

PBM Transactions

- Medicaid DRA Rule
 - Proposed Rule
 - AMP includes “Discounts, rebates or other price concessions to PBMs associated with sales for drugs provided to the retail pharmacy class of trade.”
 - Best Price includes “Prices to any retailer, including PBM rebates, discounts, or other price concessions that adjust prices either directly or indirectly on sale of drugs.”

PBM Transactions

- CMS Response to Comments in the final rule:
 - “the administrative burden for manufacturers to gather confidential information from PBMs and others in the drug chain...is significant.”
 - “Manufacturers do not have to collect rebate data with respect to [PBM] transactions between such downstream entities.”

PBM Transactions

- Final Rule

- AMP excludes “Discounts, rebates, or other price concessions to PBMs, except for their mail order pharmacy’s purchases.”
- Best price excludes “PBM rebates, discounts or other price concessions except their mail order pharmacy’s purchases or where such rebates, discounts or other price concessions are *designed* to adjust prices at the retail or provider level.”

- \$64,000 question: What does “designed” mean?

- **Potential liability in connection with Best Price reporting.**

Part D Transparency

- Part D transparency includes
 - Retail price of drugs on Plan Finder
 - Cost to beneficiary based on cost sharing
 - Premium price
- Plan reporting includes:
 - Drug cost (ingredient cost + dispensing fee + sales tax)
 - Administrative cost
 - Profit/return on investment
 - Quarterly rebate and price concession information for each drug
 - Aggregate negotiated price concessions passed through

Part D Transparency – Protection of Information

- Section 1860D-15(d)(2) and 1860D-15(f) of Social Security Act– limit on use of payment related information CMS collects to payment purposes
- Aggregate rebate information – data may not be disclosed in a form which discloses identity of manufacturer or price charged except to CBO or GAO (Medicaid rebate statute confidentiality applied through Section 1860D-2(d)(2))

Part D Data Disclosure: CHAMP Provisions

- Provided for disclosure of certain negotiated price, rebates, discounts, bid information, and prescription drug event data to congressional support agencies- CBO, GAO, MedPAC
- Data cannot be disclosed in identifiable form which is defined as information that permits identification of a PDP, MA-PD plan, PBM, drug manufacturer, drug wholesaler or enrollee
- Data can only be used by a Congressional Support Agency for carrying out the functions and activities of the agency mandated by Congress.