

## CMS Provides Clarifications on Medicare Part D Fraud, Waste and Abuse Training

During a recent call with the American Pharmacists Association (APhA), Food Marketing Institute (FMI), National Association of Chain Drug Stores (NACDS), the National Alliance of State Pharmacy Associations (NASPA), and the National Community Pharmacists Association (NCPA), the Centers for Medicare and Medicaid Services (CMS) clarified the requirement for pharmacies participating in Medicare Part D to complete training on fraud, waste and abuse. CMS rules require each plan sponsor to adopt a comprehensive program to prevent, detect, and correct fraud, waste and abuse, and ensure that its first tier, downstream and related entity has completed compliance training. Pharmacies are considered downstream entities.

To meet this requirement, Chapter 9 of the 2006 CMS Medicare Manual stated that pharmacies could either complete their own training or take the training offered by Part D plans. Relying on the policy in the Medicare Manual, since 2006, many pharmacies had implemented their own training while others adopted training developed by third party vendors. In October 2008, however, CMS issued a memorandum suggesting that pharmacies should not develop their own training and that plans should provide the training to pharmacies directly or provide the appropriate training materials. The memorandum also stated that CMS was working with a few associations to help the industry develop a standardized training program. To date, a standardized training program has not been developed through the agency. With the December 31, 2009, deadline for pharmacies to complete training for the 2009 plan year fast-approaching, CMS issued another memorandum in August 2009 reiterating that plans may either provide the training directly or provide appropriate training materials to pharmacies to meet the training requirements.

During the recent call, given the discrepancy between the 2006 guidance (which permitted pharmacies to implement their own training program) and the subsequent 2008 and 2009 memorandums (which suggested that pharmacies must be trained by Part D plans or use training materials provided by Part D plans), CMS made several suggestions in an attempt to provide some clarification. CMS noted that a set of FAQs will be released toward the end of October to address common pharmacy questions. ***Please note that until the CMS FAQs are released, the following clarifications by CMS personnel are non-binding on the agency; therefore, pharmacies are strongly urged to consult with Part D plans to devise a workable solution for both parties.***

### **October 6, 2009, CMS Clarifications:**

- The October 2008 and August 2009 memorandums were not intended to supersede policy stated in the 2006 Medicare Manual, which permitted pharmacies to implement their own training or take the training offered by Part D plans.
- Plans bear the responsibility of ensuring that pharmacies have completed training. The August 2009 memorandum was intended to provide flexibility for plans to work with pharmacies to ensure training. CMS stated that the upcoming FAQs will address the concern that plans may demand pharmacies to use a particular training module, potentially requiring pharmacies to undergo multiple trainings.

- Pharmacies may continue to meet the rule by certifying or attesting to plans that the pharmacies have completed their own training. Plans may seek such attestation from pharmacies as part of their network contracts. **Please note that training programs should address the following topics listed by CMS in the [August 2009 memorandum](#).**

- 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

- At this time, CMS is not requiring Part D plans to attest to CMS that pharmacies have completed training. However, plans may be required to provide evidence of compliance during a plan audit. Plans may use pharmacy attestations, among others, as such evidence.
- Given the delay in releasing its guidance and the looming December 31, 2009, deadline, CMS has agreed to consider pharmacy's request for CMS to exercise enforcement discretion until the 2010 plan year. However, we continue to strongly urge pharmacies to meet the December 31, 2009, deadline.

Allied pharmacy associations continue to engage CMS and other stakeholders on the need to ensure workable training requirement for pharmacies and plans. Please stay tuned for further information as CMS releases its FAQs. For more information, please contact the appropriate organizations listed below.

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