

(b) *Approval of proposed plans.* CMS approves the Part D plan only if the plan and the Part D sponsor offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

(1) *Application of revenue requirements standard.* CMS approves a bid submitted under § 423.265 only if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under § 423.329(c).

(2) *Plan design.* (i) CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.

(ii) If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, the formulary categories and classes alone will not be found to discourage enrollment.

(iii) A plan that adopts the categories and classes discussed in paragraph (b)(2)(ii) of this section may nevertheless be found to discourage enrollment because it excludes specific drugs from the formulary.

(3) *Substantial differences between bids—(i) General.* CMS approves a bid only if it finds that the benefit package or plan costs represented by that bid are substantially different as provided under § 423.265(b)(2) of this subpart from the benefit package or plan costs represented by another bid submitted by the same Part D sponsor.

(ii) *Transition period for PDP sponsors with new acquisitions.* After a 2-year transition period, as determined by CMS, CMS approves a bid offered by a PDP sponsor (or by a parent organization to that PDP sponsor) that re-

cently purchased (or otherwise acquired or merged with) another Part D sponsor if it finds that the benefit package or plan costs represented by that bid are substantially different from benefit packages or plan costs represented by another bid submitted by the same Part D sponsor (or parent organization to that Part D sponsor), as provided under § 423.265(b)(2).

(4) CMS may decline to approve a bid if the Part D sponsor proposes significant increases in cost sharing or decreases in benefits offered under the plan.

(c) *Limited risk plans.* (1) Application of limited risk plans. There is no limit on the number of full risk plans that CMS approves under paragraph (b) of this section. CMS approves a limited risk plan in accordance with paragraphs (c)(2) and (c)(3) of this section only if the access requirements under § 423.859 are not otherwise met for a PDP region.

(2) *Maximizing assumption of risk.* CMS gives priority in approval for those limited risk plans bearing the highest level of risk, but may take into account the level of the bids submitted by the plans and is not required to accept the limited risk plan with the highest assumption of risk. In no case does CMS approve a limited risk plan under which the modification of risk level provides for no (or a minimal) level of financial risk.

(3) *Limited exercise of authority.* CMS approves only the minimum number of limited risk plans needed to meet the access requirements.

(d) *Special rules for private fee-for-service (PFFS) plans that offer prescription drug coverage.* PFFS plans (as defined at § 422.4(a)(3)) choosing to offer prescription drug coverage are subject to all MA-PD bid submission and approval requirements applicable to MA-PD plans with the following exceptions:

(1) *Exemption from negotiations.* These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet