

Via Electronic Transmission to: [AdvanceNotice2011@cms.hhs.gov](mailto:AdvanceNotice2011@cms.hhs.gov)

March 5, 2010

Department of Health and Human Services  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

ATTN: Jonathan Blum, Center for Medicare Management

**Subject: 2011 Medicare Part D Draft Call Letter**

Dear Jon:

The National Community Pharmacists Association (NCPA) represents the interests of the owners and operators of nearly 23,000 independent community pharmacies in the United States. We are major providers of Part D prescription drugs and pharmacy services to Medicare patients. We welcome this opportunity to comment on certain proposals in the draft Part D 2011 Call Letter.

**Coverage of Certain Medicare Part D drugs under Medicare Part B for ESRD Patients (p. 82)**

NCPA is concerned with the proposal to move coverage of certain Medicare Part D drugs used to treat ESRD to Medicare Part B. We believe that patients' quality of care will be fragmented because Part B coverage of these drugs may result in their movement to specialty-only pharmacies. This means that these patients could be required to obtain non-ESRD drugs from their community pharmacy, and their ESRD drugs from another remote pharmacy. We believe that a coverage change to the Medicare Part B benefit would add burden to the system as the Part D payment and network system is more robust and navigated more easily than its Part B counterpart.

In addition, it appears by reading public comments that small dialysis units also believe they will be unable to continue operations under CMS' proposal, which would have a significant negative impact on the quality and access to ESRD care for their patients. Bundling the medications, labs and home training into an ESRD prospective payment system (PPS) is not possible for many entities – dialysis units cannot, for example, dispense medications -- and will result in a diminishment in the quality of care for these patients.

For the reasons stated above, NCPA requests that CMS not include any such drugs and biologicals defined as “renal dialysis services” under the new ESRD PPS.

**Policies Relating to Curbing Waste of Unused Drugs Dispensed in the Retail Setting (p. 83)**

NCPA very much supports the goal of containing health care costs, reducing drug waste, and ensuring proper consumption of prescription drugs. Prescription drugs work best for patients that use them appropriately. Inadequate medication adherence and overstocking of medications by patients create additional costs that reduce the efficiency of our health care system. According to the New England Institute of Health, inadequate utilization of medication including waste and poor adherence costs our health system \$290 billion annually.<sup>1</sup> We therefore support efforts to improve health outcomes by increasing adherence and reducing waste of unused drugs.

Reasons for Patient Nonadherence: The Call Letter focuses on a mechanical approach to provide plans with an option, discussed only for community pharmacies, to offer a trial supply of prescription medication in an attempt to reduce drug waste. CMS speculates that a low rate of refills for chronic medications could be addressed by allowing beneficiaries the option of obtaining a trial supply of a first fill at a lower cost, which will be more appreciated by beneficiaries and their physicians when initiating new therapies and for expensive medications.

It is unclear, however, if such a correlation between an initial trial fill and reduction in waste can be made with any degree of confidence. Medicare Part D already has a high generic use rate; therefore slightly lowering costs through trial supplies would likely not influence obtaining the initial fill. In addition, there are a myriad of reasons why beneficiaries and individuals do not refill a script besides the cost sharing amount, which the Call Letter does not address, such as perceived ineffectiveness of the medication, resolution of the condition for which the medication was prescribed, and poor adherence to prescribed therapies.

Lack of Focus on Mail Order Waste: One study has demonstrated that **mandatory mail order prescription drug plans create 3.3 times more prescription drug waste** than plans that allow patients to choose their own pharmacy for acquiring prescription drugs.<sup>2</sup> This is often due to the fact that mail order pharmacies encourage patients to purchase medications in bulk that they may not use. The president and CEO of Walgreens, Greg Wasson, once claimed that “there’s a whole lot of waste being created by mandatory mail programs” due to excessive overutilization of 90 day scripts.<sup>3</sup>

Another study found that when prescription drug waste occurred in mandatory mail order plans, the average amount of waste was 42.5 days’ supply of the medication. For non-mandatory mail order plans the average amount of waste was only 14.6 days supply of the medication.<sup>4</sup> Despite this research, the Call Letter only addresses curbing waste of unused drugs dispensed in the community pharmacy setting. It is unclear to us if by stating “community (versus institutional) setting” CMS is referring to strictly retail community pharmacy or mail order pharmacy as well. This raises the question of how CMS plans to address pharmaceutical waste in the mail order pharmacy setting where 90-day fills of chronic medications started and where NCPA contends

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<sup>1</sup> New England Healthcare Institute. “Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Medication Adherence for Chronic Disease.” August 2009.

<sup>2</sup> Daniel Halberg, Erin Smith, and Kevin Sedlacek. “Effect of Mail-Order Pharmacy Incentives on Prescription Plan Costs”, University of Arkansas for Medical Sciences College of Pharmacy, October 2000.

