

Department of Health & Human Services  
Centers for Medicare & Medicaid Services  
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Baltimore, Maryland 21244-1850



## **CENTER FOR DRUG and HEALTH PLAN CHOICE**

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TO: All Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Shortages of Formulary Drug Products During a Plan Year

DATE: July 21, 2009

This memorandum addresses a number of questions received from the industry regarding the subject of drug shortages. Specifically, this memorandum provides the Centers for Medicare & Medicaid Services' (CMS) expectations of Part D sponsors when shortages impact the offering of drug products on plan formularies. By “shortages”, CMS is referring to those drug products that have been identified on the FDA Drug Shortage webpage:

<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>.

When establishing policies and procedures to address shortages, Part D sponsors should not adopt a one-size-fits-all approach. Drug shortages may occur for differing reasons and impact Part D sponsor application of its formulary in different ways. Therefore, when a drug shortage occurs, Part D sponsors should begin by considering the type of drug involved, condition(s) being treated by the drug, expected length of the drug shortage, and which enrollees are impacted. Based on this information, Part D sponsors can work with their enrollees and providers to find appropriate therapeutic alternatives.

The Part D sponsor will need to evaluate the availability (or unavailability) of therapeutically equivalent drug products. Different scenarios to be addressed include:

- A single-source formulary brand drug product is temporarily unavailable—no therapeutically equivalent products are available;
- A multiple-source formulary brand drug product is temporarily unavailable—only therapeutically equivalent generic products are available;
- A multiple-source formulary generic drug product is temporarily unavailable (all makers)—only therapeutically equivalent brand product is available; or
- A multiple-source formulary drug product is temporarily unavailable—no brand or generic therapeutically equivalent product is available.

In order to minimize unnecessary changes in therapy resulting from temporary shortages of multiple-source formulary drug products, CMS expects Part D sponsors to provide access to therapeutically equivalent non-formulary drug products, or therapeutically equivalent formulary drug products that otherwise require prior authorization or step therapy, for those enrollees currently taking the drug product subject to a shortage. When applicable, Part D sponsors should allow pharmacies to utilize a value of “8” in field 408-D8 (Dispense as Written/Product Selection Code) of the NCPDP v5.1 Telecommunication Standard to specify that an equivalent brand product is being dispensed due to the unavailability of any generic formulary products. The Part D sponsor is not required to charge the same cost-sharing that applies to the unavailable formulary product and may charge the applicable non-formulary or brand cost-sharing that would otherwise apply to the substituted therapeutically equivalent product.

Under these circumstances, CMS does not consider access to therapeutically equivalent non-formulary drug products, or therapeutically equivalent formulary drug products that otherwise require prior authorization or step therapy, to be formulary exceptions and, therefore, access to such drug products may be limited to the duration of the shortage. In the event that the shortage becomes a market withdrawal, Part D sponsors must follow notice requirements consistent with §42 CFR 423.120(b)(5) if the Part D sponsor intends to discontinue coverage of the therapeutically equivalent product. This policy does not preclude a beneficiary from seeking a non-formulary or tiering exception to obtain access to a non-formulary drug product or formulary drug product otherwise requiring prior authorization or step therapy.

If you have any questions regarding this memorandum, please contact Craig Miner at 410-786-7937.