in your provision of DMEPOS and the associated services under this program?

10. How do you think the competitive bidding program has changed the DMEPOS supplier market in this area?

- *In terms of concentration in a given geographic area?*
- *Is there a change in the dominant company?*
  - *Does it vary, if at all, by product type?*
- *Are there an adequate number of suppliers?*
  - *Does this vary by product type?*

11. Has the competitive bidding program changed your location in the supplier market?

a. Where you fit in this market?

b. How you compete with other suppliers?

- *Price*
- *Service / Quality*
- *Referral agents' preferences*

c. Competition with mail-order suppliers**?**

12. How do you think the program has been successful? Why?

13. What do you think have been the failures or limitations of the program? Why?

14. How has the competitive bidding affected the provision of DMEPOS for Medicare beneficiaries? (From the referral process all the way to the arrival of the product in the beneficiaries home)

15. Lastly, what feedback do you have for CMS to improve the program for your area and the new areas that will begin competitive bidding?

Key Informant Discussion Guide

COMPARISON AREA: Beneficiary Groups/Advocates (WAVE 1)

Questions:

1. **What is the name of your organization?**

2. **What type of organization are you? What role do you serve?**
    a. Are you a local/national organization?
    b. Does your organization use resources, activities etc. from a parent organization?
    c. Is your organization part of a coalition? Working with other organizations? Please describe.
    d. Who are your clients/constituents?

3. **Do you work with Medicare beneficiaries? With DMEPOS?**
    a. What do you do for Medicare beneficiaries with regard to DMEPOS? Please provide examples?
        i. Educational services?
        ii. Outreach?
        iii. Advocacy?
        iv. Lobbying?
        v. Referral?
        vi. Financial Assistance?

4. **How is the DMEPOS supplier market in this area currently?**
    a. Are suppliers spread out or are they concentrated in a geographic area?
    b. Is there a dominant supplier?
    c. Are there both large and small suppliers?
    d. Do you perceive that there are an adequate number of suppliers in this area?

e. Do suppliers have to compete? Based on what?
   - *Quality?*
   - *Price?*
   - *Service?*
   - *Referral agents' preferences?*

f. How do suppliers market their products and services?

g. Do the suppliers compete with mail-order suppliers**?**

5. **Do you refer beneficiaries to suppliers?**
   a. Which ones?
   b. How do you decide which suppliers to refer clients to? Do you have a list?
   c. From where do you get your referral list? (or how do you create it)?

6. **What do you think of the current level of DMEPOS products and services provided Medicare beneficiaries? Please provide examples.**
   a. Access to DMEPOS?
   b. Quality of DMEPOS?
   c. Diversity of products? Choice?
   d. Ancillary services – education, maintenance, etc.

7. **Do you have any additional comments or information that might be helpful if I am trying to understand the DMEPOS market in this area?**

Key Informant Discussion Guide

COMPARISON AREA: Beneficiary Groups/Advocates (WAVE 2)

Questions:

1. **Since we last spoke (*X months ago*) have there been any changes in the DMEPOS products and services in this area? And why?**
   - *Number of suppliers?*
   - *Quality of products and services?*

2. **Since we last spoke have there been any changes in <u>your role</u> working with Medicare beneficiaries and their DMEPOS ?**

3. **What, if anything, has <u>your organization</u> been doing differently (the past few months) with regard to Medicare beneficiaries and DMEPOS ?**
   - *New education programs*

4. **Have your clients raised any new questions or concerns over the past months? If so, what were they?**

5. **Have you heard of or are you familiar with the new Quality Standards for DMEPOS put out by the Centers for Medicare and Medicaid Services (CMS)?**

QUALITY STANDARDS DESCRIPTION: As a part of the Medicare Modernization Act 2003, the Center for Medicare and Medicaid Services (CMS) requires Durable Medical Equipment, Prosthetic, Orthotic Supplies (DMEPOS) Suppliers to comply with newly established quality standards in order to receive payment for items or services provided to Medicare beneficiaries.

a. What information have you received about them?

- From whom?
- When?

b. Have they changed your role?

c. Are beneficiaries aware of them?

d. How do you think the standards will affect beneficiaries?

e. What have you heard from suppliers about them?

f. What do you think about them?

i. Positives?

ii. Negatives?

6. **Have there been any changes in the DMEPOS supplier market the past few months?**

   a. Number of suppliers? Is it adequate?

   b. Competition among suppliers? Based on what?

      - *Quality? Price? Service? Referral agents?*

   c. Suppliers marketing their products and services?

7. **Are you aware of any occurrences in health care or this area that have impacted DMEPOS products, services, provision, etc.?**

   - *Product recall*
   - *New type of equipment*
   - *Health care crisis – (e.g. higher incidence of pneumonia)*
   - *New regulations or policies (e.g. Deficit Reduction Act cap on rentals)*

8. **Has the level of care beneficiaries are provided for DMEPOS changed over the past few months?**

   a. Access to DMEPOS?

   b. Quality of DMEPOS?

   c. Diversity of products? Choice?

d. Ancillary services – education, maintenance, etc.

