February 5, 2013

The Honorable Max Baucus
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Dave Camp
Chairman
Ways & Means Committee
United States House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20510

The Honorable Sander M. Levin
Ranking Member
Ways & Means Committee
United States House of Representatives
1106 Longworth House Office Building
Washington, D.C. 20510

Subject: Impact of Recent Harmful Medicare Policies on Diabetes Care

Dear Chairman Baucus, Ranking Member Hatch, Chairman Camp, and Ranking Member Levin:

The National Community Pharmacists Association (NCPA) would like to take this opportunity to express our concerns with recent developments relating to provision of care to Medicare patients with diabetes. In particular, we would like to bring to your attention the likely negative impact of recent Congressional action and agency policies on the quality of care received by Medicare patients with diabetes. We believe these recent changes will increase overall Medicare costs and have a negative impact on patients’ quality of life.

NCPA represents the interests of America's community pharmacists, including the owners and managers of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions.

These policies are diametrically opposed to the trend towards more integrated care, and include: 1) a draconian reduction in the payment rate for diabetes testing supplies (DTS) to retail pharmacies which will likely lead to most independent community pharmacies dropping out of the program, thus compromising care and counseling for frail, elderly seniors who rely on these pharmacies for these services and supplies; 2) a prohibition on community pharmacies delivering these supplies to patients’ homes and assisted living facilities, likely reducing the frequency and quality of testing undertaken by these patients; and, 3) the promotion of wasteful mail order to deliver these supplies to beneficiaries, even with the extensive and convincing evidence that mail order costs the Medicare Part B program millions of dollars each year in unused testing supplies.

Community Pharmacists are Indispensable in Combating Diabetes

Community pharmacists are indispensable to helping combat diabetes, whether it is the counseling they offer, the medications they dispense, the lifestyle modification classes they provide, or the wide variety of testing supplies they carry. Community pharmacists have always played an active role in helping patients cope with diabetes through prescription management, dispensing supplies such as glucose meters and therapeutic shoes, and vital diabetes education services. Community pharmacists sell diabetic testing supplies in order to provide a full spectrum of services to patients suffering from diabetes.
Now, in addition to the already burdensome regulations to participate in Part B, Congress is slashing reimbursement for Part B DTS, which will lead to decreases in beneficiary access to care. Congress recently enacted Section 636 of *The American Taxpayer Relief Act of 2012*, which imposes two cuts in reimbursement to Part B DTS. On April 1, 2013 payment for DTS will decrease approximately 14.5%, which will reduce reimbursement for diabetic strips from approximately $37 to $32. In addition, on July 1, 2013, this legislation will apply mail order DTS reimbursement rates to small independent community pharmacies.

CMS recently released the National Mail Order single payment rate for diabetic strips, which drastically decreases reimbursement an average of 72% for retail pharmacies, with only 15 suppliers expected to be awarded contracts. The single payment amount for diabetic strips per box of 50 is $10.41. This is significantly lower than even the average Round 1 CBP single payment amount for a box of 50 that was $14.62, and much lower than the fee schedule amount of $37. In reality, this $37 fee schedule amount barely covers the pharmacy’s costs of goods plus dispensing and counseling for these products and services, plus the costs to pharmacies of participation in Medicare Part B, which includes surety bonding, accreditation, the costs of arduous pre and post payment reviews, separate contractors to help process Part B claims, and the audit recoveries. Now, Congress has decided to drop these rates to $10.42 per box. At the end of the day, the cuts that Congress made under Section 636 will directly impact Part B beneficiaries, decrease beneficiaries’ access to vital DTS, and decrease adherence. At a time where Congress is working toward coordinated care within our health care system, this section does nothing more than further segregate care, drive up long-term health care costs, and force beneficiaries into mail order where even CMS has identified rampant waste.

**Section 636 Drastically Decreases Beneficiary Access and Eliminates Beneficiary Choice of Supplier**

According to a January 2013 survey of over 300 community pharmacies, a sharp reduction in payment for diabetes test strips would result in about 92% of independent community pharmacies leaving the Part B program. In addition, 89% of independent community pharmacies state that moving diabetes supplies to mail order would have a significant impact on Medicare patients. Lack of customer service and being delivered supplies that were not requested are common complaints about mail order pharmacy that community pharmacies frequently hear about from Medicare patients.

To witness the drastic decrease in suppliers, one does not have to look much further than the results of CBP. Prior to the CBP, each MSA was represented by hundreds of DMEPOS suppliers. Whereas, after the CBP, only 356 DMEPOS suppliers were awarded contracts and allowed to serve beneficiaries.1 The result of this drastic decrease in suppliers of DTS is that beneficiaries can no longer obtain the DTS brand chosen by their physician from the pharmacy of their choice.

