Centers for Medicare & Medicaid Services Competitive Bidding Program: Assessment of Impact on Beneficiary Acquisition of Diabetes-Testing Supplies and Durable Medical Equipment Prosthetics Orthotics and Supplies–Associated Health Outcomes

A National Minority Quality Forum Report

November 13, 2015

Introduction

The Centers for Medicare & Medicaid Services (CMS) manages the Medicare program, which generally pays for durable medical equipment, prosthetics, orthotics, and other medical supplies (DMEPOS) on the basis of fee schedules. The fee schedules list Medicare payments for specific items and services, which are calculated according to statutorily specified formulas and which take into account the actual amounts of care (or items) provided. Medicare reimburses for 80% of the fee-schedule amount, whereas the beneficiary is responsible for paying the remaining 20% (co-payment), in addition to any unmet deductible.

Unless otherwise specified by Congress, fee-schedule amounts are updated each year by a measure of price inflation and economy-wide productivity. However, investigations by the General Accounting Office and the US Department of Health and Human Services' Office of Inspector General have suggested that Medicare pays above-market prices for certain items of DMEPOS and that such overpayments may be due partly to the fee-schedule mechanism of payment, which does not reflect market changes, such as new and less-expensive technologies, changes in production or supplier costs, and variations in prices in comparable localities.[*]

The General Accounting Office has reported that the Medicare program and beneficiaries are disadvantaged when Medicare pays above-market prices for DMEPOS. First, the higher payments result in an otherwise greater amount of Part B (Supplementary Medical Insurance) program payments, which are financed primarily through general tax revenues and beneficiary premiums. Second, the beneficiaries who use DMEPOS pay more; though the beneficiary's co-payment remains at 20%, the higher fee-schedule payment increases the co-payment. Third, the payment differential between market prices and Medicare payments for DMEPOS make fraud "particularly lucrative, further attracting bad actors to the system."[†] However, legitimate Medicare suppliers and DMEPOS manufacturers are advantaged by the higher Medicare prices, which may, in part, enable businesses that operate less efficiently run businesses to survive.[‡]

---

[*] Health Education and Services Division, General Accounting Office, *Medicare: Comparison of Medicare and VA Payment Rates for Home Oxygen* (15 May 1997, GAO/HEHS-97-120R), http://www.gao.gov/assets/90/86388.pdf (accessed 15 November 2015); Office of Inspector General, Department of Health and Human Services, *Medicare Home Oxygen Equipment: Cost and Servicing* (September 2006, EOI-09-04-00420), http://oig.hhs.gov/oei/reports/oei-09-04-00420.pdf (accessed 15 November 2015); and Office of Inspector General, Department of Health and Human Services, *Medicare and FEHBP Payment Rates for Home Oxygen Equipment* (March 2005, EOI-0-03-00160), http://oig.hhs.gov/oei/reports/oei-09-03-00160.pdf (accessed 15 November 2015).

[†] *Testimony of Daniel R. Levinson, Inspector General, U.S. Department of Health and Human Services* (15 September 2010, House Committee on Energy and Commerce, Subcommittee on Health, http://oig.hhs.gov/testimony/docs/2010/testimony_levinson_09152010.pdf (accessed 15 November 2015).

[‡] Davis PA, *Medicare Financing* (19 September 2013, Congressional Research Service Report R41436), https://www.fas.org/sgp/crs/misc/R41436.pdf (accessed 15 November 2015); *Testimony of Daniel R. Levinson, Inspector General, U.S. Department of Health and Human Services* (15 September 2010, House Committee on Energy and Commerce, Subcommittee on Health, http://oig.hhs.gov/testimony/docs/2010/testimony_levinson_09152010.pdf (accessed 15 November 2015).

The DMEPOS Competitive Bidding Program (CBP) is CMS's prescription to remedy the overpayments engendered by fee-schedule reimbursements. The principal objective of the CBP is to lower reimbursements for certain DMEPOS products. In structuring the CBP, CMS has recognized that DMEPOS suppliers in the program "may respond to lower prices by offering lower quality products, delaying routine maintenance, or employing fewer service technicians and customer service representatives, thereby increasing the need for service calls, extending waiting times, and decreasing access."[§] With this potential built into the CBP, there is an inherent need for continuous safety monitoring of the program to protect beneficiaries from poor health outcomes induced by disruptions in access to quality products and services.

This report reviews the impact of the CBP on the health of Medicare beneficiaries. The primary questions are: Does the CBP disrupt beneficiary access to prescribed DMEPOS? If it does, what impact does the disruption have on beneficiary health outcomes?

This report presents clear evidence that CMS's monitoring of CBP safety is inadequate, making it difficult to determine from CMS's safety monitoring studies whether the CBP is not producing higher costs for the Medicare program by raising hospitalization rates, causing longer inpatient stays, and increasing mortality among millions of beneficiaries. This report also presents non CMS sponsored research that provides evidence that the CBP is disrupting access to prescribed DMEPOS and that the disruptions are contributing to poor health outcomes. The report recommends strengthening the CBP's safety-monitoring protocols to protect beneficiaries.

The National Minority Quality Forum thanks Chris Parkin for his help in writing this report and the team at the Diabetes Translational Research Center (Indianapolis, IN) for their scientific review of the CMS's CBP health-status monitoring.

Acknowledgments

The National Minority Quality Forum received support for this report from Abbott Laboratories; Acelity L.P. Inc.; LifeScan, Inc., part of the Johnson & Johnson Diabetes Solutions Companies; Roche Diabetes Care; US Healthcare Supply LLC.; American Association for Homecare; and US MED.

About the National Minority Quality Forum

The National Minority Quality Forum (The Forum) is a Washington, DC–based not-for-profit, non-partisan, independent research and education organization dedicated to improving the quality of health care through data driven initiatives. The Forum develops user-friendly, web-based disease indices that provide a unique two-dimensional view of the prevalence and impact

[§] Karon S, Jewell K, Hoerger T, et al., *Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS: First-Year Annual Evaluation Report: HCFA Contract No. 500-95-0061/T.O. #3*. September 2000 (revised January 2001), https://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/karon_2001_1.pdf (accessed 15 November 2015), p. 3-1

of diseases by zip code, including diabetes, kidney disease, heart disease and HIV/AIDS. Visit our website at www.nmqf.org. Look for us on Facebook (National Minority Quality Forum), and follow us on Twitter (http://www.twitter.com/NMQF).

#

Contents

Centers for Medicare & Medicaid Services Competitive Bidding Program: Assessment of Impact on Beneficiary Acquisition of Diabetes-Testing Supplies and Durable Medical Equipment Prosthetics Orthotics and Supplies–Associated Health Outcomes

Executive Summary

Background

- In January 2011 the Centers for Medicare & Medicaid (CMS) launched the first phase of the Medicare Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) in nine different areas of the country.

- In April 2012 CMS reported that no disruption of access to the CBP-covered DMEPOS occurred and that no negative health-care consequences to beneficiaries were seen as a result of the program. Subsequent reports from CMS reiterate these findings.

- In May 2012, the Government Accountability Office challenged the CMS report, stating that the monitoring methods used by CMS in assessing the impact of competitive bidding did not show directly whether beneficiaries received the durable medical equipment needed on time or whether health outcomes were caused by problems accessing CBP-covered equipment.

- In June 2015, Puckrein et al. ("CMS Competitive Bidding Program Disrupted Access to Diabetes Supplies with Resultant Increased Mortality," American Diabetes Association 75th Scientific Sessions, 5–7 June 2015, Boston, MA) reported that access to diabetes-testing supplies (one of the nine product groups covered by the CBP) was disrupted in the nine test markets and that this disruption was linked to reductions in use of testing supplies, increases in mortality, and a doubling of inpatient admissions, and higher associated costs.

- In July 2013, the CBP was implemented nationally for diabetes supplies, affecting more than 30 million traditional fee-for-service Medicare beneficiaries. National rollout rates for other products categories will be July 1, 2016.

- The National Minority Quality Forum asked the Diabetes Translational Research Center to review CMS's methodologies for monitoring the impact of the CBP on beneficiaries' access and health outcomes as reported by CMS. The issues and concerns described in this report are based upon findings from the center.

No Safety Arm in the Competitive-Bidding Demonstration Projects

The launch of the CBP was proceeded by several demonstration projects. In conducting those demonstration projects, CMS operated under a waiver of the provisions of the Common Rule—a set of regulations that government departments use to define human-subject research and to establish protocols to protect human subjects. The Common Rule, however, gives a waiver to research on "possible changes in methods or levels of payment for benefits or services." The CBP demonstration projects were studying changes in "the methods or levels of payment for benefits or services" and were therefore exempted from the protections that the Common Rule would have afforded Medicare beneficiaries as subjects in a research study. As a consequence, CMS could study competitive bidding without the inclusion of safety monitoring protocols to protect beneficiaries.

Issues and Concerns

- *Inappropriate study design.* CMS failed to establish (or report on) baseline values for DMEPOS acquisition behaviors and health status, thus making it impossible to determine whether changes in either measure occurred. CMS also failed to construct a matched control group, which would have allowed the agency to determine whether changes in acquisition and health status were, in fact, results of the CBP, as well as the significance of any changes seen compared with beneficiaries who were not affected by the CBP. Without appropriate baseline measures and a matched control group, CMS could not actually assess the impact of the CBP on changes in acquisition and health outcomes. Therefore, CMS's claim of no disruption and no adverse outcome is unfounded.

