

Data on Medicare's net prices for prescription drugs and other drug pricing metrics

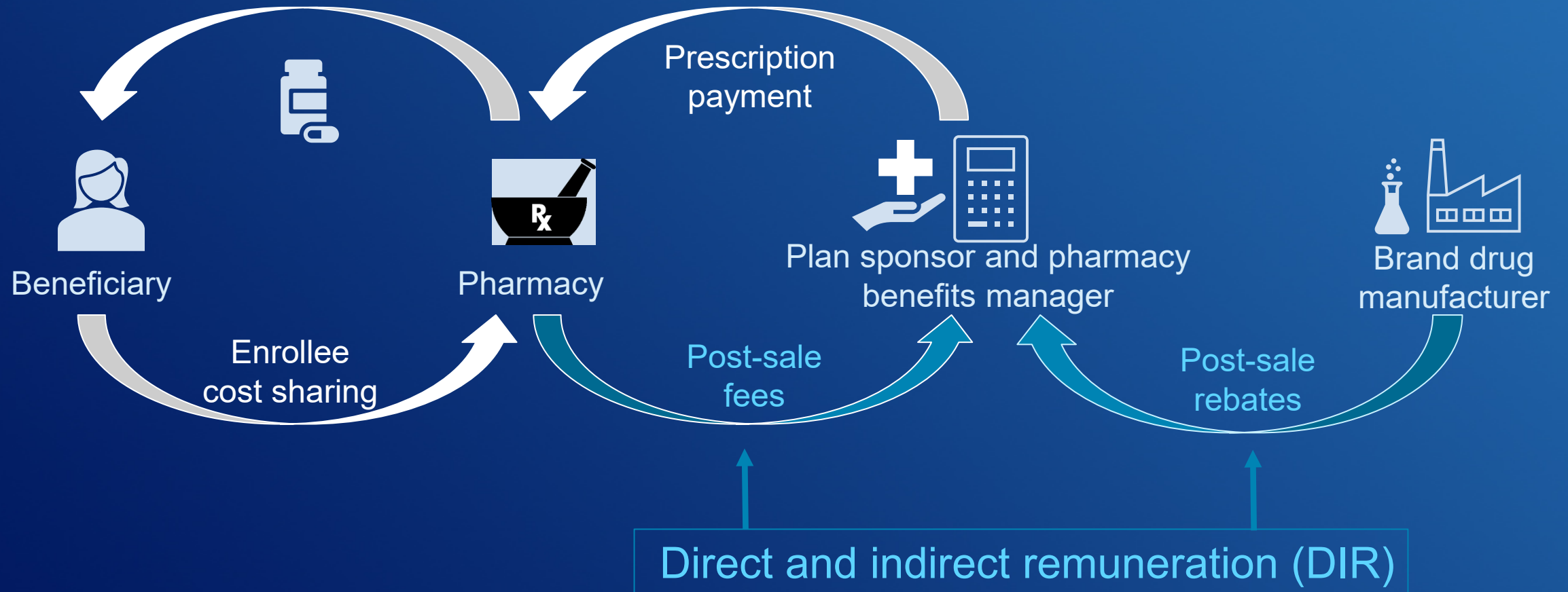
Shinobu Suzuki, Rachel Schmidt, Kim Neuman, and Nancy Ray

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Consolidated Appropriations Act, 2021, newly provides Commission with access to two sets of data

- Post-sale rebates and fees (direct and indirect remuneration (DIR) data) for Part D outpatient drugs
- Pricing data for provider-administered drugs under Part B and drugs covered under Medicaid
 - Average sales price (ASP)
 - Average manufacturer price (AMP)
 - Best price (BP)
- Data subject to disclosure limitations defined by statute

Gross drug prices at the pharmacy do not reflect post-sale rebates and pharmacy fees



Sponsors report plan-level DIR to CMS retrospectively for each benefit year

- Any price concession to the sponsor or an intermediary that decreases a plan's costs directly or indirectly
- Used to reconcile prospective plan payments with plan's final costs of providing benefits
- DIR has grown from <10% of gross Part D spending in 2007 (~\$5 billion) to >26% in 2019 (\$48 billion)
- Two types of DIR reports
 - Summary report shows categories of DIR for each plan
 - Detailed report shows DIR at national drug code (NDC-11) level

Manufacturers report ASP data to CMS to establish Part B drug payment rates

- Drug manufacturers report ASP and utilization data to CMS at the 11-digit NDC-level
- Medicare generally pays 106% of ASP for Part B drugs
- Part B drug payment rates are set at the billing code level
 - CMS calculates the volume-weighted average ASP across all NDCs assigned to a billing code
- Payment rates are public, but NDC-level ASP data are not
- CAA, 2021, grants MedPAC access to NDC-level ASP data

Manufacturers report AMP and BP data to CMS

- Manufacturers report NDC-level AMP and BP data to CMS for administration of Medicaid
 - States receive rebates on Medicaid-covered outpatient drugs using formulas that are based on AMP and/or BP
- AMP and BP data also have broader implications
 - For Part B drugs, if OIG finds ASP > AMP by at least 5%, CMS can substitute 103% AMP for 106% ASP
 - For providers that purchase outpatient drugs via the 340B program, the 340B ceiling price = AMP – Medicaid unit rebate amount

CAA, 2021's limitations on disclosure

- Prohibits disclosure in a form that would reveal the identity of a specific manufacturer or wholesaler or the prices they charged
- For DIR data, it also prohibits revealing plan-level dollar amounts or identities of sources of price concessions

Plans for analysis using DIR data

- Initially focus on:
 - Validating the accuracy of the data
 - Understanding the limitations of its use in research (e.g., sponsors use different algorithm to allocate DIR across plans and/or NDCs)
- Potential Part D research topics:
 - Effects of competition on rebates
 - Relationship between rebates and point-of-sale prices
 - Effects of rebates on the accuracy of Part D's risk adjustment

Plans for analysis of ASP and other data

- Initially focus on:
 - Data validation – replicate Part B drug payment rates
- Potential Part B research topics
 - Combined billing code policies
 - Variation in ASP within billing codes
 - Generic drug pricing and utilization dynamics
- Compare Part B and Part D net price growth for similar types of products

Next steps

- In April, we plan to come back to you with preliminary information about the pricing data, including their strengths and limitations
- We would like your feedback on:
 - Analytical plans discussed in this presentation / mailing material
 - Relative priority among the research projects
 - Additional research ideas