In order to explore the CBP further, OIG released a report entitled, *Supplier Billing for Diabetes Test Strips and Inappropriate Supplier Activities in Competitive Bidding Areas*, OEI-04-11-00760. The report shows that beneficiaries are switching to retail pharmacies based on product choice and on dissatisfaction with mail order. For 88% of beneficiaries, the switch from mail to retail community pharmacy happened because their suppliers were no longer able to provide DTS under the CBP or their preferred brand of DTS was no longer available through their mail supplier. Another 10% of beneficiaries said they switched from mail to retail because of dissatisfaction with service.

1 See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Contract-Supplier-Lists.html.
This provides evidence that community pharmacies play a vital role as the safety net in providing DTS to beneficiaries. This report further demonstrated that beneficiaries turn to their local community pharmacist when they can no longer obtain the product that their prescriber has determined is best for them through mail and when they are dissatisfied with mail.

Section 636 Decreases Beneficiaries’ Choice of Product

Just as the number of suppliers that provide DTS decreased after the CBP was implemented, the range of DTS offered to beneficiaries also plummeted. A study conducted by the American Association of Diabetes Educators (AADE) entitled, *Competitive Bidding Program for Mail-Order Diabetes Testing Supplies: Product Availability Survey*, looked at the range of DTS offered by mail order suppliers to Medicare beneficiaries by surveying suppliers in the nine competitive bid areas. AADE found that of the nine brands that OIG identified as the top mail order DTS brands by percent of market share, mail order contract suppliers only cover an average of 1.44 brands – only 16%. From these findings, AADE concluded that “beneficiaries in competitive bidding areas do not have access to most brands available in the market, or to brands most commonly prescribed by physicians and selected by beneficiaries.”

As this study demonstrates, the products that independent pharmacies and mail order provide to beneficiaries are very different. Community pharmacists are motivated to have products that local physicians prescribe and local beneficiaries prefer. Community pharmacists play a key role in the spectrum of providing tailored, personal care to the beneficiary. Due to the customized treatment that diabetes demands, DTS should not be treated as interchangeable. On the other hand, mail order suppliers promote a limited range of products based on lowest cost and questionable quality, and often direct beneficiaries to these products. The AADE study concludes that “[u]nder the CBP, contract suppliers have powerful incentives to maximize profit margins by purchasing and offering a limited range of products, and only the lowest cost products available.”

With respect to quality, a recent study presented at the American Association of Clinical Endocrinologists 2012 meeting revealed that some of the products frequently sold by mail order suppliers, including those participating in Round 1 CBP, but rarely sold by retail suppliers, fail performance accuracy standards set by FDA. The results demonstrated that out of seven systems tested in the study and three different strip lots from each system, three systems failed the International Organization for Standardization (ISO) and FDA accuracy standards (≥95% within ±15 mg/dL for values <75 mg/dL and ±20% for values ≥75 mg/dL), in at least one lot, and some missed in two lots.

For the few community pharmacies that may choose to continue to participate in the Part B program and endure these drastic cuts in reimbursement, these community pharmacies will no longer be able to offer the customized DTS that beneficiaries and their physicians prefer. To the contrary, community pharmacies will be forced to only provide a limited range of products to beneficiaries just as mail order has done, if at all.

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3 *Id.*
4 *Id.*
Section 636 Disproportionately Impacts Rural America

The significant impact of independent pharmacies dropping out of the Medicare Part B program is certain to be felt disproportionately in rural areas. Independent community pharmacies are far more likely than chain pharmacies to operate in traditionally underserved and rural areas where patient accessibility is a deep concern. Community pharmacies in these areas serve some of the frailest Medicare beneficiaries.

A study conducted by the RUPRI Center for Health Policy Analysis and the North Carolina Rural Health Research & Policy Analysis Center found that 91% of all sole community pharmacies are located in rural communities, and that 22% are located more than 20 miles from the next closest retail pharmacy. In addition, rural community pharmacies generate $26.9 billion in annual revenue and hire 71,000 full-time employees. Unfortunately, the number of retail pharmacies located in rural areas has declined. From March 1, 2003 to December 1, 2011, 852 independently-owned rural pharmacies closed.

Thus, as our Medicare population continues to grow, the amount of suppliers that can provide DTS to beneficiaries, as well as the number of brands offered in the supply chain, continues to decrease. Implementing such drastic cuts to community pharmacies will force community pharmacists out of the Part B program, decrease beneficiary access to these vital supplies, and increase health care costs.

Section 636 Does Nothing to Address Mail Order Waste While Cutting Beneficiary Access

Despite findings of rampant waste in mail order, CMS continues to promote mail order to beneficiaries over retail community pharmacies, stating that mail order saves money for beneficiaries as well as the Medicare program. In a November letter to Medicare beneficiaries, CMS stated, “[i]f you don’t want your diabetic testing supplies delivered to your home, you can go to a local store and buy them there, but you’ll probably pay more. If you take advantage of the national mail-order program, Medicare will save money and your copayment will be lower.”

