

**VIA Electronic Submission to <http://www.regulations.gov>**

September 4, 2012

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1590-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

**Re: CMS-1590-P; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013.**

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 2013. As CMS considers issues pertinent to changes to Medicare Part B for CY 2013, the National Community Pharmacists Association (NCPA®) appreciates the opportunity to share our perspectives.

The National Community Pharmacists Association (NCPA) represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a \$93 billion health-care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions. NCPA members are 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.

**CMS Should Consistently Apply Payment Policies for Part B Pharmacist Prepared Drugs Dispensed “Incident To” a Covered Physician Service**

The proposed rule proposes to clarify payment policies regarding billing for certain drugs under Medicare Part B by stating that CMS considers drugs used by a physician to refill an implantable item of DME to be within the “incident to” benefit category and not the DME benefit category. As such, the proposed rule emphasizes that the physician must buy and bill for the drug, and a nonphysician supplier that has shipped the drug to the physician’s office may not do so (except as may be permitted pursuant to a valid reassignment).

NCPA supports this proposal so long as the payment policies are implemented consistently among all suppliers and this clarification does not result in pharmacies facing audits or recoupment of funds from properly following the instructions they were previously given by Medicare contractors. NCPA is very concerned that, while pharmacies were acting in good faith under the instructions that they were given by a CMS' contractor, pharmacies will nevertheless face recoupment for following these instructions. NCPA would strongly oppose any audits or recoupment of funds from pharmacists related to this clarification. In addition, NCPA would like to reiterate the importance of these payment policies being applied consistently among all suppliers.

### **CMS Should Not Place the Burden of Obtaining Documentation for Face-to-Face Encounters on Pharmacies**

NCPA is very concerned that the proposed rule does not make clear that the burden to obtain documentation of face-to-face encounters will not be placed on pharmacies. The proposed rule provides a list of covered items that will be subject to the face-to-face documentation requirement. Community pharmacists provide many of the items on the list of items subject to the face-to-face requirement, including nebulizers, infusion pumps, home blood glucose monitors and oxygen supplies. The proposed rule states that, for the listed items, a physician must have documented and communicated to the DME supplier that the physician or a PA, a NP, or a CNS has had a face-to-face encounter with the beneficiary no more than 90 days before the order is written or within 30 days after the order is written.

The proposed rule lays out four options regarding supplier notification: (1) the practitioner who wrote the order (which could be a PA, a NP, or a CNS) is required to provide the physician documentation of the face-to-face encounter directly to the DME supplier; (2) the physician who completes the documentation of the face-to-face encounter (regardless of whether a PA, a NP, or a CNS wrote the order) is required to provide that documentation directly to the DME supplier; (3) the documentation, no matter who completes it, be provided to the DME supplier through the same process as the written order for the covered item of DME; and (4) the physician is required to provide a copy of the face-to-face documentation to the beneficiary for the beneficiary to deliver to the DME supplier.

NCPA strongly opposes the fourth option of requiring the physician to provide a copy of the face-to-face documentation to the beneficiary and disagrees with the proposed rule's reasoning that this option would, "ensure that the supplier receives the documentation of face-to-face encounter directly and limits the supplier's need to rely on the PA, NP, or CNS to receive this documentation completed by the physician." Without further clarification, this option places the burden on the pharmacy in a situation where the beneficiary does not bring the documentation of the face-to-face encounter to the pharmacy. Under this option of supplier notification, the pharmacy is placed in the position of refusing to dispense the beneficiary's DME if the beneficiary doesn't provide the documentation.

In addition, a scenario could exist whereby the beneficiary may not have the face-to-face documentation available for the supplier upon processing of the order, as their face-to-face encounter occurs AFTER the order has been filled. NCPA contends there will be no incentive at this point for a beneficiary to deliver the documentation to the pharmacy at all. The pharmacist will be forced to deny the beneficiary access to care and will likely be forced to contact the provider in an attempt to retrieve the documentation of the face-to-face encounter. Since this option only requires the physician to provide a copy of the face-to-face documentation to the beneficiary, when the pharmacy does contact the physician, the physician is not mandated in any way to provide the pharmacy with a copy of this documentation. Furthermore, this option should not be an option at all in the evolving world of Health IT where Part B should be moving in the direction of real-time data and e-prescribing. Part B should be moving in the direction of practitioners communicating directly and electronically with other practitioners.

Since the proposed rule states that CMS is considering one of the four options listed in the proposed rule, but its consideration is not limited to those four options, NCPA would like to take this opportunity to express strong opposition to any supplier notification requirement that would place the burden on community pharmacies to obtain documentation of a face-to-face encounter. Independent community pharmacists must already comply with multiple requirements in order to participate in 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.