9. **Do you have any additional comments about new occurrences in your area with regard to Medicare beneficiaries, DMEPOS and suppliers?**

Key Informant Discussion Guide

COMPARISON AREA: Beneficiary Groups/Advocates (WAVE 3)

Questions:

1. **Since we last spoke (*X months ago*) have there been any changes in the DMEPOS products and services in this area? Why?**
   - *Number of suppliers?*
   - *Quality of products and services?*

2. **Since we last spoke have there been any changes in your role working with Medicare beneficiaries and their DMEPOS?**

3. **What, if anything, has your organization been doing differently (the past year) with regard to Medicare beneficiaries and DMEPOS? (e.g. education).**

4. **Have your clients raised any new questions or concerns over the past year? If so, what were they?**

5. **What has changed with regard to the Quality Standards for DMEPOS?**

   a. Have they changed your role?
   b. Are beneficiaries aware of them?
   c. How do you think the standards are impacting beneficiaries' care?
   d. What have you heard from suppliers about the standards?

e. What do you think about them, a year since they were required?
    i. Positives?
    ii. Negatives?

6. **How do you think the DMEPOS supplier market has <u>changed</u> over the past year?**
    a. Number of suppliers? Is it adequate?
    b. Competition among suppliers? Based on what?
        - *Quality? Price? Service? Referral agents?*
    c. Suppliers marketing their products and services?

7. **Are you aware of any occurrences in health care or this area that have impacted DMEPOS products, services, provision, etc.?**
    - *Product recall*
    - *New type of equipment*
    - *Health care crisis – (e.g. higher incidence of pneumonia)*
    - *New regulations or policies (e.g. Deficit Reduction Act cap on rentals)*

8. **Has the level of care beneficiaries are provided for DMEPOS changed over the past year?**
    a. Access to DMEPOS?
    b. Quality of DMEPOS?
    c. Diversity of products? Choice?
    d. Ancillary services – education, maintenance, etc.

9. **Do you have any additional comments about new occurrences in your area with regard to Medicare beneficiaries, DMEPOS and suppliers?**

Key Informant Discussion Guide

COMPARISON AREA: Referral Agents (Wave 1)

Questions:

Role

1. **What is your title and training?**

2. **What organization are you affiliated with and what type of an organization is it?**

3. **What is your role in working with clients generally and Medicare beneficiaries specifically?**

4. **What DMEPOS products do your clients use?**

Referral Process

5. **Could you describe the referral process from beginning to end?**
    a. **How or when do you get involved with patients/clients?**
        - *Discharged from hospital?*
        - *Referral from doctor's office*?
    b. **What do you do for patients?**
        - *CMN – do you fill out?*

6. **Regarding the suppliers you refer beneficiaries to, how do you decide to whom you refer your patients?**
        - *Do you have a list of suppliers?*
        - *Where did you get the list or how did you create that list?*

7. **How competitive is the DMEPOS market in this area?**

- *Enough suppliers? A lot of options?*
- *A dominant supplier?*

8. **What do you think of the current level of care provided beneficiaries in this area?**
    a. Quality of DMEPOS?
    b. Access to DMEPOS?
    c. Diversity of products?
    d. Ancillary services?

Quality Standards

9. **Have you heard of or received information about the new Quality Standards for DMEPOS put out by the Centers for Medicare and Medicaid Services (CMS)?**

QUALITY STANDARDS DESCRIPTION: As a part of the Medicare Modernization Act 2003, the Center for Medicare and Medicaid Services (CMS) requires Durable Medical Equipment, Prosthetic, Orthotic Supplies (DMEPOS) Suppliers to comply with newly established quality standards in order to receive payment for items or services provided to Medicare beneficiaries.

    a. What information have you received about them?
        i. From whom?
        ii. When?
    b. What has CMS done to inform you?
    c. Has your professional organization informed you about it?

10. What do you think of the Quality Standards generally?

    a. What is good about them?
    a. What is a problem with them?
    b. Are they appropriate/fair?
    c. Will they change your business/role?

d. How will they affect beneficiaries?

11. What do you think of the specific aspects of the Quality Standards, are they appropriate, inappropriate, excessive, etc.?

a. Consulting with prescribers
b. Assessing appropriateness of the equipment
c. Develop service plan
d. Equipment management? Repairs? Adjustments?
e. Replacing equipment
f. Procedure for equipment delivery and set-up? Who sets up? Their background?
g. Provide training or instruction? Who does this?
h. What information or training is provided? Operation? Safety? Repair? Written or oral?
i. Follow-up

Key Informant Discussion Guide

COMPARISON AREA: Referral Agents (Wave 2)

Questions:

1. **Since we last spoke (*X months ago),* have there been any changes in the referral process for you?**
    - *Which supplier you refer clients to?*
    - *Changes in paperwork needed/requested by suppliers?*

2. **How do you think the DMEPOS supplier market has <u>changed</u> over the past few months?**
    a. Number of suppliers? Is it adequate?
    b. Competition among suppliers? Based on what?
        - *Quality? Price? Service? Referral agents?*
    c. Suppliers marketing their products and services?

3. **Have there been any changes in the level of care provided beneficiaries?**
    a. Access to DMEPOS?
    b. Quality of DMEPOS?
    c. Diversity of products? Choice?
    d. Ancillary services – training, maintenance, etc.

4. **Have your clients/patients raised any new questions or concerns over the past months? If so, what were they?**

5. **Have there been any occurrences in health care or this area that have impacted DMEPOS products, services, provision, etc.?**

- *Product recall*
- *New type of equipment*
- *Health care crisis – (e.g. higher incidence of pneumonia)*
- *New regulations or policies (e.g. Deficit Reduction Act cap on rentals)*

6. How have the DMEPOS Quality Standards affected you?

a. Have they changed your role?
b. Are beneficiaries aware of the standards?
c. How are the standards affecting beneficiaries?
d. What do you think about them now, a few months later?
    i. Positives?
    ii. Negatives?