<sup>3</sup> Chain Drug Review. “Advantage90 takes on mail order: Walgreens Co. offers 90-day prescription drugs to avoid waste of drugs.” April 10, 2006.

<sup>4</sup> Daniel Halberg, Erin Smith, and Kevin Sedlacek. “Effect of Mail-Order Pharmacy Incentives on Prescription Plan Costs”, University of Arkansas for Medical Sciences College of Pharmacy, October 2000.

the majority of waste occurs due to auto-shipment of large supplies of medications that the patient may never use.

Travel Concerns for Patients: We are also concerned that this proposal could lead to plans mandating trial supplies for all first fills of certain prescriptions. Such a policy could have a very negative impact on patients in certain areas, where they might have to travel to reach their community pharmacy and could not make additional visits easily. The community pharmacist, who physically interacts with their customers, should have the opportunity to decide if it is in the patient's best interest to dispense a partial fill based on factors such as the patient's medication profile and reaction to therapy, not the plan.

Focus Efforts on High-Cost and Certain Drugs: To make this potential policy most effective, CMS may want to focus on certain high cost drugs, drugs that are known to have a significant prevalence of side effects, and certain controlled substances. In general, generic drugs should not be eligible for this policy. Involving plans' P+T Committees could help determine the drugs subject to this policy, based on guidelines given to the plans by CMS.

Impact on Pharmacy Workflow and Reimbursement: Related to our concerns of plans imposing trial fills on beneficiaries and pharmacies, NCPA has very strong reservations with CMS' assertion that "only a change in payer practices including negotiation of appropriate dispensing or incentive fees for promotion of these trial fills may be needed to implement this waste reduction strategy at the pharmacy counter."

Regardless of whether a pharmacist fills a prescription for 7 days, 14 days, or 30 days the same amount of careful consideration and work occurs. Labor costs, supplies, transaction fees and administrative fees are generally all the same regardless of the quantity of prescription dispensed. NCPA is strongly opposed to any measure that would decrease or remove a dispensing fee that is paid for a partial fill of medication. Our members simply can't operate in an environment where they are being required to process two prescriptions when they would normally fill one, but paid a reduced amount for either the initial or subsequent fill. Community pharmacists must be reimbursed for their time and expertise in filling each and every prescription, whether it is a trial supply or not. It is the pharmacist's responsibility to monitor the response of the patient to a trial supply of medication to determine if they will be able to continue on with the entire fill. Also, guidance must be provided to the plans as to what documentation would be required for each trial fill, therefore avoiding problems we foresee for our members related to auditors demand for certain compliance requirements.

NCPA is also concerned that by leaving the discretion of whether to implement trial fills up to the plans, pharmacies may be confronted with differing administrative burdens depending on how any given plan decides whether to, or how to implement beneficiaries receiving trial fills. There must be uniform guidelines across all plans as to how the trial fill policy is implemented and which entity ultimately makes the decision a patient will receive a trial fill – is it the plan, the beneficiary, the prescriber or the pharmacist?

Notwithstanding operational concerns, NCPA could support an optional trial supply policy if our concerns with ensuring appropriate dispensing fees for each fill are addressed and if CMS

encourages medication therapy management (MTM). Regarding MTM, it is essential to have pharmacists educate and monitor patients who receive partial fills. The pharmacist should receive incentive for patients who continue medications after receiving partial fills due to increasing medication adherence. In addition, NCPA respectfully notes that the Call Letter is at most brief, and in general silent, on how CMS will conduct its trial supply policy, such as not describing the role, restrictions and requirements that a prescriber must follow in writing a trial supply prescription, which could have ramifications in the pharmacy discussed above. That is, we reiterate the importance of having a consistent policy regarding who will make the determination to partially fill a prescription originally written for 30 or 90 days.

#### **Reassignments (p. 84)**

NCPA is opposed to CMS' proposal to expand the number of reassignments by including "choosers" in the reassignment process. This annual process already results in confusion to millions of beneficiaries who are unknowingly reassigned to new plans each year. We further believe that the procedure proposed in the Call Letter of reassigning "choosers" is not a sound policy. Not only does it use reverse logic, whereby inaction on the part of the beneficiary results in plan reassignment, it increases the number of beneficiaries who will come to a pharmacy on Jan. 1, unaware that they have a new plan. NCPA supports the current process in which CMS sends tan-colored letters to beneficiaries, alerting them of lower-cost options and leaving the decision to switch plans in the hands of the beneficiary. This method accomplishes the objective of informing beneficiaries of their choices without switching people who do not wish to be switched to another plan.

NCPA supports the use of "intelligence assignment" for the reassignment process. Currently, patients are reassigned to plans regardless of whether the new plan covers their medications. This can result in confusion for the patient, and additional uncompensated administrative hassles for the pharmacist. Taking patients' medications into consideration in the reassignment process can greatly reduce the amount of service delays and disruptions in the pharmacy.

