December 12, 2011

Jonathan Blum, Deputy Administrator and Director of Center for Medicare
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave SW
Washington, D.C. 20201

Subject: Impact of Medicare Part D Program Integrity Practices on Community Pharmacists

Dear Jon:

The National Community Pharmacists Association (NCPA) is writing to raise our concerns with certain Medicare Part D program integrity practices that are impacting the ability of community pharmacies to provide pharmacy services.

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 the primary providers of drugs and pharmaceutical supplies to millions of Americans. Focusing on the Medicare Parts C and D programs, NCPA members are a primary access point for prescription medications for millions of Medicare beneficiaries and NCPA members comprise a critical piece of the Medicare prescription drug distribution system.

CMS Should Develop Consistent Part D Auditing Standards: First let us state that we believe that CMS, Part D plans and pharmacies all have an important role to play in assuring that fraud, waste and abuse is rooted out of the Medicare program. We have raised with the CMS Part D staff, however, issues relating to how some Part D plans currently conduct audits of community pharmacies.

For example, last summer, NCPA conducted a survey of 1,800 small business community pharmacies regarding challenges that they face with regard to both commercial and Part D audits. The results include reporting by almost 62% of respondents that PBMs apply inconsistent auditing standards across various plans. Not only are the auditing standards inconsistent, but over 79% of respondents reported that PBM auditors always or often require recordkeeping requirements above and beyond state and federal law requirements. Most significantly, almost 60% of respondents reported that PBM auditing practices have a very significant impact on respondents' ability to provide patient care and remain in business, which can lead to decreased access to care.

These survey results are emblematic of specific auditing issues which greatly concern NCPA. NCPA's members have informed us of widespread disparity in how clerical, typographical and related prescription errors are treated by Part D plans during audits.

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

Some Part D plans recoup for such errors without providing pharmacies with an opportunity to remedy those errors, while other plans allow pharmacies the opportunity to make corrections. Significantly, these errors are not representative of fraud and they are not representative of abuse of the Part D program. These are simple clerical errors associated with valid prescriptions, which pharmacies can easily remedy, if given the opportunity.

Given existing inconsistencies and the administrative nature of these errors, NCPA requests that CMS institute a consistent standard across Part D plans regarding audit practices and that CMS instruct plans to not recoup for clerical and typographical errors without providing pharmacies an opportunity to correct such errors. These are not "contractual" issues subject to negotiations with Part D plans. There are no negotiations with Part D plans, and the "take it or leave it" contract language we are given is so ambiguous relating to audits that it leaves us exposed to the whims of Part D plans abusive tactics.

CMS Should Halt NPI Requirements Until Credible Data Base Established: There is inconsistency in how Part D plans treat the requirement to have valid prescriber identifiers on prescription drug claims. Under the existing Part D program, valid prescription claims could include a valid prescriber NPI, prescriber UPIN, prescriber DEA number or prescriber state license number. Despite these existing rules, NCPA members have examples that some Part D plans are recouping pharmacy reimbursements, unless the underlying claims contain only valid individual NPI numbers. These Part D plans are imposing requirements above and beyond those required under current federal regulations or what many pharmacies can practically obtain, given the current limitations of the NPI system.

We are attaching an example of an audit, which demonstrates a PBM, on behalf of a Part D plan, refusing to provide a pharmacy with the opportunity to correct a prescriber identifier error. In the attached example from 2011, despite guidance from CMS instructing that Part D plans should retrospectively correct invalid prescriber identifier errors, Prime Therapeutics refused to allow the pharmacy the opportunity to correct the error. Such actions are in direct opposition with CMS guidance on Part D auditing practices and prescriber identification errors. The guidance in the 2013 proposed Part D regulation indicates that CMS expects "that pharmacies will be permitted to correct any invalid [prescriber identifier] data before payment for a claim is reversed whether or not a negotiated contract delegates any sponsor duties in this regard to the pharmacy."

Unless certain changes are made, there will be implementation problems with the new 2013 proposed rules for use of only valid individual NPI numbers on prescription claims. One problem is that some Part D prescriptions come to pharmacies from an individual prescriber who uses a group NPI number on the prescription. It appears that CMS is working to eliminate the use of group NPI numbers on Medicare claims. However, unless group NPI numbers are prohibited from being used on prescription claims, it will be very difficult for pharmacies and Part D plans to ensure that a valid individual NPI number is on each Part D prescription.

Similarly, NCPA is aware that most medical interns and residents do not have individual NPI numbers. Accordingly, interns and residents usually put their supervisor's individual NPI number or a group/hospital NPI number on their prescriptions. Neither the 2012 Part D Call Letter nor the 2013 Part D Proposed Rule appears to address this issue.

Unless interns and residents are required to obtain and use individual NPI numbers on their prescriptions, pharmacies and Part D plans will be unable to ensure that prescription claims from intern and resident prescriptions contain the individual NPIs of those interns and residents.

