



**MEDICARE'S NEW COMPETITIVE
ACQUISITION PROGRAM FOR DURABLE
MEDICAL EQUIPMENT:**

**POLICY CONSIDERATIONS INVOLVING
BENEFICIARIES WITH DIABETES,
COMMUNITY-BASED RETAIL PHARMACIES
AND BLOOD GLUCOSE MONITORING**

**On Behalf of the
National Association of Chain Drug Stores**

HealthPolicy R&D
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TABLE OF CONTENTS

CHAPTER ONE: INTRODUCTION.....	1
A. Report Objectives.....	2
B. Report Methodology	2
C. Summary of Findings	3
CHAPTER TWO: COMPETITIVE ACQUISITION – A WORK IN PROGRESS.....	5
A. Medicare’s Competitive Bidding Demonstration for DME	5
B. Medicare’s New Competitive Acquisition Program for DME.....	7
CHAPTER THREE: FINDINGS	9
A. The Use of Glucose Monitors is an Integral Component of the Pharmacologic Interventions Used in the Chronic Management of Diabetes	10
B. The Leading Source of Glucose Monitors and Supplies for the Elderly is the Community-Based Retail Pharmacy Setting, and This is in Contrast to Most Items Potentially Subject to the DME Competitive Acquisition Program	11
C. DME Competitive Acquisition may Interact with Part D to Create Unnecessary Fragmentation of the Provision of Medications, Equipment and Supplies for the Control of Glucose Levels in Patients with Diabetes.....	12
D. CMS Does Not Have Experience with DME Competitive Bidding or Acquisition of Glucose Monitors and Supplies in the Retail Pharmacy Setting.....	13
E. The Diversity of Functional Characteristics among Glucose Monitors for Patients with Differing Needs Provides a Significant Complicating Factor for the Application of DME Competitive Acquisition to Glucose Monitors ..	14
F. The DME Competitive Acquisition Program Could Operate Contrary to Medicare’s Current and Future Initiatives that are Designed to Promote Adherence to Blood Glucose Regimens and Reduce Overall Costs	17

**MEDICARE’S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE
MEDICAL EQUIPMENT**

G. Community-Based Pharmacy Programs are Improving Blood Glucose Management and Health Outcomes for Patients with Diabetes and Attracting Interest from Employer-Based and Other Private Sector Efforts to Improve Diabetes Care20

CHAPTER FOUR: CONCLUSIONS24

APPENDIX A. LIST OF STAKEHOLDER INTERVIEWEES I

APPENDIX B. INTERVIEW GUIDEIII

CHAPTER ONE: INTRODUCTION

Medicare provides beneficiaries with access to glucose monitors and test strips that are necessary for the self-monitoring of blood glucose under Medicare Part B.^{1,2} Self-monitoring of blood glucose levels with glucose monitors and test strips is an integral component of the pharmacologic therapies used for the chronic management of patients with both type 1 and type 2 diabetes.

In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). This legislation directs the Centers for Medicare and Medicaid Services (CMS) to change the Medicare program in several ways that are significant for patients treated with insulin or other prescription drug therapies used to control blood glucose levels. Specifically:

- The MMA establishes a new prescription drug benefit under Medicare Part D that became effective on January 1, 2006. This benefit provides Medicare coverage for the first time for the chronic use of subcutaneous insulin and oral prescription drugs used to control blood glucose levels in persons with diabetes. In addition, certain high-cost beneficiaries with diabetes and other chronic illnesses will receive medication therapy management services under Part D to optimize their drug regimens and to improve adherence to their medication therapies.
- The MMA also directs CMS to establish a competitive acquisition program for durable medical equipment (DME), related supplies and certain other items under Medicare Part B.³ CMS must begin implementation of this program in 2007. At this point, it is unclear whether, when and how CMS might apply the new competitive acquisition program to glucose monitors and test strips.

This Report arises from concerns regarding how Medicare's new prescription drug benefit and other recent efforts to improve care for Medicare beneficiaries with diabetes may be adversely altered if glucose monitors, test strips and related services are subject to the DME competitive acquisition program. Medicare's prior DME competitive bidding demonstration program did not include glucose monitors or supplies, and there is no experience to indicate whether these products can be purchased in this manner without undue risk to beneficiaries.⁴

¹ Centers for Medicare and Medicaid Services (CMS). Medicare National Coverage Determinations Manual. CMS Pub. 100-3. Accessed September 18, 2005 at http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp.

² Palmetto GBA. Local Coverage Determinations (LCD) for Glucose Monitors (L11520). Accessed on CMS's Medicare Coverage Database August 8, 2005 at

http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=11520&lcd_version9&show=all.

³ Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Pub. L. 108-173, § 302(b), (2003), *amending* Social Security Act (SSA) § 1847.

⁴ Government Accountability Office (GAO). Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies. September 2004. GAO-04-765. [GAO 2004]

A. Report Objectives

The National Association of Chain Drug Stores (NACDS) commissioned *HealthPolicy R&D*⁵ to examine potential considerations for policymakers involving Medicare beneficiaries with diabetes who must use blood glucose monitors as part of the pharmaceutical management of their blood glucose levels. This Report examines Medicare's new DME competitive acquisition program and the potential impacts for beneficiaries with diabetes.

In this Report, *HealthPolicy R&D* examines the following issues:

- The chronic management of blood glucose levels in patients with diabetes — including the use of blood glucose monitors and test strips — and the clinical, technical and patient access issues that policymakers should understand in the context of Medicare's new competitive acquisition program for DME.
- Initiatives by employers and the private sector to develop and implement community pharmacy-based interventions to help manage the care of patients with diabetes.
- Medicare's policies and initiatives that have direct impacts on beneficiaries with diabetes, such as the new prescription drug benefit under Medicare Part D, the coverage policies for blood glucose monitors and supplies under Medicare Part B and the new competitive acquisition program for DME under Medicare Part B. This analysis includes the possible effects of these policies and initiatives on the provision of diabetic care for Medicare beneficiaries.

B. Report Methodology

In preparing this Report, *HealthPolicy R&D* used the following methodology:

- **Literature Review:** *HealthPolicy R&D* conducted a review of the existing literature to identify important themes and trends relating to diabetes disease management, self-monitoring of blood glucose, pharmacy services for diabetes patients and CMS's competitive acquisition program for DME. This literature review included medical and peer-reviewed journals, government-sponsored publications, databases maintained by the U.S. Food and Drug Administration (FDA) and news media sources.
- **Statutory and Regulatory Review:** *HealthPolicy R&D* conducted an analysis of current federal statutory provisions governing the implementation of Medicare's competitive acquisition program for DME. *HealthPolicy R&D* attended the meetings of the Program Advisory and Oversight Committee (PAOC), which Congress and CMS established to provide a public forum to discuss the implementation of the DME competitive acquisition program. Additionally, *HealthPolicy R&D* examined federal laws and regulations

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MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

governing Medicare programs and benefits affecting beneficiaries with diabetes, including: the coverage policies governing glucose monitors and supplies; the new prescription drug benefit and medication therapy management services provided under Part D; and the ongoing demonstration and pilot programs that target beneficiaries with chronic illnesses, including diabetes.