7. Do you have any additional comments about new occurrences in your area with regard to Medicare beneficiaries, DMEPOS and suppliers?

Key Informant Discussion Guide

COMPARISON AREA: Referral Agents (Wave 3)

Questions:

1. **Since we last spoke (*X months ago),* have there been any changes in the referral process for you?**
    - *Which supplier you refer clients to?*
    - *Changes in paperwork needed/requested by suppliers?*

2. **How do you think the DMEPOS supplier market has <u>changed</u> over the past year?**
    a. Number of suppliers? Is it adequate?
    b. Competition among suppliers? Based on what?
        - *Quality? Price? Service? Referral agents?*
    c. Suppliers marketing their products and services?

3. **Have there been any changes in the level of care provided beneficiaries?**
    a. Access to DMEPOS?
    b. Quality of DMEPOS?
    c. Diversity of products? Choice?
    d. Ancillary services – training, maintenance, etc.

4. **Have your clients/patients raised any new questions or concerns over the past months? If so, what were they?**

5. **Have there been any occurrences in health care or this area that have impacted DMEPOS products, services, provision, etc.?**
    - *Product recall*

- *New type of equipment*
- *Health care crisis – (e.g. higher incidence of pneumonia)*
- *New regulations or policies (e.g. Deficit Reduction Act cap on rentals)*

6. How have the DMEPOS Quality Standards affected you?

a. Have they changed your role?

b. Are beneficiaries aware of the standards?

c. How are the standards affecting beneficiaries?

d. What do you think about them now, a few months later?

i. Positives?

ii. Negatives?

7. Do you have any additional comments about new occurrences in your area with regard to Medicare beneficiaries, DMEPOS and suppliers?

Key Informant Discussion Guide

COMPARISON AREA: Suppliers (Wave 1)

Questions:

Baseline Environment

1. **What DMEPOS do you provide?**
    - *Oxygen*
    - *Wheelchairs*
    - *Hospital beds*
    - *Orthotics*
    - *Prosthetics*

2. **Are you accredited? By whom?**

3. **How would you describe yourself as a supplier?**
    a. How long have you been supplying DMEPOS?
    - *Large vs. small*
    - *Niche vs. full service*
    - *Geographic limitations*

4. **How do beneficiaries get to you as a supplier?**
    a. Discharged from hospital? Referred from clinic? Walk-in?
    b. Who refers them to you?
    c. How do referral agents know about your services?
        - *Do you market your products and services?*
        - *What is your relationship with referral agents?*

5. **Are you satisfied with your referral patterns?**
    b. How do referral agents know about your services?

c. How do you market your products and services?

d. What types of referrals do you get?

e. How are your relationships with referral agents?

6. What services are beneficiaries typically provided as a part of the DMEPOS?

a. Delivery and set-up

i. Who does it? Their background or training?

b. Equipment maintenance

i. Who does it? Their background or training?

c. Frequency of follow-ups

i. Who does it? Their background or training?

Market

7. How would you describe the DMEPOS supplier market in this area?

- *Are suppliers spread out or concentrated in a particular geographic area?*
- *Is there a dominant company?*
- *Do you perceive that there are an adequate number of suppliers?*

8. How do you view yourself as a supplier?

a. Where do you fit in this market?

b. How do you compete with other suppliers?

- *Price*
- *Service / Quality*
- *Referral agents' preferences*

c. To what extent do you compete with mail-order suppliers?

Quality Standards

9. Have you heard of or received information about the new Quality Standards for DMEPOS put out by the Centers for Medicare and Medicaid Services (CMS)?

a. What information have you received about them?
    i. From whom?
    ii. When?
b. Has CMS or its representatives been available to respond to concerns?
c. Has your professional organization informed you about it?

10. What do you think of the Quality Standards generally?

a. What is good about them?
b. What is a problem with them?
c. Are they appropriate/fair?
d. Will they change your business/role?
e. How will the affect beneficiaries?

11. What do you think of the specific aspects of the Quality Standards, are they appropriate, inappropriate, excessive, etc.?

a. Consulting with prescribers
b. Assessing appropriateness of the equipment
c. Develop service plan
d. Equipment management? Repairs? Adjustments?
e. Replacing equipment
f. Procedure for equipment delivery and set-up? Who sets up? Their background?
g. Provide training or instruction? Who does this?
h. What information or training is provided? Operation? Safety? Repair? Written or oral?
i. Follow-up

Key Informant Discussion Guide
COMPARISON AREA: Suppliers (Wave 2)

Questions:

Skip questions 1 to 6 if supplier participated in wave 1.

1. **What DMEPOS do you provide?**
    - *Oxygen*
    - *Wheelchairs*
    - *Hospital beds*
    - *Orthotics*
    - *Prosthetics*

2. **Are you accredited? By whom?**

3. **How would you describe yourself as a supplier?**
    - **a.** How long have you been supplying DMEPOS?
        - *Large vs. small*
        - *Niche vs. full service*
        - *Geographic limitations*

4. **How do beneficiaries get to you as a supplier?**
    - a. Discharged from hospital? Referred from clinic? Walk-in?
    - b. Who refers them to you?
    - c. How do referral agents know about your services?
        - *Do you market your products and services?*
        - *What is your relationship with referral agents?*

5. **Are you satisfied with your referral patterns?**
    - a. How do referral agents know about your services?

b. How do you market your products and services?

c. What types of referrals do you get?

d. How are your relationships with referral agents?

