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Appreciating 340B Drug Pricing Program In Relation to Recent Circuit Court Opinions

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Appreciating 340B Drug Pricing Program In Relation to Recent Circuit Court Opinions.

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Celesq

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Disclaimer

The information is not meant to constitute legal advice and is current as the of the date of the initial presentation. Participants are encouraged to continually review updated case law, government websites, and other reputable and relevant sources.

Overview

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Introduction

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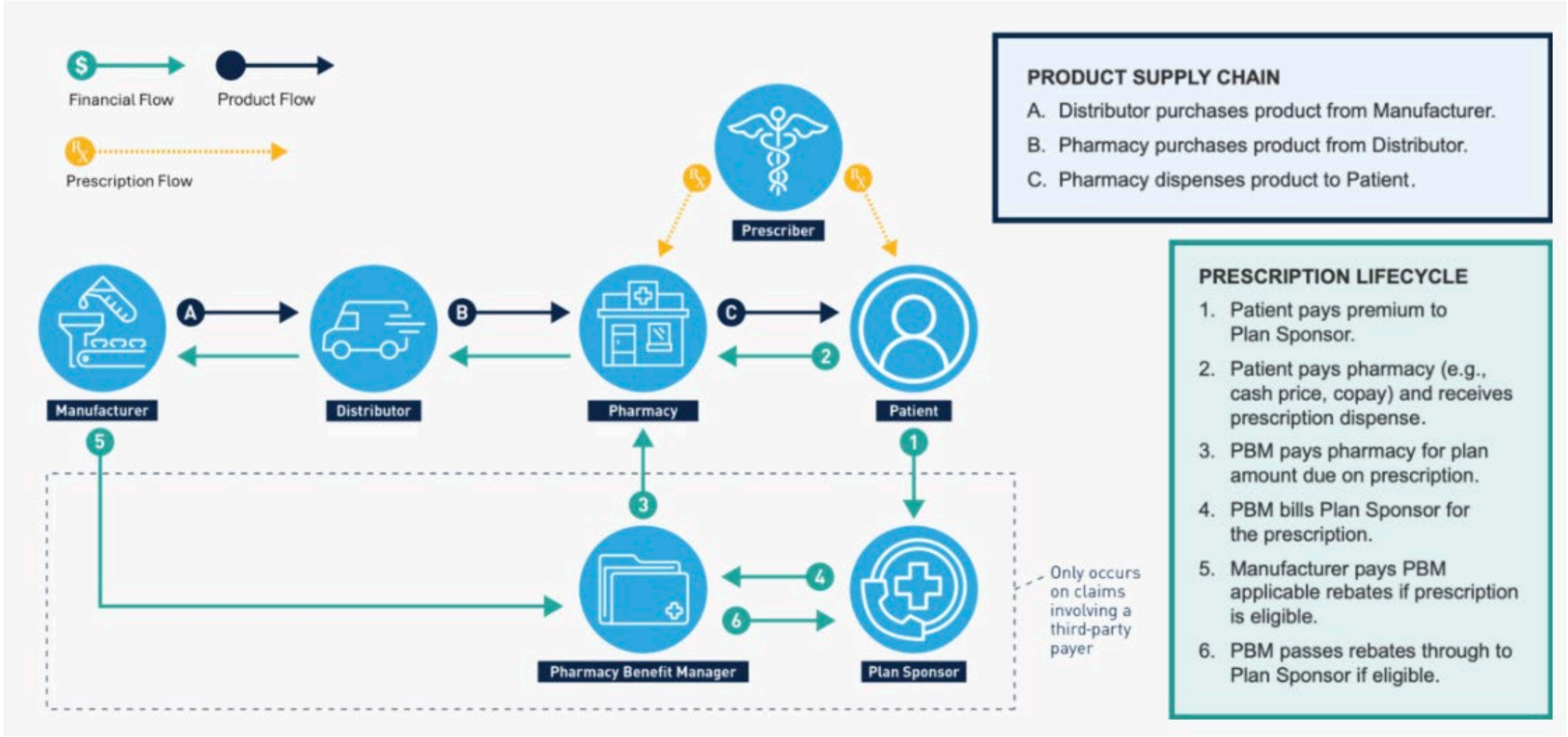
- “The Medicaid Drug Rebate Program and the 340B Drug Pricing Program both require drug manufactures to provide significant discounts on their products.
- Under Medicaid, these discounts are provided in the form of rebates on covered outpatient drugs paid for by state Medicaid programs.
- Under 340B, manufacturers also are required to sell drugs to participating providers at a significantly reduced price but states may not claim a Medicaid rebate for a drug that was purchased under 340B. **This is known as the prohibition on duplicate discounts.”**

