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August 24, 2010

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1503-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1503-P; Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on the CMS proposed rule regarding changes to the Medicare Part B program for CY 2011. As CMS considers issues pertinent to changes to Medicare Part B for CY 2011, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives.

NCPA represents America's community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises, and chains. Together these represent an $84 billion healthcare marketplace, employ nearly 60,000 licensed pharmacists, employ over 300,000 fulltime employees, and dispense nearly half of the nation's retail prescription medicines. NCPA members are the primary providers of Medicare Part B drugs and supplies to millions of Americans. We urge CMS to promulgate Part B regulations that will help our members to continue in their role as critical access points for Medicare Part B beneficiaries to much needed Part B drugs and supplies.

NCPA is particularly focused on four areas of CMS's Part B proposed rule. First, NCPA requests that CMS exclude community pharmacies from the competitive bidding program (CBP) for diabetic testing supplies (DTS), off-the-shelf (OTS) orthotics, and ideally, all other durable medical equipment (DME) supplies, as well as protecting NCPA members from the cut-rate pricing resulting from the CBP. Second, NCPA requests that CMS increase the supplying and dispensing fees for Medicare Part B drugs for CY 2011. Third, NCPA requests that CMS raise the threshold for provider eligibility for the e-prescribing incentive program. Fourth, NCPA requests that CMS take efforts to waive the co-pays, coinsurance and deductibles for diabetic self-management training (DSMT). Finally, NCPA urges CMS to add pharmacists to the list of providers approved to provide DSMT telehealth services.

DMEPOS COMPETITIVE BIDDING PROGRAM (CBP) ISSUES

CMS Should Continue to Exclude Small Independent Pharmacies from a Diabetic Testing Supply CBP

NCPA appreciates CMS's proposal to continue to exclude retail pharmacies from a DTS CBP and its recognition of the major problems posed by a national, regional or local CBP on beneficiaries and suppliers. Of the options presented, we agree with CMS's proposal that a national mail order CBP that excludes retail pharmacies is the best option for a DTS CBP. As discussed in the preamble, the other three options considered by CMS would "likely eliminate beneficiary choice to obtain replacement diabetic supplies on a non-mail order basis from any enrolled supplier that is a pharmacy or other local supplier storefront…" If CMS were to include small independent pharmacies in a CBP, such a program would prove unduly burdensome to independent pharmacies and could cause many of them to leave the program.

Going back to the aborted first round of the CBP, less than two percent of the suppliers submitting bids were independent pharmacists, despite the fact that community pharmacies hold one-third of all, and one-half of the active, DME supplier numbers. The reason for small independent pharmacists terminating sales of DTS under a CBP is because independent community pharmacies do not have the volume of diabetic testing supply business or DMEPOS business to be able to submit successful competitive bids.

The result of small independent pharmacists potentially terminating their sales of DTS is that patients will be forced to use mail order, will loss access to care, and the patients and the health care system will incur unnecessary costs in the long term. The resulting narrowing of patient access is demonstrated by predictions that 38 to 40 percent of DME suppliers are expected to go out of business under the CBP and 80,000 people will lose their jobs. 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. Various studies have documented the benefits of personal care, particularly in diabetes care, and some have extrapolated the negative effect on patient care of placing diabetes test supplies in competitive bidding. The preamble of the proposed rule recognizes as much, noting the value of "a licensed pharmacist [being] on hand to offer guidance and consultation to the beneficiary."

Viewing the DTS CBP over the long term, even if the per unit cost of DTS is lower under a CBP than a non-CBP environment, the cost savings are illusory as the per unit costs do not account for long term waste and additional medical spending that inevitably follow a CBP. Converse to the hidden long term costs of a CBP, there are hidden long term savings inherent in the value of the face-to-face relationship between a patient and his or her independent pharmacist. Because of that face-to-face relationship, our patients are more likely to: take their

medicines on-time; take them properly; refill meds before they run out; and avoid harmful drug interactions. This patient behavior, in turn, helps to lower health care costs by promoting patient health every day. Accordingly, the alternative, forcing patients to turn to mail-order suppliers, will lead to reduced quality of health care and health outcomes, and higher health care costs.

Accordingly, NCPA urges CMS to continue to exclude small independent pharmacies from the CBP in order to protect patients' important face-to-face interaction with their independent pharmacists for effective diabetes monitoring and to ensure that beneficiaries will have immediate access to the specific DTS they need. Because of the importance in protecting meaningful beneficiary access to small independent pharmacies, NCPA also urges CMS to promulgate regulations that prevent the DTS prices established in the Round 1 Rebid and any future national mail order CBP from negatively influencing the prices established in the local retail pharmacy market.

