Statement to the
United States House of Representatives Committee on Small Business Subcommittee on Healthcare and Technology

Hearing on Medicare's Durable Medical Equipment Competitive Bidding Program: How are Small Suppliers Faring?

September 11, 2012

Chairwoman Elmers, Ranking Member Richmond, and Members of the Subcommittee, the National Community Pharmacists Association (NCPA) is pleased to submit the following written comments for inclusion in the record of today's hearing on the Medicare Durable Medical Equipment Competitive Bidding Program (CBP). We commend you for holding this hearing given the impact that competitive bidding will likely have on beneficiary access to needed diabetic testing supplies (DTS) and other DME supplies as well as the ability of community pharmacies to serve the DME supply needs of Medicare Part B beneficiaries.

NCPA represents the interests of pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies across the United States. NCPA has a strong interest in this issue because independent community pharmacies hold one-half of all active DME supplier numbers and serve as a critical access point for DME supplies, especially DTS, for the large fragile population of Medicare Part B beneficiaries suffering from diabetes in the United States. According to a 2011 survey by NCPA, 67% of our members provide DME products to patients. It is important to note that independent community pharmacists provide DME not as a profit center, but in order to make certain that the beneficiaries they serve have access to the supplies they need at a single point of care. Only 6%-8% of an average independent pharmacy's annual sales are from DME.

NCPA's Primary Points

1. ***Community pharmacists are indispensable. From face-to-face counseling to the DME they dispense, independent community pharmacists play an essential role in improving health care outcomes and decreasing long-term health care costs.***

2. ***Independent community pharmacists must already comply with multiple criteria in order to participate in Medicare Part B including: obtaining expensive DME accreditation; possessing a surety bond; paying to obtain the actual product; complying with extremely burdensome documentation requirements; and working with a secondary payer in order to receive payment; all the while receiving much slower than-normal payments.***

3. ***Community pharmacists must bear all of these burdensome regulations even when only 6%-8% of an average independent pharmacy's annual sales are from DMEPOS. Therefore, independent community pharmacists generally sell diabetic testing supplies to provide a service to beneficiaries and not because of profit.***

4. ***Forcing community pharmacists to participate in the CBP or to take the CBP reimbursement for DME, which will become a reality in 2016, would decrease beneficiary access and increase health care costs. At a time where Congress and CMS are trying to move towards a coordinated care approach, it is unacceptable to drastically reduce access to DME and drive up costs, which will lead to increased hospital stays and decreased quality of care.***

5. ***According to an August 2012 survey that NCPA conducted of over 400 independent community pharmacists regarding consequences of a sharp reduction in payment for diabetes test strips, 92% of the pharmacies said they would likely drop out of the program if forced to either (1) take a reduction in payments for diabetes testing strips, or (2) take a competitively-bid chain or mail order price to continue to provide Medicare diabetes testing supplies.***

6. ***The significant impact of independent pharmacies dropping out of the Medicare Part B program is certainly 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.***

7. ***Prohibiting community pharmacies from delivering DTS to homebound Medicare patients is unconscionable. The way in which CMS has defined the term "mail order" will prevent community pharmacists from delivering DTS to homebound beneficiaries beginning on July 1, 2013. We urge 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.***

8. ***While CMS is considering drastically cutting DME reimbursement for non-mail order diabetes testing supplies via an inherent reasonableness authority, CMS is wasting millions of dollars on mail order diabetes testing supplies that are automatically shipped to patients that are never used. Waste is rampant in Medicare Part B mail order diabetes testing supplies. CMS turns a blind eye to this fact in its holy grail pursuit of lower mail order DTS prices. One should look no further than the One Year Implementation Update to Round 1 published this past April to see the large amount of waste being generated by mail order supplies.***

9. ***CMS' recent efforts to use inherent reasonableness as a substitute for the CBP in an effort to drastically cut reimbursement for non-mail order DME is misused and would decrease access to care and beneficiary health. CMS has presented no evidence that the current fee schedule is grossly excessive as compared to the cost to independent pharmacies to purchase these supplies. Congress must take action to ensure that CMS cannot use this authority in a manner that would decrease access, decrease overall health care, and increase overall health care costs.***