- **Interviews with Thought Leaders:** *HealthPolicy R&D* conducted telephone interviews with a range of stakeholders with expertise in the care, training and education of patients with diabetes, including physicians, pharmacists, diabetes educators, researchers and other professionals from the pharmacy and manufacturing sectors. A list of interviewees and *HealthPolicy R&D's* interview guide are provided at Appendices A and B.
- **Analysis of the Marketplace for Blood Glucose Monitors and Supplies:** *HealthPolicy R&D* collaborated with IMS Health, Inc. to conduct an analysis of industry data involving sales of blood glucose test strips in retail and mail order channels, including an analysis of purchasing patterns by age and type of health care coverage. Data were from the second quarter of 2005 and were obtained from two databases: IMS National Sales Perspective and IMS Xponent Plan Trak. Data for the IMS National Sales Perspective database reflect retail pharmacies (independent/chain pharmacies, mass merchandisers, proprietary stores and food stores with pharmacies) and non-retail pharmacies (federal and non-federal hospitals, clinics, health maintenance organizations, long-term care facilities, home health agencies and other entities). The IMS Xponent Plan Trak data are based on prescriptions filled and are obtained from more than half of all retail pharmacies in the United States, approximately one-quarter of all long-term care facilities and over 70 percent of all mail order outlets.

C. Summary of Findings

A number of findings are discussed in greater detail in this Report, including the following:

- **The Current Role of Community-Based Retail Pharmacies:** Most Medicare beneficiaries currently obtain medically necessary glucose monitors and related supplies from community-based retail pharmacies rather than from home care suppliers or mail order companies.
- **Limitation on Access:** Competitive acquisition programs generally limit the number of entities that may participate in such programs. If glucose monitors and supplies were subject to the competitive acquisition program, then some or all of the community pharmacies in a region could lose the bidding process and be unable to supply these items under Medicare. As a result, a competitive acquisition program that includes glucose monitors and supplies could create a confusing and perhaps contradictory situation. Medicare beneficiaries with diabetes could find it impossible or difficult to obtain medically necessary medications to control their glucose levels (under Medicare Part D) and glucose monitors and supplies (under Medicare Part B) from the same pharmacy.

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

- **Fragmentation of Care:** Such fragmentation in the provision of the full spectrum of diabetic medications, supplies and equipment is inconsistent with virtually all other policies and initiatives (both public and private) with respect to the care of persons with diabetes.
- **Diversity of Products and Patient Needs:** There are many different types of glucose monitors and supplies grouped together under the same billing codes. A competitive acquisition program may easily create incentives for winning bidders to promote lower cost items rather than matching the patients' needs with the most appropriate equipment and supplies.
- **The Costs of Failing to Control Glucose Levels in Patients with Diabetes:** Mismanaged care for diabetes patients and the failure to achieve control of patients' glucose levels could result in sizable healthcare expenditures that are borne by the Medicare program and other health insurance plans.
- **The Educational Role Played by Pharmacists:** Mounting evidence shows that pharmacist-based programs can result in clinically significant improvements in health outcomes for patients with diabetes. Given the growing interest in these initiatives as part of disease management programs in both the private and public sectors, it may be ill-advised to risk disrupting these patient-pharmacy relationships at the same time that further experience is being gained in the use of community-based pharmacies to promote adherence to blood glucose treatment and monitoring regimens.

CHAPTER TWO: COMPETITIVE ACQUISITION – A WORK IN PROGRESS

Under the Balanced Budget Act of 1997, Congress authorized CMS to test competitive bidding as a method for Medicare to establish prices and to reimburse for some categories of DME covered under Medicare's outpatient (Part B) benefit.⁶ Under this demonstration program, CMS opted to exclude glucose monitors and test strips due to concerns that competitive bidding could interfere with beneficiary access to the full range of necessary supplies.⁷ As a result, Medicare has never applied competitive bidding or competitive acquisition principles to glucose monitors or test strips.⁸

In 2003, Congress directed CMS to establish a competitive acquisition program for certain categories of DME and other items under Medicare Part B beginning in 2007.⁹ Under this competitive acquisition program, CMS can limit the number of suppliers selected to participate based on CMS's assessment of the needs of the Medicare beneficiaries in a particular area. As a result, Medicare beneficiaries will be unable to obtain Medicare coverage for DME items and services from suppliers that are not selected by CMS in the bidding process.

It remains unclear whether or when glucose monitors and supplies will be included under the DME competitive acquisition program. Under the MMA, CMS has the authority to exclude items and services that are unlikely to result in significant savings. CMS also has the authority to phase-in first those items that CMS deems to be the highest cost or highest volume items, as well as those deemed to have the greatest potential to achieve savings for Medicare under competitive acquisition.¹⁰

A. Medicare's Competitive Bidding Demonstration for DME

CMS conducted the competitive bidding demonstration program in Polk County, Florida and San Antonio, Texas between 1999 and 2002.¹¹ Items included in the demonstration were identified by Healthcare Common Procedure Coding System (HCPCS) codes.

⁶ Balanced Budget Act of 1997. Pub. L. No. 105-33, § 4319(a), 111 Stat. 251, 392 (1997).

⁷ GAO 2004.

⁸ Congress and CMS has used the term "competitive bidding" to refer to the demonstration project authorized under the Balanced Budget Act of 1997 and the term "competitive acquisition" to refer to the program for DME established under the MMA. The competitive bidding demonstration was a precursor to the new competitive acquisition program, and many people use the terms "competitive bidding" and "competitive acquisition" interchangeably. The terminology is complicated further by the "competitive acquisition program" for Medicare Part B prescription drugs that Congress also established under the MMA. The program for prescription drugs, often referred to as "the CAP," is structured differently from the DME competitive acquisition and is a separate program.

⁹ MMA, § 302(b), (2003), *amending* Social Security Act (SSA) § 1847.

¹⁰ *Id.*

¹¹ The Polk County demonstration prices were in effect from October 1999 through September 2002. Demonstration prices in the San Antonio area were in effect from February 2001 through December 2002.

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

CMS's decision to exclude glucose monitors and test strips from the demonstration was based in part on the large range of glucose monitors that fall within the existing HCPCS code (E0601) and the corresponding large range of products that fall within the existing HCPCS code for glucose monitor test strips (A4253).¹² The potential application of competitive acquisition to these products is complicated because most commercially-available monitors have unique test strips that each type of monitor must use. The range of unique monitors and the lack of interchangeability of the test strips render this product area readily distinguishable from many other types of DME (see additional discussion in Chapter Three).

Of the eight categories of products included in the demonstration, CMS included two product areas (oxygen and related products and hospital beds and accessories) in both demonstration sites. In addition to these two products, the Polk County demonstration site initially included the following three categories of products: enteral nutrition formulas, equipment and supplies; urological supplies; and surgical dressings. In San Antonio,¹³ the categories of products selected for the demonstration in addition to oxygen and hospital beds were: manual wheelchairs and accessories; nebulizer inhalation drugs; and non-customized general orthotics.

After the demonstration's initial year in Polk County, CMS decided to remove enteral nutrition formulas because the common setting of care for enteral formulas differed significantly from most other items subject to competitive bidding. Specifically, although most products included within the competitive bidding demonstration are provided by traditional DME suppliers in the home of the beneficiary, the majority of beneficiaries receiving enteral nutrition under Medicare Part B are residents of nursing homes.¹⁴

Generally, CMS concluded that the demonstration program resulted in lower prices without substantial negative impacts on beneficiaries' access to products or the quality of the goods and services provided. However, concerns were raised about product substitution and inadequate service for some items. In the final evaluation of the demonstration program, the evaluators concluded that urological supplies were a poor candidate for future competitive bidding programs.¹⁵

For urological supplies, concerns were raised in the final evaluation of the demonstration about at least two factors: suppliers did not always provide the most functionally-appropriate catheter because of variation of products within the HCPCS code; and there was a significant increase in the percentage of beneficiaries who reported receiving no training when obtaining their urological equipment and supplies.¹⁶

CMS concluded that these issues may have resulted from the relative inexperience of some

¹² GAO 2004.

¹³ There was no second bidding cycle in San Antonio.

¹⁴ University of Wisconsin-Madison, Center for Health Systems Research and Analysis—RTI International, Division of Health Economics Research. Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS. November 2003. Accessed July 18, 2005 at <http://www.cms.hhs.gov/healthplans/research/dmebid.asp>.

