

(4) The financial condition of the Part D sponsor.

(5) The history of prior offenses by the Part D sponsor or principals of the Part D sponsor.

(6) Such other matters as justice may require.

(b) *Amount of penalty.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees—up to \$25,000 as adjusted annually under 45 CFR part 102 for each determination.

(2) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees, CMS may calculate a CMP of up to \$25,000 as adjusted annually under 45 CFR part 102 for each Part D enrollee directly adversely affected (or with a substantial likelihood of being adversely affected) by a deficiency.

(3)(i) Definitions for calculating penalty amounts—

(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(ii) CMS sets minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(iii) CMS announces the standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(iv) CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) of this section when CMS determines that an organization's non-compliance war-

rants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

(4) For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to \$10,000 as adjusted annually under 45 CFR part 102.

(5) If CMS makes a determination that a Part D sponsor has terminated its contract other than in a manner described under 423.510 and that the Part D sponsor has therefore failed to substantially carry out the terms of the contract, \$250 as adjusted annually under 45 CFR part 102 per Medicare enrollee from the terminated Part D sponsor or plans at the time the Part D sponsor terminated its contract, or \$100,000 as adjusted annually under 45 CFR part 102, whichever is greater.

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 423.752(a):

(1) Civil money penalties of not more than \$25,000 as adjusted annually under 45 CFR part 102 for each determination made.

(2) With respect to a determination made under § 423.752(a)(4) or (a)(5)(i), not more than \$100,000 as adjusted annually under 45 CFR part 102 for each such determination except with respect to a determination made under § 423.752(a)(5), an assessment of not more than the amount claimed by such plan or PDP sponsor based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 423.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 423.752(a)(4), \$15,000 as adjusted annually under 45 CFR part 102 for each individual not enrolled as a result of the practice involved.

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