10. ***Congress should pass HR 1936, The Medicare Access to Diabetes Supplies Act. In light of the negative impact of a CBP for DTS on the ability of community pharmacies to continue to supply DTS, NCPA urges Congress to pass H.R. 1936 and permanently exclude small independent pharmacies from the CBP and CBP pricing.***

Community Pharmacies Will be forced to Cease Supplying DTS When Faced with Drastic Reimbursement Cuts Decreasing Patient Access and Driving up Health Care Costs

While the Round 1 Rebid for mail order DTS in nine competitive bid areas (CBAs) has been in place for over a year, within the next year CMS will fully implement the national mail order competitive bidding program for diabetic testing supplies (DTS). For the time being, CMS has excluded, from competitive bidding, DTS supplied by retail pharmacies. We are grateful for this exclusion. However, by 2016, all DME suppliers, mail order and retail, will be subject to competitive bidding or competitive bidding pricing for DTS. In addition, unfortunately, in the context of the national mail order CBP, CMS is prohibiting retail pharmacies from providing home delivered DTS unless such a pharmacy wins a national mail order CBP contract.

From face-to-face counseling to the DME they dispense, independent community pharmacists play an essential role in improving health care outcomes and decreasing long-term health care costs. 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. Also, it is oftentimes the case that independent pharmacists service very distinct and culturally diverse populations. Many of these beneficiaries do not speak English as their first language and are accustomed to seeking services from a community pharmacist they can effectively communicate with, which certainly can't be replicated by their mailbox or a 1-800 number.

Independent community pharmacists must already comply with multiple criteria in order to participate in Medicare Part B including: obtaining expensive DME accreditation; possessing a surety bond; paying to obtain the actual product; complying with extremely burdensome documentation requirements; and working with a secondary payer in order to receive payment; all the while receiving much slower than-normal payments. Community pharmacists must bear all of these burdensome regulations even when only 6%-8% of an average independent pharmacy's annual sales are from DMEPOS. Thus, community pharmacists generally sell diabetic testing supplies to provide a service to beneficiaries and not because of profit. Even CMS in the preamble to its 2010 Proposed Rule on competitive bidding noted the value of "a licensed pharmacist [being] on hand to offer guidance and consultation to the beneficiary."

The inability of small independent pharmacists to remain viable DTS suppliers is further demonstrated by comparing the average supply fee schedule reimbursement for retail DTS with the Round 1 CBP average reimbursement amounts for mail-order DTS. The average National retail single payment amount for diabetes testing supplies is $37.67 whereas the average Round 1 Competitive Bidding Program single payment amount, across nine geographic regions, was $14.62. Small business retail community pharmacies will not be able to continue providing DTS to Part B beneficiaries, when faced with over a 60% decrease in reimbursement.

Additionally, according to an August 2012 survey that NCPA conducted of over 400 independent community pharmacists regarding negative consequences for a sharp reduction in payment for diabetes test strips, 92% of the pharmacies said they would likely drop out of the program if forced to either (1) take a reduction in payments for diabetes testing strips, or (2) take a competitively-bid chain or mail order price to continue to provide Medicare diabetes testing supplies. In addition, 86% of respondents said that their average Medicare patient visits the pharmacy two or more times a month for counseling. The message from our survey is clear: drastically reducing payments for diabetes testing supplies to independent community pharmacies is financially unsustainable for these pharmacies and will diminish beneficiary access to DME.

This significant impact is certainly 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. 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.[1] 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.[2]

[1] *Andrew D. Radford, Michelle Lampman. A Profile of Sole Community Pharmacists: Their Role in Maintaining Access to Medications & Pharmacy Services in Rural Communities. 2009 Medication Use in Rural America Conference. September 9, 2009.*

[2] Kaitlin Boyle, Fred Ullrich, Keith Mueller. *Independently Owned Pharmacy Closures in Rural America. RUPRI Center for Rural Health Policy Analysis: Rural Policy Brief, Brief No. 2012-4, July 2012, www.public-health.uiowa.edu/rupri.*

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. Even with the decrease of suppliers that can provide DTS to beneficiaries and the number of brands offered in the supply chain, CMS is proposing drastic cuts in reimbursement for DME and prohibiting retail pharmacies from providing home delivered DTS unless such a pharmacy wins a national mail order CBP contract.

