

Medicare Competitive Acquisition: Implications for Persons with Diabetes

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Executive Summary

Nearly one in five Medicare beneficiaries has diabetes and these patients face major challenges in managing their health. The high diabetes rate among beneficiaries also means that the Medicare program itself is highly vulnerable to the high costs of uncontrolled diabetes. As a result, great care must be taken when implementing any new cost containment strategy that has the potential to disrupt access to preventive health care. This is particularly in the case of the Medicare Competitive Acquisition Program for Durable Medical Equipment and Supplies (DMEPOS), because of its potential impact on access to products needed for a basic preventive service, diabetes testing supplies. Yet despite these concerns over both beneficiary health and program costs, the DMEPOS program, as it is now being implemented, lacks the types of basic patient safeguards considered standard in competitive bidding arrangements such as Medicare Advantage and Medicare Part D.

A key component of the current DMEPOS program where diabetes testing is concerned is an aggressive effort to expand the use of mail-order purchasing strategies for diabetes test strips. This expansion appears to have been made without any analysis of the quality of mail-order services, beneficiaries' early experiences with mail-order, or the effects of mail-order purchases on overall Medicare costs. The CMS decision to proceed with mail order was instead based on an aggregate estimate (no evidence was cited) of mail-order use, without further analysis of the quality of mail-order services, beneficiary experiences with mail-order, or the effects of mail-order purchases on overall Medicare

costs. Indeed, as recently as March 2008, CMS touted unit cost savings achieved through competitive acquisition, without offering any accompanying estimate of the overall cost of treatment for patients with diabetes in the competitive bidding regions, and without any analysis of the impact of competitive acquisition on patient care and health outcome. There simply is no evidence regarding the effects of mail-order on overall diabetes-related Medicare costs in the competitive bidding regions, and no analysis of the effects of the aggressive use of mail order on health care access or quality or health outcomes.

The competitive acquisition program, as described in both the statute and regulations, is virtually devoid of beneficiary protections generally, and details concerning the use of mail order for diabetes testing supplies in particular. CMS standards appear simply to assume that beneficiaries who can make the system work will try to do so and that no harm can result, since unhappy users always can return to retail outlets. But the net effect of this haphazard approach to the question of how elderly and disabled patients acquire and use an essential preventive service invites patient safety problems if beneficiaries, unable to navigate mail order, test themselves less frequently. Moreover – and paradoxically – mail order could actually expose Medicare to potentially heightened costs, as consumers who experience problems with mail-order suppliers return to retail purchasing, even as stockpiles of inappropriate, high-volume, mail-order supplies continue to mount in these patients' homes.

This analysis leads us to two basic recommendations:

- An immediate focus should be on the development of patient protections specifically applicable to the mail-order diabetes supplies market. To an extent far greater than recognized under the statute and regulations, Part B durable medical equipment, prosthetic and orthopedic items, and medical supplies all touch beneficiaries in very real ways. The items and services covered by DMEPOS – in particular, diabetes supplies – are purchased not by health care professionals but by the beneficiaries themselves. Over one quarter of all Medicare beneficiaries experience some level of cognitive dysfunction, and millions lack the ability, knowledge and experience to navigate a competitive system on their own without additional assistance or education. Essential protections are needed in the areas of marketing, enrollment and disenrollment, benefit design, quality standards, and patient protections.
- Second, comprehensive evaluation is essential; it would be ironic indeed if mail order actually increased overall Medicare costs, but this is not an outcome that can be discounted. This is particularly true in view of the fact that to date, CMS' focus has been on unit price discounts rather than overall cost-savings. For this reason, CMS should halt any expansion of competitive acquisition of diabetes supplies in the absence of further research. In view of the current, inadequate level of understanding of the effects of competitive bidding, we believe that before any further expansion of competitive acquisition, careful evaluation of Medicare patient behavior is essential, particularly the behavior of vulnerable beneficiaries in navigating competitive systems.

Introduction

The ultimate test of health insurance is its ability to assure access to high quality health care, particularly treatments and services essential to the management of serious, long-term, and deadly conditions that nonetheless are amenable to early and continuous management.¹ For this reason, it is essential to understand the access, quality, and patient safety implications of cost containment approaches, even those that might superficially appear to present minimal risk.

No patient population presents a stronger case for cautiously introducing – and carefully measuring the patient impact of – cost containment strategies than persons with diabetes. This is particularly the case for Medicare beneficiaries with diabetes. This is true because of their heightened vulnerability to the ravages of the disease, as well as to cost containment strategies that lack basic patient safeguards. It is also true because of the high cost of diabetes: Medicare spent more than \$47.6 billion in direct medical costs for diabetes-related care in 2002.² Indeed, the health services research literature is replete with studies underscoring how patient cost-sharing, another seemingly modest cost containment strategy, can impair the safety and quality of essential services, while paradoxically elevating health care costs among vulnerable populations.³

This analysis examines the implications of Medicare’s competitive acquisition program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) in the context of beneficiaries with diabetes who depend on routine blood glucose testing as a basic element of their health care. Following an overview of the competitive acquisition statute and its implementing regulations and guidelines, this policy brief then assesses the access, quality, and safety implications of competitive acquisition. Negative unintended consequences are especially likely to arise as a result of the introduction of competitive purchasing arrangements that lack essential patient safeguards.

Background

The Medicare Competitive Acquisition Statute

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)⁴ amended Medicare to create a permanent competitive acquisition program for DMEPOS. The purpose of the amendments was to bring competitive purchasing

¹ Institute of Medicine, *Care Without Coverage: Too Little, Too Late* (National Academy Press, Washington D.C. 2002).

² Zhang, P, Engelgau, MM., Norris, SL, Gregg, EW, Narayan, KM. 2004. "Application of Economic Analysis to Diabetes and Diabetes Care" *Annals of Internal Medicine* 140:11 972-977.

³ Brook, R. et al. 1984. *The Effect of Coinsurance on the Health of Adults: Results from the RAND Health Insurance Experiment*, Rand Corporation. ISBN 0-8330-0614-2; Lurie, N., W. Manning, C. Peterson, G. Goldberg, C. Phelps and L. Lillard. "Preventive Care: Do We Practice What We Preach?" *American Journal of Public Health* 77(7): 801-804; Goldman, D., G. Joyce and Y. Zheng. 2007. "Prescription Drug Cost Sharing." *Journal of the American Medical Association* 298(1): 61-69.