#### **Specialty Tier Threshold (p. 96)**

Maintaining the \$600 threshold for drugs on the specialty tier should help to maintain access to these products at local community pharmacies. NCPA agrees that claims data must demonstrate that the majority of fills exceed the specialty tier cost criteria. The specialty tier threshold should be set at no lower than the current \$600 level, and should be adjusted upwards annually at least at the rate of inflation.

#### **Release of Part C and Part D Payment Data (p.97)**

The release of Part D payment data will allow the public to understand the subsidies paid under Part D to health plans. It has been argued that the release of the risk scores for each plan benefit package could allow the general public to estimate the bids of each health plan. Transparency of the estimated bids of each health plan and the actual costs will allow the general public to better understand the impact of inaccurate bids on the pocketbooks of seniors and taxpayers. Such information will not undermine the competitive aspects of the program as the information will be

released well after bids have been submitted, but will provide seniors with greater information to make more informed decisions regarding their selection of a Part D plan.

NCPA supports the proposal to routinely release Part C and Part D payment data. Such systemic transparency would enable Part D stakeholders to better understand the operations of prescription drug plans without impacting the confidentiality of beneficiaries and the plans.

### **NCPA Response to Pending Part D Rule**

Given that some sections of the upcoming final Part C and D proposed regulation might appear in the final Call Letter, NCPA would like to take this opportunity to reiterate several comments to the proposed rule, as well as some other issues we ask CMS address in the Call Letter:

Fraud, Waste and Abuse Training and Education Requirements: The exemption CMS proposes for MA organizations' downstream entities related to the application of training for fraud, waste and abuse, should be applied to a pharmacy contracting with Part D sponsors if the pharmacy has provided similar certification during the Part B enrollment process. If CMS will not extend the exemption for MA organizations' downstream entities to pharmacies contracting with Part D sponsors, the need for multiple trainings as now stated should be eliminated by CMS.

NCPA urges CMS to issue a guidance stating that a training program will be deemed as satisfactory if it contains the following elements identified in the August 2009 CMS memorandum on fraud, waste and abuse training:

- Laws and regulations related to MA and Part D fraud, waste and abuse (i.e., False Claims Act, Anti-Kickback statute, HIPAA, etc.)
- Obligations of the first tier downstream, and related entities to have appropriate policies and procedures to address fraud, waste, and abuse
- Process for reporting to the MAO or PDP sponsor suspected fraud, waste and abuse in first tier, downstream, and related entities
- Protections for employees of first tier, downstream, and related entities who report suspected fraud, waste and abuse
- Types of fraud, waste and abuse that can occur in first tier, downstream, and related entities

Lastly, NCPA requests that FWA training and education should be required one-time only unless changes in the laws and regulations related to FWA are significantly changed.

Collection of Additional Part D Claims' Elements for Nonpayment-Related Purposes: NCPA respectfully questions CMS' conclusion that it may, under the authority it claimed in its May 28, 2008 Part D Claims Data final rule (73 FR 30664) in which it interpreted its authority under Section 1860D-12(b)(3)(D) of the Social Security Act, add new elements to the PDE record without undertaking rulemaking for each additional element added in the future.

First, as CMS notes, interested parties were not afforded an opportunity to comment to the proposed rule (71 FR 61447, October 18, 2006) on whether new elements that were added to the PDE record for 2008 (or any PDE elements that might be added in the future) should be collected

under that section of the Act, and, consequently, used or disclosed to other parties for non-payment related purposes.

Second, it is clear from CMS statements in this section of the preamble of the current proposed rule that CMS is predisposed to rapidly add elements to the PDE record. There are costs that are born by different sectors of pharmacy when a PDE element is added. Particularly for pharmacies, submitting such information to PBMs has both immediate and longer term costs and policy implications. NCPA strongly believes that a full rule-making process should attach with any attempt to add elements to the PDE record.

NCPA Concerns with Part D Plans Circumvention of Prompt Pay Law: NCPA would also like to take this opportunity to officially request that the Centers for Medicare and Medicaid Services (CMS) instruct, via the 2011 final Call Letter, Medicare Part D plans to halt what appears to be the improper and illegal imposition of extraneous fees and charges on Part D network pharmacies in response to the implementation of prompt pay provisions contained in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). We have attached the letter we sent to CMS Acting Administrator Charlene Frizzera on March 4<sup>th</sup> regarding these issues. We ask that these be addressed in the upcoming Call Letter.

As you finalize plans for release of the final Medicare Part D Call Letter and final publication of the final rule (4085-F), NCPA respectfully urges you to consider these issues. We appreciate the opportunity to share our concerns and recommendations with you.

Sincerely,



John M. Coster, PhD, RPh  
Senior Vice President, Government Affairs

Attachment