Prohibiting Community Pharmacists from Delivering DTS to Homebound Medicare Patients will Decrease Access and Healthy Outcomes

There is an urgent need for legislation to exempt small community pharmacies from the CBP for DTS and CBP pricing. In 2013, CMS will apply a national CBP to mail order DTS. In doing so, CMS has defined the term "mail order" to mean "any item . . . shipped or delivered to the beneficiary's home, regardless of the method of delivery." Conversely, CMS has defined the term "non-mail order" as "any item . . . that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront." Essentially, these two definitions prevent small independent pharmacies, which are not a part of the CBP, from providing home delivery, which is a valuable and necessary service for some beneficiaries who have difficulty getting to a pharmacy.

According to an August 2012 survey, 94% of independent community pharmacies regularly deliver diabetes testing supplies to patients (often free of charge) with almost 20% making 30 or more deliveries per month to different beneficiaries. 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.

As of July 1, 2013, these community pharmacists will no longer be able to deliver to homebound Medicare patients the DTS they desperately need. Three scenarios further demonstrate the problems with prohibiting community pharmacies from engaging in some home delivery of DTS.

First, many Medicare Part B beneficiaries that are in need of DTS are homebound and may not have a caregiver available to pick up DTS from the local independent pharmacy. Many beneficiaries, especially in rural areas, receive all their mail at a P.O. Box location that is miles from their home, and are unable to get to their P.O. Box more than once a week or every few weeks. In these instances, the beneficiary relies upon the independent pharmacy to deliver supplies to their home. This is done for the benefit and convenience of the beneficiary, and not to undermine the CBP.

The second scenario occurs when a small independent pharmacist temporarily delivers supplies to a patient. This scenario involves the "snowbird" patients, who live in the North during the summer and head south to places like Florida in the winter. Their pharmacist in the North, for the convenience and benefit of the patient, may be willing to mail winter supplies to the patient at their southern address. This is a temporary arrangement and is not done to undercut the CBP, yet the proposed definitions would prohibit small independent pharmacists from performing this helpful service. Notably, under either of the above scenarios the independent pharmacist obtains a receipt that the item was received by the beneficiary, the same documentation that the pharmacist receives from an in-store pick-up.

The third scenario involves community pharmacies that routinely deliver medications to assisted living facilities for residents. Again, under CMS' rule, these pharmacies will no longer be allowed to deliver supplies to these facilities, which is completely unacceptable and must be addressed. Almost 50% of all community pharmacists deliver DTS to assisted living facilities. Asking frail homebound patients, as well as those in assisted living facilities, to visit a store front to obtain their supplies while having their other medications delivered to their place of residence, makes no sense.

NCPA believes this was a severe oversight by CMS and urges Congress to act to address this issue. In light of the concerns raised by CMS's definition of the terms "mail order item" and "non-mail order item," NCPA urges Congress to act now to exempt independent community pharmacies from a DTS CBP. Such immediate legislative action is necessary to ensure that community pharmacies are able to continue to deliver DTS supplies to homebound beneficiaries, "snowbird" patients, and assisted living facilities. To do so would be consistent with the Medicare Part D program, which does not consider a small independent pharmacy providing home delivery of a Part D drug to be providing a mail order service.

CMS is Wasting Millions of Dollars on Mail Order Diabetes Testing Supplies

The result of small independent pharmacists potentially terminating their sales of DTS is that patients will be forced to use mail order, will lose access to care, and the patients and the health care system will incur unnecessary costs in the long-term. Through mail order, patients will also lose access to care because they will lose access to the valuable consultation, fitting and monitoring services provided by independent pharmacists.

Medicare Part B pays for billions of dollars each year in diabetes test strips – the majority of which are dispensed through mail order. Yet, community pharmacists continually hear stories from patients about how the mail order company continues to send strips to the beneficiary, even if they don't need them. Some patients indicate they have closets full of these strips! This means that either the mail order company is disregarding "stop orders" and has placed the person on automatic renewal even if they don't need the strips, or the person is not testing correctly, which could lead to further diabetes complications. This is a lose-lose situation for Medicare and the beneficiaries. Medicare pays for strips that aren't needed, while patients are not being managed well because they are getting their strips from a mail order firm rather than being managed by their community pharmacist.