PBMs

- **Pharmacy Benefit Manager (PBM) –** ”a person or entity that has, as its principal focus, the implementation of one or more device and/or prescription drug benefits programs.” (Title 21, Section 99.3(h)).
  - As stated in BRG’s *Pharmacy Benefit Manager Overview* (Apr. 2025), [a] pharmacy benefit manager (**PBM**) is a participant in the pharmaceutical supply chain that establishes and manages contractual relationships with employers, health plans, pharmacies, and pharmaceutical manufacturers to administer prescription drug benefit plans; manage a network of retail, mail, and specialty pharmacies; process prescription drug claims; develop formularies that clients may adopt; negotiate rebates from manufacturers; and offer additional services that its clients may adopt to reduce prescription drug costs or improve clinical outcomes.



Noteworthy Items

- *"According to the Kaiser Family Foundation, private insurers, Medicare Part D, and Medicaid account for 82 percent of total retail prescriptions in the United States[.]"*
- *2026 – Maximum Fair Price (MFP) as part of the Inflation Reduction Act. Applies to Medicare under the Medicare Drug Price Negotiation Program. On March 13, 2026, CMS announced that the drug companies that manufacture all 15 drugs payable under Medicare Part B and/or covered under Medicare Part D selected for the third cycle of negotiation have chosen to participate in the Negotiation Program. Negotiations with participating drug companies are occurring in 2026 and any negotiated prices will become effective beginning in 2028.*

The Workings of the 340B Program & Best Price.

Evolution of the 340B Program

- Congress **created the 340B Drug Discount Program (340B) in 1992** through the Veteran's Health Care Act (P.L. 102-585) to enable health care providers that serve low-income and uninsured patients to purchase drugs at lower costs.
- **Section 340B of the Public Health Service Act (42 U.S.C. § 256b**), which is considered the "authorizing statute," requires drug manufacturers that participate in the Medicaid Program to offer certain outpatient drugs to "covered entities" at discounted prices.
- The Health Resources and Services Administration (HRSA), part of the U.S. Department of Health and Human Services (HHS), **administers** the Program.
- As of October 14, 2022, HRSA estimates that 340B sales constitute about 7.2% of the overall U.S. drug market and reports that in 2021, total program sales reached approximately $44 billion, an almost 15% increase over 2020.

Medicaid Drug Rebate Program

- Created under the Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508.
- *"Medicaid Best Price Program. Basically, best price is the lowest price available to any wholesaler, retailer, or provider, with the exception of certain government programs. Created under the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) as part of the Medicaid Drug Rebate Program (MDRP), '[b]est price is used in the basic rebate formula to determine the rebates a manufacturer owes Medicaid; best price is not the amount Medicaid pays for a drug.'"*
- Objective is to ensure that Medicaid receives a net price for a drug that is consistent with the lowest or best price for which manufacturers sold the drug.
- In order participate, the drug manufacturer MUST enter into a Medicaid national drug rebate agreement with HHS in order for states to receive federal funding for use of its products (§1927(a)(1) of the Social Security Act).

How are Medicaid drug rebates calculated?