6. What services are beneficiaries typically provided as a part of the DMEPOS?

a. Delivery and set-up

i. Who does it? Their background or training?

b. Equipment maintenance

c. Level of training or instruction provided

d. Frequency of follow-ups

7. Since we last spoke a few months ago, have there been any changes in the referral process (how beneficiaries get to you as a supplier)?

a. Discharged from hospital? Referred from clinic? Walk-in?

b. Who refers them to you?

c. How do referral agents know about your services?

- *Do you market your products and services?*
- *What is your relationship with referral agents?*

8. Are you currently satisfied with your referral patterns?

9. Have you changed any of the DMEPOS products and services you provide beneficiaries? For what reason?

- *Delivery and set-up*
  - *Who does it? Their background or training?*
- *Equipment maintenance*
- *Level of education or instruction provided*
- *Frequency of follow-ups*
- *Product makes and models offered?*

10. Have there been any significant changes in the DMEPOS supplier market in this area over the past few months? What? Why?

- *Change in the suppliers in the area*

11. Have there been any occurrences in health care or this area that have impacted DMEPOS products, services, provision, etc.?

- *Product recall*
- *New type of equipment*
- *Health care crisis – (e.g. higher incidence of pneumonia)*
- *New regulations or policies (e.g. Deficit Reduction Act cap on rentals)*

12. How have the DMEPOS Quality Standards affected you?

a. Affected your business?
b. Have they changed your role?
c. Are beneficiaries aware of the standards?
d. How are the standards affecting beneficiaries?
e. What do you think about them now, a few months later?
    i. Positives?
    ii. Negatives?

13. Do you have any additional comments about new occurrences in your area with regard to Medicare beneficiaries, DMEPOS and suppliers?

Key Informant Discussion Guide
COMPARISON GROUP: Suppliers (Wave 3)

Questions:

Skip questions 1 to 6 if supplier participated in wave 1.

1. **What DMEPOS do you provide?**
    - *Oxygen*
    - *Wheelchairs*
    - *Hospital beds*
    - *Orthotics*
    - *Prosthetics*

2. **Are you accredited? By whom?**

3. **How would you describe yourself as a supplier?**
    - **a.** How long have you been supplying DMEPOS?
        - *Large vs. small*
        - *Niche vs. full service*
        - *Geographic limitations*

4. **How do beneficiaries get to you as a supplier?**
    - a. Discharged from hospital? Referred from clinic? Walk-in?
    - b. Who refers them to you?
    - c. How do referral agents know about your services?
        - *Do you market your products and services?*
        - *What is your relationship with referral agents?*

5. **Are you satisfied with your referral patterns?**
    - a. How do referral agents know about your services?

b. How do you market your products and services?

c. What types of referrals do you get?

d. How are your relationships with referral agents?

6. What services are beneficiaries typically provided as a part of the DMEPOS?

a. Delivery and set-up

i. Who does it? Their background or training?

b. Equipment maintenance

c. Level of training or instruction provided

d. Frequency of follow-ups

7. Since we last spoke, have there been any changes in the referral process (how beneficiaries get to you as a supplier)?

a. Discharged from hospital? Referred from clinic? Walk-in?

b. Who refers them to you?

c. How do referral agents know about your services?

- *Do you market your products and services?*
- *What is your relationship with referral agents?*

8. Are you currently satisfied with your referral patterns?

9. Have you changed any of the DMEPOS products and services you provide beneficiaries? For what reason?

- *Delivery and set-up*
  - *Who does it? Their background or training?*
- *Equipment maintenance*
- *Level of education or instruction provided*
- *Frequency of follow-ups*
- *Product makes and models offered?*

10. Have there been any significant changes in the DMEPOS supplier market in this area over the past few months? What? Why?

- *Change in the suppliers in the area*

11. Have there been any occurrences in health care or this area that have impacted DMEPOS products, services, provision, etc.?

- *Product recall*
- *New type of equipment*
- *Health care crisis – (e.g. higher incidence of pneumonia)*
- *New regulations or policies (e.g. Deficit Reduction Act cap on rentals*

12. Now that the DMEPOS quality standards have been in place a year what do you think?

a. How have they affected your business?
b. Have they changed your role?
c. Are beneficiaries aware of the standards?
d. How are the standards affecting beneficiaries?
e. What do you think about them now, a few months later?
   - **i.** Positives?
   - **ii.** Negatives?

13. Do you have any additional comments about new occurrences in your area with regard to Medicare beneficiaries, DMEPOS and suppliers?

APPENDIX D

Nonstatistical Informed Consent Forms and Scripts

INFORMED CONSENT FORM

Referral Agent Focus Group

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting focus groups to learn about the perceptions and experiences of referral agents with durable medical equipment and the competitive bidding program in the area. These focus groups will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries.

You are being asked to participate in a focus group because you are a referral agent for Medicare beneficiaries and their durable medical equipment. A total of 6 focus groups with both suppliers and referral agents are being held as part of the study and each focus group will have up to 10 participants and two moderators. Abt Associates will conduct the focus groups and other forms of data collection, analysis, and reporting. Debra Frankel is the Principal Investigator at Abt Associates.