- *Unstable, Unrepresentative Study Cohorts.* CMS bases its assessment of CBP health outcomes on monthly outcome rates (e.g., death, hospitalizations) for two groups of beneficiaries: the Utilizer Group, and the Access Group Neither is a representative sample of the beneficiaries affected by the CBP.

- The Utilizer Group is composed of Medicare beneficiaries who have at least one claim for a specific DMEPOS product in the month of observation or any of the previous three months. The one claim is not indication that a beneficiary was regularly accessing a DMEPOS product as prescribed by a physician, so the possibility of irregular access occasioned by the CBP is simply ignored by CMS monitoring. Equally important, any beneficiary whose access was completely disrupted and who therefore would not have one claim in a four-month period is excluded from the Utilizer Group, and the health consequence of the disruption goes unmonitored.

- The Access Group includes beneficiaries who are "likely to use the product," which is determined by whether a beneficiary has a condition related to product use. Access beneficiaries need not have a prescription for a DMEPOS product; they simply need to have

a condition that required someone with that condition to use a DMEPOS product. The Access Group is a mix of beneficiaries who need a DMEPOS product and those who do not. Because CMS repopulated the Access and Utilizer Groups every month in the first year of the CBP and has repopulated them quarterly thereafter, the agency routinely creates a heterogeneous mix of beneficiaries (apples one month and oranges the next).

- The shifting nature of the study groups is not the only problem that could contribute to distortions in CMS findings. Before the third quarter of 2014, beneficiaries in the Access Group were identified by related condition categories based on the CMS beneficiary risk-adjustment model. Because Medicare makes periodic updates to its risk-adjustment model, the ICD-9 diagnosis codes that are aggregated under a given condition category may change over time. As a result, in CMS's own words, the Access Group "may include ICD-9 diagnosis codes that are not as closely associated with product category usage."[1] Thus, CMS is never certain whether the CBP increased beneficiaries' risk of poor health outcomes by disrupting access to a needed DEMPOS.

- *Lack of transparency and incomplete disclosure of methodology.* CMS has exhibited a significant lack of transparency in providing essential data and in describing its methodology. For example:

    - CMS has not explained its decision to develop and study the Access Group, which includes beneficiaries who were not prescribed a DMEPOS product and therefore would not be impacted by the CBP.

    - CMS has not explained its decision not to exclude from monitoring Utilizer Group beneficiaries who may have suffered complete disruption of their access to a DMEPOS product as a result of the CBP.

    - CMS reports monitoring the impact of the CBP from January 2011; however, it provides no outcome data for the first six months of 2011.

    - CMS states that it provided a historical baseline for each health-outcome rate beginning January 2011 to control for historical trends; however, no baseline data are reported, nor is the method for determining the baseline described.

    - Most importantly, CMS has provided neither data nor a description of the methodology used to support its contention that no disruption of access occurred.

    Therefore, the lack of critical data and a description of the methodologies used by CMS makes it impossible to verify the accuracy of their reported findings. The provision of such data and methodologies is standard protocol so that the scientific and interested party communities can replicate and substantiate reported findings.

- *Failure to identify the appropriate research question.* Rigorous assessment of cause-and-effect relationships requires investigators first to define the relevant research question (e.g., Did the CPB change beneficiaries' acquisition behaviors, and did those changes impact health outcomes?) and then to use appropriate analytical methodologies to answer that question. CMS failed to meet these requirements. Although CMS may have used appropriate (albeit unknown) statistical methods in their assessment, we are unclear about the specific research question the agency attempted to answer. Given the findings of Puckrein et al., we suspect that the question was, in fact, inappropriate.

- *Immunity.* The failure of CMS's to adequately monitor health status in CBP was probably informed by the Common Rule waiver (see above) and the immunity from administrative review that was granted in the authorizing legislation

    - The authorizing legislation that established CBP states that there "shall be no administrative or judicial review pertaining to (A) the establishment of payment amounts under paragraph (5); (B) the awarding of contracts under this section; C) the designation of competitive acquisition areas; (D) the phased-in implementation; (E) the selection of items and services for competitive acquisition; (F) the bidding structure and number of contractors selected under this section; or (G) the implementation of the special rule described in paragraph. A Federal Court in reviewing a case challenging CBP as it touched the provisioning of low-profile feeding tubes concluded that "Unfortunately insofar as DMEPOS are concerned it appears that Congress may not have contemplated the unjust result of its legislation with which individuals with developmental and other disabilities in need of low-profile feeding tubes are now faced".

    - The consequence of the immunity and waiver allowed CMS to implement CBP without oversight and without adherence to standards that could have produced more effective safety monitoring of CBP

Conclusions

- CMS's findings of no disruption of access to DMEPOS and no adverse health outcome among beneficiaries within the nine test CBP markets are not supported by the data and methodology descriptions presented in its reports.

- CMS's approach to monitoring health status in the CBP raises concerns about safety monitoring of the CBP. The alternative analysis by Puckrein et al. is more firmly aligned with standard, scientific safety monitoring of health studies; CMS's health-status monitoring is not.

- Whether CMS intended to obscure the impact of the CBP can only be determined by a thorough investigation of the agency regarding its motives and decision-making processes.

- Regardless of CMS's motives and rationale for their inadequate monitoring program, findings from Puckrein et al. clearly show a significant disruption in acquisition of diabetes-testing supplies among beneficiaries who require these products for the safe and effective management of their disease. This disruption prompted a large percentage of beneficiaries to reduce or cease acquisition of diabetes-testing supplies. This behavior that was linked to increased mortality, hospitalizations, and associated costs.

- It is reasonable to conclude that disruption of acquisition and subsequent adverse health outcomes likely occurred among beneficiaries who purchased the other CBP-covered DMEPOS; however, no formal analyses of the impact of the CBP within these populations have been reported.

- Because adverse health consequences have been detected and can be associated with the CBP among patients with diabetes, nationwide implementation of the CBP should be suspended immediately, the impact of reduced access to patients dependent on other program products evaluated, transparent science-based methodologies should be adopted, and the ability of beneficiaries to seek redress should be clarified by amending the immunity and waiver provisions that compromise current beneficiary protections in the Medicare program.

Centers for Medicare & Medicaid Services Competitive Bidding Program: Assessment of Impact on Beneficiary Acquisition of Diabetes-Testing Supplies and Durable Medical Equipment Prosthetics Orthotics and Supplies–Associated Health Outcomes

Objective

The National Minority Quality Forum asked the Diabetes Translational Research Center (Indianapolis, IN) to review the health-status monitoring of a competitive-bidding program (CBP) that the Centers for Medicare & Medicaid Services (CMS) implemented "in order to protect the interests of potentially affected Medicare beneficiaries."[2] This review was prompted by a May 2012 United States Government Accountability Office (GAO) report to Congress on the CBP for durable medical equipment (DME), which stated:

> CMS's daily monitoring of national Medicare claims data in real time found no changes in health outcomes in competitive bidding areas in 2011, but this method may not fully capture the relationship between access to DME and health outcomes. … CMS reports that, in 2011, the rate of use of hospital services, emergency room visits, physician visits, and skilled nursing facility care for beneficiaries in competitive bidding areas remained consistent with national trends. While these results are reassuring, these measures do not show directly whether beneficiaries received the DME they needed on time, or whether health outcomes were caused by problems accessing CBP-covered DME.[3]

An early finding of disruption of beneficiary access to diabetes-testing supplies came from a survey conducted by the American Association of Diabetes Educators in August 2011.[4] In that study, seven diabetes educators surveyed 23 contract mail-order suppliers to determine the range of diabetes-testing products offered and the accuracy of information supplied by CMS via the Medicare website (https://www.medicare.gov/). It was found that none of the mail-order suppliers offered products reflecting greater than 50% of the market, as required by Congress, and only three suppliers carried each of the brands of diabetes-testing supplies listed in their reports to Medicare of what they carried. These findings demonstrate that as a result of the CBP, Medicare beneficiaries had fewer choices and limited access to the diabetes-testing supplies most commonly used. Thus, beneficiaries participating in the CBP were effectively being made to either switch to different testing systems or purchase their supplies through non-mail-order suppliers.

The Forum was further encouraged to ask the Diabetes Translational Research Center to review CMS's health-status monitoring of the CBP by an order and memorandum issued by Federal Judge Donovan W. Frank of the United States District Court District of Minnesota in *Key Medical Supply v. Sebelius and Tavenner*.[5] Judge Frank noted that the legislation authorizing the

CBP provided CMS with immunity from judicial and administrative review of the program. Nevertheless, he added:

> Notably, if the Court did have jurisdiction over this case, it would likely conclude that the Defendants' decision was arbitrary and capricious. While the 1,300 page administrative record makes references to low profile enteral feeding tubes with respect to children and individuals with dementia, Defendants appear indifferent to, if not ignore entirely, the large number of individuals in the United States of America that are developmentally disabled and have other disabilities, who have been prescribed and provided low profile enteral feeding tubes for a number of years. In fact, more than 80 percent of Plaintiff's approximately 5,000 clients are individuals with developmental and other disabilities.[5]

A further impetus for the expert review came from research by the Forum demonstrating that the CBP interrupted access to blood-glucose-testing supplies by Medicare beneficiaries who were on insulin therapy and that these beneficiaries experienced poor health outcomes as a consequence.[6] This disruption resulted in reduced or no acquisition of supplies, which was linked to increased mortality and hospitalizations. Specific findings from this analysis and the methodologies used are described below, in "Assessment of the Competitive Bidding Program's Impact on Medicare Beneficiaries~~Assessment of the Competitive Bidding Program's Impact on Medicare Beneficiaries~~."