Even if small independent pharmacies are excluded from a national mail order CBP, they may still terminate DTS sales and hinder beneficiary access to DTS if the prices established under such a program are allowed to negatively impact the prices within their market, making it cost prohibitive for our members to continue supplying DTS products. In the end, if CMS 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.

CMS Should Define the Terms "Mail Order Item" and "Non-Mail Order Item" to Protect Small Independent Pharmacists' Ability to Occasionally Deliver DTS to Needy Patients

NCPA urges CMS to revisit its proposed definitions of the terms "mail order item" and "non-mail order item." While NCPA understands CMS's concerns with the Round 1 and Round 1 Rebid definitions of those two terms, the proposed revised definitions cause other problems for patients and independent pharmacy suppliers. Essentially, the proposed revised 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. For example, in 2009, 76% of independent pharmacies offered home delivery services. 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.

Two 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. 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. Accordingly, CMS should define the terms "mail order item" and "non-mail order item," so that small independent pharmacies can continue to provide this service without participating in the CBP.

The second scenario occurs when an 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 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.

Due to the strict nature of the proposed revised definitions of the terms "mail order item" and "non-mail order item," and the probability of hindering beneficiary access to needed diabetic supplies, NCPA requests that CMS address these concerns in its revised definitions. To do so would also provide regulatory consistency, as presently, CMS does not consider an independent pharmacy providing home delivery of a Part D drug to be providing a mail order service, whereas under the proposed rule, CMS would consider delivery of a Part B supply item to be a mail order service.

CMS Should Delay Implementation of a National Mail Order DTS CBP until the Round 1 Rebid CBP is Complete

NCPA applauds CMS for not proposing an implementation timetable for a national mail order DTS CBP. As discussed above, there are strong negative health care costs and health outcomes consequences associated with diminished diabetes monitoring compliance, and NCPA believes that a national mail order program for DTS may lead to diminished compliance. The only way to determine the impact of a CBP on diabetes monitoring compliance and health care and health cost outcomes is to evaluate the mail order DTS data from the Round 1 Rebid. Presently, CMS does not have available data from any prior DTS CBP or pilot program to evaluate and to use in formulating a national mail order CBP. With the Round 1 Rebid, CMS is entering uncharted territory and CMS should not move forward on a grander, national scale without evidence from the Round 1 Rebid. Accordingly, NCPA urges CMS to complete the Round 1 Rebid program and to gather, review and analyze data from the Round 1 Rebid before implementing the national mail order CBP for DTS.

CMS Should Adopt a Strong Anti-Switching Rule

NCPA appreciates CMS's proposed Anti-Switching Rule. A strong Anti-Switching Rule is necessary to ensure that patients have access to the DTS products that are most clinically appropriate, and that are compatible with the meters prescribed by their physician. This means that patients should be protected from the influence of suppliers who have powerful self-interested cost saving incentives under a CBP to limit choice and offer only the lowest cost products, regardless of whether those products are the most clinically appropriate for each individual patient. CMS's proposed Anti-Switching Rule directly addresses this vital issue.

Physicians prescribe particular diabetic testing systems on the basis of medical necessity, the needs of individual patients, and their experiences with the reliability and performance of specific products. There is a general recognition in the medical community that testing systems differ in accuracy, reliability, and ease of use. For these and other reasons, testing systems are not interchangeable, and physicians often prescribe and patients often choose particular meters for important clinical reasons.

Once patients find a suitable testing system, most will use it for many years. While consumers certainly switch testing systems from time to time, Medicare patients change meters on average every 3.8 years.[1] According to one study, 40 percent of Medicare meter owners reported owning their meter three or more years and 22 percent reported owning their meter for five years or more.[2] When a beneficiary is forced to use a testing system that is unknown, difficult, confusing, or unreliable, their adherence to testing will diminish, and the risk of complications may rise. This is perhaps even truer in the mail order context, where patients lack access to an independent pharmacist who could otherwise provide face-to-face counseling to assist patients in navigating such changes.

To promote maximum clinical effectiveness of DTS products and to minimize diabetes monitoring compliance problems and subsequent complications, CMS should ensure that Medicare patients, most of whom are quite vulnerable, should not feel pressured by suppliers, with economic motives, to switch from testing systems with which they are familiar to systems which may have different operating instructions and maintenance requirements. Accordingly, we urge CMS to include the proposed Anti-Switching Rule in the final rule.