- Rebates are calculated based on the average manufacturer price (**AMP**).
- **AMP is defined** as the average price paid to the manufacturer for the drug in the US by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer (§ 1927(k)(1)) of the SSA).
- **CMS calculates** the unit rebate amount (**URA**) for each drug based on the established formula for that type of drug and provides this URA to each State.
- In turn, the State collects the rebate dollars from the manufacturer and reports the rebate amount as an offset to the drug expenditures on **Form CMS 64, which is a Quarterly Medicaid Statement of Expenditures and has been used since 1980 as part of the Medical Assistance Program and is also used in State budget and expenditure reporting for Medicaid and CHIP.**
- **NOTE:** there are separate formulas for brand name drugs (aka multiple source drugs) and generic drugs (aka non-innovator multiple source drugs.

The intersection of 340B & Best Price.

- The main issue confronting state Medicaid programs with regard to 340B is preventing duplicate discounts.
- HRSA, which administers the 340B program, requires drug manufacturers to sell drugs to select safety-net providers at a reduced price (aka the ceiling price).
- **Ceiling Price = AMP – URA** (this is the same process for 340B and for determination of the drug's rebate under Medicaid Drug Rebate Program)

The intersection of PBMs & Best Price.

- 42 C.F.R. § 447.505(b) - unless the exemptions specifically enumerated in subsection (c) of the rule are met, the "best price" calculation "includes **all prices**, including applicable discounts, **rebates**, or other transactions **that adjust prices either directly or indirectly**" to any wholesaler, **retailer, provider,** health maintenance organization, nonprofit entity, or governmental entity."
- 42 C.F.R. § 447.505(c)(17) – limited in its application and excludes from Best Price,
  - "**PBM rebates, discounts, or other financial transactions <u>except</u>** their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions *are designed* to adjust prices at the retail or provider level."
  - "except" means that rebates passed through PBMs, which are available from manufacturers to retailers and providers are required be included in the best price calculation.

Notable 340B Program District Court Cases & the Pilot Program

340B Pilot Program Update

- On February 10, 2026, in *American Hospital Association et al. v. Kennedy et al.*, No. 25-cv-600 (D. Me.), the U.S. District Court for the District of Maine vacated and remanded to HHS the 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 36,163 (Aug. 1, 2025), the Corrected 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 38,165 (Aug. 7, 2025), and the approvals of applications from drug manufacturers submitted pursuant to those notices (announced between October 30 and November 14, 2025).
- HHS is reconsidering whether to implement a 340B Rebate Model Pilot Program consistent with its statutory authority. HRSA is issuing a Request for Information (RFI) to gather input from interested parties regarding the potential use of rebates to effectuate the ceiling price under the 340B Program. For more information on how to submit a response to the RFI by the April 20, 2026 deadline, please visit Request for Information: 340B Rebate Model Pilot Program

District & Non-FCA Appellate Court Cases

Against Manufacturers

- ***American Hospital Association et al. v. AbbVie Inc. et al., Case No. 25-2237 (1st Cir.)***

Against U.S. Gov't

- **Sanofi-Aventis U.S., LLC v. Department of Health and Human Services, et al.,** Case No. 3:21-cv-00634 (D. N.J.) – decision issued.

Sheldon (4th Circuit)

Deborah Sheldon v. Allergan Sales, LLC, No. 24-1793 (4**th** Cir. 2026).

- In a decision issued on March 13, 2026, and amended on March 19, 2026, the Fourth Circuit reversed and remanded the dismissal of a *qui tam* suit brought by a former pharmaceutical company employee against his former employer, Forest Laboratories, LLC (now Allergan Sales, LLC).
- Fourth Circuit held that the district court erred by dismissing the case because the relator, Troy Sheldon, had adequately alleged that Forest acted with reckless disregard in reporting its Medicaid "Best Price" (the lowest price available from a manufacturer to any purchaser) without aggregating rebates and discounts provided to multiple entities in the same drug distribution chain.

Reasons the Decision is Notable.