You are being asked to sign a consent form to participate in the focus group.

PROCEDURES

You will be asked to join with other referral agents in a 1.5-hour discussion about the Medicare competitive bidding program for DMEPOS. A researcher will facilitate the group in discussing your experiences with the Medicare competitive bidding program. The focus group will not be audio or video taped.

The discussion will be confidential. You can refuse to take part in this focus group if you wish without losing any rights or benefits related to your professional relationship with CMS. You can also refuse to answer a question during the focus group, without affecting your continued participation in the group or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researchers do not foresee any possible risks to you from participating in this focus group, other than the minimal risk that your confidentiality might not be preserved. One of the risks to confidentiality is that other focus group participants may repeat what they hear during the group. The researchers will do everything allowable by law to assure that your privacy is protected and will ask all participants at the beginning of the focus group not to repeat the focus group discussion outside of the group.

Additionally, the focus group discussion notes will be labeled with a study code, not your or another participant's name. Notes and reports from the discussion will be stored in a secure

location (i.e. locked office file cabinet) and electronic materials will be stored in a password-protected computer. Your comments, and those of others in the focus group, will be presented in reports to the government in summary form. Your name will not be included in any reports.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the focus group.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from joining the focus group, although you may benefit from the opportunity to hear about others' experiences with the competitive bidding program.

COMPENSATION

You will receive $75 for participating in the focus group today, after the discussion is held. You will also receive dinner at the focus group facility.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to participate in the focus group. If you decide not to participate in the focus group, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Debra Frankel of Abt Associates (617 349-2875) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Frankel at:

Debra Frankel
Abt Associates Inc.
55 Wheeler Street
Cambridge, MA 02138

You may also phone Marianne Beauregard, the chairperson of Abt Associates' Institutional Review Board (617 349-2852) if you have other questions about your rights as a focus group participant. All of these numbers are toll calls.

STATEMENT BY <u>FOCUS GROUP MODERATOR</u> IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

_____	_____	_____
Moderator's Name	Moderator's Signature	Date

STATEMENT BY <u>PERSON AGREEING TO PARTICIPATE</u> IN THIS RESEARCH STUDY

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the focus group. I have been given a copy of this consent form.

_____	_____	_____
Volunteer's Name	Volunteer's Signature	Date

INFORMED CONSENT FORM

Supplier Focus Group

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting focus groups to learn about the perceptions and experiences of referral agents with durable medical equipment and the competitive bidding program in the area. These focus groups will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries.

You are being asked to participate in a focus group because you are a DMEPOS supplier who provides these supplies to Medicare beneficiaries

A total of 6 focus groups with both suppliers and referral agents are being held as part of the study and each focus group will have up to 10 participants and two moderators. Abt Associates will conduct the focus groups and other forms of data collection, analysis, and reporting. Debra Frankel is the Principal Investigator at Abt Associates.

You are being asked to sign a consent form to participate in the focus group.

PROCEDURES

You will be asked to join with other suppliers in a 1.5-hour discussion about the Medicare competitive bidding program for DMEPOS. A researcher will facilitate the group in discussing your experiences with the competitive bidding program. The focus group will not be audio or video taped.

The discussion will be confidential. You can refuse to take part in this focus group if you wish without losing any rights or benefits related to youtr professional relationship with CMS. You can also refuse to answer a question during the focus group, without affecting your continued participation in the group or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researchers do not foresee any possible risks to you from participating in this focus group, other than the minimal risk that your confidentiality might not be preserved. One of the risks to confidentiality is that other focus group participants may repeat what they hear during the group. The researchers will do everything allowable by law to assure that your privacy is protected and will ask all participants at the beginning of the focus group not to repeat the focus group discussion outside of the group.

Additionally, the focus group discussion notes will be labeled with a study code, not your or another participant's name. Notes and reports from the discussion will be stored in a secure location (i.e. locked office file cabinet) and electronic materials will be stored in a password-protected computer. Your comments, and those of others in the focus group, will be presented in reports to the government in summary form. Your name will not be included in any reports.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the focus group.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from joining the focus group, although you may benefit from the opportunity to hear about others' experiences with the competitive bidding program.

COMPENSATION

You will receive $75 for participating in the focus group today, after the discussion is held. You will also receive dinner at the focus group facility.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to participate in the focus group. If you decide not to participate in the focus group, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

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Cambridge, MA 02138

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STATEMENT BY <u>FOCUS GROUP MODERATOR</u> IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

_____	_____	_____
Moderator's Name	Moderator's Signature	Date

STATEMENT BY <u>PERSON AGREEING TO PARTICIPATE</u> IN THIS RESEARCH STUDY

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the focus group. I have been given a copy of this consent form.

_____	_____	_____
Volunteer's Name	Volunteer's Signature	Date

INFORMED CONSENT FORM

Key Informant Discussion: *Beneficiary Group/Advocate*

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting discussions to learn about the perceptions and experiences of beneficiary groups and advocates. These discussions will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries.

You are being asked to participate in a discussion because you are with a beneficiary group or are an advocate for Medicare beneficiaries and their durable medical equipment.

A total of 12 discussions with different groups are being held as part of the study. Abt Associates will conduct the discussions and other forms of data collection, analysis, and reporting. Debra Frankel is the Principal Investigator at Abt Associates.