However, OIG recently released a report that showed a 22% reduction in Medicare claims for DTS in CBP areas, which suggests adherence and mail order waste issues. To address these issues, Director Wilson stated in his testimony before the House Small Business Committee that during Round 1 of the CBP CMS’ monitoring revealed declines in the use of mail-order diabetes test strips and Continuous Positive Airway Pressure (CPAP) supplies in the CBAs. In response to these utilization declines, CMS initiated three rounds of outbound phone calls to users of these supplies in the nine CBAs, two rounds of calls for users of mail-order diabetes test strips and one round of calls to users of CPAP supplies. In each round, CMS staff randomly identified 100 beneficiaries who used the items before the program began but had no claims for the items in 2011.

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The calls revealed that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months’ worth, which would suggest that beneficiaries had historically received excessive replacement supplies before they were medically necessary. When asked by Committee members for more information on these findings, Director Wilson expressed that 60% of these beneficiaries that were no longer ordering DTS had over a 10-month supply on hand already. Thus, CMS is wasting millions of dollars each year on mail order diabetes testing supplies that are automatically shipped to patients and are never used.

Eliminate Prohibition on Delivery of DTS to Homebound Beneficiaries and Beneficiaries in ALFs

In addition to the drastic cuts that Section 636 imposes on community pharmacies, community pharmacies will be prohibited beginning July 1, 2013 from providing home delivery of DTS to Medicare beneficiaries and to beneficiaries in Assisted Living Facilities (ALF). Home delivery is a staple of the various patient-oriented services that community pharmacies provide.

According to an August 2012 survey, 94% of independent community pharmacies regularly deliver DTS to patients (often free of charge). According to a recent survey that NCPA conducted in January 2013, over 26% of community pharmacists make 30 or more deliveries per month to beneficiaries. In addition, 86% of community pharmacists believe that their patients would suffer moderate to significant impact if they were no longer able to provide home delivery. Moreover, anecdotal evidence suggests that 40-50% of Medicare beneficiaries do not pick up their pharmaceutical drugs or supplies themselves meaning they are either delivered to the beneficiary by the independent community pharmacy or picked up at the pharmacy by a caregiver.

This prohibition of delivery always violated common sense, and now that Section 636 has equalized reimbursement for both mail and non-mail, distinguishing between delivery methods and prohibiting community pharmacies from delivering DTS to homes and ALFs has no bearing. Prohibiting community pharmacies from delivering DTS to homebound Medicare patients and patients in ALFs is unconscionable. We strongly encourage Congress to address CMS’ oversight and to ensure some of the frailest Medicare beneficiaries are not faced with the harsh reality that they have no way to receive the supplies they need to stay alive.

Conclusion

Section 636 of The American Taxpayer Relief Act of 2012 provides drastic cuts to retail pharmacies supplying DTS to Medicare beneficiaries in the Part B program. By going forward with these cuts, Congress will decrease beneficiary access to care, decrease adherence, and increase long-term health care costs. At a time when our health care system is moving toward coordinated care, NCPA urges Congress to prevent these drastic cuts to community pharmacies and preserve access to vital DTS for Medicare Part B beneficiaries.
In addition, NCPA urges Congress to act to allow community pharmacists to continue to deliver DTS to homebound beneficiaries and beneficiaries in ALFs. These beneficiaries are often the frailest of the Medicare population, and it is unconscionable for CMS to assume that these beneficiaries are capable of physically coming to a community pharmacy to pick up their supplies or to get to a mailbox or PO Box across town to obtain their supplies from mail order. These beneficiaries depend upon delivery to their home or caregiver’s home in order to obtain their vital DTS and administer their DTS properly. Delivery to homebound Medicare beneficiaries and beneficiaries in ALFs provides a valuable service to the patient, encourages adherence, and decreases long-term health care costs. In addition, we encourage you to put stricter controls around the mail order companies that prey on seniors’ fears and concerns so they can ship them – and bill the Federal government – for as many diabetes-testing supplies as possible.

Finally, NCPA asks that you consider the impact that pharmacy services can make in improving the quality and length of life of Medicare patients with diabetes. Pharmacists help to improve adherence with medications and testing, which can lead to a reduction in Part A and Part B expenses. We urge Congress to invest in the services provided by pharmacists in Medicare and enhance their role as providers.

Sincerely,

John M. Coster, Ph.D., R.Ph
Senior Vice President, Government Affairs

Cc:
The Honorable Harry Reid, Majority Leader, United States Senate
The Honorable Mitch McConnell, Minority Leader, United States Senate
The Honorable John Boehner, Speaker of the House, United States House of Representatives
The Honorable Nancy Pelosi, Minority Leader, United States House of Representatives
The Honorable Eric Cantor, Majority Leader, United States House of Representatives
Mr. Jonathan Blum, Deputy Administrator & Director of Center for Medicare