- The first time the Fourth Circuit has applied the subjective scienter standard that the Supreme Court unanimously adopted in *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023).
- The case centers on Forest's obligations under the Medicaid Rebate Statute, which requires drug manufacturers to report their "Best Price" to CMS.
- Sheldon, who worked in managerial roles at Forest from the 1990s until his termination in 2014, alleged that Forest routinely "stacked" rebates, where it provided separate discounts to both a wholesaler and a downstream entity such as a pharmacy provider or group purchasing organization for the same drug dispensed to the same patient, but failed to aggregate those rebates when reporting its Best Price to CMS.
- The result, Sheldon alleged, was that Forest underpaid Medicaid by approximately $686.64 million over nearly a decade.

Adventist (9th Circuit)

United States ex rel. Adventist Health System of West v. Abbvie, Inc., et al., Case No. 24-2180 (9th Cir. 2026).

- March 17, 2026 decision reversing dismissal of a *qui tam* brought by a "covered entity," as that term is defined in the law, against several drug manufacturers.
- Ninth Circuit Holding - Adventist plausibly alleged FCA claims and that neither the 340B statute nor the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara County* categorically bars such a suit.
- The relator, Adventist Health System of West (Adventist), alleged that four drug manufacturers knowingly charged covered entities more than statutorily permitted, particularly in circumstances where Adventist contends the 340B pricing formula would yield a ceiling price at or below zero, requiring a $0.01 "penny price."
- Adventist did **not** seek to recover its own alleged overcharges as a purchaser. Instead, it alleged that the manufacturers' pricing practices **harmed the federal (and state) governments** by increasing amounts paid under government healthcare programs and by other government purchasers.

The United States' Related Amicus Brief

- The United States filed an amicus brief urging reversal of the district court's dismissal.
- The government argued that FCA claims alleging financial harm to the United States are not foreclosed simply because the 340B statute does not provide a private right of action for covered entities and because 340B has an administrative enforcement framework.
- The government also emphasized the FCA's role as a principal anti-fraud tool and stated it took no position on the ultimate merits of the relator's claims.

Conclusion

Parting Thoughts

- Two areas of litigation trends: (1) False Claims Act cases and(2) Pharmaceutical Companies suing HHS.
- Stay abreast of the HHS and HRSA websites regarding the Pilot Program after the U.S. District Court's ruling.
- Effective compliance programs (42 CFR §483.85) are critical for risk mitigation and ensuring that the appropriate rebates are submitted.
- Read the attestation/certification language on Form CMS 64 carefully.

Thank You & Questions

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Resources

- https://cdn.ca9.uscourts.gov/datastore/opinions/2026/03/17/24-2180.pdf (9th Circuit *Adventist* Opinion)
- https://law.justia.com/cases/federal/appellate-courts/ca4/24-1793/24-1793-2026-03-19.html (4th Circuit *Sheldon* Opinion)
- https://www.congress.gov/crs-product/IF12232#:~:text=111%2D148)%2C%20which%20expanded,settle%20disputes%20regarding%20340B%20purchases. (Congressional History)
- R.V. Rose, *Recent Final Rule Confirms No Wiggle Room for Pharma - PBMs are in the Medicaid Best Price Calculation, ABA Health eSource* (Mar. 2021). Attached.
- https://litigationtracker.law.georgetown.edu/issues/340b-program/ (340B cases)

Recent Final Rule Confirms No Wiggle Room for Pharma - PBMs are in the Medicaid Best Price Calculation

By Rachel V. Rose, JD, MBA, Attorney at Law, PLLC, Houston, TX

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Introduction

It is widely accepted that prescription drugs play a vital role in the management of both chronic diseases and acute conditions.[1] "At the same time, the rate of growth in prescription drug spending has concerned both public and private payers."[2] According to the Kaiser Family Foundation, private insurers, Medicare Part D, and Medicaid account for 82 percent of total retail prescriptions in the United States, which total over $274 billion annually.[3]