Recently, CMS released a report touting positive health outcomes and significant savings from the Round 1 Rebid for mail order DTS. CMS claimed that the Round 1 Rebid yielded over $51 million in savings with few beneficiary complaints and no negative health care outcomes. We believe that CMS's report does not paint a complete picture and is too quick to jump to conclusions.

For example, CMS claims that the Round 1 Rebid resulted in a decrease in overutilization of DTS. They reach this conclusion by looking at the decrease in mail order DTS utilization following implementation of the Round1 Rebid. However, CMS neglects to mention, per the Round 1 Rebid parameters, that beneficiaries in CBAs were not required to use mail order competitive bidding suppliers. Beneficiaries had the choice to move to retail suppliers outside of competitive bidding if they wanted. Accordingly, even though CMS found that mail order diabetic testing supply utilization decreased following implementation of the Round 1 Rebid, this could mean that patients in CBAs chose to go to retail over mail order in order to receive more face-to-face high touch care.

Even if CMS is correct that the Round 1 Rebid resulted in a reduction in DTS waste through a reduction in overutilization of DTS, such a reduction was only measured with regard to mail order suppliers. The fact that CMS found that beneficiaries had excess mail order supplies prior to the Round 1 Rebid reinforces our position that mail order waste, not retail waste, for DTS is the major waste problem in Medicare Part B. Accordingly, a similar reduction in DTS utilization may not be apparent, once the CBP expands to retail pharmacy. In contrast to mail order suppliers, small retail pharmacies do a better job of monitoring when and how often patients need refills and when and how often patients' testing regimens change. Mail order, on the other hand, through its auto-refill policies, generates substantial stockpiling waste of DTS for patients and measures adherence through whether an auto-refill was delivered, not whether it was actually and appropriately used by the patient.

CMS' Actions to Cut DTS Reimbursement by its Inherent Reasonableness (IR) Authority as a Substitute for the CBP will Decrease Access to Care and Beneficiary Health

Recently, CMS has started exploring its inherent reasonableness authority to cut DTS reimbursement to community pharmacists as a substitute for competitive bidding. CMS announced in its notice, 77 Fed. Reg. 38,067, on June 26, 2012, that it would begin accepting oral and written comments as to whether the use of IR is justified. IR can be used as a substitute for the CBP where CMS wishes to make drastic cuts to DTS.

NCPA strongly disagrees with CMS' decision to use its IR authority to drastically cut reimbursement for DTS and urges Congress to act to make certain these drastic cuts do not take place. CMS' decision to cut reimbursement via the IR process on the assumptions that (1) retail pharmacies and mail order pharmacies purchase DTS at the same cost; and (2) the savings seen in placing mail order DTS in the CBP due to waste will also be present within the retail sector. In fact, CMS is using the information from the Round 1 Rebid for mail order supplies in determining that the fee schedule amounts in retail are grossly excessive.

CMS states in the notice of the IR meeting, "[a]lthough we recognize that there are pricing differences between mail order and non-mail order diabetic testing supplies because of the delivery methods for these supplies, information about the prices of mail order diabetic testing supplies can inform the analysis of prices for non-mail order diabetic testing supplies because several key cost components are identical for both, such as product acquisition costs and administrative costs, including claims processing and paperwork costs." CMS is acting under the assumption that there is no difference in purchasing in different pharmacy channels, and as such, CMS is viewing mail-order prices as reasonable for the retail sector. That is simply not the case. Product pricing in the retail and mail order channels is in fact different.

While CMS has presented no evidence that the current fee schedule prices are inconsistent with the purchasing costs for community pharmacists, independent community pharmacies cannot purchase diabetes test strips at the same prices as large self-warehousing chains or mail order pharmacies. Contrary to CMS' statements, there are different costs for acquiring the product. Since CMS uses the quantity of 50 test strips for the basis of pricing for the CBP, NCPA also looked at acquisition costs for community pharmacists for multiples brands of 50-count test strips. According to data that NCPA has collected, independent community pharmacists' average acquisition costs for multiple brands of 50-count test strips is multiple times more than the average supply fee schedule reimbursement for the Round 1 Rebid CBP (which was $14.62). Moreover, only 6%-8% of an average independent pharmacy's annual sales come from DMEPOS. With the low margin on those supplies and drastic price reductions, many independent pharmacists will likely be forced out of the program and terminate sales of DTS.

