Statement of the National Community Pharmacists Association (NCPA)

United States Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies

Hearing on Fighting Fraud and Waste in Medicare and Medicaid

February 15, 2011

NCPA recommends that Congress:

(1) Pass legislation to rein in the waste being generated by PBMs within Medicare and Medicaid.
(2) Pass legislation to increase the transparency of PBM audit practices within Medicare and Medicaid and to prohibit certain abusive auditing practices by PBM auditors.
(3) Address through oversight or legislation CMS’s failure, in certain circumstances, to assert its authority to fight fraud, waste and abuse.

Chairman Harkin, Ranking Member Shelby, and Members of the Subcommittee:

The National Community Pharmacists Association (“NCPA”) welcomes and appreciates this opportunity to provide input and suggestions regarding efforts to combat fraud, waste and abuse in Medicare and Medicaid as they relate to pharmacy care providers and the health care arena in general. NCPA represents the pharmacist owners, managers and employees of more than 23,000 independent community pharmacies across the United States. The nation’s independent pharmacies, independent pharmacy franchises and independent chains dispense nearly half of the nation’s retail prescription medicines.

NCPA strongly believes in the mission to cut fraud, waste and abuse in Medicare and Medicaid in order to bolster the integrity of the two programs and maximize the benefits provided to beneficiaries. NCPA and our members strive hard to do their part to help ensure the integrity of Medicare and Medicaid and to cooperate with Medicare and Medicaid auditors. In fact, statistics demonstrate that independent community pharmacists are not a significant part of the fraud, waste and abuse problem.

NCPA thanks Congress for recognizing the integrity demonstrated by independent community pharmacists in their participation in Medicare and Medicaid. While no industry can claim to be completely void of bad actors, Congress has recognized that independent community pharmacists, as a whole, represent a very low risk in terms of fraud, waste and abuse of the Medicare and Medicaid programs.

For example, in 2008, Congress enacted The Medicare Improvements for Patients and Providers Act (MIPPA), which, in part, required Part D sponsors to pay all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise.
Similarly, just this past year, through the Patient Protection and Affordable Care Act (PPACA), Congress enacted legislative provisions to allow most independent community pharmacists to be exempt from Medicare DME accreditation requirements. Recent legislative history demonstrates the trust that Congress has in the integrity of independent community pharmacies. We appreciate that trust and try to live up to high standards every day.

Contrary to the trust that Congress holds for independent community pharmacies, the same cannot generally be said of policymakers’ view of Pharmaceutical Benefit Managers (PBMs). Through recent legislative action, Congress has seemingly demonstrated that it continues to be concerned regarding how PBMs run their businesses. While Congress provided additional flexibility for independent community pharmacies through accreditation exemptions under the PPACA, in the same legislation Congress imposed new transparency requirements on the PBMs operating within the Medicare Part D program and for PBMs operating in the new state-based health insurance exchanges, which come on line in 2010.

Congress apparently has strong reservations regarding the integrity of the PBMs and, we believe, rightfully so. From 2004 – 2008, the three major PBMs (Medco, CVS Caremark, and Express Scripts) faced six major federal or multidistrict cases over allegations of fraud; misrepresentation to plans, patients, and providers; improper therapeutic substitution; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. These cases have resulted in over $370 million in payments for fines and damages to states, plans, and patients so far. The most prominent cases were brought by a coalition of over 30 states and the Department of Justice.

Because NCPA and independent community pharmacists are committed to fighting fraud, waste and abuse within Medicare and Medicaid, we have a number of concerns regarding existing fraud, waste and abuse within Medicare and Medicaid and how those problems are presently being addressed. First, NCPA is concerned that some PBMs are apparently contributing to waste within the Medicare and Medicaid system. Second, NCPA believes that PBMs, in their auditing capacity, are abusing their oversight authority to the detriment of independent community pharmacists and the beneficiaries that they serve. Finally, NCPA believes that CMS, in some instances, is not effectively performing its oversight role for fraud, waste and abuse.