¹⁵ *Id.*

¹⁶ *Id.*

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

suppliers with urologicals, cost pressures related to underbidding or an increase in mail delivery of urological supplies. CMS determined that there could be a deleterious effect on product selection if suppliers offering a choice of urological products left the market and only suppliers that limited their offerings to a single brand remained.¹⁷

Given the very significant range of products and functional characteristics among commercially-available glucose monitors and test strips that fall within the same HCPCS codes, similar concerns should exist for glucose monitors and test strips (see discussion in Chapter Three).

B. Medicare's New Competitive Acquisition Program for DME

CMS must implement the new DME competitive acquisition program in ten of the largest metropolitan statistical areas (MSAs) by 2007, 80 of the largest MSAs by 2009 and other areas after 2009. Congress instructed CMS to phase-in first those items and services that are among the highest cost and highest volume items and services, as well as those deemed by CMS to have the greatest potential to achieve Medicare savings.

To date, CMS has not published any proposed or final decisions regarding the items, services, MSAs or terms applicable to DME competitive acquisition. Congress and CMS created the PAOC to provide technical guidance on the establishment and implementation of the competitive acquisition program. The PAOC has held periodic public meetings to explore issues related to competitive acquisition of DME, including payment issues, data collection and quality standards.¹⁸

There are several components of the DME competitive acquisition program that are particularly relevant to this analysis. For example, the MMA required CMS to develop and implement quality standards for DME, prosthetic devices, orthotics and prosthetics, and parenteral and enteral nutrition.¹⁹ Once developed by CMS, the standards must be applied by independent accrediting organizations.²⁰ Suppliers must comply with the standards to maintain or receive a supplier number, which is necessary to bill the Medicare program for covered items and services.

On September 23, 2005, CMS posted draft quality standards on its website and requested public comments.²¹ The comment period ended on November 28, 2005. These draft quality standards are divided into two parts — general requirements (mostly financial and organizational requirements) that apply to all Part B suppliers, and product-specific requirements that apply

¹⁷ *Id.*

¹⁸ Information regarding the PAOC and the substance of its meetings is available on the CMS website at (accessed November 22, 2005) <http://www.cms.hhs.gov/suppliers/dmepos/compbid/paoc.asp>.

¹⁹ See generally, Section 302 of the MMA, creating § 1834(a)(20) of the Social Security Act (SSA) (42 U.S.C. § 1395m(a)(2)).

²⁰ *Id.*

²¹ CMS. Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services: Draft of Proposed Recommendations. Sept. 26, 2005. Accessed at <http://www.cms.hhs.gov/suppliers/dmepos/compbid/default.asp>.

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

only to suppliers of particular products and services. The draft quality standards include standards for diabetic equipment and supplies.²²

Congress directed CMS to develop the quality standards on a parallel track with the competitive acquisition program. Congress intended that the quality standards would play an important role in the competitive acquisition program, helping to ensure that Medicare beneficiaries receive quality care. The strength of the standards in a particular area, as well as the degree to which the standards ensure patient access to a range of products, will have important impacts on whether a product area is a good candidate for inclusion in the competitive acquisition program.

There are a number of other aspects of the competitive acquisition program that warrant examination, including the following:

- CMS must select more than one supplier for each competitive acquisition area for each product category chosen for the program, but CMS can limit the number of suppliers chosen to the amount deemed by CMS sufficient to meet beneficiaries' demand in the area.
- CMS must ensure consideration of small businesses in selecting suppliers to participate in the program, but CMS is not required to establish a small business carve-out to ensure that a particular percentage of Medicare beneficiaries are treated by small businesses.
- Based on the bids submitted, CMS will establish a single payment amount for each item or service in each competitive acquisition area.
- Competitive acquisition contracts must be re-competed at least every three years.
- CMS's selection of suppliers and pricing decisions are not subject to administrative or judicial review.²³

²² *Id.*

²³ Section 302(b) amending SSA § 1847 (42 U.S.C. § 1395w-3).

CHAPTER THREE: FINDINGS

Providing effective treatment and chronic management of diabetes is an important objective for the Medicare program. Diabetes is responsible for significant morbidity and mortality. Nearly one-fifth (18 percent) of all Medicare beneficiaries have diabetes, and beneficiaries with diabetes account for approximately one-third of all Medicare spending.²⁴ Controlling blood glucose levels in individuals with type 1 or type 2 diabetes improves health outcomes, slows the progression of disease and prevents complications of diabetes.^{25,26,27}

For example, the importance of glucose control and the daily use of home glucose monitors is demonstrated in a recent study funded by the National Institutes of Health. The investigators found that intensive efforts to control blood glucose levels in patients with type 1 diabetes — including self-monitoring of blood glucose levels by patients at least four times per day — resulted in significant reductions in cardiovascular complications (such as heart attacks and strokes) over long-term follow-up. Patients with less intensive efforts to control blood glucose levels without daily monitoring of blood glucose levels experienced a greater incidence of adverse cardiovascular events during long-term follow-up.²⁸

The findings of this Report focus on issues of importance to policymakers when considering whether or how to subject glucose monitors and test strips to the new competitive acquisition program for DME under Medicare Part B. Among other issues, these findings examine the following questions:

- How do glucose monitors and testing supplies differ, if at all, from other items that are potentially subject to Medicare's DME competitive acquisition program?
- What roles do community-based retail pharmacies play in providing Medicare beneficiaries with access to glucose monitors and test strips?
- What are some of the potential concerns that exist in applying competitive acquisition to glucose monitors and test strips?

²⁴ CMS. Medicare Health Support to Improve Care of Beneficiaries with Chronic Illnesses. Medicare Fact Sheet. Accessed September 8, 2005 at <http://www.cms.hhs.gov/medicarereform/ccip/>.

²⁵ McCulloch D. Managing diabetes for improved health and economic outcomes. *The American Journal of Managed Care*. 2000;6(21):S1089-S1095.

²⁶ Diabetes Control and Complications Trial (DCCT) Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine*. 1993;329(14):977-986.

²⁷ UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*. 1998;352(9131):837-853.

²⁸ The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group. Intensive Diabetes Treatment and Cardiovascular Disease in Patients with Type 1 Diabetes. *New England Journal of Medicine*. 2005; 353(25):2643-53.

These issues are discussed in greater detail below.

A. The Use of Glucose Monitors is an Integral Component of the Pharmacologic Interventions Used in the Chronic Management of Diabetes

The use of glucose monitors is a recommended and integral component of the pharmacologic regimens that are used to manage both type 1 and type 2 diabetes. The roles that glucose monitors play in these pharmacologic regimens are reflected in longstanding Medicare policy. For example, the policies of Medicare's durable medical equipment regional carriers (DMERCs) allow coverage of glucose monitors for beneficiaries with diabetes regardless of whether they use insulin. The volume of testing supplies for which the patient is eligible varies (those using insulin are expected to self-monitor their glucose levels more frequently).²⁹

Under current policies, Medicare beneficiaries may secure their glucose monitors and supplies from any pharmacy that participates in the Medicare program as a supplier of DME. In practice, this means that Medicare beneficiaries can obtain all of their covered equipment, supplies and prescription drugs for managing their diabetes from a single source — their community-based retail pharmacy.

The total financial costs of diabetes and its complications are staggering. Controlling blood glucose levels can reduce the occurrence of costly complications from diabetes.³⁰ In fact, the majority of the health care expenses for diabetes are spent on the complications arising from diabetes.