⁴ Section 302(b) P.L. 108-173 (108th Cong. 1st Sess.).

techniques to the acquisition of certain Medicare Part B covered items or services, including diabetes supplies. The legislation authorized the Secretary to employ competitive acquisition techniques in the case of “competitively priced items and services”⁵ for which payment can be made under Part B. The amendments enumerated a series of Part B items and services that qualified for competitive acquisition.⁶ The legislation authorized the Secretary to exempt otherwise included items and services in low density rural areas and non-competitive urban areas “unless there is a significant national market through mail-order for a particular item or service,” as well as “items and services for which the application of competitive acquisition is not likely to result in significant savings.”⁷

Unlike Medicare’s outpatient prescription drug and Medicare Advantage programs – which were the subject of extensive patient protection discussions during enactment of the 2003 amendments – the DMEPOS competitive acquisition statute lacks basic safety, quality, and access safeguards that have become staples of modern, market-based competitive purchasing arrangements. These competitive acquisition amendments are almost totally devoid of quality and safety standards; in marked contrast to Medicare Part D prescription drug benefits and Medicare Advantage, the competitive acquisition amendments have cost-cutting as their sole focus. This legislative focus on price discounts – to the exclusion of other, potentially countervailing considerations – reveals itself in numerous ways:

- First, the legislation permits the Secretary to extend competitive acquisition to items and services that have the “highest volume” and the “largest savings potential.”⁸
- Second, the only required contracting standards are first, that amounts paid to winning entities be expected to be “less than the total amounts that would otherwise be paid” and second, that individuals have a “choice of multiple suppliers.”⁹
- Third, the statutory text is completely permissive where beneficiary safeguards and patient safety are concerned: winning contractors must meet “applicable quality standards,”¹⁰ but in referencing “applicable” quality standards, the text of the law gives the Secretary discretion over whether to develop any quality standards at all.
- Fourth, even where coverage design and safety are concerned, the law is permissive with respect to whether beneficiaries must be given advance

⁵ §1847 of the Social Security Act, 42 U.S.C. §1395w-3(a)(1)(A).

⁶ §1395w-3(a)(1)(A)(2)(A)-(C).

⁷ 42 U.S.C. §1395w-3(a)(3).

⁸ 42 U.S.C. §1395w-3(a)(1)(B)(ii).

⁹ 42 U.S.C. §1395w-3 (b)(2)(A)(iii) and (iv).

¹⁰ 42 U.S.C. §1395w-3 (b)(2)(A)(i).

information regarding what services and supplies will be available to them or what the costs will be.¹¹

- Fifth, the legislation prohibits the Secretary from delaying competitive acquisition even if there is a “delay in implementation of quality standards...or receipt of advice from the program advisory committee.”¹²
- Sixth, the law gives the Secretary the discretion to require contractors to provide exceptions to coverage limits and exclusions, even when the beneficiary’s prescribing physician determines that “use of the particular item or service would avoid an adverse medical outcome on the individual.”¹³

In sum, the competitive acquisition legislation marks a fundamental departure from other legislative initiatives aimed at introducing market principles into Medicare. Even as Congress was simultaneously addressing issues of information, quality, safety, and beneficiary protections in enacting Part D, the same considerations were virtually non-existent in the case of the competitive acquisition of Part B services and supplies. Despite the fact that prescribed medical equipment and supplies may raise precisely the same questions of appropriateness and quality that exist in the case of prescription drugs and biologicals, the legislation remained silent on patient safeguards, entrusting the Secretary with expansive power to design an appropriate program.

Under the statute, the Secretary is authorized to create a class of “competitive” supplies and services for which the Department’s dominant policy focus becomes the achievement of unit price savings. Safeguards essential to high volume discount purchasing involving a frail population are not addressed, nor is the question of overall value for Medicare. Instead, the legislation appears to empower the Secretary to take aggressive action to get price discounts without regard to overall value or basic beneficiary protections, even in the case of services and supplies that play a central and direct role in beneficiary health maintenance.

In these respects, the competitive acquisition statute represents a fundamental departure from previous Congressional efforts to inject market competition into high volume purchasing of covered items and services that directly “touch” beneficiaries, such as prescribed drugs and comprehensive managed care plans. Furthermore, the legislation extends extraordinary powers to the Secretary, waiving fundamental elements of public administration law that are designed to bring transparency and accountability to agency conduct. As such, federal contracting laws are waived¹⁴ as are the provisions of the Federal Advisory Committee Act (FACA).¹⁵

¹¹ 42 U.S.C. §1395w-3 (b)(5)(D) sets forth a rule of construction that specifies simply that “nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to competitively priced items and services.” No mandatory disclosure requirements are specified.

¹² 42 U.S.C. §1395w-3(b)(B).

¹³ 42 U.S.C. §1395w-3(a)(5).

¹⁴ 42 U.S.C. §1395w-3(a)(1)(C).

¹⁵ 42 U.S.C. §1395w-3(c)(4).

CMS Implementation of the Competitive Acquisition Program

CMS' implementation of competitive acquisition rests on a single evaluation of a national competitive bidding demonstration¹⁶ involving DMEPOS. The evaluation took place in two sites (Polk County, Florida, and three counties in the San Antonio, Texas metropolitan statistical area) over a three-year time period (1999-2002). In neither site was mail-order purchasing of diabetes supplies evaluated. Many of the items and services covered in the demonstrations were of a type that tends to be low volume and purchased on an infrequent basis (e.g., hospital bed, wheelchairs, and orthotics). The demonstration was short (one round of competitive bidding in San Antonio, two rounds in Polk County) and the results showed certain quality related problems as well as a reduction in the use of daily oxygen among beneficiaries.

The analysis compared the price of items and services purchased through competitive acquisition to their price in an open market, but did not assess the overall value to Medicare in terms of patient health and functional status, or the consequential costs related to the use of inappropriate, inadequate or inferior services and supplies. Furthermore, in the Florida site, the analysis found an actual increase in the amount of services purchased under the demonstration in the case of oxygen, with commensurate volume drops in surrounding counties, a suggestion that far from producing savings, volume purchasing may distort the market for certain goods and services that are used regularly and continuously and that must be re-supplied frequently. In the words of the evaluation, there was some evidence of "volume responses to fee changes brought about by competitive bidding."¹⁷ There is no evidence that CMS has made a further effort to understand the underlying drivers of these market distortions.

The analysis also found "global" measures of access and satisfaction, noting "evaluation data on issues of quality and product selection suggested that quality did not change appreciably."¹⁸ Despite the fact that Medicare is an insurance program, whose patient protections and safeguards are designed to operate at the individual beneficiary level rather than in a global context, the report lacked any evaluation of individual cases in which "global" satisfaction measures did not apply, nor did the final report recommend patient protections. In other words, the evaluation was focused on the bulk purchasing aspects of the demonstration and its aggregated effects on beneficiaries, not on the experiences of individual patients with access, quality or safety. For example, only in passing did the report indicate a "doubling" of reports of no help in securing assistance with insurance and a "halving" of reports indicating that help was provided. Also mentioned in passing was a doubling of complaints in the case of certain products sold in San Antonio and a drop in patient willingness to recommend their nebulizer suppliers, a product that involves frequent purchase and use.¹⁹ This lack of assistance may have a

¹⁶ *Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies* (United States Department of Health and Human Services, Tommy Thompson, Secretary) (2004).

http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf

¹⁷ Id. p. 6.