PROCEDURES

You will be asked to discuss the durable medical equipment and the Medicare competitive bidding program in this discussion that will last approximately 45 minutes.

The discussion will be confidential. You can refuse to take part if you wish without losing any rights or benefits related to your professional relationship with CMS. You can also refuse to answer any particular question during the discussion, without affecting your continued participation in the discussion or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researcher does not foresee any possible risks to you from participating in this discussion, other than the minimal risk that your confidentiality might not be preserved.

The discussion notes will be labeled with a study code, not your name. Notes and reports from the discussion will be stored in a secure location (i.e. locked office file cabinet) and electronic materials will be stored in a password-protected computer. Your comments will be presented in reports to the government in summary form. Your name will not be included in any reports.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the interview.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from being interviewed, although you may benefit from the opportunity to share your experiences.

COMPENSATION

You will not receive compensation.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to be interviewed. If you decide not to participate in the discussion, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Debra Frankel of Abt Associates (617 349-2875) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Frankel at:

Debra Frankel
Abt Associates Inc.
55 Wheeler Street
Cambridge, MA 02138

You may also phone Marianne Beauregard, the chairperson of Abt Associates' Institutional Review Board (617 349-2852) if you have other questions about your rights as an interview participant. All of these numbers are toll calls.

STATEMENT BY <u>INTERVIEWER</u> IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

_____	_____	_____
Interviewer's Name	Interviewer's Signature	Date

STATEMENT BY <u>PERSON AGREEING TO PARTICIPATE</u> IN THIS DISCUSSION

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the discussion. I have been given a copy of this consent form.

_____	_____	_____
Volunteer's Name	Volunteer's Signature	Date

INFORMED CONSENT FORM

Key Informant Discussion: *CMS Officials/ Bidding Program Managers*

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting discussions to learn about the perceptions and experiences of CMS officials and bidding program managers. These discussions will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries.

You are being asked to participate in a discussion because you are a CMS official/bidding program manager who works with Medicare beneficiaries to receive durable medical equipment.

A total of 12 discussions with different groups are being held as part of the study. Abt Associates will conduct the focus groups and other forms of data collection, analysis, and reporting. Debra Frankel is the Principal Investigator at Abt Associates.

PROCEDURES

You will be asked to discuss the Medicare competitive bidding program in this discussion that will last approximately 45 minutes.

The discussion will be confidential. You can refuse to take part in this discussion if you wish without losing any rights or benefits related to my professional relationship with CMS. You can also refuse to answer any particular question during the discussion, without affecting your continued participation in the discussion or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researcher does not foresee any possible risks to you from participating in this discussion, other than the minimal risk that your confidentiality might not be preserved.

The discussion notes will be labeled with a study code, not your name. Notes and reports from the discussion will be stored in a secure location (i.e. locked office file cabinet) and electronic materials will be stored in a password-protected computer. Your comments will be presented in reports to the government in summary form. Your name will not be included in any reports.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the discussion.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from being interviewed, although you may benefit from the opportunity to share your experiences.

COMPENSATION

You will not receive compensation.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to be interviewed. If you decide not to participate in the interview, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Debra Frankel of Abt Associates (617 349-2875) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Frankel at:

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STATEMENT BY <u>INTERVIEWER</u> IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

_____	_____	_____
Interviewer's Name	Interviewer's Signature	Date

STATEMENT BY <u>PERSON AGREEING TO PARTICIPATE</u> IN THIS DISCUSSION

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the discussion. I have been given a copy of this consent form.

_____	_____	_____
Volunteer's Name	Volunteer's Signature	Date

INFORMED CONSENT FORM

Key Informant Discussion: *Referral Agents*

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting discussions to learn about the perceptions and experiences of referral agents. These discussions will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries.

You are being asked to participate in a discussion because you are a referral agent who works with Medicare beneficiaries to receive durable medical equipment.

A total of 12 discussions with different groups are being held as part of the study. Abt Associates will conduct the discussions and other forms of data collection, analysis, and reporting. Debra Frankel is the Principal Investigator at Abt Associates.

PROCEDURES

You will be asked to discuss the Medicare competitive bidding program in this discussion that will last approximately 45 minutes.

The discussion will be confidential. You can refuse to take part in this discussion if you wish without losing any rights or benefits related to your professional relationship with CMS. You can also refuse to answer any particular question during the discussion, without affecting your continued participation in the discussion or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researcher does not foresee any possible risks to you from participating in this discussion, other than the minimal risk that your confidentiality might not be preserved.

The discussion notes will be labeled with a study code, not your name. Notes and reports from the discussion will be stored in a secure location (i.e. locked office file cabinet) and electronic materials will be stored in a password-protected computer. Your comments will be presented in reports to the government in summary form. Your name will not be included in any reports.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the discussion.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from being interviewed, although you may benefit from the opportunity to share your experiences.

COMPENSATION

You will not receive compensation.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to be interviewed. If you decide not to participate in the discussion, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Debra Frankel of Abt Associates (617 349-2875) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Frankel at:

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STATEMENT BY <u>INTERVIEWER</u> IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

_____	_____	_____
Interviewer's Name	Interviewer's Signature	Date

STATEMENT BY <u>PERSON AGREEING TO PARTICIPATE</u> IN THIS DISCUSSION

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the discussion. I have been given a copy of this consent form.