**PBM Waste within Medicare and Medicaid**

PBMs administer the pharmacy benefit within some Medicaid managed care programs and many in Medicare Part D. These complex business entities have multiple, extremely profitable, revenue streams. The “Big 3 PBMs” (Medco, Express Scripts, and CVS/Caremark) manage drug benefits for approximately 95% of Americans with prescription drug coverage, and each of these companies have annual revenues exceeding $15 billion. In spite of these facts, PBMs are virtually unregulated at the state or federal level—even though they manage numerous prescription plans funded by billons of taxpayer dollars.

PBMs negotiate contracts with many participants in the pharmaceutical supply chain; two of the most important contracts are with pharmacies (“the pharmacy network”) and plan sponsors. PBMs primary profit streams include rebates provided by drug manufacturers for driving brand drug market share; administrative fees charged directly to the health plans; revenues from PBM-owned mail service pharmacies and the clinical programs sold to health plans. From each of these revenue streams the PBMs are earning sizeable profits, which are enhanced by potential conflicts of interest built into the
payment system. Such profits are a waste of taxpayer money used to fund Medicaid managed care and Medicare Part D. Outlined below is a description of how these large profits arise under each revenue stream and the conflicts of interest within each revenue stream.

**PBM Pocket Manufacturer Rebates**

Pharmaceutical manufacturers provide “rebates” to PBMs on brand name drugs purchased on behalf of PBM clients. The manufacturers pay billions of dollars to the PBMs to drive/increase certain brand drug usage by Medicare and Medicaid beneficiaries. These manufacturer incentives and the resulting PBM behavior conflict with the interests of patients and Medicare/Medicaid, which seek to maximize the use of generic drugs that are equally as effective as brand name drugs, but are less costly and save money. In 2009, retail pharmacies drove a 69% generic dispensing rate (GDR) while the mail order PBMs Medco Health Solutions, Inc., Express Scripts, Inc. and CVS/Caremark had GDRs under 58% generic dispensing rate. In the end, the PBMs do not share all of the rebate savings with the patients, the plans or the government.

**PBM “Play the Spread” in Retail Pharmacy Networks**

The PBMs also generate substantial profits by charging Part D plans and Medicaid one price for a given drug and then reimbursing retail pharmacies a lower dollar amount. This practice needlessly adds costs for the government and squeezes retail providers.

**PBM-Owned Mail Order Pharmacies**

Along with supplying drugs to retail pharmacies, the PBMs also own and operate their own mail order pharmacies. These mail order pharmacies are automated dispensing facilities that fill and ship prescriptions requiring 90-day supplies. They operate in a “Black Box” environment without transparency. Accordingly, these mail order pharmacies are able to engage in practices that can provide the PBMs with large profits, with little or no scrutiny.

Not only do the PBM mail order pharmacies pad the PBM’s profits, but they do so without delivering to the patient the benefits of a traditional community pharmacy. Face-to-face consultation between a pharmacist and patient, the most effective type of intervention to ensure that patients adhere to their prescribed medication regime and are counseled about possible negative side effects, is replaced with patient email and calls to 1-800 numbers to seek assistance from rotating out-of-state corporate pharmacists. Outlined below are a couple of examples of problems faced by mail order patients.

First, no patient can “fire” their PBM-owned mail service, no matter how poorly it performs. Patients have reported numerous delivery (or non-delivery) issues that have caused patients to be unable to take medications that are vital to their health and well-being, yet they are forced to continue using the PBM-owned mail service.
Second, when given a choice, 83% of customers prefer to fill their prescription at a community pharmacy rather than at a so called mail order pharmacy. Nonetheless, PBMs support policies that penalize patients for using community pharmacies.

**PBM Make Money on Provider Reimbursement Float**

PBMs also pocket the monetary interest generated from the lag time between the pharmacy dispensing a drug to plan members and the time when reimbursements are paid to the pharmacy. While this practice was all but eliminated in Medicare Part D, it continues to exist in other Federal programs and the commercial market. On a macro-scale the amount of interest generated during this time lag period is significant and it is inequitable that community pharmacies do not share in the value of the interest generated during this lag time.