¹⁸ Id. p. 17.

¹⁹ Id. p. 15.

significant effect on the appropriate use of a product and inappropriate use and reduced health outcome. Despite the potential importance of assistance in use, the effects of withdrawing such assistance were not separately tested.

In spite of the study's evident limitations and findings of problems with safety, quality, and access, CMS moved ahead with the competitive acquisition program, not only in product categories covered by the demonstrations but also with respect to mail-order diabetes supplies, which had not been the subject of the pilot. Final regulations published in April 2007²⁰ noted that "over 60 percent of Medicare expenditures for diabetic supplies are for items furnished by nationwide mail-order suppliers" and that a separate mail-order program for diabetes supplies was appropriate:

"We believe that the implementation of a separate mail-order competitive bidding program would result in significant savings because it would focus on suppliers that can obtain discounts from manufacturers because they furnish a large volume of items to beneficiaries through the mail."²¹

The CMS decision to proceed was thus based on an aggregate estimate (no evidence was cited) of mail-order use, without further analysis of the quality of mail-order services, beneficiary experiences with mail-order, or the effects of mail-order purchases on overall Medicare costs. Indeed, as recently as March 2008, CMS touted unit cost savings achieved through competitive acquisition, without offering any accompanying estimate of the overall cost of treatment for patients with diabetes in the competitive bidding regions, and without any analysis of the impact of competitive acquisition on patient care and health outcome.²²

The final rules essentially parrot the statute and are virtually devoid of the types of patient protection standards that have come to be customary in Medicare competitive market programs. The regulations specify that suppliers must meet "applicable quality standards developed by CMS,"²³ but the regulations never state what those standards will be or the purchasing and oversight procedures that CMS will utilize in order to assure that services and supplies remain accessible, safe, and of appropriate quality. The Preamble to the final rules notes simply that "it is in the best interest of the industry and beneficiaries to select the accreditation organizations and publish . . . quality standards through program instructions."²⁴ In other words, the standards against which suppliers are to be governed are to be shaped by suppliers themselves. What, precisely, these industry standards are, or how they would assure quality and safety or avoid potential conflicts of interest, remains totally unexplained.

²⁰ 72 Fed. Reg. 17992-18090 (April 10).

²¹ 72 Fed. Reg. 18018.

²² CMS, Medicare to Save an Average of 26% for Some Durable Medical Equipment, Prosthetics, Orthotics and Supplies in Selected Areas; Beneficiaries to Join in Savings.

<http://www.cq.com/displayfile.do?docid=2691163&productId=5> (Accessed March 21, 2008).

²³ 42 C.F.R. §414.414(c).

²⁴ 72 Fed. Reg. 18035.

The rules specify the need for a “sufficient number of suppliers,”²⁵ but do not address the sufficiency of the manufacturer products (or choice of products) that actually is available through participating suppliers. Despite concerns that CMS provided insufficient information regarding how the agency would measure supplier capacity within any competitive bidding area, CMS provided no additional guidance, despite the fact that none of the regional demonstrations had involved mail-order diabetes supplies.²⁶ Although the regulations require suppliers to adhere to physician prescriptions for specific items or services, they set forth no formal exceptions system as in the case of Part D and authorize suppliers to “consult with the treating physician to find an appropriate alternative brand” or “assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery.”²⁷ While these “assistance” and “consultation” services may sound innocuous, they lack basic safeguards such as prompt timelines or an obligation to provide a short term supply that conforms to the prescription while “assistance” and “consultation” are pursued. The regulations provide neither grievance nor appeals rights, allowing companies to use high pressure tactics to induce patients to switch products or to invite non-cooperative patients to leave their systems without any means of appealing.

In essence, the competitive acquisition program, as articulated in statute and regulation, is virtually devoid of beneficiary protections generally, and in relation to mail-order diabetes supplies in particular. Beneficiaries who can make the system work for themselves are free to try to do so, with an apparent assumption by CMS that no harm will flow from its system and that unhappy participants always can return to the retail market. The net effect of this haphazard approach to an important matter of health care policy is to invite both patient safety problems and – paradoxically – program exposure to excess product costs, as consumers who experience problems with mail-order suppliers return to retail purchasing, even as inappropriate, high-volume mail-order supplies continue to arrive at patients’ homes.

Proposed regulations promulgated in 2008 would limit the direct solicitation of beneficiaries (i.e., cold calling).²⁸ At the same time, however, the proposed rules contain two major loopholes: cold calls would be permitted where the individual has given written permission to the supplier to continue contact, or where the cold call concerns a second item or service not previously purchased and the supplier has furnished at least one covered item during the 15-month time period preceding the date of contact.²⁹ The regulation specifies no standards aimed at assuring that written permission is the result of a specific informed consent to continue to receive subsequent calls related to product marketing, nor is it clear why current customers should be subjected to cold calls regarding other products that they have never purchased, may never have seen or used, and that may be completely unrelated to their underlying condition. Furthermore, while the proposed rule would prohibit efforts to “directly solicit” business, it contains no

²⁵ 42 C.F.R. §414.414(h).

²⁶ 72 Fed. Reg. 18042-18043.

²⁷ 42 C.F.R. §414.420(b).

²⁸ 73 Fed. Reg. 4513 (January 25, 2008).

²⁹ *Id.*

definition of what it means to “directly solicit” patient business, thereby leaving the door open to deceptive or high pressure marketing practices of the type that have emerged in other Medicare competitive markets. Conversely, the standard also fails to delineate what constitutes appropriate contact within an existing health professional/patient relationship.

Implications of the Competitive Acquisition Program for Medicare Beneficiaries with Diabetes, and for Medicare Costs

In order to assess the implications of competitive acquisition in a diabetes context it is important to understand the nature of diabetes, its incidence and prevalence among the Medicare population, and its consequences for beneficiary health and Medicare costs.

Medicare and Diabetes

Because of whom it affects and its toll on health, diabetes has a profound relationship with Medicare patients and costs, as underscored by these key points:

- The Centers for Medicare and Medicaid Services (CMS) reports that diabetes affects nearly one-fifth of all Medicare beneficiaries and that Medicare beneficiaries with diabetes account for nearly one third of all Medicare expenditures.³⁰
- More than one-quarter (27%) of low-income seniors and people with disabilities who are enrolled in both Medicaid and Medicare (also known as dual enrollees) have diabetes.³¹
- A recent analysis of Medicare claims data and other program data, which applied newer criteria for diagnosing diabetes at an earlier stage, found that between 1994-1995 and 2003-2004, the annual incidence of diabetes increased by 23 percent while its prevalence increased by 62 percent. While mortality rates fell by 8.3 percent, complication rates among persons with diagnosed diabetes generally increased or stayed the same. The study found high rates of major complications, in particular a doubling of the risk for congestive heart failure and myocardial infarction.³² The rate of congestive heart failure during the 1999-2004 time periods among beneficiaries with diabetes stood at 47.5 percent. Among beneficiaries who experienced at least 6 years of diagnosed diabetes, nearly 90 percent experienced at least one adverse outcome. Researchers noted the

³⁰ CMS, Medicare Health Support to Improve Care of Beneficiaries with Chronic Illnesses. Medicare Fact Sheet, cited in Health Policy R and D, Medicare’s New Competitive Acquisition Program for Durable Medical Equipment: Policy Considerations Involving Beneficiaries with Diabetes, Community Based Retail Pharmacies, and Blood Glucose Monitoring (Washington D.C., January 2006), p. 9.