_____	_____	_____
Volunteer's Name	Volunteer's Signature	Date

INFORMED CONSENT FORM

Key Informant Discussion: *Supplier*

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting discussions to learn about the perceptions and experiences of suppliers of durable medical equipment. These discussions will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries. You are being asked to participate in a discussion because you are a DMEPOS supplier who provides durable medical equipment to Medicare beneficiaries.

A total of 12 discussions with different groups are being held as part of the study. Abt Associates will conduct the discussions and other forms of data collection, analysis, and reporting. Debra Frankel is the Principal Investigator at Abt Associates.

PROCEDURES

You will be asked to discuss the Medicare competitive bidding program in this discussion that will last approximately 45 minutes.

The discussion will be confidential. You can refuse to take part in this discussion if you wish without losing any rights or benefits related to your professional relationship with CMS. You can also refuse to answer any particular question during the discussion, without affecting your continued participation in the discussion or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researcher does not foresee any possible risks to you from participating in this discussion, other than the minimal risk that your confidentiality might not be preserved.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the discussion.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from being interviewed, although you may benefit from the opportunity to share your experiences.

COMPENSATION

You will not receive compensation.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to be interviewed. If you decide not to participate in the discussion, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Debra Frankel of Abt Associates (617 349-2875) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Frankel at:

Debra Frankel
Abt Associates Inc.
55 Wheeler Street
Cambridge, MA 02138

You may also phone Marianne Beauregard, the chairperson of Abt Associates' Institutional Review Board (617 349-2852) if you have other questions about your rights as an interview participant. All of these numbers are toll calls.

STATEMENT BY <u>INTERVIEWER</u> IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

_____	_____	_____
Interviewer's Name	Interviewer's Signature	Date

STATEMENT BY <u>PERSON AGREEING TO PARTICIPATE</u> IN THIS DISCUSSION

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the discussion. I have been given a copy of this consent form.

_____	_____	_____
Volunteer's Name	Volunteer's Signature	Date

INFORMED CONSENT SCRIPT
Comparison Area Key Informant Discussion: Beneficiary Group /Advocate

Hello/Good morning/Good afternoon…May I speak with…(if not available, leave a message)

My name is [Interviewer name]. I am calling from Abt Associates Inc. You are scheduled to conduct an interview on the evaluation of the Centers for Medicare and Medicaid Services' Durable Medical Equipment, Prosthetic, Orthotic Supplies' competitive bidding program. Is this still a good time to do the interview?

[If no] May I reschedule the interview at a time that is convenient for you?
[If yes] Before we begin, I need to review a few details about the study with you.

As you may or may not know, Medicare is implementing a new fee schedule for durable medical equipment, prosthetic, and orthotic supplies (DMEPOS) in various areas of the United States. The purpose of our study is to evaluate the affect of the competitive bidding program on suppliers, beneficiaries and referral agents. The study is being conducted by Abt Associates on behalf of the Centers for Medicare and Medicaid Services (CMS).

You were chosen to participate as a member of a beneficiary group or an advocate to provide an understanding of the current environment for Medicare beneficiaries and their durable medical equipment in your area, as a comparison. [If relevant] You were also recommended by [name referral].

Our interview today should last about 45 minutes. Please understand that your participation in this study is voluntary and that if you choose not to participate you will not be penalized in any way. You can refuse to answer any question I ask and may even ask to stop the interview at any time. This interview will not be tape-recorded. Instead I will take notes. These notes will be used to create summaries, which will not include your personal information, and will be used to write a report to CMS on the education and outreach program for the new Medicare drug benefit. Do you have any questions?

If you have any questions that I may not be able to answer at this time, or at any time after this interview, you may contact _____, at the Centers for Medicare and Medicare Services (___) ___-____and she will be happy to assist you. Note, this is a toll call.

Given the information that I have just reviewed with you, do you still wish to participate in this study/interview?
If Yes, _____ [Interviewer's Initials}. Great. Let me begin with the first question.

If No, _____ [Interviewer's Initials]. That is fine. We appreciate your time. Thank you.

INFORMED CONSENT SCRIPT
Comparison Areas Key Informant Discussion: Referral Agents

Hello/Good morning/Good afternoon…May I speak with…(if not available, leave a message)

My name is [Interviewer name]. I am calling from Abt Associates Inc. You are scheduled to conduct an interview on the evaluation of the Centers for Medicare and Medicaid Services' Durable Medical Equipment, Prosthetic, Orthotic Supplies' competitive bidding program. Is this still a good time to do the interview?

[If no] May I reschedule the interview at a time that is convenient for you?
[If yes] Before we begin, I need to review a few details about the study with you.

As you may or may not know, Medicare is implementing a new fee schedule for durable medical equipment, prosthetic, and orthotic supplies (DMEPOS) in various areas of the United States. The purpose of our study is to evaluate the affect of the competitive bidding program on suppliers, beneficiaries and referral agents. The study is being conducted by Abt Associates on behalf of the Centers for Medicare and Medicaid Services (CMS).

You were chosen to participate as a referral agent to provide an understanding of the current environment for Medicare beneficiaries and their durable medical equipment in your area, as a comparison. [If relevant] You were also recommended by [name referral].

Our interview today should last about 45 minutes. Please understand that your participation in this study is voluntary and that if you choose not to participate you will not be penalized in any way. You can refuse to answer any question I ask and may even ask to stop the interview at any time. This interview will not be tape-recorded. Instead I will take notes. These notes will be used to create summaries, which will not include your personal information, and will be used to write a report to CMS on the education and outreach program for the new Medicare drug benefit. Do you have any questions?