The GAO guidance about inadequacies in CMS's methodology for monitoring of health status, Judge Frank's memorandum on indifference to children, the Forum's findings demonstrating adverse outcomes for those on insulin therapies, and concerns expressed by beneficiaries and patient advocacy organizations (Appendix C:) prompted this review.

Background

In January 2011 CMS launched the first phase of the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) CBP in nine different areas of the country. These nine areas included 2.3 million beneficiaries in the Medicare Fee-for-Service Program.[7] The intent of the CBP was to reduce beneficiary out-of-pocket expenses and reduce Medicare costs while ensuring beneficiary access to quality items and services. Supplies for self-monitoring of blood glucose (SMBG) for beneficiaries managing diabetes were among the products included in the program.

In April 2012 CMS reported that no disruption of access to the CBP-covered DMEPOS occurred and that no negative health-care consequences to beneficiaries were seen as a result of the program.[7] Initially CMS published monthly updates to this information, but because the first full year of data indicated no change in beneficiary health-status outcomes resulting from the CBP, CMS changed its reporting to quarterly updates on its website

(https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html).

In May 2012 GAO issued its report to Congress stating that the monitoring methods used by CMS in assessing the impact of competitive bidding did not show directly whether beneficiaries received the DME needed on time or whether health outcomes were caused by problems accessing CBP-covered DME, thereby calling the CMS findings into question.[3]

In June 2015 Puckrein et al. presented a late-breaking poster at the American Diabetes Association 76th Scientific Sessions, reporting their analysis of data provided by CMS to determine the impact of the CBP on insulin-treated beneficiaries with diabetes.[6] This analysis showed that acquisition of SMBG supplies was disrupted among beneficiaries in the nine test markets, leading to increased migration from full acquisition of diabetes-testing supplies to partial or no acquisition, with associated increases in mortality, a doubling of inpatient admissions, and higher costs.

No Safety Arm in the Competitive-Bidding Demonstration Projects

The Balanced Budget Act of 1997 required the secretary of health and human services to establish demonstration projects to test the competitive-bidding concept.[8] In these projects, DMEPOS were to be reimbursed under competitively awarded contracts. Beginning in 1999, CMS designed and implemented demonstrations in two sites—one in Polk County, FL, and the other in Bexar, Comal, and Guadalupe Counties, TX. Competitively bid contracts were awarded for oxygen supplies and equipment, hospital beds and accessories, urological supplies, and surgical dressings.

CMS's predecessor agency, the Health Care Financing Administration, understood that competitive bidding reduces the number of approved suppliers. A report prepared for the agency calculated that by shrinking the number of suppliers, the winners of a competitive-bidding process "could adapt to the potential for increased market share by advertising, opening new locations to fill in geographic gaps left by unapproved suppliers, or improving service, thereby increasing beneficiary access. Or they may respond to lower prices by offering lower quality products, delaying routine maintenance, or employing fewer service technicians and customer service representatives, thereby increasing the need for service calls, extending waiting times, and decreasing access."[9]

CMS's awareness that CBP suppliers could reduce the quality of products and services to beneficiaries implies that the agency recognized the potential for risk to beneficiaries. This potential for risk raises critical questions: Were these demonstration projects research in human subjects? Did the CBP go forward without adequate protection for the safety of beneficiaries?

In response to the Tuskegee experiment, which was a study by the US Public Health Service that withheld treatments for black men with syphilis, Congress impaneled a national commission to make recommendation so that there would be no more Tuskegee experiments funded by government agencies. The commission issued the Belmont Report, which offered guidance that is worth considering in the context of this review the CBP demonstration projects:

> It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.
>
> For the most part the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast the term "research" designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.[10]

The commission did not contemplate such programs as the CBP; nevertheless, it is worthwhile to ask: Were the CBP demonstration projects research or standard practice? Were they "designed solely to enhance the well-being of an individual patient or client," and did they "have a reasonable expectation of success"? Or were they research projects "designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge"? The commission advised:

> When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees for example, to insist that a major innovation be incorporated into a formal research project.[10]

For federal agencies, the findings of the Belmont Report were embodied in a set of federal regulations called the Common Rule. The Common Rule's definition of research in human

subjects mirrors the prescription of the Belmont Report, and it mandates that if a project meets that definition, it must follow a set of protocols designed to protect study subjects. A case could be made that the CBP demonstration projects were research in human subjects. At minimum, they should not have launched without a formal discussion about whether they were standard practice or research.

However, the Common Rule exempts "research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs."[11] The CBP demonstrations were thus exempted from protocols established to monitor the safety of human subjects.

The demonstration projects required by the Balanced Budget Act of 1997 did not follow the formal research protocols specified by the Common Rule, and there was therefore no safety-monitoring arm in the CBP demonstration projects. CMS mailed survey instruments to a sample of beneficiaries to determine whether they experienced any disruption in accessing DMEPOS caused by the change from a fee schedule that was open to all accredited users to a market where beneficiaries were obliged to buy certain DMEPOS from winners of a competitive-bidding process. There was no attempt to measure change in health status that may have resulted from the transition to a limited number of suppliers with recognized incentives to reduce the quality of products and services provided. The CMS report to Congress on the findings from the demonstrations was silent on changes in health outcomes that could be associated with the CBP.[7]

Centers for Medicare & Medicaid Services Monitoring and Reported Methodology

CMS states that it conducts real-time claims analysis to monitor health status for groups of Medicare beneficiaries in competitive-bidding areas "in order to protect the interests of potentially affected Medicare beneficiaries."[2] The agency makes health-status results available in a series of files to be found on its website (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html). Each file includes a written summary of results and graphical displays of key indicators reflective of the health status of beneficiaries and their access to DMEPOS items and services. CMS derives the data from claims for Medicare populations in each competitive-bidding area and a corresponding "comparator" region that is similar to the competitive-bidding area. CMS reports health outcomes for two distinct groups (Appendix D:):

- Diabetic Supplies Access Group: Beneficiaries are included in an access group if they have a claim that indicates eligibility in the given month or any of the prior three months. Eligibility

is determined by a beneficiary's health conditions as defined by International Classification of Diseases, Ninth Revision (ICD-9) diagnosis codes.

- Diabetic Supplies Utilizers: Beneficiaries are included in a utilizer group if they are actively using a competitively bid product and are defined as having a claim for the product in the month of observation or any of the previous three months.

CMS reports the following health outcomes: death, hospitalization, emergency-room visit, physician visit, admission to a skilled-nursing facility, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month. CMS also states that it provided a historical baseline for each rate beginning January 2011 to control for historical trends.

Issues and Concerns

Although CMS reported that implementation of the CBP resulted in no disruption of access to diabetes-testing supplies or adverse health outcomes among beneficiaries, the program design, structure, and oversight methodology did not provide the basis for these conclusions. The Diabetes Translational Research Center identified a number of issues, summarized below, that may have produced erroneous findings.

Inappropriate Study Design

CMS failed to identify the proper cohort of beneficiaries in the test markets and an equivalent control group in nontest markets. Additionally, CMS failed to take into consideration the baseline trend as an outcome of interest when assessing the change from baseline to post-implementation of the CBP and then comparing the changes between the two groups in the test and nontest markets.

It is impossible to determine whether changes in acquisition behavior and health outcomes occurred without baseline information about beneficiary behaviors and health status prior to CBP implementation, nor is it possible to determine whether any changes in acquisition behavior or health status are significant without identifying a comparison group with similar baseline behaviors and health status in the non-CBP markets. **Therefore, CMS claim of no disruption or adverse health outcome is unfounded.**

Unstable, Unrepresentative Study Cohorts

CMS bases its assessment of CBP health outcomes on monthly outcome rates (e.g., death, hospitalizations) for two groups of beneficiaries: the Utilizer Group, and the Access Group Neither is a representative sample of the beneficiaries affected by the CBP. The Utilizer Group is composed of Medicare beneficiaries who have at least one claim for a specific DMEPOS product in the month of observation or any of the previous three months. The one claim is not indication

that a beneficiary was regularly accessing a DMEPOS product as prescribed by a physician, so the possibility of irregular access occasioned by the CBP is simply ignored by CMS monitoring. Equally important, any beneficiary whose access was completely disrupted and who therefore would not have one claim in a four-month period is excluded from the Utilizer Group, and the health consequence of the disruption goes unmonitored. The Access Group includes beneficiaries who are "likely to use the product," which is determined by whether a beneficiary has a condition related to product use. Access beneficiaries need not have a prescription for a DMEPOS product; they simply need to have a condition that required someone with that condition to use a DMEPOS product. The Access Group is a mix of beneficiaries who need a DMEPOS product and those who do not. Because CMS repopulated the Access and Utilizer Groups every month in the first year of the CBP and has repopulated them quarterly thereafter, the agency routinely creates a heterogeneous mix of beneficiaries (apples one month and oranges the next). The Utilizer and Access Groups are not representative samples of beneficiaries affected by the CBP. The shifting nature of the study groups is not the only problem that could contribute to distortions in CMS findings. Before the third quarter of 2014, beneficiaries in the Access Group were identified by related condition categories based on the CMS beneficiary risk-adjustment model. Because Medicare makes periodic updates to its risk-adjustment model, the ICD-9 diagnosis codes that are aggregated under a given condition category may change over time. As a result, in CMS's own words, the Access Group "may include ICD-9 diagnosis codes that are not as closely associated with product category usage."[12] Thus, CMS is never certain whether the CBP increased beneficiaries' risk of poor health outcomes by disrupting access to a needed DMEPOS.

