(d)(1)(i) of this section, may be covered under Part D. For purposes of this paragraph (d) these compounds are referred to as Part D compounds.

(iii) For a Part D compound to be considered on-formulary, all ingredients that independently meet the definition of a Part D drug must be considered on-formulary (even if the particular Part D drug would be considered off-formulary if it were provided separately—that is, not as part of the Part D compound).

(iv) For a Part D compound that is considered off-formulary—

(A) Transition rules apply such that all ingredients in the Part D compound that independently meet the definition of a Part D drug must become payable in the event of a transition fill under §423.120(b)(3); and

(B) All ingredients that independently meet the definition of a Part D drug must be covered if an exception under §423.578(b) is approved for coverage of the compound.

(2) Establish consistent rules for beneficiary payment liabilities for both ingredients of the Part D compound that independently meet the definition of a Part D drug and non-Part D ingredients.

(i) For low income subsidy beneficiaries the copayment amount is based on whether the most expensive ingredient that independently meets the definition of a Part D drug in the Part D compound is a generic or brand name drug (as described under §423.782).

(ii) For any non-Part D ingredient of the Part D compound (including drugs described under §423.104(f)(1)(i)(A)), the Part D sponsor’s contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.


§423.124 Special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies.

(a) Out-of-network access to covered Part D drugs—(1) Out-of-network pharmacy access. A Part D sponsor must ensure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when the enrollees—

(i) Cannot reasonably be expected to obtain such drugs at a network pharmacy; and

(ii) Do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

(2) Physician’s office access. A Part D sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician’s office.

(b) Financial responsibility for out-of-network access to covered Part D drugs. A Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs as provided in paragraph (a) of this section to assume financial responsibility for any differential between the out-of-network pharmacy’s (or provider’s) usual and customary price and the Part D sponsor’s plan allowance, consistent with the requirements of §§423.104(d)(2)(i)(B) and 423.104(e).

(c) Limits on out-of-network access to covered Part D. A Part D sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

§423.128 Dissemination of Part D plan information.

(a) Detailed description. A Part D sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

(b) Content of Part D plan description. The Part D plan description must include the following information about the qualified prescription drug coverage offered under the Part D plan—