

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

*Downstream entity* means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

*Final settlement adjustment period* means the period of time between when the contract terminates and the date the Part D sponsor is issued a notice of the final settlement amount.

*Final settlement amount* means the final payment amount that CMS owes and ultimately pays to a Part D sponsor, or that a Part D sponsor owes and ultimately pays to CMS, with respect to a Part D contract that has consolidated, nonrenewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and all of the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(1) Risk adjustment reconciliation, as applicable (described in § 422.310 of this chapter).

(2) Part D annual reconciliation (described in § 423.343).

(3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320).

(4) MLR remittances (described in §§ 422.2470 of this chapter and 423.2470).

*Final settlement process* means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS does all of the following:

(1) Calculates the final settlement amount.

(2) Issues the final settlement amount along with supporting documentation in the notice of final settlement to the Part D sponsor.

(3) Receives responses from the Part D sponsor requesting an appeal of the final settlement amount.

(4) Takes action to adjudicate an appeal (if requested) and make payments to or receive payments from the Part D sponsor. The final settlement amount is calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

*First tier entity* means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

*Party in interest* means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

*Prescription drug pricing standard* means any methodology or formula for varying the pricing of a drug or drugs