Lack of Transparency

Missing Data from January through June 2011

Noticeably absent from the CMS report were data from the first six months (January–June 2011) of the CBP implementation. As an example, Table 1~~Table 1~~ shows the reported death rates (utilizer and access groups) for diabetes-testing supplies as presented by CMS.

Table 1. Death Rates starting from July 2011

Death Rate in Diabetic Supplies Utilizers

West	Rates		
	Round 1 RC	Round 2	Rest of National Mail Order - West
Jul-11	0.47%	0.42%	0.43%
Aug-11	0.35%	0.40%	0.39%
Sep-11	0.43%	0.38%	0.40%
Oct-11	0.48%	0.39%	0.38%
Nov-11	0.44%	0.41%	0.39%
Dec-11	0.54%	0.43%	0.43%
Jan-12	0.57%	0.47%	0.45%
Feb-12	0.59%	0.44%	0.38%
Mar-12	0.46%	0.47%	0.45%
Apr-12	0.44%	0.44%	0.39%
May-12	0.60%	0.42%	0.40%
Jun-12	0.41%	0.41%	0.40%

Death Rate in Diabetes Access Group

West	Rates		
	Round 1 RC	Round 2	Rest of National Mail Order - West
Jul-11	0.56%	0.54%	0.57%
Aug-11	0.62%	0.52%	0.58%
Sep-11	0.55%	0.51%	0.57%
Oct-11	0.67%	0.53%	0.59%
Nov-11	0.61%	0.54%	0.58%
Dec-11	0.69%	0.61%	0.63%
Jan-12	0.73%	0.61%	0.65%
Feb-12	0.66%	0.57%	0.58%
Mar-12	0.73%	0.63%	0.66%
Apr-12	0.61%	0.57%	0.57%
May-12	0.62%	0.55%	0.55%
Jun-12	0.59%	0.53%	0.54%

Source: CMS. Health Status Monitoring. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html

Without data from the first six months of implementation, it is impossible to determine conclusively whether the CBP had an impact on health outcomes. However, it is reasonable to postulate that the impact of the CBP would have been most noticeable during this period, when beneficiaries were trying to secure new mail-order suppliers. Also missing in CMS's report are the historical baseline data as stated on the CMS website. CMS's unwillingness to make these data available to the public or explain why it chose to ignore the 2011 six-month data raises troubling questions about the agency's lack of transparency.

Failure to Include Findings from All Product Groups

In its March 2014 report GAO states:

> To examine the extent to which beneficiaries have been affected by the CBP round 1 rebid, we analyzed changes in utilization of CBP-covered DME items by comparing Medicare claims data from 2010, the year prior to the CBP round 1 rebid, to post-CBP round 1 rebid claims data from 2011 and 2012. We used these data to determine whether the number of CBP-covered beneficiaries utilizing CBP-covered items and services increased or decreased in each month of 2011 and 2012 compared to the same month in 2010 for six of the round 1 rebid's nine product categories.[13]

However, the footnote to this statement indicates that three DMEPOS categories were not included in the assessment of the CBP impact from 2011 through 2012:

> We did not include three round 1 rebid product categories in this analysis: (1) the mail-order diabetic testing supplies category because data are limited due to *some beneficiaries*

> *switching to non-mail-order sources*; (2) the complex power wheelchair category due to potential data reliability concerns reported by CMS; and (3) the support surfaces category because it was limited to only the Miami competitive bidding area in the round 1 rebid.[13] (emphasis added)

The Forum finds it troubling that GAO chose *not* to include diabetic testing supplies in its analysis because *some* beneficiaries switched to non-mail-order sources. The 2015 study by Puckrein et al. found that a significant number of beneficiaries switched from mail-order to retail acquisition channels.[6] Whether GAO's decision was based on its own analysis of the data or was guided by CMS is not reported.

Incomplete Disclosure of Methodology for Assessing Disruption

Although CMS reported that beneficiaries experienced no disruption of access to DMEPOS, we were unable to locate any methodology describing how disruption was assessed in either the CMS or the GAO reports. Nor were any data regarding disruption of access reported, although such data could have been ascertained from a correct review of the claims data.

Failure to Identify and Assess the Appropriate Research Question

Rigorous assessment of cause-and-effect relationships requires investigators first to define the relevant research question (e.g., Did the CBP change beneficiaries' acquisition behaviors, and did those changes impact health outcomes?) and then to use appropriate analytical methodologies to answer that question. CMS failed to meet these requirements. Although CMS may have used appropriate (albeit unknown) statistical methods in their assessment, we are unclear about the specific research question that the agency attempted to answer. Given the findings of Puckrein et al.,[6] we suspect that the question was, in fact, inappropriate.

Moreover, although CMS considered a number of important health outcomes to assess the impact of the CBP, it presented only a partial summary of its data, with no statistical analyses. For example, an incidence outcome, such as number of times admitted to hospital during a particular period, should be considered as count data and analyzed by Poisson regression.[14] For mortality or morbidity outcomes, the Cox Proportional Hazard model may be used.[15] Number of days spent for each incidence of hospitalization may be considered as a repeated measured outcome, and repeated measure analysis of variance may be used to analyze such outcome.

Impact of the Competitive Bidding Program on Beneficiary Safety and Access to Diabetes-Testing Supplies

Importance of Self-Monitoring of Blood Glucose

The importance of SMBG among all diabetic individuals treated with insulin cannot be ignored. National diabetes organizations recommend that all patients with insulin-treated diabetes

routinely perform blood-glucose testing.[16, 17] Frequent blood-glucose testing is particularly important in elderly individuals with diabetes, because the risk of severe or fatal hypoglycemia associated with the use of sulfonylureas or insulin increases exponentially with age.[18], [19], [20]

Achievement of optimal glycemic control has been shown to prevent the acute complications of diabetes (e.g., severe hypoglycemia and hyperglycemia) and to prevent and/or slow the progression of diabetes-related microvascular and macrovascular disease.[21, 22] However, because diabetes is a self-managed disease, every effort should be made by clinicians and health-care payers to encourage and support adherence to prescribed treatment regimens.

Assessment of the Competitive Bidding Program's Impact on Medicare Beneficiaries

The recent study by Puckrein et al. assessed the impact of the CBP on Medicare beneficiaries with insulin-treated diabetes.[6] They presented their findings in a late breaking poster at the American Diabetes Association 76th Scientific Sessions (June 5–9, 2015, Boston, MA).

Study Design

In this four-year, retrospective, longitudinal study, the investigators compared Medicare beneficiaries within the nine test markets (intervention group) with those in the nontest markets (control group) to assess the impact of the CBP during the first year of the program's implementation. Beneficiary data for the analysis were obtained from CMS. Access was assessed according to each beneficiary's acquisition of insulin and diabetes-testing supplies (SMBG) as prescribed by the health-care provider. For beneficiary on insulin by rule Medicare reimburses for the acquisition of three strips per day. Based on that reimbursement schedule, full procurement of self-monitoring blood glucose supplies (Full SMBG) is defined here as the purchase of diabetes testing strips so that from the date of the first purchase the beneficiary continued to acquire testing supplies, resulting in their purchasing enough blood glucose testing supplies to allow them to test their blood glucose three times per day >80% of the year.

Primary outcome measures included the following:

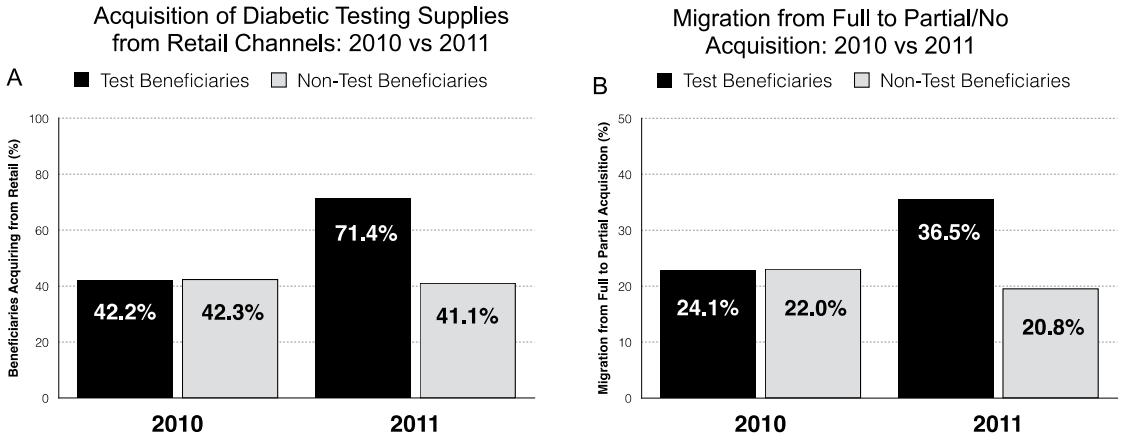
- Relationships of full SMBG acquisition and partial SMBG acquisition to survival probability over four years
- Changes in percentages of beneficiaries with full and partial SMBG acquisition from 2009 through 2012
- Changes in SMBG supply acquisition channels (retail and mail order) from 2010 through 2011
- Impact of migration from full to partial SMBG acquisition on mortality, inpatient admissions, and associated costs from 2010 through 2011

The intervention group included all insulin-treated beneficiaries who resided in the nine CBP markets (n = 43,939) in 2009. The control group included all nontest-market insulin-treated beneficiaries (n = 485,688). Within each study group, beneficiaries were divided into two clusters: those with full SMBG acquisition and those with partial SMBG acquisition in 2009. Propensity-score-matched analysis, which included 15,538 beneficiaries within each study group who matched for age, gender, comorbidities, and SMBG-acquisition behaviors, was performed to reduce selection bias due to imbalance in study covariates. The beneficiary clusters were followed from year to year, from 2009 through 2012, to assess changes in acquisition behavior.