³¹ Henry J. Kaiser Family Foundation. “Dual Eligibles: Medicaid’s role for Low-Income Medicare Beneficiaries.” (2006), <http://www.kff.org/medicaid/upload/Dual-Eligibles-Medicaid-s-Role-for-Low-Income-Medicare-Beneficiaries-Feb-2006.pdf> (accessed March 10, 2008).

³² Frank A. Sloan et al., The Growing Burden of Diabetes Mellitus in the US Elderly Population, *Archives of Internal Medicine* 168:2 192-199 (Jan. 28, 2008).

“overwhelming burden” of diabetes and the low rates of adherence to health care utilization guidelines among patients,³³ which if anything, would have placed these estimates at a lower bound. The study underscores the fact that lower rates of surrogate markers for diabetes complications does not necessarily “translate into reduction in adverse events.”³⁴

Figure 1 underscores the extent to which the Medicare population falls squarely within the risk factors for diabetes and its complications. These factors include age,³⁵ racial or ethnic minority status,³⁶ disability and activity limitations,³⁷ and low family income.³⁸ The Medicare population is disproportionately low income, in fair to poor health, and significantly affected by activity limitations and cognitive and mental impairments. At particular risk may be the 7.5 million dual enrollees who receive both Medicare and Medicaid; by definition these beneficiaries are poor, and due to the link between poverty and membership in a disadvantaged racial or ethnic group, they are disproportionately racial and ethnic minorities. Their low income makes dual enrollees more likely than other Medicare beneficiaries to have low health literacy, potentially limiting the appropriate use of health care and rendering them less capable of navigating competitive purchasing arrangements.

³³ Id. p. 198.

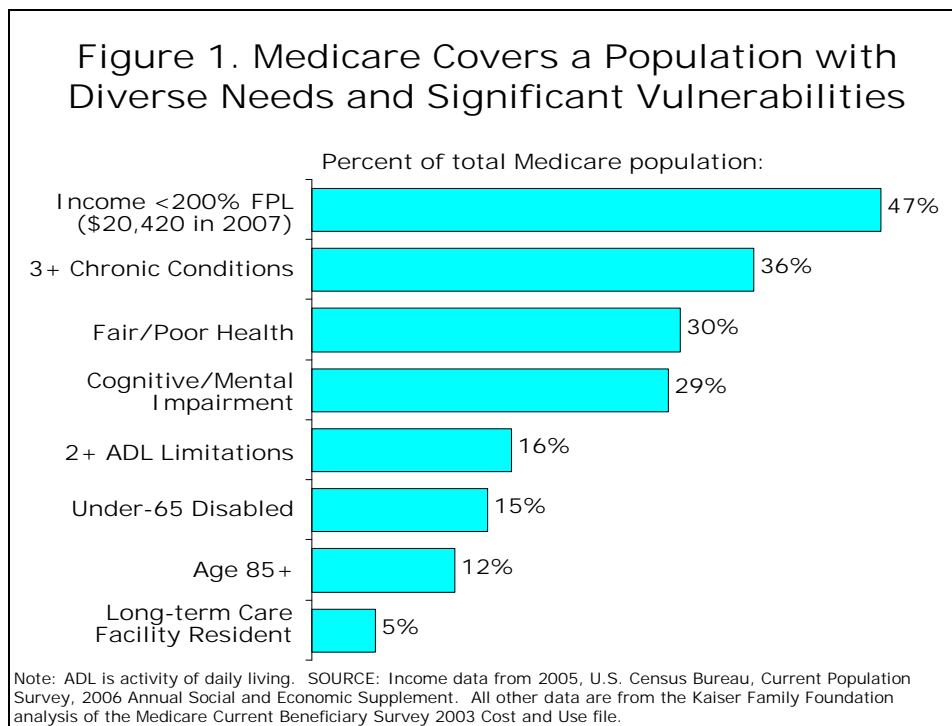
³⁴ Id.

³⁵ Ashkenazy, Rebecca and Abrahamson, Martin. 2006. “Medicare Coverage for Patients with Diabetes: A National Plan with Individual Consequences.” *Journal of General Internal Medicine* 21: 382-392.

³⁶ Centers for Disease Control and Prevention. 2005. “National Diabetes Fact Sheet: United States, 2005.”

³⁷ Gregg, EW, Beckles, GLA, Williamson, DF, Leveille, SG, Langlois, JA, Engelgau, MM, Narayna, KM, 2000. “Diabetes and Physical disability Among Older U.S. Adults” *Diabetes Care* 23:9 1272-1277.

³⁸ Valdmanis, V., D. Smith and M. Page. 2001. “Productivity and Economic Burden Associated with Diabetes.” *American Journal of Public Health* 91(1): 129-130.



Treating diabetes begins with controlling blood glucose levels. Like other persons with diabetes, Medicare beneficiaries depend on constant health maintenance with treatments and therapies to avert the type of life-threatening deterioration that is heavily associated with the condition. Self-monitoring of blood glucose levels is essential to good diabetes control, particularly in the case of persons with diabetes who take insulin.³⁹ Indeed, self-monitoring is considered so vital to disease management that increasing the proportion of persons with diabetes who self-monitor represents a national public health objective under *Healthy People 2010*.⁴⁰ As a result, any policies that even potentially impair access to diabetes supplies merit close scrutiny and careful implementation.

Potential Consequences of Mail-order Competitive Acquisition of Diabetes Testing Supplies for Beneficiaries and Program Costs

No systematic evaluation was undertaken prior to launching a competitive acquisition system for mail-order diabetes supplies. As a result, it is extremely important to consider the possible outcomes of the CMS program. In examining the potential issues raised by competitive acquisition of diabetes testing supplies, it quickly becomes evident that a major paradox emerges: *because the system lacks fundamental patient safeguards, it may harm patients as it also increases program cost and waste.*

³⁹ Adams, A, Mah, C, Soumerai, SB, Zhang, F, Barton, MB, Ross-Degnan, D. 2003. "Barriers to self monitoring of blood glucose among adults with diabetes in an HMO: A cross sectional study" *BMC Health Services Research* 3:6.

