

*Funds* for purposes of this section, means any payment that a Part D sponsor has received that is based on data submitted by the Part D sponsor to CMS for payment purposes, including data submitted under § 423.329(b)(3), § 423.336(c)(1), § 423.343, and data provided for purposes of supporting allowable costs as defined in § 423.308 which includes data submitted to CMS regarding direct or indirect remuneration.

*Overpayment* means funds that a Part D sponsor has received or retained under title XVIII of the Act to which the Part D sponsor, after applicable reconciliation, is not entitled under such title.

(b) *General rule.* If a Part D sponsor has identified that it has received an overpayment, the Part D sponsor must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment.* The Part D sponsor has identified an overpayment when the Part D sponsor has determined, or should have determined through the exercise of reasonable diligence, that the Part D sponsor has received an overpayment.

(d) *Reporting and returning of an overpayment.* A Part D sponsor must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment.

(1) *Reporting.* A Part D sponsor must notify CMS of the amount and reason for the overpayment, using the notification process determined by CMS.

(2) *Returning.* A Part D sponsor must return identified overpayments in a manner specified by CMS.

(e) *Enforcement.* Any overpayment retained by a Part D sponsor is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) of this section.

(f) *Look-back period.* A Part D sponsor must report and return any overpayment identified within the 6 most recent completed payment years.

[79 FR 29963, May 23, 2014]

## Subpart H [Reserved]

## Subpart I—Organization Compliance with State Law and Preemption by Federal Law

### § 423.401 General requirements for PDP sponsors.

(a) *General requirements.* Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) *Licensure.* Except in cases where there is a waiver as specified at § 423.410 or § 423.415, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. If not otherwise licensed, the sponsor obtains certification from the State that the organization meets a level of financial solvency and other standards as the State may require for it to operate as a PDP sponsor.

(2) *Assumption of financial risk for unsubsidized coverage.* The PDP sponsor assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b) of the Act.

(b) *Reinsurance permitted.* The PDP sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage.

(c) *Solvency for unlicensed sponsors.* In the case of a PDP sponsor that is not described in § 423.401(a)(1) and for which a waiver is approved under § 423.410 or § 423.415, the sponsor must meet the requirements in § 423.420.

### § 423.410 Waiver of certain requirements to expand choice.

(a) *Authorizing waiver.* In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the entity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (b), (c), or (d) of this section are met.

(b) *Grounds for approval of waivers.* Subject to the waiver requirements specified in § 423.410(e), waivers may be