

March 1, 2006

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

Re: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse

Dear Centers for Medicare & Medicaid Services (CMS):

The National Community Pharmacists Association (NCPA) respectfully submits the following comments regarding Chapter 9 – Part D Program to Control Fraud, Waste and Abuse. NCPA represents the nation's community pharmacists, including the owners of more than 24,000 pharmacies. The nation's independent pharmacies, independent pharmacy franchises, and independent chains dispense nearly half of the nation's retail prescription medicines.

Exhibit 1: MEDIC Responsibility and Activity Summary (pages 10-11)

Under the audit responsibility of the Medicare Drug Integrity Contractors (MEDICs), NCPA recommends that CMS add the following information to be monitored by MEDICs:

- Medication therapy management programs
- Maintenance of TRICARE standards of access
- Compliance with level playing field requirement (availability of 90 day supply at retail pharmacy)
- Timely payment to pharmacies

Section 50.2.3 – Training and Education (pages 25 -28)

NCPA asks that CMS exclude pharmacies from the compliance training requirement given their extensive regulations on the state and federal level.

As drafted, the training and education section in the general compliance training specifies a required annual two (2) hours of training in the general area of compliance, some of which may not be very applicable to the role of the pharmacy provider. The guidance then requires an additional annual four (4) hours of specialized training that is more targeted to specific topics that could be tailored to the role of pharmacies in the Part D program.

Pharmacies are working with a significant number of Part D plans, more so than most other subcontractor groups. Consequently, if a pharmacy accepts all Part D plans in a service area, the requirement as drafted could require that a pharmacy participate in more than 20 different

compliance training programs, which would correlate to more than 120 hours of training annually just to participate in Part D. This is an undue burden on community pharmacies and could significantly affect beneficiary access, especially in independent pharmacies, which cannot rely on centralized Part D compliance training.

With such a large burden of compliance training, NCPA requests that CMS reevaluate the necessary number of training hours. Additionally, the potential methods/approaches for training (e.g., use of web-based and other computer technology that permits flexibility in scheduling and the ability to complete training on an individualized basis) should be evaluated.

We recommend that CMS considers compliance training for pharmacies from an industry-wide perspective. The major pharmacy industry associations, working with CMS, can develop a reasonable approach to compliance training and education related to Part D compliance. By creating an industry-wide solution, Part D sponsors' role principally could focus on informing pharmacies of the channels for reporting/communicating with any particular Part D sponsors' compliance program.

Section 50.2.4.2 Screening Enrollee Complaints (page 30)

NCPA strongly contends that beneficiary grievances should not be collected on the community pharmacy level.

The requirements as drafted require Plans to provide meaningful procedures for timely hearing and resolving of grievances. If Plans are required to hold pharmacies accountable for recording these grievances, the Plan should be required to facilitate and communicate a method for pharmacies to provide this feedback. Additionally, notification of this requirement should, at a minimum, be presented to pharmacies in writing 60 days in advance of implementation and, in some cases, may legally require a new participating pharmacy agreement between the Plan and/or PBM and the network pharmacy.

Section 50.2.6.1.2 Audit Schedule and Methodology (pages 34-36)

In their current form, desktop audits often place pharmacies in an untenable position and result in an overall reduction in the quality of care. In particular, these extrapolation audits do not take into account unintentional provider error. Moreover, it is illogical to consider a few cases of provider error as large scale fraud and abuse. The audit schedule defined in this chapter is particularly burdensome to community pharmacy. We request that CMS convene an industry-wide work group before adopting the audit provisions as currently defined.

Section 50.2.6.1.3 Monitoring and Auditing Subcontractors (pages 36 – 37)

NCPA requests that sponsors be required to monitor timely payments under the “payment reports” section.

Overall, Part D plans and the current high participation of pharmacies in Part D plan networks represent a particularly challenging area as it relates to monitoring and auditing. Potentially, the

CMS requirements, as now drafted, could result in large numbers of pharmacies having to respond to questionable audits by numerous (e.g., 15 – 20+) PDP sponsors, as well as several MA-PDs and government auditors (e.g., CMS MEDIC contractors, OIG). This level of audit burden does not seem comparable to the experience of other Medicare Parts A, B, and C health care providers.

As stated previously, further discussion with the pharmacy industry and the Part D plans is warranted to develop a reasonable, coordinated approach to pharmacy monitoring and auditing so as to avoid an unreasonable response burden and duplication of effort on the part of all parties involved.

50.2.6.3.2 Identifying Providers with a History of Complaints (page 39)

NCPA acknowledges the importance of maintaining files on providers who have been the subject of civil and/or criminal investigations. We remind CMS that several large PBMs, who often serve either as Part D plans or subcontractors, including Medco Health Solutions, Express Scripts and Caremark/Advance PCS, have been the subject of federal/state investigations and prosecutions. In fact, both Medco and Caremark/Advance PCS are required to abide by consent agreements based on previous lawsuits. We urge CMS to require all Part D plans to maintain files on all subcontractors who have been the subject of such investigations. Further, we urge CMS to guarantee that all Part D plans and subcontractors, especially the PBMs mentioned above, comply with any consent agreements resulting from previous lawsuits.

Requirements of Pharmacies

As drafted, the fraud, waste and abuse requirements are enforced by Part D plans to their subcontractors, including pharmacies. But these new requirements have not been specifically addressed in participating pharmacy agreements between pharmacies and PBMs and/or Part D plans originally signed in 2005. NCPA is asking CMS to require that new participating pharmacy agreements be offered to pharmacies that clearly state these new requirements, including any enforcement penalties (e.g., monetary penalties) should program fraud or abuse be documented, investigated, and confirmed.

Program Implementation Challenges and Errors

The implementation of Medicare Part D has been an unprecedented challenge for all involved. Undoubtedly, during the first few months of implementation, errors have occurred. It is critically important that the challenges faced by pharmacies during the program's implementation be recognized, and unintended mistakes not be misconstrued as program abuse or fraud. On the contrary, community pharmacists should be applauded for their ingenuity and for making sure patients left their pharmacy with the medication prescribed for them. As clear examples of unintended mistakes, the confusion over when a drug should be billed as Part B versus Part D was an instance in which CMS found a need to provide additional ongoing guidance, and the area of cost-sharing liability for low-income beneficiaries required ongoing efforts on the part of CMS, Part D plans, and pharmacies to attempt to resolve this concern in the best interest of beneficiaries.

NCPA urges CMS to establish a grace period for at least the first six months of Part D implementation to satisfactorily address the above concerns. Further, given that most pharmacies will not have implemented every fraud, waste and abuse requirement without notification of these requirements by Part D plans, it is essential that no enforcement procedures be applied retroactively before such requirements are outlined contractually to pharmacies.

NCPA would like to thank CMS for the opportunity to submit these comments on behalf of the nation's community pharmacists. We look forward to continuing to work with CMS to help ensure that the Medicare Part D program is one that seniors and their local pharmacist can trust. For additional information or questions about these comments, please contact Stacey Swartz, Pharm.D., Director of Management & Educational Affairs, on my staff at Stacey.swartz@ncpanet.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'B. Roberts', with a long horizontal flourish extending to the right.

Bruce T. Roberts, R.Ph.
Executive Vice President and CEO
National Community Pharmacists Association