⁴⁰ Center for Disease Control and Prevention 2007. "Self-Monitoring of Blood Glucose Among Adults with Diabetes—United States, 1997-2006" *Morbidity and Mortality Weekly Report* 56:43 1133-1137.

Potential risks flowing from the absence of patient safeguards

As noted, these federal regulations lack key patient safeguards that have come to be customary in competitive acquisition and market-driven arrangements. The chief implication flowing from the absence of such safeguards is reduced access to essential services, with an attendant adverse health impact. Where diabetes is concerned, the health implications of limiting access to health maintenance services such as appropriate testing supplies are especially severe.

For many years, researchers at the George Washington University have studied the design of laws and legal instruments such as procurement contracts in a consumer protection context. Our patient protection research⁴¹ (which has been extensively supported by federal funding over the years) has focused on competitive purchasing arrangements, and has been recognized as a seminal contribution to the field. Indeed, our study *Negotiating the New Health System*, first published in 1997, served as the research basis for the statutory patient safeguard provisions that were added to the Medicaid managed care statute by the Balanced Budget Act of 1997.

Our research has taught us over the years that although the precise nature of competitive purchasing arrangement can vary – in addition to DMEPOS, Medicare today permits the competitive purchase of outpatient prescribed drugs and Medicare Advantage plans – the key elements of patient protection nonetheless remain the same. These critical elements reflect safeguards against the excesses of competition, in recognition of the limited ability of most patients – and in particular, patients with limited cognitive skills and in poorer health – to navigate market complexities.

Table 1 sets forth key patient safeguard categories that have been identified by GW researchers through our analyses over the years. Our work has underscored the fact that these categories are pertinent, regardless of whether the competitive arrangement is offered to beneficiaries on a mandatory (e.g., Medicaid managed care) or voluntary basis. Table 1 shows that in virtually every safeguard category, the DMEPOS competitive acquisition regulations fall short where patient safety is concerned, even though similar standards are consistently present in the case of both Medicare Part D prescription drugs and Medicare Advantage plans. Either of these program designs could have readily served as a template for CMS in the development of DMEPOS patient safeguards.

As Table 1 shows, even a cursory examination of its five major patient protection domains and 17 sub-domains illustrates the weaknesses of the CMS regulatory structure. The DMEPOS regulations address – barely – precisely two sub-domains of safety and protection. Instead, the regulations essentially parrot the competitive acquisition statute, which as noted, is silent on patient safeguards but which empowers the Secretary to design the system and develop patient safety standards. This key additional step did not occur, and is not required by law or regulation to occur.

⁴¹ Rosenbaum, S. et al., *Negotiating the New Health Care System: A Nationwide Study of Medicaid Managed Care Contracts* (George Washington University, Washington D.C. 1997, 1998, 2000, 2001).

Table 1. Key Beneficiary Safeguard Lapses Under CMS DMEPOS Regulations

Patient Protection Domains	Addressed/Not Addressed
<p>Marketing and Information Prohibition against cold calling</p> <p>Clear communication regarding benefits and limitations, low health literacy standards</p> <p>Minimum information content requirements regarding services and benefits</p> <p>Compliance with Title VI Limited English Proficiency (LEP) guidelines and disability communication access under Americans with Disabilities Act (ADA)</p>	<p>Limited protections, major exceptions, no definition of direct solicitation</p> <p>Not addressed</p> <p>Not addressed</p> <p>Not addressed</p>
<p>Program membership rights Toll-free assistance number</p> <p>Clear communication requirements in accordance with low literacy readability standards related to use of services</p> <p>Translation compliance with Title VI guidelines for persons with Limited English Proficiency (LEP)</p> <p>Compliance with ADA communication access standards</p> <p>Membership information about services, cancellation, grievance and appeals rights</p>	<p>Not addressed</p> <p>Not addressed</p> <p>Not addressed</p> <p>Not addressed</p> <p>Not addressed</p>
<p>Benefit Design A range of manufacturer items and services meeting evidence-based standards for quality and safety</p> <p>Clear exceptions process for medically indicated need</p>	<p>Not addressed</p> <p>Exception system contains no standards, procedures or timelines</p>
<p>Access and Quality Clear standards by which suppliers will be measured in such areas as timeliness, and product condition and suitability Response time to oral or written requests for service modifications</p> <p>Internal and external quality measurement and performance improvement requirements covering both technical performance and patient experience</p>	<p>Not addressed</p> <p>Not addressed</p>
<p>Grievances and Appeals Timely and accessible grievance and appeals procedures</p>	<p>Not addressed</p>

Numerous potential risks flow from the absence of patient safeguards applicable to diabetes mail-order systems (or any other competitive acquisition service or product for that matter). Since no evidence regarding who does or does not use mail-order accompanies the CMS mail-order estimates, it is impossible to know how mail-order affects the experiences of certain beneficiary subgroups. A few of the issues that may present themselves are as follows:

- The lack of definitions related to direct solicitation means that patients who had an isolated prior business dealing with a company may encounter cold calls and pressure sales tactics.
- The enrollment process may yield disproportionate enrollment among patients with limited English or health literacy abilities, or who experience higher levels of mental and cognitive impairments.
- Because detailed quality standards are lacking in the regulations, patients may be simultaneously inundated with supplies they do not need while being denied the monitoring supplies they seek. To the extent that patients' clinicians are willing to attempt to intervene in order to help patients, the regulations fail to specify any process for such intervention and allow the supplier to continue to furnish inappropriate services while telling the patient to go elsewhere.
- Failing to specify a grievance and appeals system allows suppliers to refuse services to beneficiaries whose treating physicians seek customization for medical reason. Mail-order could have the perverse effect of actually driving up costs, not only because patients are improperly self-monitoring, but because they may stop testing.

What Impact Might a System Without Patient Protections Have on Beneficiary Access to Diabetes Testing Supplies?

In considering the implications of an expanded mail-order competitive acquisition system, four distinct and major issues arise. These issues could significantly and adversely affect beneficiary health and access to health care, even if the CMS competitive acquisition system were to leave retail purchasing as a coverage option. These issues are as follows:

- First, problems with access and choice, both of which carry attendant health and cost consequences, including a potential Medicaid spillover problem
- Second, problems related to the quality of care and its health consequence
- Third, the exacerbation of racial, ethnic, and socioeconomic health disparities
- Fourth – and paradoxically – Medicare cost increases for diabetes testing supplies, despite somewhat lower unit prices, as the volume of deliveries skyrockets, with

an attendant spike in retail purchasing as beneficiary confusion over sources of products grows and as they attempt to compensate for inappropriate mail-order products.