Regarding the burdensome documentation requirements that community pharmacists must already bear, currently to provide blood glucose monitors, which are also subject to the face-to-face documentation requirement within the proposed rule, community pharmacists must obtain medical record documentation that shows that all coverage requirements were met. Currently, for Medicare to cover a blood glucose monitor, community pharmacists must obtain documentation of the following: a diagnosis of the diabetes; the number of test strips and lancets required for one month's supply; the type of meter required (if a special type of meter is required, the community pharmacists must obtain information from the physician stating the medical reason for the special meter); a statement that the beneficiary requires insulin or does not require insulin; and how often the beneficiary should test the level of blood sugar.

If the physician fails to provide such information, it is the community pharmacist that suffers contentious audits and recoupment of reimbursement. It is also the community pharmacist that must monitor when the beneficiary is utilizing their Part B supplies in excess of the Medicare amount. If the beneficiary goes above this amount, even when prescribed, the community pharmacist can face recoupment. Placing the burden of obtaining documentation of a face-to-face encounter on community pharmacists in addition to the documentation requirements that community pharmacists already must undertake, is overly burdensome and takes away valuable time that community pharmacists need to spend with beneficiaries.

Therefore, NCPA would urge that the final rule be very specific as to the physician's responsibilities in directly providing such documentation to the supplier. NCPA would strongly oppose any language in the final rule that only makes this documentation available "upon request" of the supplier. The physician should be required to directly and automatically, without request, provide documentation of a face-to-face encounter to the supplier. Any other option would overburden community pharmacies in an environment where community pharmacies are already struggling to comply with all Part B requirements that have been placed upon them.

### **CMS Should Not Expand the Requirement for Documentation of a Face-to-Face Encounter Until Further Clarification is Provided**

As stated above, NCPA is very concerned as to whether pharmacies in a direct or indirect way will bear the burden of obtaining documentation of a face-to-face encounter from a provider. While the proposed rule states that CMS is not requiring documentation of a face-to-face encounter for prosthetic devices, orthotics, and prosthetics but will look at expanding this requirement to these areas in future rulemaking, NCPA would oppose such an expansion where the burden of obtaining the documentation of a face-to-face encounter falls either directly or indirectly on a community pharmacy.

The proposed rule provides a list of covered items that will be subject to the face-to-face documentation requirement. Community pharmacists provide many of the items on the list of items subject to the face-to-face requirements including, nebulizers, infusion pumps, home blood glucose monitors and oxygen supplies. NCPA would strongly oppose an expansion of items that are subject to the face-to-face documentation requirement until CMS provides clear clarification that the burden of obtaining such face-to-face documentation does not fall on community pharmacists.

### **CMS Must Enforce That Supplier Notification of Face-to-Face Encounter Has Occurred Before Issuing Additional Documentation Payment to Physicians**

NCPA is concerned with CMS' proposal to compensate a physician for the "burden associated with the requirement placed on the physician to document that a face-to-face encounter has occurred between a PA, a NP, or a CNS practitioner." Community pharmacists have undergone countless burdens all the while experiencing drastic cuts within the Part B program. From face-to-face counseling to the medications they dispense, independent community pharmacists play an essential role in improving health care outcomes and decreasing long-term health care costs. As stated above, independent community pharmacists must already comply with multiple criteria in order to participate in 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.

Recently, CMS has started exploring its inherent reasonableness authority to cut diabetes testing supplies (DTS) reimbursement to community pharmacists even more. With these drastic cuts to reimbursement for DTS, many of our members have expressed they will no longer be able to dispense Part B DTS. Since only 6%-8% of an average independent pharmacy's annual sales are from DMEPOS, independent 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."

According to a October 2011 survey that NCPA conducted of over 800 independent community pharmacists regarding negative consequences for a sharp reduction in payment for diabetes test strips, 84% 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, 81% 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 access to diabetic testing supplies.

NCPA is very concerned that while CMS is considering drastic cuts to community pharmacists within the Part B program, CMS is issuing a convenience payment of \$15 to physicians to compensate for the burden that CMS claims is placed on the provider for simply documenting that a face-to-face encounter occurred between their patient and a PA, a NP, or a CNS in the provider's own facility. We find it ironic that CMS is issuing an additional payment to doctors even in situations where CMS has not enforced that supplier notification has occurred.