- For patients of all ages, only about 25 percent of health care expenses for diabetes are due to uncomplicated diabetes and diabetes-related supplies and the majority of costs arise from the treatment of diabetes-related conditions and complications.³¹
- The direct medical cost of treating elderly patients with diabetes in 2002 was estimated to be \$48 billion.³²
- Medicare beneficiaries with diabetes account for a disproportionate share of Medicare expenditures. The estimated 18 percent of Medicare beneficiaries with diabetes account

²⁹ Palmetto GBA. Local Coverage Determinations (LCD) for Glucose Monitors (L11520). Accessed on CMS's Medicare Coverage Database August 8, 2005 at

http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=11520&lcd_version9&show=all.

³⁰ Centers for Disease Control and Prevention (CDC). National Diabetes Fact Sheet, United States, 2003. Accessed November 23, 2005 at <http://www.cdc.gov/diabetes/pubs/factsheet.htm>.

³¹ Hogan P, Dall T, Nikolov P. Economic costs of diabetes in the U.S. in 2002. *Diabetes Care*. 2003;26(3):917-932.

³² *Id.* This estimate reflects the amount of health care expenditures attributable to providing services to diabetes above the costs they would have incurred if the patients did not have diabetes. This estimate includes expenditures for the treatment of medical conditions directly related to diabetes and for conditions that are complications of the disease.

for 32 percent of total Medicare spending.³³

- The most costly 10 percent of beneficiaries with diabetes have annual health care expenditures in excess of \$25,000 per patient.³⁴

B. The Leading Source of Glucose Monitors and Supplies for the Elderly is the Community-Based Retail Pharmacy Setting, and This is in Contrast to Most Items Potentially Subject to the DME Competitive Acquisition Program

Elderly persons with diabetes purchase more than half (62 percent) of their blood glucose test strips from one of the more than 55,000 community-based retail pharmacies currently in operation.^{35,36} These community pharmacies include chain drug stores, independent pharmacies and pharmacies located in other stores, including supermarkets or mass merchandisers such as Wal-Mart. Patients with diabetes are reported to visit their pharmacies at least once each month to purchase diabetes medications and supplies.³⁷ In contrast, the predominant source of most other items of DME is the traditional DME supplier — not community-based retail pharmacies.

The purchase patterns of patients buying blood glucose monitors and supplies raises some concern regarding the inclusion of these supplies in a competitive bidding program. Patients currently are using a variety of monitors for self-testing their blood glucose levels whether they are paying out-of-pocket for the device (cash) or have health insurance that covers the cost.³⁸ This distribution suggests that there may be differences in monitor functional characteristics and design that are important for some individuals.

Most glucose monitors fall within a single HCPCS code. If there are important clinical or performance differences associated with the costs of monitors categorized within the same HCPCS code, a competitive bidding regimen could result in many beneficiaries having to switch monitors. Competitive bidding creates an incentive for suppliers to provide lower-cost monitors to beneficiaries. This competitive pressure may result in suppliers limiting the choice of monitors readily available to patients or forcing substitution to lower-cost brands of monitors or supplies. This type of forced change could be disruptive for beneficiaries with diabetes, especially for patients with strong preferences or whose conditions and circumstances make the use of a certain device more appropriate.

³³ CMS. Medicare Fact Sheet: Medicare Health Support to Improve Care of Beneficiaries with Chronic Illnesses. Accessed November 23, 2005 at <http://www.cms.hhs.gov/medicarerereform/ccip/factsheet1105.pdf>.

³⁴ Krop JS, Powe NR, Weller WE, Shaffer TJ, Saudek CD, Anderson GF. Patterns of expenditures and use of services among older adults with diabetes: implications for the transition to capitated managed care. *Diabetes Care*. 1998;21(5):747-752.

³⁵ IMS Health, Inc. Data were from first quarter 2005 from IMS National Sales Perspective and IMS Xponent Plan Trak databases. [IMS Data] (See additional discussion in Chapter One of this Report.)

³⁶ Knapp K, Ray M, Okamoto M, Chang P. The Role of Community Pharmacies in Diabetes Care: Eight Case Studies. *California HealthCare Foundation*. July 2005. [Knapp et al. 2005]

³⁷ *Id.*

³⁸ IMS Data.

C. DME Competitive Acquisition may Interact with Part D to Create Unnecessary Fragmentation of the Provision of Medications, Equipment and Supplies for the Control of Glucose Levels in Patients with Diabetes

Under DME competitive acquisition, CMS would limit the number of pharmacies and other suppliers that may provide glucose monitors and supplies to Medicare beneficiaries. This initiative could interfere with the ability of beneficiaries to obtain their glucose medications, glucose monitoring products and related professional guidance from a single source.

Such an outcome would be in direct conflict with basic principles and safeguards for access to pharmacies that Congress established under the new Medicare Part D prescription drug benefit. Under Medicare Part D, Congress ensured that beneficiaries would have access to retail pharmacies of their choosing within close proximity to their homes.

Section 1860D-4(b)(1) of the Social Security Act requires Part D plans to permit any pharmacy that is willing to accept the plans' terms and conditions to participate in the plan pharmacy network.³⁹ This requirement is intended to ensure adequate participation by community-based retail pharmacies as well as to support beneficiaries' access to prescription drugs.⁴⁰

In its interpretation of these provisions, CMS acknowledges that Part D plans may develop different sets of standard terms and conditions, one set for "preferred" retail pharmacies, another set of standard terms and conditions for "non-preferred" retail pharmacies, and additional sets for mail-order, infusion and long-term care pharmacies. Nonetheless, plans must accept into their pharmacy networks any pharmacy that is willing to contract with the plan based on the standard terms and conditions for that type of pharmacy.⁴¹

CMS also established retail pharmacy network standards that are similar to the Department of Defense's TRICARE program to ensure that plans satisfy the statutory requirement for providing "convenient access" to beneficiaries. The retail pharmacy network standards require that plans ensure the following:

- Ninety percent of Medicare beneficiaries in urban areas served by the plan live within two miles of a network pharmacy.
- Ninety percent of Medicare beneficiaries in suburban areas served by the plan must live within five miles of a network pharmacy.
- Seventy percent of enrollees in rural areas served by the plan must live within 15 miles of

³⁹ SSA § 1860D-4(b).

⁴⁰ Committee on Ways and Means, U.S. House of Representatives, Joint Explanatory Statement H.R. 1, 108th Cong. 146 (2003). Accessed at <http://waysandmeans.house.gov/Special.asp?section=43>.

⁴¹ Medicare Program; Medicare Prescription Drug Benefit; Final Rule, 70 Fed. Reg. 4193, 4254 (Jan. 25, 2005) (codified at 42 C.F.R. pts. 400, 403, 411, 417 and 423).

a network pharmacy.⁴²

Mail-order pharmacies may supplement a plan's retail pharmacy network, but mail-order pharmacies are not counted toward meeting the Part D pharmacy network standards. Plan networks also may include pharmacies outside of the plan's service area, although these pharmacies also do not count toward meeting the access requirements.⁴³

As discussed below, the predominant model in place for Medicare beneficiaries and other patients in the United States is one in which patients can access their glucose medications, glucose monitors and monitor supplies all from a single source — the local retail pharmacy. At the same time that many policymakers are recognizing the problems associated with the fragmented nature of our health care system, it may well be problematic to implement a system that would appear to interfere with the ability of beneficiaries to obtain their glucose management products — and related professional assistance — from a single source.

Given the well-established role that glucose monitors play in the pharmacologic management of diabetes, it appears inconsistent for Medicare to limit access to pharmacies for blood glucose equipment and supplies at the same time CMS is implementing multiple safeguards to ensure wide access to pharmacies providing prescription drugs for blood glucose management under Medicare Part D. This initiative could be disruptive to care as well as frustrating and confusing for Medicare beneficiaries.