1) Mail-order systems may create access and choice problems, with potential overall cost consequences if routine testing declines

The wide range of blood glucose monitoring systems available in the market demonstrates the highly variable and complex nature of beneficiary needs; thus, an exclusionary competitive acquisition program has the potential to act as a barrier to necessary care among vulnerable beneficiaries.⁴²

The rule provides one payment level for test strips and one payment level for monitors under the Healthcare Common Procedure Coding System (HCPCS). As a result, CMS has no means of identifying which products – by manufacturer name and model number – are provided to beneficiaries. The implications of this incomplete coding system is its tendency to mask a mail-order supplier's dangerous narrowing of beneficiary access to products, fostering wholesale product substitution even when clinical customization may be essential. Furthermore, unless a beneficiary thinks to tell a treating health professional that the products received were not, in fact, the product prescribed, the health professional may have no way to appeal or protest, since the rules do not require suppliers to inform treating clinicians that product substitution has taken place.

There are important functional differences between different monitors: some monitors offer audible, step-by-step directions; some monitors work well in high altitude, temperature, or humidity; some monitors transmit data to a physician's office; some monitors are more adaptable to individuals with motor skill related disabilities. A winning supplier may limit access to some products, sacrifice quality, and substitute lower quality products. By limiting the choice of products, suppliers may leave Medicare beneficiaries without access to their prescribed products. Dissatisfaction with lower-quality substitute products may cause patients, in turn, to monitor their blood glucose less frequently or to stop testing, which can result in increased diabetes complications and costs to the Medicare program.

In this way, unit price discounts achieved from suppliers might adversely affect patients, as suppliers limit their products to the least expensive and those that yield the most profit. At the same time, treating health professionals may have no idea that a substitution occurred until the damage has been done, because of the absence of safeguards.

⁴² Health Policy R and D. "Medicare's New Competitive Acquisition Program for Durable Medical Equipment: Policy Considerations Involving Beneficiaries with Diabetes, Community Based Retail Pharmacies, and Blood Glucose Monitoring." Washington D.C., January 2006.

Another important issue raised by the spread of mail-order without careful evaluation is the loss of the role of the retail pharmacist as an intermediary and educator. As noted, diabetes supplies are different from other products that have been considered for competitive bidding because of the lack of a ready intermediary to assist patients through the purchasing process. Patients rely heavily on intermediaries such as pharmacists to guide them when purchasing medical equipment and supplies. The substitution of mail-order essentially eliminates the personal interaction that comes with retail purchasing, leaving patients without a dependable source of expertise at the point of service. Diabetes supplies must be purchased much more often than other types of equipment and supplies subject to the DMEPOS system. By contrast, evidence suggests significant instability in the high volume DMEPOS market, with extensive turnover and difficult-to-track vendors.⁴³

Mail-order compels navigational skills on the part of patients, who in turn may experience trouble in gaining access to diabetes supplies that are optimal for their care. Were competitive acquisition further devolved to the retail level, this navigational problem would only intensify, as beneficiaries experience an erosion of outlets possessing an appropriate choice of product.

To the extent that an expanded use of the competitive acquisition program relies on use of Internet to communicate educational materials to beneficiaries, extensive evidence shows that, by and large, Medicare beneficiaries do not use the Internet⁴⁴ and may in fact have age-related vision problems that create access barriers to any competitive acquisition program that relies on Internet use.⁴⁵ An internet based approach, for example, lacks the type of hands-on assistance that comes from Certified Diabetes Educators (CDEs), health care professionals who, when made available as part of an overall care management plan, can help patients navigate care options including the purchase of equipment and supplies.

The CMS program lacks certain other important safeguards. For example, the competitive acquisition demonstrations on which the program is based do not shed light on how people are informed of coverage changes in their market. No major campaigns comparable to that which followed the enactment of Part D have been proposed. It is unclear how beneficiaries would learn to navigate the market to obtain daily products; indeed, it appears that they are simply expected to respond to aggressive marketing by online firms or through cold calls, precisely the type of aggressive marketing approaches that have raised concerns in other markets.

To the extent that competitive acquisition impairs access to access to health management services such as testing, cost savings achieved through discount pricing for

⁴³ HHS, Office of the Inspector General, *Semi-Annual Report to Congress (Oct. 1, 2006 – March 31, 2007)* Available at <http://oig.hhs.gov/publications/docs/semiannual/2007/semiannualfirsthalf07.pdf> (Accessed April 2, 2008).

⁴⁴ Kaiser Family Foundation. 2005. "Seniors and the Internet Survey."

⁴⁵ O'Hara, Karen. 2004. "'Curb Cuts' on the Information Highway: Older Adults and the Internet." *Technical Communications Quarterly* 13(4): 423-445.

diabetes supplies could quickly be swamped by elevated costs elsewhere in the system. The most recent study of the economic cost of diabetes in the U.S. in 2007⁴⁶ shows a cost of \$174 billion in a single year, including \$116 billion flowing from excess medical expenditures alone. Because persons with diabetes have per capita medical expenditures that are approximately 2.3 times higher than expenditures in the absence of a condition, the emphasis must be on disease management. Efforts to reduce the immediate costs associated with health maintenance pale next to the cost of hospital inpatient care, which represented 50 percent of total medical expenditures attributable to diabetes in 2007.

A final cost-related problem stemming from diminished access should be noted in the case of dual enrollees. Because of the high number of dual enrollees with diabetes, Medicare policy changes that limit access under one payer could have a spillover effect by increasing Medicaid exposure to (suddenly) uncovered testing supplies not available through mail-order businesses but available for retail purchase in pharmacies. This spillover phenomenon could in turn prompt Medicaid programs to reduce their own coverage of diabetes testing supplies in order to shield their own budgets from this rollover effects. Unlike Medicare Part D, nothing in the DMEPOS amendments disentitles dual enrollees from Medicaid coverage of diabetes testing supplies under state plans. Thus, coverage that is denied or disallowed in Medicare potentially rolls over onto state Medicaid programs if patients buy from retail outlets that participate in Medicaid.

In sum, to the extent that mail-order purchasing drives down adherence to frequent testing, the potential health consequences to patients – and cost consequences to Medicare and Medicaid alike from uncontrolled diabetes – loom as key possibilities that compel further study. The need to study the potential effects of primary care access restrictions is particularly urgent in the case of diabetes because alternative pathways to cost-savings exist. While the evidence is inconclusive, it appears that a viable cost reduction strategy is aggressive primary management, including efforts to maintain blood glucose levels as a means of maintaining health and averting complications. For example, between 1994 and 1998, Veterans Administration facilities spent more than \$214.8 million in outpatient and \$1.45 billion in inpatient expenditures for patients with diabetes.⁴⁷ During this time period, disease management was strengthened, resulting in a decrease in the number of diabetes-related hospitalizations and an increase in outpatient visits by patients with diabetes.⁴⁸

2) *Reduced use of testing leads to diminished quality of care*

For the reasons set forth above, access barriers carry health care quality implications. If prescribed testing equipment and supplies are not accessible, then the overall quality of diabetes care for Medicare beneficiaries also suffers. Conditions that could have been managed at a relatively early stage are transformed into later stage

⁴⁶ ADA, Economic Costs of Diabetes in the U.S. in 2007 *diabetes Care* 31:3 (March 2008) pp. 1-19.