**Legislative Solutions**

In light of the PBM generated Medicare/Medicaid waste and abuse outlined above, NCPA urges Congress to pass legislation that includes the following provisions:

- Requiring PBMs to fully disclose to Part D plans and Medicaid potential conflicts of interest in PBM service contracts.
- Establishing an “any willing provider provision” in all PBM mail service contracts.
- Requiring PBMs to fully disclose “spread” pricing to all impacted parties, including pharmacies, patients and Part D plans/Medicaid.
- Require PBMs to pass through to pharmacies at least a portion of the interest earned by the PBM on the pharmacy reimbursement “float.”

**PBM Audit Abuses**

Not only do PBMs generate their own waste within Medicare and Medicaid, but they also seem to abuse their role as auditors of pharmacies within both programs, as well. PBMs typically audit pharmacies in order to detect any improper payment by the PBM on behalf of Medicare or Medicaid and to verify that the patient received the correct medication in the appropriate dose. NCPA believes that auditing is a necessary activity in order to detect and prevent fraud, waste and abuse in Federal health care programs.

However, many times PBM auditors, some of whom are paid based on the number of “discrepancies” found, go beyond the basic intent of the audit (to detect fraud, waste and abuse) and instead focus on typographical or administrative errors for which they use as the basis to recoup money from the pharmacy.

In most cases, if a PBM auditor does identify an administrative error, he or she will “take back” 100% of the value of the prescription—an extreme financial penalty that is out of proportion to the gravity of the offense.

In most cases, money recouped from a pharmacy as the result of an audit is not returned to the plan sponsor—but is simply pocketed by the PBM. Many times, PBM audits of pharmacies-- operating under the guise of combating fraud, waste and abuse-- are simply an additional revenue stream for the PBM.
One way many PBMs “ensure” that discrepancies will be found is to establish elaborate record keeping requirements well in excess of what is required under state or federal law. Pharmacies typically maintain contracts with multiple PBMs. The result is a myriad of conflicting documentation requirements that can make operating a busy pharmacy and responding to patient concerns an even greater challenge.

Another abusive audit practice involves PBM auditors who, in order to maximize revenue generation, zero in on auditing high dollar specialty prescriptions. One pharmacist reported that he gets audited very frequently based on the fact that he serves a large number of HIV patients -- typically prescribed very expensive medications. Pharmacists also report that auditors frequently question the directions for use that the pharmacist typically types onto the medication. Many physicians will include “take as directed” on the prescription that they issue to a patient and the pharmacist is therefore charged with providing the appropriate instructions. Auditors frequently question whether or not the directions are specific enough. One particularly egregious example of this occurs when auditors question the adequacy of instructions included on a “Z-Pak”. A Z-Pak is a pre-packaged dosage form that simply requires the patient to “punch out” a specified number of pills per day at designated intervals from the blister packaging.

To increase the chances of a “successful” audit and more revenue, PBMs also focus on claims in which they can easily question the professional judgment of the pharmacist. Many times a physician will issue a prescription that directs the pharmacist to dispense a certain number of days supply of a medication. There are times when this is open to interpretation—particularly with respect to lotions, creams or particularly eye drops. Another area of concern is dispensing a certain number of days supply of insulin; depending on blood sugar levels, the amount of insulin that a patient needs on any particular day can vary.

Pharmacists frequently report that many times elderly patients need an additional quantity of eye drops that somewhat exceeds that which may be necessary for other patients. Many elderly patients have difficulty instilling just one or two drops or due to hand tremors, and typically end up spilling a fair quantity of the product. Auditors typically do not accept these types of explanations, which boil down to questioning the professional judgment of the pharmacist. In response, many pharmacists have had to stop dispensing larger sized ophthalmic solutions.

PBM’s audit revenue is also enhanced inappropriately through the questionable statistical methods that some of them use to assess fines. Sometimes PBM auditors will use extrapolation or other statistical expansion techniques to calculate the amount of any audit recoupment.

With extrapolation, a few prescriptions are extracted from the total number of prescriptions filled for the particular PBM—and those are examined for any errors. The number of errors detected in the small sample is then extrapolated across a pool of prescriptions to arrive at a arguably inflated number of discrepancies and corresponding penalties.