D. CMS Does Not Have Experience with DME Competitive Bidding or Acquisition of Glucose Monitors and Supplies in the Retail Pharmacy Setting

Blood glucose monitors and supplies were excluded from Medicare's DME competitive bidding demonstrations conducted in Polk County, Florida, and San Antonio, Texas. This exclusion was due, in part, to concerns by CMS regarding the complexity of matching glucose monitors with the appropriate testing supplies in the context of such a program.⁴⁴ In general, most types of monitors are designed to work only with a specific type of test strip.

One issue that arose within CMS's competitive bidding demonstration provides a cautionary tale for including diabetes supplies in the competitive acquisition program. In the demonstration's final evaluation, it was noted that suppliers did not always provide preferred brands for urological supplies. One supplier consolidated its product line to one brand to obtain lower prices from the wholesaler and remain competitive under the demonstration — requiring beneficiaries to use this brand or go to another supplier if they preferred a different brand.

Evaluators of the demonstration noted that this type of response by suppliers could result in a deleterious effect on product selection, especially if suppliers offering a choice of urological

⁴² 42 C.F.R. § 423.410(a) (2005).

⁴³ *Id.*; 70 Fed. Reg. at 4249.

⁴⁴ GAO 2004.

products left the market and only suppliers that limited their offerings to a single brand remained. In addition, there was a significant increase in the percentage of beneficiaries who reported receiving no training when receiving their urological equipment and supplies.

These issues, which in part arose due to the diversity of functional characteristics among urological supplies, raise concerns about the potential adverse impacts of competitive acquisition for glucose monitors. As discussed below, there is significant diversity among the various functional characteristics available in glucose monitors.

E. The Diversity of Functional Characteristics among Glucose Monitors for Patients with Differing Needs Provides a Significant Complicating Factor for the Application of DME Competitive Acquisition to Glucose Monitors

There is a wide array of blood glucose monitors for home use that have different functional characteristics. These functional capabilities, which a number of interviewees described as being important to enhance patient adherence rates to blood glucose testing regimens, include the ability to draw blood from alternate sites, the ability to use smaller quantities of blood for each reading and the ability to store multiple readings.

An analysis of the IMS databases revealed that the majority of monitor and monitor supply purchases are for full feature, brand name items that are in the higher cost range of the monitors available on the commercial market.⁴⁵ The DME competitive acquisition program could require elderly patients to substitute their current monitors with lower-cost monitors. A number of interviewees stated that monitors should be selected on a patient-by-patient basis to match patient's clinical needs and circumstances. Interviewees also noted that monitor selection may be especially important for the elderly.

Interviewees from the pharmacy community highlighted that pharmacists can assist beneficiaries in selecting an appropriate monitor, and that retail pharmacies typically stock a range of monitors. In total, the IMS Data indicates that more than 50 types of diabetes test strips are purchased by elderly patients from retail pharmacies.⁴⁶ Interviewees reported that retail pharmacies typically can order and obtain the appropriate supplies for virtually any type of monitor that a beneficiary may be using.

Currently available monitors offer an array of functional characteristics, and interviewees noted that matching monitors to patients' needs and preferences was important to achieve improved adherence with self-monitoring activities. Patients can choose monitors that provide audible word prompts or larger displays, require less blood or produce results more quickly, to name a few of the ways in which monitor functional characteristics differ. A few monitors also

⁴⁵ IMS Data.

⁴⁶ *Id.*

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

minimize the effect of environmental factors or agents, such as humidity, which is known to affect the accuracy of results. The test strips used with the monitors differ as well. For example, some test strips are designed to handle easily or work with monitors that automatically draw the amount of blood required (See Table 1).⁴⁷

Table 1:
Summary of Select Monitor Functional Characteristics⁴⁸

Functional Characteristic	Number of Monitors with Functional Characteristic	Percent of Monitors with Functional Characteristic
Requires few steps (2 or fewer) to operate	11	33%
Monitor calibrates automatically for new test strips	5	15%
Test strip designed for improved ease of handling	19	58%
Testing can be done at alternate sites (e.g., palm, arm)	14	42%
Requires smaller amount of blood	19	58%
Notifies patient if blood sample is too small	7	21%
Offers warning or minimizes effects of blood-related or environmental factors that can effect accuracy (e.g., automatically corrects testing for variations in hematocrit levels and temperature)	2	6%
Provides test results in 10 seconds or less	12	36%
Display screen designed for improved ease of reading (e.g., larger size, backlighting provided)	11	33%
Stores 100 or more test results in memory	20	61%
Averages test results over time	14	42%
Results can be downloaded to a computer for analysis	21	64%
Total number of monitors reviewed	33	100%

Manufacturers continue to improve the functional characteristics of blood glucose monitors. According to the FDA, newer monitors have functions that make them easier to use than older meters, such as automatic timing, error messages or barcode readers to help patients calibrate

⁴⁷ American Diabetes Association. Resource Guide 2005. *Diabetes Forecast*. January 2005.

⁴⁸ *Id.*

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

their monitors.⁴⁹ In a recent eighteen month period, the FDA approved twenty-one applications for over-the-counter blood glucose test systems that were either new or offered improved testing capabilities or functional characteristics, such as accuracy at a wider range of glucose levels.⁵⁰

The range of currently available monitor functional characteristics allows patients to find a self-testing system with which they are comfortable and, in some cases, one that provides more accurate results given their individual circumstances. Interviewees and the literature identified the need to match patients with a specific monitor: no single monitor is optimal for everyone. The interviewees highlighted that monitors are not clinical substitutes for one another.

For example, monitor selection may have a direct impact on accuracy for patients with certain physical and cognitive conditions or for patients who reside in certain geographic areas. For example:

- Patients with diseases that affect hemoglobin in the blood (such as anemia) need a glucose monitor that can accommodate a wider-than-normal range of hematocrit levels or their blood-glucose results could be inaccurate.^{51,52}
- Patients who have memory problems, such as those in the early stages of Alzheimer's disease, may benefit from monitors that can provide audible, step-by-step directions for testing.
- Certain geographic factors, such as high altitude, temperature or humidity produce unpredictable results in some devices and should be considered when selecting a monitor.^{53,54}
- Patients in rural locations may benefit from monitors that allow data to be transmitted electronically to the doctor's office for review.⁵⁵

Older patients also may have different age-related needs and preferences for monitors, which could be adversely affected by limits that competitive bidding may place on the variety of blood glucose monitors available for purchase. Several age-related changes in perception, cognition and movement control can affect the ability of older diabetes patients to self-test.^{56,57,58} For

⁴⁹ FDA. Glucose Meters & Diabetes Management. Updated 2005. Accessed July 2005 at www.fda.gov/diabetes/glucose.html. [FDA 2005]

⁵⁰ FDA. Review of FDA's CHRH 5109(k) Premarket Notification Database. Search of database conducted September 6, 2005 for product codes NBW (Device: System, Test, Blood Glucose, Over The Counter).

⁵¹ Foster SA, Goode JV, Small RE. Home blood glucose monitoring. *The Annals of Pharmacotherapy*. 1999;33(3):355-363. [Foster et al. 1999]

⁵² FDA 2005.

⁵³ FDA 2005.

⁵⁴ Kirk and Rheney 1998.

⁵⁵ Foster et al. 1999.

⁵⁶ McLaughlin AC, Rogers WA, Fisk AD. Age-related glucomonitor design and selection: tools and principles for optimal solutions. *Diabetes Technology & Therapeutics*. 2004;6(3):319-325. [McLaughlin et al. 2004]

example, older adults may find color-coding on screens and flashing indicators difficult to detect or find using small buttons or touch screen icons difficult to use.^{59,60,61,62,63}

The incentives inherent in competitive bidding could drive suppliers to offer lower-cost monitors and supplies and may limit the choice of monitors available to patients. These factors could make it difficult to effectively match monitors with patients' needs and circumstances. The American Diabetes Association has stated in a recent publication that any type of controls to manage costs, such as the use of competitive bidding, should ensure that diabetes patients have access to "all classes of equipment and supplies for use with such equipment without undue controls" in order to help them achieve glycemic goals and reduce the risk of complications.⁶⁴

As noted above, an array of monitors are available for sale in the commercial market, most of which fall under the same HCPCS code. One interviewee described the application of a competitive acquisition program to diabetes self-monitoring supplies as "a step back" in time away from the many advances in diabetes medication and supplies that provide patients with an "arsenal" of tools to combat their disease.

