

50.2 - Mail-Order Pharmacy Access

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

The inclusion of mail-order pharmacies in Part D plan networks is optional. However, network mail-order pharmacies will not count toward meeting the retail pharmacy access requirements specified in section 50.1. Since network inclusion of mail-order pharmacies is optional, sponsors may designate a subset of formulary drugs (e.g., particular tiers or “maintenance drugs” only) for availability via network mail-order pharmacies. As described in section 50.10, to the extent that a Part D plan offers benefits, including extended supplies of drugs (e.g., 90-day supplies), through network mail-order pharmacies, the plan must ensure that enrollees have reasonable access to the same benefits at network retail pharmacies. *CMS recognizes that some pharmacies may utilize common carriers in order to meet the needs of their patients, such as Part D enrollees residing in LTC facilities or in remote areas. A pharmacy that makes some, but not predominantly all, deliveries by common carrier is not a mail order pharmacy.*

50.3 - Limited Access Drugs and “Specialty” Pharmacies

(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

Part D sponsors may not limit access to certain Part D drugs to "specialty" pharmacies within their Part D network in such a manner that contravenes the convenient access protections

described in section 50.1. In other words, limited access to a Part D drug may not be based solely on the placement of a Part D drug in a specialty or high-cost tier because this tier placement alone is not indicative of any special requirements associated with such drug.

Part D sponsors may only restrict access to Part D drugs to a subset of their network pharmacies for the following reasons:

1. The FDA has restricted distribution of the drug to certain facilities or physicians; or
2. Appropriate dispensing of the Part D drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy.

Additional education or counseling alone does not qualify a drug for limited distribution within the overall pharmacy network.

Part D sponsors may specify, on a drug-by-drug basis, reasonable requirements for network pharmacies to ensure appropriate handling and dispensing of a particular Part D drug that requires special attention. These drug-by-drug requirements should only apply to special handling and dispensing that may be required for a particular “specialty” drug and not to reimbursement or other standard contracting terms and conditions. Offering pharmacies unreasonably low reimbursement rates for certain “specialty” drugs may not be used to subvert the convenient access standards. In other words, Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by 42 CFR 423.505(b)(18).

In addition, Part D sponsors may not require network pharmacies to qualify as a “specialty” pharmacy in order to dispense any drug that requires special attention if the network pharmacy is capable of appropriately dispensing the particular Part D drug or drugs in question. The convenient access standards dictate that “specialty” pharmacies be used to supplement network pharmacy access when necessary and not otherwise restrict it.

If a Part D sponsor finds it necessary to restrict access to a Part D drug for either of the two reasons listed above, it must indicate this on the formulary information page in the Formulary Submission module, as well as identifying these drugs in the formulary flat file. Additionally, Part D sponsors must be prepared to provide CMS with documentation substantiating the limited access drug criteria.