

Sent via PHARMACY_MMA-L@LIST.NIH.GOV on October 23, 2008

CLARIFICATION OF CMS' REQUIREMENT FOR PART D FRAUD, WASTE, AND ABUSE TRAINING LISTSERVE ALERT

The Centers for Medicare and Medicaid Services (CMS) has received hundreds of phone calls and emails from Part D Sponsors and their first tier, downstream, and related entities about the fraud, waste, and abuse training requirement that becomes effective as of January 1, 2009.

Quick facts about the requirement:

- 1) It is the Part D Sponsor's responsibility to provide their first tier, downstream, and related entities with the appropriate training;
- 2) This training requirement becomes effective January 1, 2009. Since this is a yearly requirement, each Sponsor has from January 1, 2009 to December 31, 2009 to meet this requirement; and
- 3) This requirement could be cumbersome for first tier, downstream, and related entities because these entities often contract with multiple Part D Sponsors. To alleviate the necessity for first tier, downstream, and related entities to take training multiple times, there are a few associations that are working to create a training that will meet CMS' requirements. The goal would be to offer training that employees from the Part D Sponsor and the first tier, downstream, and related entities could take once a year to meet their annual obligation with all the Part D Sponsors with which they contract.

If you would like more specific details, please read below:

The final rule entitled, "Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes," FR Doc. 07-5946 ([72 FR 68700 through 68741](#)), published December 5, 2007, updated the compliance plan requirements for Medicare Advantage (MA) organizations and Part D Sponsors. Specifically, the compliance regulation states that a compliance plan, which must include measures to detect, correct, and prevent fraud, waste and abuse, must consist of training, education, and effective lines of communication between the compliance officer and the organization's employees, managers, and directors, as well as first tier, downstream, and related entities. This change clarifies that MA organizations and Part D Sponsors need to apply these training and communication requirements to all entities they are partnering with in the MA and Part D programs, not just the direct employees within their organizations.

MA organizations and Part D Sponsors are responsible for ensuring that all employees (including managers and directors) and the first tier, downstream, and related entities are provided appropriate training. MA organizations and Part D Sponsors must either provide the training directly to all of its employees (including managers and directors) and first tier, downstream, and related entities or provide the appropriate training materials to its employees (including managers and directors) and first tier, downstream, and related entities and ensure that the training has been taken. First tier, downstream, and related entities, including pharmacies, should **not** develop their own training. The first tier, downstream, and related entities can administer the training if the materials are provided by the Sponsor.

This change in the training requirement becomes effective **January 1, 2009**. Therefore, the mandatory training of the MA organization and the Part D Sponsor's employees (including managers and directors) and the first tier, downstream, and related entities must begin January 1, 2009, and must be completed within one year (by December 31, 2009). The training **does not** need to be completed by January 1, 2009. Thereafter, the training on the Part D program must be provided on an annual basis.

CMS recognizes that because first tier, downstream and related entities, including pharmacies, often contract with many different MA and Part D plans, this requirement would impose a burden on the first tier, downstream and related entities that contract with multiple Sponsors. As a result, CMS is currently working with a few associations to assist the industry in developing a training program that meets CMS' requirements. The training program would reduce the burden on first tier, downstream, and related entities since they would only have to take this training once a year, and the one time training would satisfy the CMS requirement for all MA Organizations and Part D Sponsors with which they are affiliated.

It is CMS' hope that training that meets CMS' requirements will be available soon. Until such time as this training program is available, MA Organizations and Part D Sponsors are responsible for either providing the training directly to all of their employees (including managers and directors) and first tier, downstream, and related entities or providing the appropriate materials to their employees (including managers and directors) and first tier, downstream, and related entities and ensuring that the training has been taken. If you have any questions about this policy, please contact either Stephanie Blaydes Kaisler at 410-786-0957 or Lynn Merritt-Nixon at 410-786-4652.