Key Findings

- Four-year survival was negatively associated with partial SMBG acquisition or no SMBG record in both groups ($p < .0001$). In both study groups, the mortality rate was higher among beneficiaries with full SMBG acquisition in 2010 who migrated to partial SMBG acquisition or no SMBG record in 2011 compared with beneficiaries who maintained full SMBG acquisition. Given the association between acquisition of diabetes-testing supplies and survival, CMS's data, which showed a noticeably higher death rate among access-group beneficiaries (see Table 1~~Table 1~~, page 5) was not surprising. Even with its flawed methodology, the CMS data shows a notably higher death rate among both utilizer and access group beneficiaries in Round 1.
- Within the full cohort, acquisition of SMBG supplies was disrupted among beneficiaries in the nine test markets (Figure 1~~Figure 1~~A). Propensity matched analysis showed that this was associated with increased migration from full acquisition of diabetes-testing supplies to partial or no acquisition. (Figure 1~~Figure 1~~B)
- Within the propensity-score-matched analysis, the disproportionate migration between groups was associated with 42 additional deaths within the intervention group, which was likely due to the increased number of patients who migrated from Full to Partial SMBG acquisition in 2011.
- Also with the propensity-score-matched analysis, more than twice as many inpatient hospital admissions were seen among intervention group beneficiaries who migrated from Full to Partial SMBG acquisition compared with control-group beneficiaries.
- Inpatient costs were also more than twice as high for intervention vs. control beneficiaries who migrated to from Full to Partial SMBG acquisition

Figure 1. Change in acquisition channels and migration from full to partial or no SMBG acquisition



1A. *Intervention beneficiaries demonstrated a significant shift in their SMBG- acquisition channels, from mail order to retail, in 2011, whereas no shift was seen among control beneficiaries. This is a strong indication of access disruption.* ***1B.*** *The percentages of beneficiaries who migrated from full to partial SMBG acquisition in 2010 were similar in both the intervention and the control groups. However, the percentage of intervention-group beneficiaries who migrated from full SMBG acquisition in 2010 to partial SMBG acquisition in 2011 increased by 58.1% ($p < .0001$), whereas the percentage of control beneficiaries who migrated from full to partial SMBG acquisition decreased by 14.4% ($p < .0001$).*

Study Conclusions

Findings from this study demonstrate that acquisition of SMBG supplies was disrupted among beneficiaries in the nine test markets, leading to increased migration from full acquisition of diabetes-testing supplies to partial acquisition, with associated increases in mortality, inpatient admissions, and costs.

Appropriate Monitoring of the Competitive Bidding Program's Impact on Patient Safety: Longitudinal Study Design

A key strength of a longitudinal study is the ability to measure change in outcomes and/or exposure at the individual level, providing the opportunity to observe individual patterns of change.[23] When the goal of monitoring patient safety is to identify and assess the causal effects of certain treatments or interventions (e.g., the CBP) on outcomes, longitudinal studies are preferred over nonlongitudinal ones, in which the temporal order of treatment and outcome may be unclear (as seen in the CBP reporting).[24]

Therefore, CMS should have used a longitudinal study design to assess the impact of the CBP on the acquisition of diabetes-testing supplies and any subsequent health outcomes. Such a design, would use each patient as his or her own control by measuring the change in acquisition from a duration of three years pre-implementation to a duration of three years of CBP post-

implementation. Use of a stratified-propensity-score method[25] would have identified an equivalent control group, allowing for a true apples-to-apples comparison between beneficiaries who were affected and those who were not affected by the CBP. The rationale for and the components of a longitudinal-study design are as follows:[26]

- Longitudinal studies are used to examine associations between exposure to known or potential health risks (disruption of access to needed treatment) and subsequent morbidity or mortality, compared with health status or behavior at baseline (prior to CBP implementation).

- In the simplest design, a sample or cohort of subjects exposed to a risk factor (CBP markets) is identified along with a sample of unexposed controls (non-CBP markets). Subjects are followed over time with continuous or repeated monitoring of risk factors and/or health outcomes.

- The incidences of changes or adverse effects in each are measured, comparing final outcomes with baseline measures within each group and between groups.

- By comparing the incidence rates, changes in health behaviors (e.g., acquisition of diabetes-testing supplies) and attributable risks (e.g., mortality, hospitalizations, costs), the impact of exposure can be estimated.

- Allowance can be made for suspected confounding factors by matching the controls to the exposed subjects (e.g., propensity-score matching) so that they have a similar pattern of exposure to the confounder.

- When the cohort method is applied to the study of chronic diseases, such as diabetes, large numbers of patients must be followed up for long periods before sufficient data accrue to give statistically meaningful results.

A comparison of the methodologies used by CMS and the Forum (Puckrein et al.[6]) to assess the impact of the CBP on beneficiary acquisition of needed medical supplies and equipment and subsequent health outcomes is presented in Table 2~~Table 2~~.

Table 2. Compliance with Longitudinal-Study Protocols by the Centers for Medicare & Medicaid Services and the National Minority Quality Forum

Required Protocols	Protocol Compliance by:	
	CMS	Forum*
Establish baseline values for DME acquisition and health status to determine whether changes have occurred	No	Yes
Use stratified propensity-score matching to correct for disparities in ethnic, socioeconomic, and comorbidity characteristics	No	Yes
Provide a description of the methodology used that adequate to permit other researchers to replicate analysis and validate findings	No	Yes
Use adequate time frames for assessment of health outcomes	No	Yes
Use research question(s) that allow for determination of cause-and-effect relationships and that support the study design and analytical methodologies employed	No	Yes

* Puckrein et al.[6]

Further Failings of Centers for Medicare & Medicaid Services Methodology and Reporting

- CMS repopulated the cohort being measured each month, making it impossible for CMS to determine if any changes were occurring in the baseline group.
- The CMS methodology was inadequately disclosed, making it impossible for independent researchers and scientists to verify and validate the CMS claims.
- The Forum (Puckrein et al.[6]) demonstrated that acquisition of diabetes-testing supplies was, in fact, disrupted in CBP markets and led to decreased use of those supplies, which was associated with increased mortality, increased hospitalizations, and higher costs.
- Assessment of CMS methodology and reporting by the Diabetes Translational Research Center confirmed that CMS's claim that there were no adverse health outcomes as a result of CBP implementation is both unfounded and misleading.

Conclusions

CMS's findings of no disruption of access to DMEPOS and no adverse health outcome among beneficiaries within the nine test CBP markets are not supported by the data and methodology descriptions presented in its reports. Whether CMS intended to obscure the impact of the CBP can only be determined by a thorough investigation of the agency regarding its motives and decision-making processes.

Regardless of CMS's motives and rationale for its inadequate monitoring program, the findings of Puckrein et al. clearly show a significant disruption in acquisition of diabetes-testing supplies among beneficiaries who require these products for the safe and effective management of their

disease.[6] **This disruption prompted a large percentage of beneficiaries to reduce or cease acquisition of diabetes-testing supplies. This behavior was linked to increased mortality, hospitalizations, and associated costs.**

It is reasonable to conclude that disruption of acquisition and subsequent adverse health outcomes likely occurred among beneficiaries who purchased the other CBP-covered DMEPOS; however, no formal analyses of the impact of the CBP within these populations have been reported. Given CMS's current monitoring methodology and reporting, the full impact of nationwide CBP implementation is not yet known. More-effective monitoring protocols and a program design that comports with commonly accepted scientific standards of health status monitoring are needed to protect beneficiary safety.

Because adverse health consequences have been detected and can be associated with the CBP among beneficiaries with diabetes, nationwide implementation of the CBP should be suspended immediately, the impact of reduced access to patients dependent on other program products should be evaluated, transparent science-based methodologies should be adopted, and the ability of beneficiaries to seek redress should be clarified by amending the immunity and waiver provisions that compromise current beneficiary protections in the Medicare program.

Discussion

We support all efforts to reduce the financial burden of disease and disability on older Americans; however, cost reductions should not be pursued at the expense of patient safety. We are concerned that the methods used by CMS to monitor patient safety are inadequate and would be considered unethical clinical trials that involve human subjects. The outcome assessments used to monitor the safety of beneficiaries affected by the CBP appear to discount the adverse clinical effects of not using blood-glucose-testing supplies and ignore the potential impact of the CBP on beneficiary self-care behaviors. **CMS's CBP should be held to the same safety-monitoring standards as other clinical trials.**

We are also troubled by the lack of transparency evidenced in CMS's reports. It remains unclear whether CMS was simply misguided in the administration and reporting of its monitoring program or whether the agency intentionally misreported outcomes in order to pursue the cost-reduction objectives of the CBP without outside interference. Specifically, we question why health-outcome data from the first six months of CBP implementation are not provided; this would be the time period when the impact of the CBP would likely be observed. We also question CMS's use of a "comparator" region; the characteristics of and methods for defining this region are undefined. Additionally, CMS's use of "utilizer" and "access" populations provides no meaningful information about the impact of the CBP. The analyses of these populations merely show associated rates of death and hospitalization when beneficiaries

continue their current behavior; they do *not* report the number of beneficiaries who changed their acquisition behaviors, which would be an indication of CBP impact.