CMS Should Exempt Small Independent Pharmacy Supplied Off-the-Shelf (OTS) Orthotics from the CBP

[1] Roper 2008 US Diabetes Patient Market Study.
[2] *Id.*

NCPA agrees with CMS's proposed decision to exempt OTS orthotics from the CBP for certain providers. However, NCPA urges CMS to broaden the exemption to exempt from the CBP small independent pharmacies who supply OTS orthotics, along with hospitals, physicians and other practitioners, as these providers are actually acting as suppliers in this capacity, there is no reason to treat community pharmacies differently. Section 154(d) of MIPPA provides the Secretary with the authority to define the term "other practitioners," and NCPA urges CMS to define that term to include small independent pharmacies.

In terms of defining the term "other practitioners" to narrowly include only small independent pharmacies, NCPA encourages CMS to use the definition of "small business concern" as that term is used in the Small Business Act, 15 U.S.C. § 632(a)(1): "A small-business concern … shall be deemed to be one which is independently owned and operated and which is not dominant in its field of operation…." More specifically, as to pharmacies for the year 2010, the Small Business Administration, pursuant to 13 C.F.R. § 121.201, has defined a pharmacy to be a small business concern if its annual receipts are $7 million or less.

As a matter of equity, there is no basis for why hospitals, physicians and other practitioners should be protected from the downward pricing pressures of a CBP in terms of providing OTS orthotics to their patients, while independent pharmacists should not be protected from such pricing pressures in providing the same products to the patients that they service. In the end, the issue is one of patient access. If OTS orthotics supplied by small independent pharmacies is not exempted from the CBP, then independent pharmacists will most likely cease to provide such products to their patients, through no choice of their own. This is because OTS orthotics, as with DTS, is a volume driven business and small independent pharmacies, individually, do not provide the volume of supplies to win competitive bidding contracts at the extremely low prices created by the CBP and still make a profit on the supplies.

Moreover, including independent pharmacies in an OTS orthotics CBP would have little effect in terms of savings, as independent pharmacists represent only a small portion of the total OTS orthotics market. However, those same pharmacists serve as an important access point for beneficiaries to OTS orthotics and if they cease to supply OTS orthotics would cause hardship to those beneficiaries in terms of access.

If independent pharmacists believe that they cannot profitably supply the OTS orthotics to their patients, then they may refrain from participating in the CBP and patient access to OTS orthotics supplies will be narrowed to those providers who are exempt from the CBP and mail order companies that can win the extremely low price competitive bids. Therefore, NCPA urges CMS to include small independent pharmacies in the definition of "other practitioners" who are exempt from the CBP in supplying OTS orthotics to their patients.

CMS Should Exempt All Small Independent Pharmacy Supplied DME from Future CBP Rounds

Along with urging CMS to exclude small independent pharmacy supplied DTS and OTS orthotics from the CBP, NCPA also requests that CMS exclude small independent pharmacies from future rounds of the CBP for all DME products that these pharmacies supply. Small independent pharmacies not only provide DTS, but also serve as a source for beneficiaries who need walkers, crutches, canes and commodes, among other supplies.

Like DTS, the sale of these DME supplies is a volume driven business. Accordingly, those suppliers with more volume, such as mail order companies and larger chain pharmacies, can afford to bid lower prices in a CBP and still profitably sell the supplies. Conversely, small independent pharmacies do not deal with such large volumes, do not have the economies of scale to match the low bids inherent in a CBP and cannot profitably sell DME supply items in the context of a CBP. As stated previously, this results in small independent pharmacies dropping out of the CBP and ceasing to supply DME supply items. The end result is that patients' access to DME supplies is narrowed, as patients are forced to turn to mail order for their supplies.

NCPA urges CMS to exempt small independent pharmacies from all future rounds of the DMEPOS CBP by narrowly defining the term "small independent pharmacies." More specifically, NCPA endorses the definition of "retail community pharmacy that is a small business concern" as that terminology is used in H.R. 5235, The Medicare Access to Diabetes Supplies Act. This bill would exempt from the CBP any retail community pharmacy supplied DTS products and defines "small business concern" per the Small Business Act, as outlined above. NCPA urges CMS to adopt such a definition or similar definition in exempting small independent pharmacies from future rounds of the DMEPOS CBP.

