

§ 423.120

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specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2).

(2) *Advance general notice of immediate negative formulary changes.* In the case of immediate negative formulary changes described in paragraph (e)(2) of this section, a Part D sponsor must provide advance general notice to all current and prospective enrollees and other specified entities in its formulary and other applicable beneficiary communication materials advising that the Part D sponsor may make immediate negative formulary changes consistent with the requirements of paragraph (e)(2) at any time. Such advance general notice must include information about how to access the plan's online formulary; about how to contact the plan; and that written notice of any change made will describe the specific drugs involved. Advance general notice of immediate substitutions must also specify that the written notice will contain information on the steps that enrollees may take to request coverage determinations and exceptions. Advance general notice of immediate substitutions is provided to CMS during bid submission. Advance general notice of market withdrawals is provided to CMS in the advance notice of immediate negative formulary changes that Part D sponsors provide to enrollees and other specified entities required earlier in this paragraph (f)(2).

(3) *Retrospective notice and update.* In the case of a negative formulary change described in paragraph (e)(2) of this section, the Part D sponsor must provide notice to other specified entities and written notice to affected enrollees as soon as possible, but no later than by the end of the month following any month in which the change takes effect. The requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2). Part D sponsors also must submit such changes to CMS, in a form and manner specified by CMS, in their next required or scheduled formulary update.

(4) *Content of written notice:* Any written notice required under this paragraph (other than advance general no-

tice) must contain all of the following information:

(i) The name of the affected covered Part D drug.

(ii) Whether the plan is removing the covered Part D drug from the formulary, moving it to a higher cost-sharing tier, or adding or making more restrictive PA, ST, or QL requirements.

(iii) The reason for the negative formulary change.

(iv) Appropriate alternative drugs on the formulary in the same or a lower cost-sharing tier and the expected cost sharing for those drugs.

(v) For formulary changes other than those described in paragraph (e)(2)(ii) of this section, the means by which enrollees may obtain a coverage determination under § 423.566, including an exception to a coverage rule under § 423.578.

(5) *Notice of other formulary changes.* Part D sponsors provide appropriate notice of all formulary changes other than negative formulary changes by providing—

(i) Advance general notice to all current and prospective enrollees, CMS, and other specified entities in formulary and other applicable beneficiary communication materials advising them that the Part D sponsor may make formulary changes other than negative formulary changes at any time and providing information about how to access the plan's online formulary and how to contact the plan; and

(ii) Notice of specific formulary changes to other specified entities by complying with § 423.128(d)(2) and to CMS by submitting such changes to CMS in their next required or scheduled formulary update.

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