

42 C.F.R. § 403.820

Sanctions, penalties, and termination.

- (a) *Intermediate sanctions.* (1) For the violations listed in paragraph (a)(3) of this section, the following intermediate sanctions may be imposed on any endorsed sponsor:
- (i) Suspension of enrollment of Medicare beneficiaries.
- (ii) Suspension of information and outreach activities to Medicare beneficiaries.
- (2) *Duration of sanctions.* The intermediate sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to recur.
- (3) *Sanctionable violations*. The violations for which intermediate sanctions may be imposed are as follows:
- (i) Substantial failure to maintain a contracted retail pharmacy network meeting the requirements of § 403.806(f);
- (ii) Substantial failure to comply with CMS Information and Outreach Guidelines;
- (iii) Substantial failure to provide discount card enrollees with negotiated prices consistent with information reported to CMS for the price comparison Web site and/or reported by the endorsed sponsor;
- (iv) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), substantial failure to ensure that the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to changes in the card sponsor's cost structure (including material changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy);
- (v) Charging drug card enrollees additional fees beyond a \$30 enrollment fee;
- (vi) Charging transitional assistance enrollees any enrollment fee;
- (vii) Charging a coinsurance more than 5 percent for those at or below 100 percent of the poverty line, or 10 percent for those above 100 percent but at or below 135 percent of the poverty line;
- (viii) Substantial failure to administer properly the transitional assistance funding for transitional assistance enrollees;
- (ix) Substantial failure to provide CMS or its designees with requested information related to the endorsed sponsor's endorsed discount card operations; or

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