In order to promote patient access to DME supplies, patient utilization of these supplies, and to maximize positive patient health care outcomes, CMS should exempt all small independent pharmacy supplied DME from future rounds of the CBP. NCPA would welcome an effort by CMS to exempt all retail pharmacies, but urges CMS to at least exempt small independent pharmacies from all future rounds of the DMEPOS CBP.

AVERAGE SALES PRICE (ASP) ISSUES

CMS Should Increase the Supply and Dispensing Fees for Part B Medications for CY 2011

NCPA is very concerned that the Proposed Rule, as in previous years, does not increase supply or dispensing fees for Part B medications to help offset low reimbursements under ASP –

which are often below acquisition costs for most small independent pharmacies -- and administrative costs incurred in Medicare Part B claim submission. CMS has not updated the supplying and dispensing fees since 2005. This is problematic as the reimbursement rates stay the same while medical care inflation continues to rise. According to the Bureau of Labor Statistics, the medical inflation rate since 2005 has increased as follows: 4.2% in 2005; 4% in 2006; 4.4% in 2007; 3.7% in 2008; 3.2% in 2009; and 3.2% from July, 2009 to July, 2010. The end result is that many of our members have advised us that they have been forced to stop providing Part B medications, which decreases access for patients. Accordingly, NCPA strongly urges that Part B drug supply and dispensing fees be increased for CY 2011.

E-PRESCRIBING INCENTIVES

CMS Should Raise the Provider Eligibility Threshold for the E-Prescribing Incentive Program

NCPA remains concerned that CMS is not raising the provider threshold to be eligible to receive incentives/avoid penalties for e-prescribing in 2011. As in 2010, CMS is again proposing that a professional be eligible for the incentive of 1% of all total estimated allowed charges covering all professional services furnished during the 2010 reporting period, provided the eligible professional meets the extremely low threshold of electronically generating and reporting one or more prescriptions associated with a patient visit for a minimum of 25 unique visits per year in 2011.

NCPA believes that there are at least four reasons why this continuation of the existing threshold level of e-prescribing is undesirably low:

1) it is not "fair" to reward providers with a generous e-prescribing bonus for conducting minimal levels of e-prescribing, while pharmacies and pharmacists receive no federal bonus for doing so;
2) it is an unsound use of taxpayer funds to provide such large sums of money for what might be an overall very small driving force to promote e-prescribing;
3) the level is so low that it might actually discourage an increase in e-prescribing by some providers, as some physicians might have been prepared to conduct much higher levels of e-prescribing, but would now be glad to be able to continue with their traditional paper and fax prescribing methods (except for in a very limited number of cases); and
4) the low level will likewise discourage both participating pharmacists, and also greater participation by those pharmacists, as they will be discouraged from spending the funds and taking the time necessary to accept electronic prescriptions , when they believe – perhaps correctly – that doctors will not significantly increase their level of e-prescribing, and thus the pharmacy's efforts will not be worthwhile.

Given NCPA's concerns, NCPA asks CMS to consider raising the minimum reporting threshold for e-prescribing to between 250 – 500 prescriptions a year per eligible professional, and 25,000 – 50,000 per year per group practice of at least 200 eligible professionals. At the very least NCPA requests that CMS present compelling reasons for continuing to set such low standards for e-prescribing adoption.

REMOVAL OF BARRIERS TO PREVENTIVE SERVICES IN MEDICARE

CMS Should Waive Co-pays, Coinsurance and Deductibles for DSMT

NCPA welcomes CMS's proposal to waive co-pays, coinsurance and deductibles for preventive services, particularly the influenza virus vaccine, the pneumococcal vaccine and the hepatitis B vaccine. However, NCPA is concerned that these waivers do not extend to Diabetes Self-Management Training (DSMT) and urges CMS to work with the United States Preventive Services Task Force (USPSTF) to assign a grade of A or B to DSMT to make DSMT eligible for these waivers under Sections 4104(b)(4), 4103(c)(1) and 4104(c) of the Affordable Care Act (ACA).

CMS and the USPSTF have recognized the vaccines subject to the waivers either demonstrate good or fair evidence of improving important health care outcomes. Moreover, waiver of co-pays, coinsurance and deductibles will encourage patients to obtain these vaccines, ultimately improving health care outcomes for more patients.

As with the evidence of positive health care outcomes for the vaccines cited in the proposed rule, NCPA believes that existing evidence also demonstrates positive health care outcomes for DSMT. The American Association of Diabetes Educators (AADE) conducted a study of 32,500 high-risk pregnant women with gestational diabetes and found that DSMT reduced healthcare costs by an average of $13,000 per pregnancy. This decrease in healthcare costs is tantamount to an increase in positive diabetes health care outcomes. Therefore, NCPA believes that the co-pay, coinsurance and deductible waivers should be extended to DSMT in order to better promote these positive health care outcomes resulting from DSMT.