One area that has received a great deal of attention over the past several years is the Medicaid Best Price Program.[4] Basically, best price is the lowest price available to any wholesaler, retailer, or provider, with the exception of certain government programs. Created under the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) as part of the Medicaid Drug Rebate Program (MDRP), "[b]est price is used in the basic rebate formula to determine the rebates a manufacturer owes Medicaid; best price is not the amount Medicaid pays for a drug."[5]

Pharmaceutical manufacturers and pharmacy benefit managers (PBMs) have not been able to avoid scrutiny related to best price.[6] For example, Mylan paid separate settlements to the U.S. Department of Justice (DOJ) and the U.S. Securities and Exchange Commission (SEC)

totaling nearly $495 million to resolve allegations that Mylan "demand[ed] massive price increases in the private market [for EpiPen] while avoiding its corresponding rebate obligations to Medicaid."[7] Recent Congressional focus and the revision to the Anti-Kickback Statute (AKS) appear to highlight the fact that attempting to circumvent paying the appropriate rebate to Medicaid under the MDRP will only invite scrutiny and enforcement actions.

Best Price, Pharmaceutical Manufacturers, and Pharmacy Benefit Managers

In order to appreciate the history of the term "best price," some key items must be defined. The 2007 version of 42 C.F.R. § 447.505(a) broadly defines best price as "the lowest price available from the manufacturer during the rebate period to any entity in the United States." By way of contrast, the 2016 version, at first blush, appears to redefine "best price" to mean "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States." So while PBMs would be included in the definition of best price using the 2007 version under the term "any entity," for the 2016 definition of best price, it's now less clear, since a PBM must be a "wholesaler, retailer, provider, health

maintenance organization, nonprofit entity, or governmental entity in the United States."

The key to reconciling the seeming discrepancy is the definition of "provider" in 42 C.F.R. § 447.505(b). *Provider* means a hospital, health maintenance organization (HMO), including a managed care organization (MCO), or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of healthcare. For example, Aetna is an MCO. Caremark, which is a PBM, owns Aetna. Aetna provides services or items in the provision of healthcare to its plan beneficiaries. PBMs and health plans, such as Aetna and Caremark, are vertically integrated. "Drug manufacturers are generally required to report an Average Manufacturer Price (AMP) as well as their "best price," accounting for any discounts or rebates provided to such entities as health plans and PBMs."[8] As one lawyer, known as one of the country's leading legal experts on government drug pricing, noted, "CMS in 2007 gave the impression that some PBM rebates might not be designed to adjust prices to insurers. That's a hard argument to sustain in 2019, knowing what we know now about the relationships between PBMs and their clients."[9] In other words, when calculating best price, both health plans and PBMs need to be included, as it is usual and customary in the industry.

Once it has been determined that an entity is required to meet "best price" obligations, a formula is utilized to calculate total Medicaid rebates. Manufacturers are required to report drug pricing information to the government on a quarterly basis, which the Department of Health and Human Services (HHS) then uses to calculate each drug's per unit Medicaid rebate, which is known as the unit rebate amount (URA).[10] The basic rebate helps ensure Medicaid gets comparable discounts to private payors by utilizing the following formula for brand drugs: 1) a fixed percentage – 23.1 percent for most brand name drugs – of the AMP; or 2) the difference between AMP and the "best price."[11] The following scenario illustrates a basic rebate example:

Assume the AMP for a brand drug is $100 and its lowest negotiated price in the market is $80, making $80 its best price.