Furthermore, the products which independent pharmacies and mail order stock are also very different. Community pharmacists are motivated to stock products which local physicians prescribe and local beneficiaries prefer. Thus, 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 having the lowest cost, potentially questionable quality, and generally direct beneficiaries to these products. From its study AADE 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."[3] Thus, the range of products offered between retail and mail order differs, the acquisition costs of these products differ, and the choice available to beneficiaries also differs.

[3] Competitive Bidding Program for Mail-Order Diabetes Testing Supplies: Product Availability Survey (November 2011).

Regardless of whether drastic cuts in reimbursement for DME are implemented by subjecting community pharmacy to CBP reimbursements or by inherent reasonableness, community pharmacists will nevertheless be forced to cease supplying DME. As a result, beneficiary access will suffer, adherence will decline, overall beneficiary health care will decrease, and health care costs will increase. Congress must act to make certain that CMS does not utilize its inherent reasonableness authority to drastically cut reimbursement for DME.

Congress Should Enact H.R. 1936, the Medicare Diabetes Access to Diabetes Supplies Act

In light of the negative impact of a CBP for DTS on the ability of community pharmacies to continue to supply DTS and in narrowing patient access to DTS, NCPA urges Congress to pass H.R. 1936 and permanently exclude small independent pharmacies from the CBP and CBP pricing. H.R. 1936 would exclude from a CBP and CBP pricing "blood glucose self-testing equipment and supplies furnished (regardless of method of delivery) by a retail community pharmacy (as defined in section 1927(k)(10)) that is not under common ownership with more than 10 other retail community pharmacies." Congress should pass H.R. 1936 because it will protect patients' important face-to-face interaction with their independent pharmacists for effective diabetes monitoring and ensure that beneficiaries will have immediate access to the specific DTS that they need.

Along with excluding community pharmacies from any DTS CBP, the proposed legislation exempts community pharmacies from any pricing resulting from a DTS CBP. Such an exemption is necessary to protect meaningful beneficiary access to small independent pharmacies. Even if small independent pharmacies are excluded from a CBP, they may still terminate DTS sales and hinder beneficiary access to DTS if the prices established under such a program are applied to the community pharmacy market. This would make it cost prohibitive for our members to continue supplying DTS products. In the end, if Congress does not protect beneficiary access to small independent pharmacies, beneficiary compliance with testing regimens may be compromised, and the risk of diabetes-related complications may rise along with costs associated therewith.

Conclusion

If community pharmacies are not exempted from the CBP and CBP pricing for Part B DME supplies and DTS, in particular, then many will likely cease to provide such supplies, thereby narrowing beneficiary access to much-needed DTS. Independent community pharmacists are working hard to provide the best care and access to beneficiaries while working with CMS to improve quality of care and drive down long-term costs. The facts are, with drastic cuts to reimbursement for supplies, beneficiaries will no longer have access to the care they need and deserve.

This is not just an issue of convenience - this is about providing reasonable access to beneficiaries. If beneficiaries do not have reasonable access to their diabetic testing supplies, this decreases adherence, decreases the quality of care that beneficiaries receive, and drives up the overall costs of health care. We all have an interest and a part in making certain that beneficiaries have access to their diabetic testing supplies that they need.

NCPA has urged CMS to continue to exempt community pharmacies from the DTS CBP, to exempt community pharmacies from the CBP pricing, and to allow community pharmacies to continue to provide home delivery of DTS outside of the CBP. However, CMS has rejected our entreaties and, in large part, is bound by statutory dictates to implement a national CBP or national CBP pricing by 2016 for all DME. Given the statutory restraints faced by CMS, Congress must act to ensure that Medicare Part B beneficiaries continue to have access to high quality DTS and other DME supplies at their local community pharmacies.

Thank you for the opportunity to submit this statement for the record.