

# Recent Pricing and Coverage Issues and Their Fraud and Abuse Implications

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# Introduction

- Transparency
  - Many Roots to this Tree
    - The Discount Statutory Exception to the Anti-kickback Statute
    - The Regulatory Safe Harbors under the AKS for Discounts and for GPO Administrative Fees
    - Corporate Integrity Agreements (“CIAs”)
      - Medco and Advanced PCS CIAs as Examples
    - OIG Compliance Guidance to Pharmaceutical Manufacturers
    - ASP Assumptions Letters
    - Reporting of Negotiated Price and LTC Pharmacy Rebates and Other Remuneration

# Introduction (cont'd)

- So, the Government wants increased transparency by manufacturers
- But, shouldn't it be a two-way street?
  - With the expectation of manufacturer transparency, there should come a corresponding expectation of issuing clear and timely guidance.
  - Particularly true in an environment where there is a duty to certify
    - Failures of transparency
      - AMP Final Rule
        - » Requires certification but government will not read reasonable assumptions letters
      - Recent VA Dear Manufacturer Letter

# Bundling—A Failure of Transparency

- 2/21/91: Medicaid Rebate Agreement (MRA)
  - Appeared in the Federal Register with Notice and Comment Period
- 8/22/06: Proposed '07 Physician Fee Schedule (PFS) Rule
  - CMS solicits comments on bundled sales in the ASP context
  - 12/1/06: Final '07 PFS Rule
    - CMS declines to rule on bundled sales in ASP context
- 7/17/07: AMP Final Rule

# Bundling Definitions

- MRA definition
  - “Bundled Sale refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.”
- AMP Final Rule definition
  - “Bundled sale means an arrangement **regardless of physical packaging** under which the rebate, discount, or **other price concession** is conditioned upon the purchase of the **same drug**, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) **or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary)**, or where the resulting discounts or **other price concessions** are greater than those which would have been available had the bundled drugs been purchased separately **or outside the bundled arrangement.**”

# Differences in Bundling Definitions

- Key Differences between **MRA** and **AMP Rule** Definitions; AMP Final Rule Adds:
  - “[R]egardless of physical packaging”
  - Reference to “other price concessions”
  - Reference to “same drug” and “another product”
  - Definition of “different types” to mean different NDCs
  - Addition of “other performance requirement”  
(including market share and formulary reference)

# Retrospective Application of New Bundling Definition

- Prospective v. Retrospective Intent of CMS
  - Signals that suggest agency's intent in a regulation:
    - “New,” “Revised,” or “Changed” = prospective intent
    - “Clarify” = retrospective intent?
  - Based on CMS' responses to comments, it seems clear that CMS intends to treat the definition of “bundled sale” in the AMP Final Rule as a “clarification” and not as a new rule.

# Retrospective Application of New Bundling Definition (cont'd)

- **AMP Final Rule Comment:** A few commenters said that the proposed definition differs significantly from the definition of bundled sales provided in the Medicaid rebate agreement . . .
  - **Response:** The *clarification* of the bundled sales definition in this final rule ***does not create a new definition or impose new obligations*** that did not already exist under the Rebate Agreement. 72 Fed. Reg. at 39158-39159 (emphasis added).
- **AMP Final Rule Comment:** One commenter requested that CMS clarify that the new definition ***does not apply for periods prior to the effective date*** of this final rule.
  - **Response:** The provisions of this final rule ***do not create a new definition*** for bundled sales, but merely clarify the existing definition. 72 Fed. Reg. at 39159.



# What's Wrong with This Picture?

- Basic notions put at risk here.
  - Notice and opportunity to comment
  - Contract rights
  - Just the notion of fairness
  - Bundling not an isolated issue, even looking just at the Final AMP Rule