The proposed rule states that in order for a physician to receive such additional payment, they must document that a face-to-face encounter has occurred between a PA, a NP, or a CNS, and the beneficiary. If CMS is determined to compensate physicians for documenting this encounter, one of the requirements that physicians should have to meet to receive such payment is to prove to CMS that such documentation was in fact delivered to the supplier. It should not be enough that the physician simply documents that the encounter took place. If the physician is able to receive incentive payments, then the physician should bear the burden in delivering the documentation to the supplier. Without showing proof of delivery, the physician should not be eligible for incentive payments.

In addition to the documentation requirements that community pharmacists must satisfy and the cuts that community pharmacies face, in some options under the supplier notification requirements, as stated above, pharmacists will either directly or indirectly bear the burden of obtaining the documentation of the face-to-face encounter.

One option to compensate community pharmacists for the added documentation burden that they bear is for Medicare to pay pharmacists for counseling diabetics under Part B. Increased face-to-face counseling and adherence leads to savings in the Medicare program, decreases hospitalizations and complications, and increases beneficiary access to care by providing pharmacists a way to continue selling Part B supplies. Medication therapy management has long been recognized under Part D as essential to increasing the quality of care that beneficiaries receive while decreasing overall health care costs. However, there is no ability for reimbursement of these medication-related counseling services currently. To the contrary, pharmacists have only received further cuts in reimbursement and more stringent requirements to participate as suppliers in the Medicare Part B program.

### **CMS Should Account for the Role of Pharmacies in Providing Transitional Care Management Services**

In the proposed rule, CMS is proposing to create a HCPCS G-code for all non-face-to-face services related to the transitional care management furnished by the community physician or qualified nonphysician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, long-term care hospital, skilled nursing facility, and inpatient rehabilitation facility; hospital outpatient for observation services or partial hospitalization services, and partial hospitalization program at a CMHC to community-based care.

This new code includes the following services: assuming responsibility for the beneficiary's care without a gap; establishing or adjusting a plan of care to reflect required and indicated elements; communication (direct contact, telephone, electronic) with the beneficiary and/or caregiver, including as assessment of the patient's or caregiver's understanding of the medication regimen as well as education to reconcile the medication regimen differences; communication with other health care professionals who will (re)assume care of the beneficiary, education of patient, family, guardian, and/or caregiver; assessment of the need for and assistance in coordinating follow up visits with health care providers and other necessary services in the community; establishment or reestablishment of needed community resources; and assistance in scheduling any required follow-up with community providers and services.

NCPA contends that community pharmacies are already performing many of these transitions of care related activities and should be compensated for them, specifically medication reconciliation. NCPA read with interest that this additional G code is being proposed where many of these services are already being performed by independent community pharmacists without any additional compensation. A beneficiary should be able to choose to seek these services from their community pharmacists. Currently, beneficiaries choose to seek medication-related services from their community pharmacist for many reasons. The beneficiary often has an established relationship with their community pharmacist and allowing the beneficiary to seek these services from their pharmacist increases the odds that medication reconciliation will occur.

Community pharmacists have the ability to increase adherence and compliance and thus drive down health care costs while promoting healthy outcomes. CMS currently recognizes community pharmacies as a provider under certain circumstances as pharmacies currently have the ability to bill G codes for a limited number of services. CMS should allow pharmacies who participate in the Part B program to bill for transitional care management services that involve medication therapy.

### **CMS Should Consider Pharmacists when Considering New Options for Payment of Primary Care Services**

NCPA read with interest the section within the proposed rule entitled, *Primary Care Services Furnished in Advanced Primary Care Practices*, where CMS states that it is “committed to considering new options and developing future proposals for payment of primary care services under the MPFS.” The proposed rule goes on to state that “[s]uch options would promote comprehensive and continuous assessment, care management, and attention to preventive services that constitute effective primary care by establishing appropriate payment when physicians furnish such services.”

CMS states within the proposed rule that five “comprehensive primary care functions provide an appropriate starting point for discussing the incorporation of the comprehensive primary care services delivered in advanced primary care practices into the MPFS.” These five comprehensive primary care functions are: risk-stratified care management; access and continuity; planned care for chronic conditions and preventive care; patient and caregiver engagement; and coordination of care across the medical neighborhood. NCPA read with interest the provisions under the *Planned Care for Chronic Conditions and Preventive Care* which detailed that this function includes “medication reconciliation and review of adherence and potential interactions, and oversight of patient self-management of medications for diabetes, anti-coagulation management or warfarin therapy, and other chronic conditions.”