⁴⁷ Maciejewski, ML, Maynard, C. 2004 “Diabetes-Related Utilization and Costs for Inpatient and Outpatient Services in the Veterans Administration” *Diabetes Care* 27:2: B69-B73.

⁴⁸ Maciejewski, ML, Maynard, C. 2004 “Diabetes-Related Utilization and Costs for Inpatient and Outpatient Services in the Veterans Administration” *Diabetes Care* 27:2: B69-B73.

complications, which are already a crisis of near-epidemic proportions among Medicare beneficiaries.

Of particular importance is the potential risk of co-morbidities as blood glucose level monitoring declines. These co-morbidities, particularly loss of limbs and cardiovascular complications, are extensively documented in Appendix A. Indeed, to the extent that introduction of competitive acquisition techniques succeeds in impairing access to appropriate testing, the entire benefit gained from the initial Congressional determination to cover diabetes testing and supplies becomes threatened.

3) *Expanded use of competitive acquisition without key patient protections may exacerbate racial, ethnic, and socioeconomic disparities in health and health care*

Poverty is a key determinant of health and life expectancy, and the gap between rich and poor in the U.S. is growing.⁴⁹ Medicare beneficiaries are not immune to this pattern; indeed, scores of studies have documented extensive disparities in health and health care among beneficiaries in relation to race, ethnicity, and socioeconomic class.⁵⁰ Because health care access is deemed by experts to be critical to narrowing the life expectancy gap,⁵¹ the introduction of potential barriers to care should be the subject of particular scrutiny.

At first blush, the use of a voluntary mail-order system for diabetes testing supplies would not appear to be related to the problem of health disparities. But it is essential to understand the racial, ethnic, and socioeconomic patterns associated with the mail-order business prior to broadening its use. To the extent that the use of mail-order tends to be disproportionately concentrated among more affluent beneficiaries, such a pattern, if not identified and taken into account prior to widening its use, can further aggravate the health gaps that separate low income beneficiaries, who are disproportionately members of racial and ethnic minority groups, and whose vulnerability to diabetes is particularly great, as illustrated in Appendix A.

Extensive use of mail-order ultimately may shrink the entire market for diabetes test strips and monitors, including the market of supplies in retail outlets. Even assuming that an appropriate range of products remains in a more restrictive market, the question becomes the effects of shrinking outlets on purchasers whose residence in low income communities already narrows their purchasing landscape, and who lack the means to navigate this landscape as it shrinks further in the face of widening use of high volume delivery business. A Medicare policy that has the effect of limiting access sites to blood glucose monitoring supplies in poorer communities could significantly widen disparities in health and health care for the very Medicare beneficiaries who are most at risk.

Diabetes already lays disproportionate claim to life and health for low income and minority persons. To the extent that low income and minority Medicare beneficiaries, as

⁴⁹ Robert Pear. "Gap in Life Expectancy Widens for the Nation," *New York Times* (March 23, 2008).

⁵⁰ See, e.g., Institute of Medicine, *Unequal Access* (National Academy Press, 1999).

⁵¹ Robert Pear. "Gap in Life Expectancy Widens for the Nation," *New York Times* (March 23, 2008).

well as those with disabilities and cognitive impairments, are more likely to purchase health care supplies through community retail outlets such as local independent pharmacies, chain drug stores, or grocery stores or community clinics with pharmacy services, the health disparity implications of an ever-broadening mail-order business may be considerable.

Mail-order exerts control over health care access by substituting high volume purchasing from limited outlets and from a limited list of products for more consumer-oriented purchasing practices involving a wider variety of products that are available at trusted sites close to home. In other instances in which primary care access limits have been introduced as a means of controlling costs, such practices have had measurable and adverse effects, with particular sensitivity among low income populations.⁵²

One diabetes-specific study found that decreasing the cost of drugs decreased total diabetes-related costs by four percent per beneficiary, highlighting the critical importance of access to supplies and drugs that help diabetes patients control their condition.⁵³ Another study found that variable coinsurance rates have a large effect on compliance for diabetes prescription drug regimens.⁵⁴ Similarly, Medicaid managed care initiatives that have sought to restrict both the supply of services and the outlets through which covered services can be secured, have been shown to raise significant issues for low income persons who have both elevated health care needs and heightened vulnerability to system navigation barriers.⁵⁵

Ostensibly of course, competitive acquisition techniques do not withdraw coverage but instead attempt to effectuate more efficient coverage by employing competition techniques to reduce the range of coverage and the outlets for services. But in real world terms, these may be distinctions without a difference where low-income beneficiaries with elevated health needs are concerned. If the practical effect of competitive acquisition is to make it harder for certain populations to secure covered services, the adverse results can be expected to be the same as the results that flow when coverage is actually limited or reduced through the use of patient cost sharing.

As this analysis underscores, there is a glaring absence of systematic evidence regarding how Medicare beneficiaries – especially those most at risk for disparities in health and health care – secure health care services that can be obtained either through community retail outlets or through mail-order. Research into the characteristics of low-

⁵² Goldman, D., G. Joyce and Y. Zheng. 2007. "Prescription Drug Cost Sharing." *Journal of the American Medical Association* 298(1): 61-69.

⁵³ Mahoney, J. 2005. "Reducing Patients Drug Acquisition Costs Can Lower Diabetes Health Claims." *American Journal of Managed Care* 11(5 Supplement): S186-188; Goldman, D., G. Joyce and Y. Zheng. 2007. "Prescription Drug Cost Sharing." *Journal of the American Medical Association* 298(1): 61-69.

⁵⁴ Dor A, Encinosa W. 2004 "Does Cost Sharing Affect Compliance? The Case of Prescription Drugs (Diabetes)." *National Bureau of Economic Research Inc; NBER Working Paper Series, No. 10738.*

⁵⁵ Michael Perry and Neil Robinson, *Individuals with Disabilities and Their Experiences with Medicaid Managed Care* (Kaiser Commission on Medicaid and the Uninsured, Washington D.C. 1999) (accessed December 9, 2007 at

<http://www.kff.org/medicaid/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=13326>)

income Medicare beneficiaries who live at home in low income communities becomes essential in assessing the implications of extending competitive acquisition to populations that are not already adept users of mail-order systems.