One pharmacist recounted an example of the use of this technique in connection with a recent Medicaid audit by a PBM. After the auditor complimented the pharmacist on his “clean documentation” for the audit sample, she presented him with an audit findings report that detailed over $137,000 in alleged extrapolated clerical errors based on findings from two prescription claims. Ultimately, the pharmacist was able to prove that the auditor made a mistake on one of the two claims, and the recoupment amount
was then reduced to $3,000. Extrapolation has been widely criticized as an auditing technique and a number of states have passed legislation to prohibit or limit its use.

Finally, pharmacists have little recourse to fight back against PBM abusive auditing practices. Pharmacists faced with significant recoupments that they believe are in error are frequently without recourse. Even if the PBM does have an appeals process, the PBM still may withhold funds while waiting for the appeals process to be completed. In addition, PBMs are not required to resolve appeals in a timely manner and many pharmacists fear that if they complain too much, the PBM may simply drop their contract. Many pharmacists, when faced with unfair audit recoupments, are forced to weigh the amount of the threatened recoupmemt with the likely cost of hiring legal council. Some pharmacists are reporting a recent trend in which PBMs are keeping recoupments to just under a certain dollar amount in recognition of the fact that the threatened dollar loss to the pharmacist will not outweigh the cost of hiring an attorney.

Legislative Solutions

In light of the PBM audit abuses outlined above, NCPA urges Congress to enact H.R. 5234, The PBM Audit Reform and Transparency Act of 2010, sponsored by Congressman Anthony Weiner (D-NY). Generally, H.R. 5234 provides for the following: 1) Requiring PBM’s to make certain disclosures in an annual report to drug plan sponsors; 2) Increased regulation of PBM contracts with pharmacies; 3) Prohibitions against certain conflicts of interest involving PBMs and the entities that they own; 3) Restrictions on PBM auditing practices of pharmacies; and 4) Restrictions on PBM use of HIPAA information.

Turning more specifically to auditing practices, NCPA endorses the following protections against abusive PBM audit practices:

- Requiring, where an audit results in the identification of solely clerical or record-keeping errors, that the pharmacy not be subject to recoupmemt of funds by the PBM unless—(i) the PBM can provide objective proof of intent to commit fraud; or (ii) such error results in actual financial harm to the PBM, a health insurance plan managed by the PBM, or a consumer.
- Prohibiting PBMs from requiring more stringent record keeping by a pharmacy than is required by State or Federal law and regulation.
- Requiring that PBMs accept records of a hospital, physician or other authorized practitioner to validate pharmacy records and prescriptions with respect to confirming the validity or claims in connection with prescriptions, refills, or changes in prescriptions.
- Requiring that PBM audits be conducted by or in consultation with a pharmacist who is licensed in the State in which the audit is being conducted, where the audit requires the application of clinical or professional judgment.
- Prohibiting PBMs from using extrapolation or other statistical expansion techniques in calculating the amount of any recoupmemt or penalty resulting from an audit.
- Requiring PBMs to establish a written appeals process that shall include procedures to allow pharmacies to appeal to the PBM the preliminary reports and final reports resulting from the audit and any resulting recoupmemt or penalty.
• Prohibiting the period covered by an audit from exceeding two years from the date that the claim was submitted to or adjudicated by the PBM.
• Providing that any legal prescription may be used to validate claims in connection with prescriptions, refills or changes in prescriptions.
• Requiring that each pharmacy be audited under the same standards and parameters as other similarly situated pharmacies.

Conclusion

NCPA and its members remain committed to combating fraud, waste and abuse within Medicaid and Medicare, and eagerly wish to be a part of the solution. However, NCPA has concerns about certain aspects of existing efforts to combat Medicare/Medicaid fraud, waste and abuse. To summarize, as to the PBMs, NCPA is concerned that more needs to be done to address the waste generated by some PBMs within Medicaid and Part D. NCPA is also concerned that there needs to be more transparency and oversight over PBM auditing practices under Medicaid and Medicare.