Medicare beneficiaries with multiple chronic illnesses see an average of 13 different physicians, have 50 different prescriptions filled per year, account for 76% of all hospital admissions, and are 100 times more likely to have a preventable hospitalization than those with no chronic conditions.<sup>1</sup> It is often the community pharmacist which helps Medicare beneficiaries navigate the daunting challenge of medication reconciliation, adherence, and compliance. The Institute of Medicine noted that while only 10% of total health care costs are spent on medications, their ability to control disease and impact overall cost, morbidity, and productivity – when appropriately used – is enormous.<sup>2</sup>

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<sup>1</sup> Anderson GF. Testimony before the Senate Special Committee on Aging. The Future of Medicare: Recognizing the Need for Chronic Care Coordination. Serial No. 110-7, pp19-20 (May 9, 2007).

<sup>2</sup> Centers for Medicare & Medicaid Services. National Health Expenditures. January 2008.

Community pharmacists play a vital role in providing medication therapy management (MTM) services. MTM can serve many beneficial purposes, including decreasing wasteful and unnecessary drug spending, reducing patient use of potentially harmful combinations of drugs, and improving patient adherence and proper usage of beneficial drugs, which ultimately decreases long-term health care costs.

MTM has become essential where beneficiaries are now taking prescription, nonprescription, alternative, traditional, vitamins, and nutritional supplements.<sup>3</sup> Where this is the case, it is essential that the community pharmacists assess that each medication is appropriate for the specific patient, effective for the medical condition, safe given the other medications being taken, and able to be taken by the patient as intended.<sup>4</sup> While physicians also play an integral role in medication reconciliation, CMS' reluctance to recognize the vital role that community pharmacists have in medication reconciliation, adherence, and overall preventive services, is very alarming and fails to take advantage of an essential tool in promoting preventive care.

There are many times when the community pharmacist is the sole health care supplier that is monitoring a beneficiary's adherence and working with the beneficiary to provide medication reconciliation. There are also many other opportunities where a primary care physician and pharmacist must work hand-in-hand to provide these services to Medicare beneficiaries. For example, "the primary care provider may seek a comprehensive medication review from a clinical pharmacist to determine medication interaction and adjustments in a patient undergoing chemotherapy for cancer, a patient taking antiseizure medications, or even a patient on multiple medications to treat a condition such as high blood pressure who is still not at goal."<sup>5</sup>

CMS' should recognize the vital role that community pharmacists have in medication reconciliation, adherence, and overall preventive services. NCPA strongly encourages CMS to work with community pharmacies on this issue and to include a role for community pharmacies in the new options for payment of primary care services.

### **CMS Should Update Existing Standards for E-prescribing and Lift the LTC Exemption**

NCPA supports CMS' proposal to retire SCRIPT version 8.1 on October 31, 2013 and adopt SCRIPT version 10.6 as the official Part D e-prescribing standard effective on November 1, 2013. Furthermore, NCPA supports lifting the Long-Term Care exemption.

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<sup>3</sup> See Patient-Centered Primary Care Collaborative, *The Patient-Centered Medical Home: Integrating Comprehensive Medication management to Optimize patient Outcomes*, Second Edition, June 2012.

<sup>4</sup> Id.

<sup>5</sup> Id.

However, NCPA agrees with concerns expressed by NCPDP and other stakeholders that the effective date of lifting the Long-Term Care exemption should be set at November 1, 2014, which is one year later than expressed in the proposed rule. It is NCPA's understanding that additional time will be needed to transition to the standard without disrupting patient care.

While NCPA supports lifting the Long-Term Care exemption, NCPA cautions that lifting this exemption will result in reengineering numerous non-NCPDP interfaces between facility and pharmacy systems and cannot be accomplished by the date proposed in the proposed rule. In addition, while NCPA supports these proposals, NCPA would also like to reiterate that these provisions in no way mandate e-prescribing.

**CMS Should Expand Coverage of Hepatitis B Vaccination Allowing Community Pharmacists to Continue to Offer a Complete Spectrum of Care to Beneficiaries**

NCPA supports CMS' efforts to expand coverage for hepatitis B vaccine and its administration to all individuals diagnosed with diabetes mellitus, not just those individuals with diabetes that are receiving glucose monitoring in facilities. Community pharmacists have long adopted a holistic approach by providing beneficiaries with a complete spectrum of care. From face-to-face counseling to the medications they dispense, independent community pharmacists play a vital role in improving the quality of life of beneficiaries. Expanding coverage for the hepatitis B vaccine will allow community pharmacists to offer this spectrum of care to more beneficiaries, which results in better health care outcomes and decreased long-term costs.

**Conclusion**

As you finalize plans for release of the Final Rule for the implementation of Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013, NCPA respectfully urges you to consider these issues. We appreciate the opportunity to share our concerns and recommendations with you.

Sincerely,



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