Although the unintended consequences of CBP implementation in the nine test markets are alarming, the potential impact of the nationwide implementation of the program raises even greater concerns. For example, when CMS implemented the national CBP launch in July 2013, reimbursement for test strips was reduced from approximately $35 to $10 per bottle of 50 strips when acquired through mail-order or retail channels. This reduction may dissuade many pharmacies (especially independent pharmacies) from providing diabetes-testing supplies to Medicare beneficiaries, which could further reduce acquisition among all Medicare beneficiaries. **It is reasonable to assume that the disruption in access among the DMEPOS categories and associated adverse health outcomes likely experienced will also be greatly magnified.**

Of additional concern is the immunity from judicial oversight bestowed upon CMS and its implementation of the CBP .[27] This immunity gave CMS the legal cover to be indifferent to the needs of beneficiaries as they implemented the CBP. However, CMS had a built-in waiver that was accorded by the Common Rule. The waiver provides definitions about the type of research that may be conducted in human subjects, who should be considered a subject, and what should happen if a project falls within the scope of research in human subjects.[28] The immunity in the law and the waiver in the Common Rule gave CMS the capacity to design the CBP in an environment where beneficiary risk could be subordinated to other objectives, such as creating savings in the program. This environment clearly contributed to the inadequate monitoring of changes in health outcomes associated with the CBP.

Although the reports provided by CMS and GAO provide extensive information about the CBP's processes, we can find no mention of how CMS assessed beneficiary risk prior to the launch of the CBP, nor is there any mention that the launch of the CBP might constitute research in human subjects in which beneficiaries should have been afforded the protections outlined in the Common Rule. **The blanket waiver given CMS under the Common Rule likely contributed to this programmatic failure to measure beneficiary risk properly prior to and during the implementation of the CBP.**

Although our analysis has focused primarily on diabetes-testing supplies, one can assume that similar disruptions were experienced across the other product categories, as indicated in CMS reports from pilot studies in Polk County, FL (oxygen supplies), and San Antonio, TX (oxygen supplies, general orthotic devices, hospital beds and accessories, nebulizer inhalation drugs, manual wheelchairs and accessories), and by anecdotal evidence. **Clearly, analyses of the impact of the CBP on other affected product categories similar to the assessment of diabetes-testing supplies presented here are urgently warranted, because expansion has already moved forward into nationwide adoption of CBP rates.**

References

[1] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html
[2] Centers for Medicare & Medicaid Services. Health Status Monitoring. CMS.gov. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html (last modified 28 October 2015, accessed 5 November 2015.
[3] United States Government Accountability Office. Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid, May 2012 (GAO-12-693), http://www.gao.gov/assets/600/590712.pdf (accessed 4 November 2015), page 42.
[4] American Association of Diabetes Educators. Competitive Bidding Program for Mail-Order Diabetes Testing Supplies: Product Availability Survey, January 2014, https://www.diabeteseducator.org/docs/default-source/legacy-docs/_resources/advocacy/aade_study_on_suppliers_2014.pdf (accessed 4 November 2015).
[5] Key Medical Supply, Inc., v. Kathleen Sebelius and Marilyn Tavenner, Civil No. 12-752 (DWF/JJG), 2013 D. Minn., http://www.gpo.gov/fdsys/pkg/USCOURTS-mnd-0_12-cv-00752/pdf/USCOURTS-mnd-0_12-cv-00752-1.pdf (accessed 6 November 2015).
[6] Puckrein GA, Zangeneh F, Nunlee-Bland G, Xu L, Parkin CG, Davidson JA. CMS Competitive Bidding Program Disrupted Access to Diabetes Supplies with Resultant Increased Mortality. American Diabetes Association 75th Scientific Sessions, 5–7 June 2015, Boston, MA. Abstract 139-LB, http://www.abstractsonline.com/pp8/#!/3699/presentation/12822 (accessed 4 November 2015).
[7] Centers for Medicare & Medicaid Services. Competitive Bidding Update—One Year Implementation Update, 17 April 2012, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf (accessed 4 November 2015).
[8] Balanced Budget Act of 1997, H.R. 2015, http://www.gpo.gov/fdsys/pkg/BILLS-105hr2015enr/pdf/BILLS-105hr2015enr.pdf (accessed 13 November 2015).
[9] Karon S, Jewell K, Hoerger T, et al. Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS: First-Year Annual Evaluation Report: HCFA Contract No. 500-95-0061/T.O. #3. September 2000 (revised January 2001). https://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/karon_2001_1.pdf (accessed 15 November 2015), p. 3-1.
[10] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report, 18 April 1979, http://www.hhs.gov/ohrp/policy/belmont.html (accessed 13 November 2015).
[11] Protection of Human Subjects, 45 CFR 46, http://www.hhs.gov/ohrp/archive/humansubjects/guidance/45cfr46.html (accessed 13 November 2015).
[12] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html
[13] United States Government Accountability Office. Medicare: Second Year Update for CMS's Durable Medical Equipment Competitive Bidding Program Round 1 Rebid, March 2014 (GAO-14-156), http://www.gao.gov/assets/670/661474.pdf (accessed 4 November 2015), page 4.
[14] McNamee R. Regression modelling and other methods to control confounding. Occup Environ Med 2005;62:500–506, doi: 10.1136/oem.2002.001115.
[15] Emura T, Cheh Y-H, Chen, H-Y. Survival Prediction Based on Compound Covariate under Cox Proportional Hazard Models. PLOS One 24 October 24 2012, DOI: 10.1371/journal.pone.0047627.
[16] American Diabetes Association. Standards of medical care in diabetes—2015. Diabetes Care 2015;38(Suppl 1):S1–93.
[17] Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology—Clinical practice for developing a diabetes mellitus comprehensive care plan. Endocr Pract 2015;21(Suppl 1):1–87.
[18] Meneilly GS, Cheung E, Tuokko H. Counterregulatory hormone responses to hypoglycemia in the elderly patient with diabetes. Diabetes 1994;43(3):403–410, doi: 10.2337/diab.43.3.403.
[19] Meneilly GS, Tessier D. Diabetes in the elderly. Diabet Med 1995;12(11):949–960, DOI: 10.1111/j.1464-5491.1995.tb00405.x.
[20] Huang ES, Laiteerapong N, Liu JY, John PM, Moffet HH, Karter AJ. Rates of complications and mortality in older patients with diabetes mellitus: the Diabetes and Aging Study. JAMA Intern Med 2014;174(2):251–258, doi:10.1001/jamainternmed.2013.12956.

[21] Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329(14):977–986, DOI: 10.1056/NEJM199309303291401.
[22] Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329(14):977–986, DOI: 10.1056/NEJM199309303291401.
[23] Toh S, Hernán MA. Causal inference from longitudinal studies with baseline randomization. Int J Biostat 2008;4(1):Article 22, doi: 10.2202/1557-4679.1117.
[24] Diggle PJ, Heagerty P, Lian K-Y, Zeger SL. Longitudinal Data Analysis. Chapter 1 IN: Analysis of Longitudinal Data, 2nd Ed. 2002. Oxford, Oxford University Press, https://faculty.washington.edu/heagerty/Courses/VA-longitudinal/private/LDAchapter.pdf (accessed 5 November 2015).
[25] Garrido MM, Kelley AS, Paris J, Roza K, Meier DE, Morrison RS, Aldridge MD. Methods for constructing and assessing propensity scores. Health Services Research 2014;49(5):1701–1720, DOI: 10.1111/1475-6773.12182.
[26] Coggon D, Rose G, Barker DJP. Longitudinal studies. Chapter 7 in Epidemiology for the Uninitiated, 4th Edition. 1997. BMJ Publishing Group Ltd. http://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/7-longitudinal-studies (accessed 5 November 2015).
[27] Key Medical Supply, Inc., v. Kathleen Sebelius and Marilyn Tavenner, Civil No. 12-752 (DWF/JJG), 2013 D. Minn., http://www.gpo.gov/fdsys/pkg/USCOURTS-mnd-0_12-cv-00752/pdf/USCOURTS-mnd-0_12-cv-00752-1.pdf (accessed 6 November 2015).

[28] Congressional Research Service Report for Congress. Federal Protection for Human Research Subjects: An Analysis of the Common Rule and Its Interactions with FDA Regulations and the HIPAA Privacy Rule. https://www.fas.org/sgp/crs/misc/RL32909.pdf; The Belmont Report. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html; Code of Federal Regulations. TITLE 45 PUBLIC WELFARE. Department of Health and Human Services PART 46 PROTECTION OF HUMAN SUBJECTS. http://www.hhs.gov/ohrp/policy/ohrpregulations.pdf

Appendix A: Timeline for DMEPOS Competitive Bidding Round 2 Recompete and National Mail-Order Recompete

CMS.gov
Centers for Medicare & Medicaid Services

Timeline for the DMEPOS Competitive Bidding Round 2 Recompete and the National Mail-Order Recompete; Begins Bidder Education Program

Date	2014-12-11
Title	Timeline for the DMEPOS Competitive Bidding Round 2 Recompete and the National Mail-Order Recompete; Begins Bidder Education Program
For Immediate Release	Thursday, December 11, 2014
Contact	press@cms.hhs.gov

Timeline for the DMEPOS Competitive Bidding

Round 2 Recompete and the National Mail-Order Recompete;

Begins Bidder Education Program

The Centers for Medicare & Medicaid Services (CMS) today announced the bidding timeline for the Round 2 Recompete and the national mail-order recompete of the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program, as required by law. CMS has also launched a comprehensive bidder education program. This program is designed to ensure that DMEPOS suppliers interested in bidding receive the information and assistance they need to submit complete bids in a timely manner.