If you have any questions that I may not be able to answer at this time, or at any time after this interview, you may contact Ann Meadows, at the Centers for Medicare and Medicare Services (___) ___-____and she will be happy to assist you. Note, this is a toll call.

Given the information that I have just reviewed with you, do you still wish to participate in this study/interview?
If Yes, _____ [Interviewer's Initials}. Great. Let me begin with the first question.

If No, _____ [Interviewer's Initials]. That is fine. We appreciate your time. Thank you.

INFORMED CONSENT SCRIPT
Comparison Areas Key Informant Discussion: Supplier

Hello/Good morning/Good afternoon…May I speak with…(if not available, leave a message)

My name is [Interviewer name]. I am calling from Abt Associates Inc. You are scheduled to conduct an interview on the evaluation of the Centers for Medicare and Medicaid Services' Durable Medical Equipment, Prosthetic, Orthotic Supplies' competitive bidding program. Is this still a good time to do the interview?

[If no] May I reschedule the interview at a time that is convenient for you?
[If yes] Before we begin, I need to review a few details about the study with you.

As you may or may not know, Medicare is implementing a new fee schedule for durable medical equipment, prosthetic, and orthotic supplies (DMEPOS) in various areas of the United States. The purpose of our study is to evaluate the affect of the competitive bidding program on suppliers, beneficiaries and referral agents. The study is being conducted by Abt Associates on behalf of the Centers for Medicare and Medicaid Services (CMS).

You were chosen to participate as supplier to provide an understanding of the current environment for Medicare beneficiaries and their durable medical equipment in your area, as a comparison. [If relevant] You were also recommended by [name referral].

Our interview today should last about 45 minutes. Please understand that your participation in this study is voluntary and that if you choose not to participate you will not be penalized in any way. You can refuse to answer any question I ask and may even ask to stop the interview at any time. This interview will not be tape-recorded. Instead I will take notes. These notes will be used to create summaries, which will not include your personal information, and will be used to write a report to CMS on the education and outreach program for the new Medicare drug benefit. Do you have any questions?

If you have any questions that I may not be able to answer at this time, or at any time after this interview, you may contact Ann Meadows, at the Centers for Medicare and Medicare Services (___) ___-____and she will be happy to assist you. Note, this is a toll call.

Given the information that I have just reviewed with you, do you still wish to participate in this study/interview?

If Yes, _____ [Interviewer's Initials}. Great. Let me begin with the first question.
If No, _____ [Interviewer's Initials]. That is fine. We appreciate your time. Thank you.

APPENDIX E

Statistical Data Collection Instruments

Federal Register Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

Office of Research, Development and Information

Proposed Information Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services

ACTION: Notice

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before…...

ADDRESSES: Direct all written comments to …….

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to ……..

ABSTRACT: Section 302(b) of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) (MMA) requires CMS to begin a program of competitive bidding for durable medical equipment, supplies, certain orthotics, and enteral nutrients and related equipment and supplies (DMEPOS). The bidding program is to be established in 10 of the largest MSAs in 2007, an additional 80 large MSAs in 2009, and additional MSAs thereafter. With certain exceptions, the Secretary of Health and Human Services has discretion to select categories of supplies and equipment for bidding to maximize savings.

MMA Section 303(d) requires a Report to Congress on the program, covering program savings, reductions in cost sharing, impacts on access to and quality of affected goods and services, and beneficiary satisfaction. The purpose of this project is to provide information for the Report to Congress and to provide a technical report on the evaluation findings for attachment to the Report. Also, interim information from site visits and other data collection may be helpful to CMS as it makes plans to implement the second phase (adding 80 large MSAs).

The major evaluation areas for the proposed project include impacts in the following seven areas, which all relate to traditional Medicare policy objectives on program costs, access, and quality:

- Expenditures

- Reductions in beneficiary cost-sharing
- Access to durable medical equipment and supplies and related services
- Quality of goods and services
- Consumer satisfaction
- Medicare administrative operations
- Savings in relation to program costs

The evaluation will draw on a range of data sources in order to explore these impacts and, when possible, to get multiple perspectives on each. These data sources include: Medicare claims (notably DMEPOS claims); data from a surveys of beneficiaries who use DMEPOS conducted before and after the initiation of the new payment approach; surveys of suppliers conducted before and after the initiation of the new payment approach that focus specifically on the diversity of products within a specific category supplied; qualitative data collection including focus groups and interviews with referral agents, suppliers, CMS officials and other stakeholders collected at three time points--before, immediately after, and 18 months after the initiation of the new payment approach; and Medicare program data. Survey data and qualitative data will be collected in three of the 10 selected Competitive Acquisition areas (CAAs) and 2 comparison areas where the program will not be implemented until a later phase.

ESTIMATED BURDEN TABLE FOR SURVEY DATA COLLECTION ACROSS TWO WAVES OF DATA COLLECTION

	Number of Respondents	Total Annual Response	Average Burden *in Hours*	Total Burden *in Hours*	% Web-Based
Beneficiary Survey	24,000	1	0.50	12,000 hours	0
Supplier Survey	1,150	1	0.75	862 hours	90

REQUEST FOR COMMENTS: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection 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 on respondents. Copies of the survey instruments may be obtained by contacting the office listed in the ADDRESSES section of this notice.

Dated:
By:
BILLING CODE: