



MEDICARE PLAN PAYMENT GROUP

DATE: September 29, 2014

TO: All Part D Sponsors and interested parties

FROM: Cheri Rice, Director
Medicare Plan Payment Group

SUBJECT: Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions

The purpose of this memorandum is to provide draft guidance for Part D sponsors on reporting direct and indirect remuneration (DIR) data for pharmacy price concessions for contract year (CY) 2016 and beyond. The Centers for Medicare & Medicaid Services (CMS) will accept comments on this draft guidance through **October 17, 2014**. Instructions for submitting comments are provided below.

In our final rule, “Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,” CMS expressed concerns regarding the differences with which Part D sponsors report costs and price concessions to CMS. See 79 FR 29843 (May 23, 2014). We stated that variations in the treatment of costs and price concessions affect beneficiary cost sharing, CMS payments to plans, federal reinsurance and low income cost-sharing (LICS) subsidies, manufacturer coverage gap discount payments, and plan bids. We noted that some Part D sponsors report certain pharmacy price concessions as DIR rather than as price concessions that affect the negotiated price, and stated that we believe it is critical that negotiated prices reported on the prescription drug event (PDE) data have a consistent meaning across the Part D program in order to preserve a level playing field in bidding and cost reporting. See 79 FR 29843, 29878 (May 23, 2014).

To address our concerns, we revised the definition of “negotiated prices” at § 423.100. Beginning with CY 2016, “negotiated prices” means prices for covered Part D drugs that meet all of the following: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug. (2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale; and (3) Include any dispensing fees; but (4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale. (5) Must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.

As stated in clause 2 of the definition above, negotiated prices include price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale. Those price concessions that cannot be determined at point-of-sale are not considered part of the negotiated prices of Part D drugs and are reported as DIR. We stated in the final rule that we would provide DIR guidance as to which types of pharmacy price concessions would meet the standard for this exception, and we would consult with industry in developing the guidance. See 79 FR 29843, 29878 (May 23, 2014). We request comments regarding the following guidance.

Administrative Costs versus Drugs Costs

Fees that offset operating costs of the sponsor or pharmacy benefit manager (PBM) in complying with Part D requirements meet the definition of administrative costs at § 423.308 and must be reported as part of the bid. Deductions from payment to pharmacies for Part D drugs dispensed are price concessions and must be reported either as DIR or on the PDE, as part of the negotiated price of the Part D drug. The requirements for reporting price concessions apply regardless of how the price concessions are characterized by the Part D sponsor, the PBM, the pharmacy, or any other entity and regardless of whether the price concession is calculated on a per-claim basis. The final rule did not modify the definition of administrative costs, but rather specifies how and when price concessions for Part D drugs must be reported to CMS.

Pharmacy Price Concessions

For the purposes of reporting, pharmacy price concessions can be broken down into two categories – those that can reasonably be determined at point-of-sale and those that cannot. Any pharmacy price concession or incentive payment that can reasonably be determined at point-of-sale must be included in the negotiated price and reported on the PDE. Pharmacy price concessions that cannot reasonably be determined at point-of-sale must be reported as DIR. We believe that determination at the point-of-sale includes an approximation of the price concession, even if the actual amount of the price concession is reconciled after the point-of-sale. In such an instance, we believe the amount that can reasonably be approximated at the point of sale would meet the standard in clause (2) of the definition of negotiated price and should be reported on the PDE. The difference between the amount determined in the final reconciliation of the price concession and the amount reported on the PDE would be reported as DIR.

The following are examples of pharmacy price concessions that we believe can reasonably be determined at the point-of-sale: 1) A Part D sponsor may pay according to a basic rate at point-of-sale, but trigger enhanced payment rates based on generic utilization, pharmacy market share, pharmacy network size, or other metric. If the contingent pricing can be reasonably approximated using recent experience, then we believe the total price, inclusive of the enhancements, should be reported in the negotiated price of the Part D drug. 2) Similarly, a Part D sponsor may agree to an additional payment based on a formula involving utilization,

pharmacy market share, or other metric. If the value of this additional payment can be reasonably approximated using recent experience, it should be reported in the negotiated price of the Part D drug. In these examples, only the difference between the approximation and the final payment should be reported as DIR.

For those price concessions that cannot be reasonably determined at point-of-sale and must be reported as DIR, beginning with benefit year 2016 (which is submitted to CMS on the DIR report in calendar year 2017), CMS intends to require that Part D sponsors report these price concessions in two new fields on the Summary DIR report, Preferred Pharmacy Price Concessions and non-Preferred Pharmacy Price Concessions. In addition, if a Part D sponsor has DIR to report in the new pharmacy price concession fields, the Part D sponsor can provide a comment explaining why the price concessions could not be reasonably determined at point-of-sale.

We believe that most pharmacy price concessions can reasonably be determined at point of sale and, therefore, should be reported through the negotiated prices. We request comments with examples of pharmacy price concessions that cannot reasonably be determined or approximated at point-of-sale.

Instructions for Submitting Comments

CMS will accept comments on this proposed guidance until **October 17, 2014**. Comments may be submitted electronically to DIR_Reporting_Reqts@cms.hhs.gov or mailed to:

Amanda Johnson
Director, Division of Payment Reconciliation
Centers for Medicare & Medicaid Services
7500 Security Boulevard C1-13-07
Baltimore, Maryland 21244

Questions regarding the policies in this guidance may be submitted to DIR_Reporting_Reqts@cms.hhs.gov.