More generally as to the NPI issue, NCPA is unaware of the existence of a single thorough, complete and accurate database that contains all prescriber NPIs. If CMS' National Plan and Provider Enumeration System (NPPES) were completely thorough and accurate there would be no need for the commercial vendor lists that pharmacies must pay very high fees to access. Moreover, access to such commercial lists is prohibitively expensive for small business independent community pharmacies.

With regard to the 2013 plan year, it is unrealistic for CMS to expect that mandating submission of valid NPIs, and only valid NPIs, on prescription claims will be a smooth process. The inaccurate and missing data within both the NPPES and commercial vendor lists will create substantial and unfair auditing burdens on independent community pharmacies. Moreover, such a requirement may also curtail patient access to necessary drugs if pharmacists are unable to find a prescriber's NPI or accurately verify that a prescriber's NPI is valid. In sum, it is extremely unrealistic for CMS to require the use of an individual NPI on Part D prescriptions when in reality not all individuals authorized to prescribe are required to have one.

For these reasons, we request that CMS delay the 2013 NPI requirement until CMS has a valid and thorough NPI database that pharmacy providers can use to access and check NPIs and CMS has notified all prescribers that pharmacies cannot fill prescriptions unless they provide a valid NPI. It is extremely important that CMS instruct plans they are not allowed to mandate the use of individual NPI's on Part D prescriptions per the reasons stated above.

Hospice Claims Represent Challenges for Pharmacies: Audits related to Part D prescriptions that should have been filed as hospice claims will become very problematic for pharmacies, once the 2012 Part D Call Letter provisions related to such audits are implemented. The 2012 Part D Call Letter states that Part D claims that should have been filed as hospice claims should be paid as Part D claims upfront with reconciliation on the back end. For pharmacies this is problematic because pharmacists do not always have real time information regarding a patient's status as a Part D patient versus a hospice patient. The hospice patient eligibility files are not real time; there is a lag in updates to those files. Accordingly, pharmacies are filling prescriptions using outdated information.

Unfortunately, the patient eligibility updates can lag months behind, and by the time a pharmacy or Part D plan realizes that a claim should have been filed as a hospice claim, months or even years may have passed. At that point, the Part D plan will recoup from the pharmacy, but the pharmacy has little recourse to get paid for the services and products it properly provided. Months or years after the prescription was filled, it will be difficult for a pharmacy to find the appropriate hospice plan, the hospice plan may no longer be an active plan and/or the patient may be deceased. All of these factors make it difficult for pharmacies to get paid by the correct payer, while being forced to refund the Part D payments they were wrongfully paid. NCPA seeks guidance on how CMS intends to address this issue and how pharmacists should address this issue.

CMS Should Stop Model Prescription Transfer Letter Mail Order Abuses: For the 2012 Part D plan year, CMS released a Model Prescription Transfer Letter, which requires plans to send beneficiaries a standard form letter to request a transfer of their prescriptions from an existing pharmacy to a different network pharmacy. The relevant language of the transfer letter states:

[Instructions: This model should be used by Part D sponsors to request permission from a member to fill his/her prescription[s] at a different network pharmacy than the one the member is currently using. The beneficiary may provide permission by calling the plan or pharmacy, or via written statement sent in the mail. Outbound phone calls made by the pharmacy or Part D sponsor seeking permission from beneficiaries are not permitted. The Part D sponsor may attach a form to this letter requesting the member's permission to switch the prescription to a different pharmacy. This model does not need to be used if the change in pharmacies is initiated by the transferring pharmacy or beneficiary.]

Despite the requirement that the model transfer letter be used by the Part D plan to initiate a transfer and despite the prohibition against outbound phone calls, we have learned that a number of Part D plans across the country are calling and harassing beneficiaries to transfer their prescriptions to a preferred network pharmacy (most commonly a mail order pharmacy). These plans repeatedly call beneficiaries to make the change. Some plans are even moving patients to mail order without telling them, such that the patient fills a prescription at their community pharmacy and receives a duplicate prescription in the mail. This is a blatant violation of the terms of the model transfer letter and will result in waste. We request that CMS have stronger oversight on this practice and require Part D plans to use only the model transfer letter and to obtain patient permission before transferring a patient's prescriptions to a preferred network pharmacy. The attempt by some Part D plans to boost their star ratings by trying to divert their patient to their own mail order operation is serious enough. CMS should also address this issue because of the amount of waste that occurs in mail order, a few examples of which we have included with this communication.

Conclusion

NCPA enthusiastically supports CMS' efforts to ensure that the Medicare Part D program saves money, avoids waste and eliminates fraud. However, NCPA believes that the auditing efforts of the Part D plans should be implemented appropriately, so as to truly target fraud, waste and abuse. Audits should not result in recoupment of reimbursement from pharmacies that provided valid services. Moreover, CMS should not require the use of an individual NPI on Part D prescriptions until such time that all individuals authorized to prescribe are required to have one. Finally, CMS should take stronger action to enforce violations of existing prescription transfer requirements. Accordingly, NCPA requests that CMS address and resolve the issues outlined above. We look forward to your response. Please do not hesitate to contact me at john.coster@ncpanet.org, (703) 600-1184 if you have any questions.

Sincerely,

John M. Coster

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