The CMS data on mail-order provide no insight into the characteristics of the Medicare beneficiaries who engage in mail-order purchasing, either by telephone or online. The evidence suggests that retail community outlets remain critical for diabetes supplies; one recent study concluded that over 60 percent of all elderly persons purchase their blood glucose test strips from a community-based retail pharmacy (no similar information appears to be available for Medicare beneficiaries with disabilities).⁵⁶

Put another way, the CMS data on mail-order reflect the *total amount of supplies purchased*. But these data are not particularly helpful, since they fail to offer any insight into the *characteristics of the Medicare beneficiaries who engage in mail-order purchasing, either by telephone or online*. For this reason, the known evidence regarding the impact of patient-centered cost containment on at-risk populations should raise red flags about the wisdom of extending competitive acquisition techniques without careful review, particularly in the case of populations for whom such services are essential to their ability to engage in self care. Indeed, for these populations, the emphasis should be on aggressive efforts to expand community access points.

4) Paradoxically, higher overall Medicare diabetes costs may result from expanded use of mail-order systems

As noted above, if the effect of aggressive use of mail-order systems lacking patient safeguards is to drive down rates of blood glucose self-testing, mail-order may ultimately produce overall negative cost consequences for Medicare. The competitive purchasing demonstrations, with their exclusive focus on driving down the unit price of testing supplies through the use of high volume competitive acquisition techniques, do not provide evidence of overall impact, a serious shortcoming of the research on which the 2003 legislation was based.

But the economic shortcomings of the demonstrations extend beyond their failure to consider broader, long term consequences to the program. The demonstrations fail to consider whether high volume purchasing at discounted unit prices may, in fact, have precisely the opposite impact on the overall cost to Medicare of diabetes testing supplies themselves. This result may obtain if mail-order systems cause the volume of testing supplies to skyrocket – albeit at discounted unit prices – even as wastage mounts and beneficiaries whose supplies do not conform to their needs return to the retail market to compensate for inappropriate supplies.

Volume purchasing can yield a decline in unit prices. But if suppliers respond to discounts by increasing the volume, and if that volume involves inappropriate services,

⁵⁶ Health Policy R and D. “Medicare’s New Competitive Acquisition Program for Durable Medical Equipment: Policy Considerations Involving Beneficiaries with Diabetes, Community Based Retail Pharmacies, and Blood Glucose Monitoring.” Washington D.C., January 2006.

then the results of volume procurements may be precisely the opposite of what was intended: an overall cost increase as supplies of inappropriate goods and services mount and patients search for substitutes. Exactly this type of phenomenon has been documented in DMEPOS supplier businesses. A recent GAO study found “atypical” increases in the volume of supplies sold to Medicare over a 12-month time period, well beyond the amount of supplies and equipment sold “in the routine course of medical care.”⁵⁷

Conclusion and Recommendations

Two basic recommendations flow from this analysis.

First, the immediate focus should be on the development of explicit patient protections applicable to the mail-order diabetes supplies market. The differential treatment of the DMEPOS competitive market from other competitive markets for Medicare items and services, especially the Part D prescription drug benefit and Medicare Advantage, is glaring. To an extent far greater than recognized under the statute and regulations, Part B durable medical equipment, prosthetic and orthopedic items, and medical supplies all touch beneficiaries in very real ways. The items and services covered by DMEPOS – in particular diabetes supplies – are purchased not by health care professionals but by the beneficiaries themselves. Millions lack the ability, knowledge and experience to navigate a competitive system. Essential protections are needed in the area of marketing, enrollment and disenrollment, benefit design, quality standards, and patient protections. The near-total absence of protections is further exacerbated by the message sent in the legislation itself, namely, that price discounting is so important that the Secretary should pursue competitive acquisition even in the absence of quality standards.

Second is the need for an evaluation of mail-order diabetes supplies in the competitive acquisition program. It would indeed be ironic if, after rushing headlong into competitive mail-order purchasing, it turned out that the very absence of safeguards incentivized suppliers to over-supply products, actually increasing spending but not improving health outcomes. What is urgently needed at this point – prior to any consideration of expansion of competitive acquisition for diabetes supplies – is a careful evaluation of the mail-order system. Such an evaluation should consider the cost, access and quality effects of mail-order product acquisition. Furthermore, unlike the earlier studies, additional research should be structured to examine not only aggregate measures of patient impact, but also the experiences of patients who face higher social and health risks as well as patients who may have encountered either excessive and unwanted supplies, supplier resistance to patient or clinician efforts to change their practices, or both.

Simply put, we believe that the federal government should halt any expansion of competitive acquisition of diabetes supplies in the absence of further research. Given the

⁵⁷ GAO, *Improvements Needed to Address Improper Payments for Medical Equipment and Supplies* (GAO-07-59, January, 2007).

current, inadequate level of understanding regarding the effects of competitive bidding, we believe that before competitive acquisition is extended, careful evaluation of Medicare patient behavior, particularly behavior of vulnerable beneficiaries in navigating competitive systems, is essential. Very little is known about how Medicare beneficiaries experience market based health care systems. The few studies that do exist focus on systems that possess relatively extensive patient safeguards compared to the current situation under the DMEPOS competitive acquisition program.

Several types of information would be useful in examining the effect on disparities. For example, what proportion of low income beneficiaries live alone or with others? Similarly, what proportion of low-income Medicare beneficiaries living in the community have telephone service or cognitive impairments that would affect their ability to order supplies by phone? What proportion have access to community health and social services supports, such as a visiting nurse or meals-on-wheels program that might step in to monitor their supplies and ensure replacement orders? In sum, it is the 40 percent of all Medicare beneficiaries who are low income – and in particular, the 7.5 million poorest beneficiaries – whose welfare should be of primary consideration in determining whether to expand competitive acquisition to essential primary health care services.

The final, though no less critical, area for study is the nature of the safeguards that would need to be in place – not only for individual beneficiaries, but also in communities that experience high concentrations of low-income and minority populations – before proceeding with further expansion of the competitive acquisition program in the case of diabetes supplies. Within large demonstration market areas, which sub-geographic areas merit particular attention to access design and to access measurement in view of high poverty and already-depressed access to care? Do these communities possess essential outlets (e.g., pharmacies, community health centers, other clinics, grocery stores) that *must* continue to participate as outlets? What process will be used to monitor the purchasing patterns of at risk beneficiaries living in the community to ensure that they are not inadvertently cut off from blood glucose monitoring equipment and supplies? What emergency bypass procedures are essential to guard against the loss of access to ready replenishment of supplies?

In considering an expansion of the competitive acquisition program, the government should bear the burden of demonstrating that the benefits significantly outweigh the risks, not only for patients in the aggregate but for discrete patient sub-populations who already experience barriers to care. This burden simply cannot be met without a commitment to additional economic and statistical research to produce evidence regarding both the direct and indirect effects of competitive bidding. Crucial direct effects are patient self-monitoring and monitoring errors, with results collected by race, ethnicity, socioeconomic status, and health status. Any further research should examine not only potential initial cost savings, but also long term health care savings through consistent or increased testing compliance.