The Medicare DMEPOS Competitive Bidding Program has saved more than $580 million in the nine markets at the end of the Round 1 Rebid's 3-year contract period due to lower payments and decreased unnecessary utilization. Additional savings are being achieved as part of the Affordable Care Act's expansion of the competitive bidding program—at the end of the first year of Round 2 and the national mail-order program, Medicare has saved approximately $2 billion. Furthermore, the monitoring data show that the implementation is going smoothly with few inquiries or complaints and no changes to beneficiary health outcomes.

Background

The Medicare DMEPOS Competitive Bidding Program was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as a way to help Medicare set appropriate payment rates for DMEPOS items and services. The program was expanded by the Affordable Care Act in 2010. In January 2011, Medicare started the program in nine areas of the country. In July 2013, Medicare expanded the competitive bidding program to more areas of the country, called the Round 2 areas, and also implemented a national mail-order program for diabetic testing supplies.

The program replaces the outdated, inflated fee-schedule prices Medicare paid for these items with lower, more accurate prices to help Medicare and its beneficiaries save money while ensuring access to quality equipment, supplies and services. It also helps limit fraud and abuse in the Medicare Program.

Summary

CMS is required by section 1847(b)(3) of the Social Security Act to recompete contracts under the DMEPOS Competitive Bidding Program at least once every three years. Suppliers must then compete to become a Medicare contract supplier by submitting bids to provide certain items in competitive bidding areas (CBA). The new, lower payment amounts resulting from the competitions replace the fee schedule amounts for the bid items in these areas.

CMS is conducting the Round 2 Recompete for seven product categories in the same geographic areas that were included in Round 2. However, as a result of the Office of Management and Budget's updates to the original 91 Round 2 metropolitan statistical areas (MSA), there are now 90 MSAs for the Round 2 Recompete. The Round 2 Recompete CBAs have nearly the same ZIP codes as the Round 2 CBAs. However, certain ZIP codes have changed since

Round 2; CMS has updated the CBAs to reflect the changes. Additionally, CBAs that were located in multi-state MSAs have been defined so that no CBA is included in more than one state. A list of the ZIP codes included in each CBA is also available on the Competitive Bidding Implementation Contractor (CBIC) website.

As in the initial Round 2 competition, CMS is conducting the national mail-order recompete for diabetic testing supplies simultaneously. The national mail-order recompete will include all parts of the United States, including the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa.

Timeline

12/18/2014*
Registration for user IDs and passwords opens

1/6/2015*
Authorized Officials are strongly encouraged to register no later than this date

1/20/2015*
Backup Authorized Officials are strongly encouraged to register no later than this date

1/22/2015*

CMS opens bid window for Round 2 Recompete and national mail-order recompete

2/17/2015*
Registration closes

2/23/2015*

Covered Document Review Date for bidders to submit financial documents

3/25/2015*

Bid window closes

Winter 2016*

CMS announces single payment amounts, begins contracting process

Spring 2016*

CMS announces contract suppliers, begins contract supplier education campaign

Spring 2016*

CMS begins supplier, referral agent, and beneficiary education campaign

July 1, 2016*

Implementation of Round 2 Recompete and national mail-order recompete contracts and prices

**Dates listed are target dates*

Round 2 Recompete Product Categories

- Enteral Nutrients, Equipment and Supplies
- General Home Equipment and Related Supplies and Accessories
  - includes hospital beds and related accessories, group 1 and 2 support surfaces, commode chairs, patient lifts, and seat lifts
- Nebulizers and Related Supplies
- Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories
- Respiratory Equipment and Related Supplies and Accessories
  - includes oxygen, oxygen equipment, and supplies; continuous positive airway pressure (CPAP) devices and respiratory assist devices (RADs) and related supplies and accessories
- Standard Mobility Equipment and Related Accessories
  - includes walkers, standard power and manual wheelchairs, scooters, and related accessories
- Transcutaneous Electrical Nerve Stimulation (TENS) Devices and Supplies

A list of the specific items in each product category is available on the CBIC website.

Review and Update Enrollment

Suppliers must maintain accurate information on their CMS-855S enrollment application with the National Supplier Clearinghouse (NSC) and in the Provider Enrollment, Chain, and Ownership System (PECOS).

- Contact information (name, Social Security number, and date of birth) for authorized official(s) and correspondence address.
- Products and services furnished by the enrolled location(s).
- Each state in which the enrolled location(s) provides items and services.
- Complete listing of authorized officials.

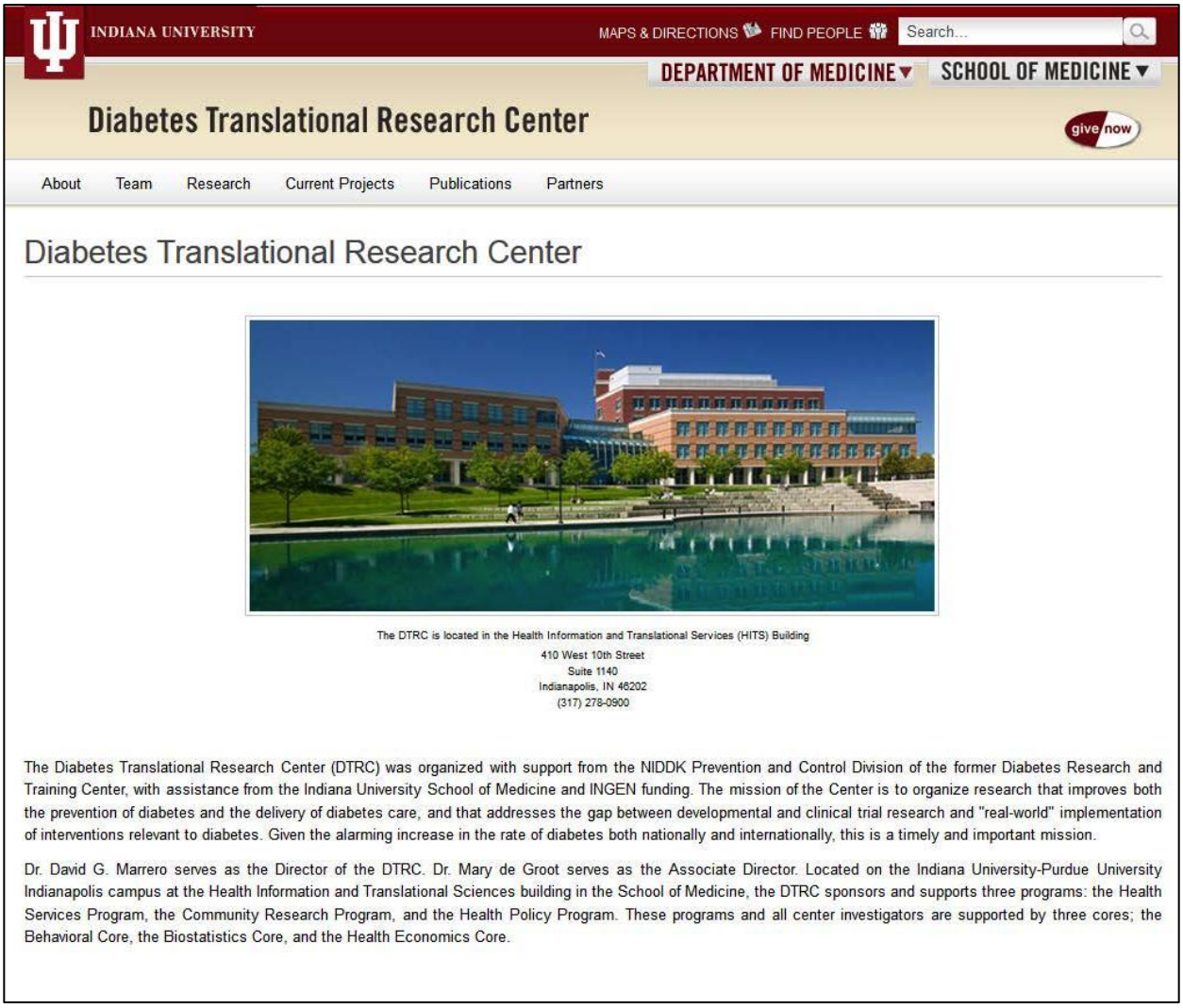
If you have only one authorized official listed on your enrollment record, consider adding one or more eligible authorized officials to help with registration and bidding.

It is important to note that if your enrollment record is not current at the time of registration, you may experience delays and/or be unable to register and bid. We will also validate your bid data with your enrollment record in PECOS during bid evaluation. If it is not accurate, your bid may be disqualified.

###

Source: https://www.coms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-12-11-3.html

Appendix B: Diabetes Translational Research Center



- The Diabetes Translational Research Center (DTRC) was organized with support from the NIDDK Prevention and Control Division of the former Diabetes Research and Training Center, with assistance from the Indiana University School of Medicine and INGEN funding.
- The mission of the DTRC is to organize research that improves both the prevention of diabetes and the delivery of diabetes care, and that addresses the gap between developmental and clinical trial research and “real-world” implementation of interventions relevant to diabetes.
- The DTRC is currently conducting research in the following areas: clinical trials; policy making and cost effectiveness of health services; medication adherence; influence of care delivery organizational structure on diabetes care delivery processes and outcomes; role of

technology in diabetes care delivery; primary prevention of diabetes; depression and diabetes mechanisms; community-based treatment program development; and provider-patient communication.