NCPA understands that under the ACA CMS is constrained by the USPSTF grading for DSMT in terms of extending the waivers to DSMT. Nonetheless, NCPA urges CMS to work with the USPSTF to positively grade DSMT, such that DSMT will be eligible for the waivers. With the extension of the waivers to DSMT more patients will seek out DSMT and diabetes health outcomes will improve, while diabetes health care costs decrease.

DSMT ISSUES

NCPA thanks CMS for proposing to increase the relative value units (RVUs) for DSMT HCPCS codes G0108 and G0109

NCPA applauds CMS for recognizing the importance of DSMT in terms of promoting positive health outcomes for diabetes patients and treating and preventing diabetic complications. CMS's decision to increase the RVUs for DSMT HCPCS codes G0108 and G0109 will result in a higher payment for our members who provide DSMT to patients and encourage more of our members to provide this valuable service to diabetes patients. Accordingly, NCPA thanks CMS for making this change.

CMS should add pharmacists to the list of approved providers for providing telehealth DSMT services

NCPA supports CMS's decision to add DSMT to the list of payable telehealth services. We agree with CMS that DSMT services are underutilized, that existing evidence demonstrates that DSMT is effective and has a positive effect on diabetes patient health and that it is important to facilitate patient access to underutilized DSMT services. However, NCPA urges CMS to add pharmacists to the list of approved providers of DSMT telehealth services.

Independent pharmacists have always played an active role in helping patients cope with diabetes through prescription management and dispensing glucose meters and therapeutic shoes, for example. Our members' role is now of increasing importance, as earlier this year, NCPA partnered with the American Association of Diabetes Educators (AADE), a federally approved diabetes education accrediting organization, to form the Diabetes Accreditation Standards – Practical Applications (DASPA) partnership. DASPA now provides training to community pharmacists in DSMT services and prepares them to obtain accreditation to provide these services.

Pharmacists are able to be accredited to provide DSMT services through 42 C.F.R. §§ 410.141(e)(3), 410.142 and 410.144(b), which collectively provide that an individual or entity can provide DSMT services if they are approved by a CMS approved accrediting organization and meet the quality standards of The National Standards for Diabetes Self-Management Education Program ("NSDSMEP"). Our members who provide DSMT services are accredited by a CMS approved accrediting organization that follows the NSDSMEP standards, which expressly allow pharmacists to provide DSMT services. Therefore, CMS, by endorsing the NSDSMEP standards, has already approved pharmacists as eligible DSMT providers and community pharmacists are already providing live, in-person DSMT services to beneficiaries.

As a result of DASPA, community pharmacists have been and will continue to play a critical role in providing DSMT services. Evidence already suggests that increased pharmacist participation in diabetes care in conjunction with physician-directed protocols helps to improve glycemic control. The National Standards for Diabetes Self-Management Education recognizes pharmacists as key members of the health care team in designing curricula, delivering care and teaching critical self-management practices. Moreover, a study of the Asheville Project, a community-based pharmacy program in Asheville, North Carolina, demonstrated a reduction in A1C values from 7.6% to 6.2%.

Pharmacists are already providing valuable DSMT services to patients in "live" settings. There is no reason why pharmacists should be excluded from providing those same valuable services via telehealth. To fail to include pharmacists on the approved provider list of telehealth DSMT providers is tantamount to limiting patient access to a sizeable population of otherwise qualified providers. Therefore, CMS should include pharmacists as approved providers of telehealth DSMT services.

Conclusion

For the reasons highlighted above, NCPA reiterates its requests that CMS: 1) Exercise its existing authority to exempt community pharmacies from the CBP for DTS, OTS orthotics and future rounds of the CBP for all DME supplies; 2) Raise the dispensing and supplying fees for Medicare Part B drugs for CY 2011; 3) Raise the threshold for providers to be eligible for the e-prescribing incentive program; 4) Take steps to waive the co-pay, coinsurance and deductibles for beneficiaries utilizing DSMT and 5) Add pharmacists to the list of approved providers of telehealth DSMT services.

NCPA appreciates the opportunity to comment on CMS-1503-P. Please do not hesitate to contact Chris Smith, Director of Public Policy and Regulatory Affairs at chris.smith@ncpanet.org, (703) 683-8200, if you have any questions.

Sincerely,

John M. Coster

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