Reducing the selection of monitors currently available also could reduce the ability of health care professionals and patients to select a monitor that best meets the needs of the patient and could result in decreased adherence with self-monitoring activities. The experts interviewed by *HealthPolicy R&D* felt strongly that the selection of a monitor involves "a lot of judgment" and is a decision that should be made by a healthcare professional who can assess and evaluate the patient rather than the result of best price or supplier competition.

F. The DME Competitive Acquisition Program Could Operate Contrary to Medicare's Current and Future Initiatives that are Designed to Promote Adherence to Blood Glucose Regimens and Reduce Overall Costs

In both the public and private sectors, payers are placing increasing emphasis on better management of the care of patients with diabetes. This dynamic is not only in response to the

⁵⁷ Skelly AH, Arcury TA, Snively BM, Bell RA, Smith SL, Wetmore LK, Quandt SA. Self-monitoring of blood glucose in a multiethnic population of rural older adults with diabetes. *The Diabetes Educator*. 2005;31(1):84-90.

⁵⁸ Mayes M. Management of the older person with diabetes in the community. *British Journal of Community Nursing*. 2000;5(9):448-453.

⁵⁹ Briggs AL and Cornell C. Self-monitoring blood glucose (SMBG): now and the future. *Journal of Pharmacy Practice*. 2004;17(1):29-38.

⁶⁰ McLaughlin et al. 2004.

⁶¹ Bernbaum M, Albert SG, McGinnis J, Brusca S, Mooradian AD. The reliability of self blood glucose monitoring in elderly diabetic patients. *Journal of the American Geriatrics Society*. 1994;42(7):779-781.

⁶² Tu KS, McDaniel G, Gay JT. Diabetes self-care knowledge, behaviors, and metabolic control of older adults—the effect of a post educational follow-up program. *The Diabetes Educator*. 1993;19(1):25-30.

⁶³ Funnell MM and Merritt JH. The challenges of diabetes and older adults. *Nursing Clinics of North America*. 1993;28(1):45-60.

⁶⁴ American Diabetes Association. Standards of medical care in diabetes. *Diabetes Care*. 2005;28:S4-S36.

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

significant adverse impacts this disease has on patient health, but also to the significant costs arising from patients with diabetes.

For example, Medicare is instituting programs to reduce costs, improve the coordination of care and improve the effectiveness of medication therapies for beneficiaries with diabetes. Since the early 1990s, the Medicare program has expanded its coverage of diabetes-related services and supplies and instituted demonstration and pilot programs to test ways to provide better care to patients with diabetes and other chronic illnesses.

The current Medicare initiatives that are designed to improve the coordination of care and produce cost savings for beneficiaries with diabetes are summarized below.

- A. *Medicare Disease Management Demonstration.* This three-year demonstration tests whether providing disease management services and a comprehensive prescription drug benefit to beneficiaries in traditional fee-for-service Medicare who have advanced stage congestive heart failure, diabetes or coronary artery disease will lead to improved health outcomes and lower total expenditures for Medicare. As part of the demonstration, beneficiaries receive disease management services and coverage of most prescription drugs (even those not related to the targeted conditions), although beneficiaries may be subject to some cost sharing for the prescription drugs.⁶⁵
- B. *Medicare Health Support Pilot Program.* The first phase of this two-phase pilot program tests whether providing increased support to beneficiaries in traditional fee-for-service Medicare who have congestive heart failure and diabetes will lead to improved clinical outcomes, increased patient satisfaction and reduced Medicare spending.⁶⁶ Nine sponsors have been selected to implement phase one of the pilot program, and each will offer self-care guidance and support to beneficiaries to manage their health as well as other strategies such as prescription drug counseling.⁶⁷ In the second phase of the program, CMS may expand successful programs or program components on a regional or national basis.⁶⁸

These pilot programs can include pharmacy services. For example, community pharmacists in Tennessee at CVS pharmacies will provide in-person medication counseling services to beneficiaries referred by XLHealth's nurse coach as part of the Medicare Health Support pilot program. These services will include a review of the patient's prescription and over-the-counter medications, as well as an assessment of existing and potential medication adherence issues.

⁶⁵ CMS. Help for Chronically Ill Beneficiaries: The Medicare Disease Management Demonstration. Medicare Fact Sheet. December 2, 2003. Accessed at: <http://www.cms.hhs.gov/researchers/demos/BIPAFctShtDec2003.pdf>.

⁶⁶ CMS. Medicare Health Support to Improve Care of Beneficiaries with Chronic Illnesses. Medicare Fact Sheet. Accessed September 8, 2005 at <http://www.cms.hhs.gov/medicarerereform/ccip/factsheet1105.pdf>.

⁶⁷ CMS. HHS Announces Awards for Programs to Improve Quality of Care for Medicare Beneficiaries with Chronic Illnesses. Medicare News Release. December 8, 2004.

⁶⁸ CMS. Medicare Health Support: Highlights of the Program. Accessed September 8, 2005 at <http://www.cms.hhs.gov/medicarerereform/ccip/highlights.asp>.

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

C. *Medicare Part D Prescription Drug Plan Medication Therapy Management Services.* As part of the new Part D prescription drug benefit, plan sponsors will provide Medication Therapy Management (MTM) program services to certain patients who have high-cost chronic illness, such as diabetes. The services are intended to help optimize therapeutic outcomes by improving medication use and reducing the risk of adverse events for these beneficiaries.⁶⁹ Congress did not set minimum requirements for the content of MTM program services, but the MMA requires that plan sponsors develop these services in cooperation with licensed and practicing pharmacists and physicians.⁷⁰ CMS has provided guidance on the types of MTM program services that plans could offer, including: patient health assessments; development of drug treatment plans; evaluation and monitoring of patient response to drug therapy; education and training; and coordination of medication therapy with other care management services.⁷¹

The assistance pharmacists provide beneficiaries with their medications and diabetes self-management regimens could diminish if CMS establishes a competitive acquisition program that results in patients being unable to purchase both their medications and blood glucose monitoring supplies from their community-based retail pharmacies. In this way, competitive bidding of blood glucose monitoring supplies could reduce the effectiveness of Medicare's coordination of care, as well as limit the natural opportunity that exists for patients to speak with and obtain professional services from their pharmacists. The cost savings Medicare is seeking in these programs may also be diminished if patients' adherence with self-care activities declines as a result of barriers to access or less effective equipment is used as a result of the competitive acquisition program.

The cost savings achieved through a competitive acquisition program could very well be less than the increased costs for adverse health outcomes, such as hospitalizations due to declines in patient self-management of their illness, which could result if competitive bidding leads suppliers to limit the range of monitors available to patients. Based on the estimated additional costs that arise when patients' blood glucose levels are not controlled, if the competitive acquisition program interfered or disrupted the glucose testing regimens of just one out of every 20 Medicare beneficiaries with diabetes, the additional costs of treating these patients could exceed \$100 to \$350 million per year.^{72,73}

⁶⁹ All sponsors of Part D benefit plans are required to provide MTM services to patients who have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia and congestive heart failure); are taking multiple covered part D drugs; and are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by CMS.

⁷⁰ SSA, Section 1860D-4(c)(2).