Source: http://medicine.iupui.edu/DTRC

Appendix C: Interested Organizations

- ADAPT
- Alliance for Aging Research
- Association of Assistive Technology Act Programs
- American Association of Clinical Endocrinologists
- American Association of People with Disabilities
- American Association of Diabetes Educators
- American College of Endocrinologists
- American Diabetes Association
- American Sleep Apnea Association
- Association of Programs for Rural Independent Living
- Association of University Centers on Disabilities
- Brain Injury Association of America
- Christopher and Dana Reeve Foundation
- Diabetes Access to Care Coalition
- Diabetes Patient Advocacy Coalition
- Disability Policy Institute
- Disability Rights Center
- Disability Rights Education and Defense Fund
- Friends of Disabled Adults and Children
- George Washington School of Public Policy
- Georgia Independent Living Council
- International Ventilator Users Network
- Montana Ability Center of Greater Toledo
- National Council on Independent Living
- National Diabetes Volunteer Leadership Counsel
- National Disability Rights Network
- National Emphysema/COPD Association
- National Family Caregivers Association
- National Organization of Nurses with Disabilities
- Pennsylvania Statewide Council on Independent Living
- People for Quality Care
- Pittsburgh United Cerebral Palsy
- Post-Polio Health International
- Shepherd Center
- Spina Bifida Association of America
- Summit Independent Living Center Inc.
- The Endocrine Society
- Three Rivers Council on Independent Living
- Touch the Future
- UCP/CLASS
- United Spinal Association
- Wisconsin Council on Physical Disabilities

Appendix D: Centers for Medicare & Medicaid Services Description of Populations Studied

Diabetic Supplies Utilizers

Health Status Outcomes Summary

No changes in beneficiary health outcomes resulting from the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program have been observed to date.

These materials contain the mortality and morbidity rates for one group of beneficiaries being monitored: the mail-order diabetic supplies utilizer group. Utilizer Groups are composed of Medicare beneficiaries who have a claim for the product in the month of observation or any of the previous three months. Access Groups include beneficiaries who are likely to use the product and are determined by whether a beneficiary has a condition related to product use.

The health outcomes being measured are deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month.

Rates for the National Mail-Order (NMO) competitive bidding areas (CBAs) are divided between Round 1 RC and Round 2 CBAs, and all the remaining NMO CBAs (Rest of NMO). Since Round 1 RC CBAs were subject to competitive bidding for mail-order diabetic supplies prior to the NMO program, this division allows us to observe any changes in outcome rates in regions subject to policy changes prior to the NMO program. Comparator regions are not used for mail-order diabetic supplies as they are now a nationally bid product. In general, outcome rates in Round 2 regions and the remaining NMO CBAs continue in line with historical rates for Round 1 RC regions.

Note that mortality and morbidity rates generally display seasonal trends. The first quarter of each year typically has elevated rates of mortality and morbidity; however, the trends generally mirror past seasons.

Additionally, rates that appear more variable tend to be based on a smaller number of beneficiaries. For example, the Utilizer Groups have fewer beneficiaries than the Access Groups, so rates for the Utilizer groups tend to be more variable.

IMPORTANT
This update incorporates changes to our monitoring approach that commenced at the end of the Round 1 Rebid program on December 31, 2013, and due to the availabililty of complete data for the first full year of the Round 1 Recompete program that was implemented January 1, 2014. These changes include:

- Monitoring usage and health outcomes related to six additional product categories (Transcutaneous Electrical Nerve Stimulation (TENS), Nebulizers, Infusion Pumps, Commode Chairs, Seat Lifts, and Patient Lifts) that were introduced under Round 1 Recompete. We monitor usage and health outcome rates in six corresponding utilizer groups, and seven access

groups. For the infusion pump product category, we monitor rates in two separate access groups.
- Monitoring both Round 1 Recompete and Round 2 using the list of Healthcare Common Procedure Coding System (HCPCS) codes that are covered by Round 1 Recompete.
- Comparing trends between the three groups of beneficiaries (mentioned above) in Round 2 and Round 1 Recompete CBAs, instead of Round 1 Rebid CBAs.

Introduction

Folder Name: Diabetic_Supplies_Utilizers_Thru_Mar_2015
Upload Date: 7/1/2015
Observation Period: 01/01/2011 to 3/31/2014
Claims Processed Through: 7/3/2015
Beneficiary Enrollment Through: May 2015
Data Types: Original Medicare (Part A and Part B) Claims; Medicare Enrollment Data
Purpose: To summarize mortality and morbidity outcomes in the diabetic supplies utilizer group in Round 1 RC CBAs, Round 2 CBAs, and all remaining NMO regions aggregated at the DME region level.

Each CSV file in this folder refers to a specific outcome of interest. Each of the outcomes is defined in the Specifications section.

Specifications

Study Population and Definitions

- Utilizers: All persons who, during the month of observation, were enrolled in Original Medicare and living in a ZIP code covered by the NMO competitive bidding policy and had a claim for a mail-order diabetic supply in the month of observation or any of the previous three months.[1]
- Round 1 RC CBAs: Includes all areas in which the competitive bidding policy was originally implemented for Round 1 RC, and subsequently for the NMO program
- Round 2 CBAs: Includes all areas in which the NMO competitive bidding policy was implemented for mail-order diabetic supplies, excluding Round 1 RC CBAs
- Rest of NMO: Includes all NMO regions except Round 1 RC and Round 2 CBAs

Outcome Definitions:

- Death: As observed in the Medicare Enrollment Database
- Hospitalization: As indicated by the service date of Inpatient (IP) claim
- ER: As indicated by the service date of Outpatient (OP) claim with emergency room flag
- Physician Visit: As indicated by the service date of Carrier (PB) claim

[1] Source:
- Round 1 RC CBAs
- Round 2 CBAs
- Round 1 RC HCPCS

Diabetic Supplies Access Group

Health Status Outcomes Summary

No changes in beneficiary health outcomes resulting from the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program have been observed to date.

These materials contain the mortality and morbidity rates for one group of beneficiaries being monitored: the diabetic supplies access group. Utilizer Groups are composed of Medicare beneficiaries who have a claim for the product in the month of observation or any of the previous three months. Access Groups include beneficiaries who are likely to use the product and are determined by whether a beneficiary has a condition related to product use. Note that the diabetic supplies access group comprises beneficiaries who are likely to need diabetic supplies.

The health outcomes being measured are deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month.

To control for historical trends, each competitive bidding area (CBA's) historical baseline for each rate is provided, beginning in January 2011. Historical rates for both Round 2 CBAs and non-CBAs are provided for each of the four DME MAC regions to provide context for the Round 1 Recompete CBA rates. The rates in Round 1 Recompete CBAs continue in line with historical rates and they also track closely with rates in non-competitive bid regions.

Note that mortality and morbidity rates generally display seasonal trends. The first quarter of each year typically has elevated rates of mortality and morbidity; however, the trends generally mirror past seasons and are closely matched by the non-competitive bid regions.

Additionally, rates that appear more variable tend to be based on a smaller number of beneficiaries. For example, the Utilizer Groups have fewer beneficiaries than the Access Groups, so rates for the Utilizer groups tend to be more variable.

IMPORTANT

This update incorporates changes to our monitoring approach that commenced at the end of the Round 1 Rebid program on December 31, 2013, and due to the availabililty of complete data for the first full year of the Round 1 Recompete program that was implemented January 1, 2014. These changes include:

- Monitoring usage and health outcomes related to six additional product categories (Transcutaneous Electric Nerve Stimulation (TENS), Nebulizers, Infusion Pumps, Commode Chairs, Seat Lifts, and Patient Lifts) that were introduced under Round 1 Recompete. We monitor usage and health outcome rates in six corresponding utilizer groups, and seven access groups. For the infusion pump product category, we monitor rates in two separate access groups.

- Monitoring both Round 1 Recompete and Round 2 using the list of Healthcare Common Procedure Coding System (HCPCS) codes that are covered by Round 1 Recompete.
- Comparing trends between the three groups of beneficiaries (mentioned above) in Round 2 and Round 1 Recompete CBAs, instead of Round 1 Rebid CBAs.

Introduction

Folder Name: Diabetes_Access_Group_Thru_Jun_2015
Upload Date: 10/1/2015
Observation Period: 01/01/2011 to 6/30/2014
Claims Processed Through: 10/9/2015
Beneficiary Enrollment Through: September 2015
Data Types: Original Medicare (Part A and Part B) Claims; Medicare Enrollment Data
Purpose: To summarize mortality and morbidity outcomes in the diabetic supplies access group in Round 1 RC and Round 2 CBAs and non-competitive bid regions aggregated at the DME region level.

Each CSV file in this folder refers to a specific outcome of interest. Each of the outcomes is defined in the Specifications section.

Specifications

Study Population and Definitions

- Access Group: Beneficiaries with a claim that indicates eligibility and who were living in a ZIP code in a Round 1 RC or Round 2 CBA or non-competitive bid region in the given month or any of the prior three months.[1] Eligibility is determined by a beneficiary's health conditions, as defined by any of the following ICD-9 diagnosis codes:
    - 24900 Secondary diabetes mellitus without mention of complication, not stated as uncontrolled, or unspecified
    - 24901 Secondary diabetes mellitus without mention of complication, uncontrolled
    - 24910 Secondary diabetes mellitus with ketoacidosis, not stated as uncontrolled, or unspecified
    - 24911 Secondary diabetes mellitus with ketoacidosis, uncontrolled
    - 24920 Secondary diabetes mellitus with hyperosmolarity, not stated as uncontrolled, or unspecified
    - 24921 Secondary diabetes mellitus with hyperosmolarity, uncontrolled
    - 24930 Secondary diabetes mellitus with other coma, not stated as uncontrolled, or unspecified
    - 24931 Secondary diabetes mellitus with other coma, uncontrolled

[1] Source:
- Round 1 RC CBAs
- Round 2 CBAs

Source: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html