

# “Netting” Prices

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# Overview of Presentation

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- Obstacles to Determining “Net” Price
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  - Rebates Realized “Out of Quarter”
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# “Net” Price Requirement

- Medicaid Rebate Agreement
  - AMP “includes all cash discounts allowed and all other price reductions [except Medicaid rebates] which reduce the actual price paid.”
  - Best Price is “inclusive of cash discounts, free goods, volume discounts, and rebates [except Medicaid rebates].”
- ASP Interim Final Rule, 42 C.F.R. § 414.804(a)(2)
  - When calculating ASP, “deduct the following types of transactions and items: (i) Volume discounts; (ii) Prompt pay discounts; (iii) Cash discounts; (iv) Free goods that are contingent on any purchase requirement; (v) Chargebacks and rebates [except Medicaid rebates].”

# “Net” Price Requirement

## OIG Guidance to Pharmaceutical Manufacturers:

- “Where appropriate, manufacturers’ reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers.”

# Administrative Fees

- CMS Guidance: Consistent?
  - Medicaid Rebate Release 14 (1994): “We consider administrative fees . . . to be included in the calculation of AMP, if those sales are to an entity included in the calculation of AMP, and best price.”
  - ASP FAQ Website (2004): “Administrative fees . . . should be included in the calculation of ASP, if those sales are to an entity whose sales are included in the calculation of ASP and *if they ultimately affect the price realized by the manufacturer.*”
  - Part D Proposed Rule (2004): “[W]e are proposing to require that any administrative fees paid to Part D plans be based on the fair market value of services rendered, and that *any fees determined to be above or below fair market value would be considered additional price concessions.*” 69 Fed. Reg. 46,632, 46,687.

# Third-Party Rebates

- Medicaid Rebate Releases 28 & 29:
  - “[M]anufacturers have developed a myriad of arrangements whereby specific discounts and other chargebacks or rebates are paid to the PBM which, in turn, passes these on to the purchaser. Where PBMs subsequently adjust drug prices by applying discounts, chargebacks or rebates, these price adjustments should be included within the best price calculations. . . . We generally consider drug prices to PBMs as having no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement.”
- Criticisms of this position:
  - How are manufacturers to know when PBMs are passing rebates on to purchasers?
  - Why Best Price and not AMP?

## Bundled Discounts

- **OIG Guidance:** “Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products . . . .”
  - Medicaid Rebate Agreement and ASP Interim Final Rule include similar direction.
- **Manufacturer contracts** to sell drug A at \$10, or \$6 if customer also purchases drug B at \$10. If a customer buys A and B, what are their true prices?
  - Are your company’s systems and procedures able to capture and process such discounts correctly?
  - Impact of differential definition of “unit” for purposes of Medicaid rebates and ASP.

# Price Concessions Realized “Out of Quarter”

- Some price concessions accrue outside of the quarter in which the sale was made and after the prices for that quarter have been calculated and reported to CMS. (Under discount safe harbor, terms must be fixed at the time of the sale.)
- AMP/Best Price: Medicaid Rebate Agreement & Medicaid Rebate Release 2 require that AMP and Best Price be adjusted “if cumulative discounts . . . adjust the prices actually realized.”
  - Implications for manufactures: Correction of reports and adjustments to Medicaid rebates and 340B ceiling prices.
- ASP: 42 C.F.R. § 414.804(a)(3) (final rule issued on Sept. 16, 2004) introduced a “rolling average” methodology for estimating such price concessions.
  - No requirement to “true up” the estimates.



# “Reasonable Assumptions”

- Medicaid Rebate Agreement: “In the absence of specific guidance in section 1927 of the [Social Security] Act, Federal regulations and the terms of this agreement, the manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of [the above]. *A record (written or electronic) outlining these assumptions must be maintained.*”
- ASP FAQ Website: “In the absence of specific guidance in the Social Security Act or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the intent of [the above] and customary business practices. *These assumptions should be submitted along with the ASP data.*”

# Questions?

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