⁷¹ 42 CFR Parts 4000, 403, 411, 417, and 423 Medicare Program; Medicare Prescription Drug Benefit; Final Rule. *Federal Register*. January 28, 2005; 70 (18).

⁷² Gilmer TP, Manning WG, O'Connor PJ, Rush WA. The cost to health plans of poor glycemic control. *Diabetes Care*. 1997;20(12):1847-1853.

⁷³ Saaddine JB, Engelfau MM, Beckles GL, Gregg EW, Thompson TJ and N KMV. The diabetes report card for the United States: quality of care in the 1990s. *Annals of Internal Medicine*. 2002;136(8):565-574.

G. Community-Based Pharmacy Programs are Improving Blood Glucose Management and Health Outcomes for Patients with Diabetes and Attracting Interest from Employer-Based and Other Private Sector Efforts to Improve Diabetes Care

Evidence exists that pharmacist-based programs can result in clinically significant improvements in health outcomes for patients with diabetes. Intensive pharmacy-centric interventions can result in positive and clinically significant improvements for patients with diabetes, and employers are contracting with pharmacies to provide these services to their workers. The clinical literature demonstrates that diabetes patients participating in pharmacy-centered interventions have lowered their A1c levels^{74,75} by as much as 2 percentage points.^{76,77,78,79} Each percentage point decrease in A1c levels is associated with a clinically significant, 40 percent decrease in the risk of diabetes-related microvascular complications such as eye or kidney damage or nerve disease.⁸⁰

Pharmacists provide a variety of services for diabetes patients as part of these interventions. Pharmacy-based interventions reported in the literature typically involve patients meeting with pharmacists every few weeks or months on an ongoing basis, and usually during scheduled appointments. Services provided in these interventions include:

- Reviewing the appropriateness of the patient's drug therapy.
- Consulting with the patient or physician and recommending changes in drug therapy to

⁷⁴ The amount of A1c in the blood reflects how well the blood glucose has been controlled, on average, for the past 2 to 3 months. A1c levels generally are tested in the physician office's at least twice a year and do not replace daily self-testing of blood glucose levels at home, which are necessary for adjusting medications and ensuring day-to-day control. American Diabetes Association. All About Diabetes. Accessed December 23, 2005. Available at: <http://www.diabetes.org/type-1-diabetes/a1c-test.jsp>

⁷⁵ Cranor CW, Bunting BA, Christensen DB. The Asheville project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *Journal of the American Pharmaceutical Association*. 2003;43(2):173-184. [Cranor, Bunting, Christensen 2003]

⁷⁶ Jaber LA, Halapy H, Fernet M, Tummalapalli S, Diwakaran H. Evaluation of a pharmaceutical care model on diabetes management. *The Annals of Pharmacotherapy*. 1996;30(3):238-243. [Jaber et al. 1996]

⁷⁷ Rothman RL, Malone R, Bryant B, Shintani AK, Crigler B, Dewalt DA, Dittus RS, Weinberger M, Pignone MP. A randomized trial of a primary care-based disease management program to improve cardiovascular risk factors and glycated hemoglobin levels in patients with diabetes. *The American Journal of Medicine*. 2005;118(3):276-284. [Rothman et al. 2005]

⁷⁸ Coast-Senior EA. Management of patients with type 2 diabetes by pharmacists in primary care clinics. *The Annals of Pharmacotherapy*. 1998; 32(6):636-641. [Coast-Senior 1998]

⁷⁹ Choe HM, Mitrovich S, Dubay D, Hayward RA, Krein SL, Vijan S. Proactive case management of high-risk patients with type 2 diabetes mellitus by a clinical pharmacist: a randomized controlled trial. *The American Journal of Managed Care*. 2005;11(4):253-260. [Choe et al. 2005]

⁸⁰ CDC, National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation. Diabetes Fact Sheet. Corrected 2005. Accessed August 2005 at <http://www.cdc.gov/diabetes/pubs/general.htm#prevention>.

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

physicians.

- Providing patient education and consultation regarding disease, its management and drug therapy.
- Obtaining patients' medical histories.
- Performing physical assessments of patients (e.g., monitoring of proper foot care for diabetes patients).
- Monitoring patients for desired and undesired health outcomes and compliance.
- Prescribing medications and ordering and evaluating laboratory tests.^{81,82}

Employers are contracting with pharmacies to provide diabetes-related care as part of the health benefits they provide their workers. A recent California HealthCare Foundation report highlighted independent and chain community pharmacies that provide health assessments and education and track health outcome measures, including changes in blood glucose levels, for employees of self-insured employers.⁸³

Many of these interventions are modeled after the successful "Asheville Project," a long-running pharmacist-based program established in 1997 by the city of Asheville, North Carolina, to promote adherence to glucose control and monitoring regimens among its employees suffering from diabetes. A large health plan in the area, Mission-St. Joseph's Health System, joined the city in offering the program to its employees in 1999. These local employers offer this pharmacy-led intervention to their employees as a benefit under their health plans. Incentives are provided to encourage employee participation, including the waiving of pharmaceutical co-payments and the provision of blood glucose monitors and education programs. Pharmacists are reimbursed for providing cognitive services to employees with diabetes, including patient education and training, and reviewing patients' self-monitoring of blood glucose data.⁸⁴

Although based on a limited number of patients, the Asheville Project has demonstrated improved patient adherence to glucose control and monitoring regimens, improved patient health and patient satisfaction and decreased overall medical costs. Patients also showed improvements in blood glucose levels and self-monitoring of their blood glucose levels. Overall, the mean direct medical costs decreased at the end of five years by \$1,200 per patient per year. Most of the reduction in costs was due to shifts in services: there was a decrease in insurance claims for

⁸¹ Beney J, Bero LA, Bond C. Expanding the roles of outpatient pharmacists: effects on health services utilization, costs, and patient outcomes (review). *The Cochrane Database System Review Library*. 2000;(3):CD000336.

⁸² Singhal P, Raisch DW, Gupchup GV. The impact of pharmaceutical services in community and ambulatory care settings: evidence and recommendations for future research. *The Annals of Pharmacotherapy*. 1999;33(12):1336-1355.

⁸³ Knapp et al. 2005.

⁸⁴ Cranor CW, Christensen DB. The Asheville Project: Short-Term Outcomes of a Community Pharmacy Diabetes Care Program. *JAMA*. 2003; 43(2): 149-59.

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

emergency department care, inpatient care and physician office visits although costs increased for prescription drugs.^{85,86,87}

Pharmacists participating in these employer-sponsored pharmacy interventions report that a competitive acquisition program that removes access to self-monitoring supplies from the pharmacy could provide them with less opportunity and ability to assist beneficiaries with the use of their monitor or to trouble-shoot problems, especially if they are unfamiliar with the patient's brand of blood glucose monitor. Beneficiaries also may be more reticent about seeking assistance from pharmacists for monitors that they purchase elsewhere.

The authors of a recent California HealthCare Foundation study suggest that community pharmacies could be an ideal place to provide professional services to individuals with chronic illnesses such as diabetes because of their prevalence, locations and long hours of operation.⁸⁸

The success of the Asheville Project has led employers in several different states to contract with pharmacies to provide diabetes care services to their workers. These employers typically offer these pharmacy-led benefits to employees and dependents as part of the self-insured health benefits they offer their workers. For example:

- Employers in North Carolina contract with the Piedmont Pharmacy Care Network (PPCN), a coalition of independent pharmacies, to provide diabetes care to workers and their dependents. For the past three years, these PPCN pharmacists have screened, educated and monitored diabetes patients on-site at their place of employment.⁸⁹
- Seven self-insured employers in Wisconsin contract with a network of eight pharmacies to provide diabetes and other health care services to their workers. (This pharmacy network includes chain and independent pharmacies as well as a pharmacy that is part of a health system.) These pharmacists follow protocols to provide workers with diabetes screening, education and monitoring services. For example, the pharmacists assess patients' needs every month for the first six months of the program, and patients who need additional education are referred to a formal diabetes education center. As an incentive, diabetes supplies are provided to patients for free, and co-pays for diabetes-related medications are waived for workers who participate in the program.⁹⁰
- A West Virginia employer contracts with pharmacists to provide in-person diabetes disease management care to its employees.⁹¹

⁸⁵ Garrett DG, Martin LA. The Asheville Project: Participants' Perceptions of Factors Contributing to the Success of a Patient Self-Management Diabetes Program. *JAMA*. 2003; 43(2): 185-90.

⁸⁶ Cranor CW, Buntin BA, Christensen DB. The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program. *JAMA*. 2003; 43(2): 173-84.

⁸⁷ Cranor CW, Christensen DB. The Asheville Project: Factors Associated With Outcomes of a Community Pharmacy Diabetes Care Program. *JAMA*. 2003; 43(2): 160-72.

⁸⁸ Knapp et al. 2005.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ Eckel F (ed.). Beyond Asheville. *Pharmacy Times*. June 2005.

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

- Clinical pharmacists at the University of Kentucky developed a pharmacy-based program for diabetes patients that is based on the Asheville model and have contracted with the University to provide these services to its employees.⁹²
- Employers in Georgia and Ohio also are contracting with pharmacists to provide diabetes care services to their employees.⁹³

This trend highlights the potential opportunities that exist now and in the future for community-based pharmacists to provide the interactions and clinical competence to promote adherence within the diabetes community. Given the growing penetration of these initiatives within the retail pharmacy setting, it may be ill-advised to risk disrupting these patient-pharmacy relationships at the same time that further experience and evidence is being gathered that supports the use of community-based pharmacies to promote adherence to blood glucose treatment and monitoring regimens.

⁹² *Id.*

⁹³ *Id.*

CHAPTER FOUR: CONCLUSIONS

CMS does not have experience with competitively bidding blood glucose monitors and supplies. This lack of experience raises two primary concerns regarding the impacts that a competitive acquisition program could have on Medicare beneficiaries with diabetes:

- Nearly two-thirds of blood glucose test strips used by elderly individuals with diabetes are purchased in community-based retail pharmacies. The assistance pharmacists provide beneficiaries with managing their diabetes may diminish if CMS establishes a competitive acquisition program in which diabetes supplies are provided through a limited number of suppliers and mail-order pharmacies. At a time when Medicare has been trying to move away from the provision of fragmented care, competitive acquisition could interfere with patient access and may adversely effect patients' management of their diabetes. For example, beneficiaries may be unable to obtain their glucose monitoring supplies and professional support under a Part B competitive acquisition program from the same in-network pharmacy under Part D that provides their medications and related professional support for controlling blood glucose levels.
- Competitive acquisition may potentially restrict the choice of monitors available to elderly persons who have diabetes. Given the important differences associated with the costs of monitors categorized within the same HCPCS code, competitive bidding could create an incentive for suppliers to provide lower-cost monitors to beneficiaries when higher-cost monitors may possess important functional characteristics for certain patients.

For some patients, pharmacists may be the most accessible healthcare professionals in the community and therefore may be able to play a unique role in caring for patients with diabetes.⁹⁴ Estimates vary, but historically diabetes patients are reported to visit the community pharmacy as much as three to eight times more per year than other patients.⁹⁵

Mounting evidence shows that pharmacist-based programs can result in clinically significant improvements in health outcomes for patients with diabetes. Given the growing interest in these initiatives as part of disease management programs in both the private and public sectors, it may be ill-advised to risk disrupting these patient-pharmacy relationships at the same time that further experience is being gained in the use of community-based pharmacies to promote adherence to blood glucose treatment and monitoring regimens.

Taken together — the positive health outcomes for patients receiving interventions involving pharmacists and the possible frequency with which patients come into contact with community pharmacists — it is reasonable to anticipate that health plans and policymakers will embrace

⁹⁴ Younis WS, Campbell S, Slack MK. Pharmacists' attitudes toward diabetes and their involvement in diabetes education. *The Annals of Pharmacotherapy*. 2001;35(7-8):841-845.

⁹⁵ Van Veldhuizen-Scott MK, Widmer LB, Stacey SA, Popovich NG. Developing and implementing a pharmaceutical care model in an ambulatory care setting for patients with diabetes. *The Diabetes Educator*. 1995;21(2):117-123.

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

increased reliance on the professional services that can be provided to patients with diabetes in the community pharmacy setting in the future.⁹⁶

The research involved in preparing this Report highlights that significant difficulties exist in attempting to estimate the magnitude of potential savings to the Medicare program of placing glucose monitors and test strips within the DME competitive acquisition program. It is well-accepted that the complications arising from poorly-controlled diabetes are extremely costly for our health care system and for the Medicare program in particular. Based on the reasonable concerns that competitive acquisition may disrupt access to blood glucose monitoring equipment and supplies, competitive acquisition could inadvertently lead to adverse outcomes for some Medicare beneficiaries and increased costs for the Medicare program arising from these adverse patient outcomes.

⁹⁶ Jaber et al. 1996.

APPENDIX A. LIST OF STAKEHOLDER INTERVIEWEES

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**MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL
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APPENDIX B. INTERVIEW GUIDE

On behalf of the National Association of Chain Drug Stores, *Health Policy R&D* is studying a number of issues related to the self-monitoring of blood glucose (SMBG), including an examination of the professional services and other clinical issues that are important to individuals with diabetes. This study is being undertaken in the context of changes that could occur should Medicare include glucose monitors and test strips in the competitive acquisition program that it must begin implementing in 2007 for items classified as durable medical equipment.

As part of this work, we are interested in gathering information and advice from experts in the field of diabetes on the following issues:

- The professional services related to SMBG that are important to individuals with diabetes, especially for elderly persons, and
- Clinical issues related to patients' adherence to SMBG activities.

I. Background

1. Name and contact information of individual being interviewed.
2. Please describe your current position and responsibilities, specifically as they relate to diabetes care and research.

II. Professional services

3. Please describe the typical roles and responsibilities of the various health care professionals involved in caring for a patient with diabetes.
4. What professional services, such as training and disease management, are provided to patients who self-test?
5. Are certain professional services particularly important for Medicare beneficiaries who self-test?
6. What are the benefits and drawbacks of pharmacy-based diabetes management services?
7. What role can retail pharmacists play in diabetes disease management and patient education?

III. Self-testing products

8. Provide an overview of the key characteristics of diabetes self-testing equipment, how prices vary, and the rate of innovation.

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT

9. Where are most self-testing devices and supplies purchased and what factors influence this purchasing decision?
10. What technical advancements and enhancements in monitors/strips/lancets are needed or currently under development?

IV. Selection of a self-testing device

11. What factors are most important in the selection of a blood glucose monitor?
12. Who is involved in the selection of a self-testing device?
13. Are there protocols or guidelines for professions that outline recommended clinical practice for helping patients in the selection of a monitor?
14. How often and why do patients change monitors?

V. Patient compliance and health outcomes

15. To what extent and in what ways might a limit on the array of glucose monitors available to Medicare beneficiaries affect patient compliance or health outcomes?
16. Is there evidence of enhanced compliance or health outcomes with certain patient-education and disease management services?
17. Does the location from which self-testing supplies are purchased (e.g. drug store, mail order) have an impact on patient education or self-testing compliance or competency?

VI. Other

18. Is there evidence from private health plans, employer health benefit programs, or other research to suggest how competitive bidding or limiting the array of glucose monitors available may affect patient outcomes?
19. Who do you recommend we talk with as part of this study?
20. What data, evidence, or other topics should we include in our research?
21. Other comments.