Basic Rebate
The greater of either:
$100 x 23.1% = $23.10
Or
$100 - $80 = $20.00

To determine the basic rebate, we look to see which is greater – 23.1% of the AMP, which is expressly stated in the statute, or

> the difference between AMP and the best price for the drug. In this scenario, the greater of the two is $23.10, which is 23.1% of AMP, also known as the "minimum rebate amount." Therefore, $23.10 per unit is the basic rebate paid to Medicaid for the drug.[12]

How does best price relate to the 340B Program? Fundamentally, in order to participate in 340B, an entity must enroll in the best price program. Pharmaceutical manufacturers want to participate in the 340B program because it gives them access to more government program beneficiaries. Enacted in the early 1990s under Section 602 of the Veterans Health Care Act of 1992, Section 340B of the Public Health Services Act requires pharmaceutical manufacturers to enter into a pharmaceutical pricing agreement (PPA) with the Secretary of HHS in exchange for having its drugs covered by Medicaid and Medicare Part B.[13]

The PPA requires the manufacturer to agree to provide discounts on the front end on covered outpatient drugs purchased by specified providers, called "covered entities."[14] These covered entities serve the most vulnerable populations in the United States. As stated on the Health Resources & Services Administration's website, the purpose of the 340B program is to enable these covered entities "to stretch scarce

federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[15]

By avoiding rebate obligations to Medicaid and increasing prices in the private market, pharmaceutical companies can and have found themselves the target of Congressional investigations.[16] The United States Senate Finance Committee held hearings on the topic in 2019.[17]

The January 14, 2021 Senate Report

Almost two years after the Senate Finance Committee's hearings, the Committee released a report entitled *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*[18] (the Report). As Senator Grassley (R-Iowa) stated:

> Whether it is about EpiPen, insulin, or other prescriptions, in the thousands of letters that I have received, Iowans have made clear that high drug prices are hurting. I have heard from people about skipping doses of their prescription drugs to make them last until the next paycheck.[19]

The Report was a bipartisan effort headed by Senator Grassley and Senator Wyden (D-Oregon)

that focused on numerous items related to insulin. "One of the things the investigation looked into was the relationship between insulin makers and pharmacy benefit managers, which are the middlemen that negotiate drug prices between insurance companies and drug manufacturers."[20] While drug companies establish the list prices for insulin, those prices are often offset by rebates (like those described *supra*). PBMs and the affiliated health insurance companies can take a bigger chunk of money through rebates, which can be used to manipulate best price.[21]

Some key takeaways from the Report include the following:

- Medicare spending on insulin increased significantly between 2010 and 2018. "The growth of CMS's pre-rebate spending on insulin also significantly outstripped the growth rate of beneficiaries utilizing insulin from 2010-2018."[22]

- In response to competition and market pressure, insulin manufacturer Sanofi aggressively increased its list price between 2012-2014. "Sanofi did this for three reasons: (1) to lock in price increases in advance of introducing a

new insulin product called Toujeo and anticipated market competition from Eli Lilly, (2) to respond to aggressive rebate and discount activity from Novo Nordisk, and (3) to respond to increased pressure from PBMs and payers to offer large rebates and discounts."[23]

- Manufacturers are retaining more revenue from insulin, in large part due to the increase in insulin rebates. This insulin rebate game in essence enabled the companies to raise the prices of insulin and offer higher rebates at the same time. "In July 2013, Sanofi offered rebates between 2% and 4% for preferred placement on CVS Caremark's client's commercial formulary. Five years later, in 2018, Sanofi rebates were as high as 56% for preferred formulary placement. Similarly, in 2017, Novo Nordisk offered Express Scripts up to a 47% rebate of Levemir for preferred formulary placement on their client's commercial formulary compared to 25% in 2014."[24]

The speed with which the various insulin market leaders reacted to one another's price changes is notable.[25] Additionally, the Report ascertained that "manufacturers seek to avoid triggering Medicaid "best price" when developing their bids

for commercial plans."[26]

The findings raised in the Report can serve as important considerations in the new AKS Final Rule safe harbors.

The New AKS Final Rule

According to a January 29, 2019 Letter to the Senate Finance Committee from the Healthcare Leadership Council, "[t]he most notable barriers in our current healthcare system, the physician self-referral law ("Stark Law"), and the Anti-Kickback Statute require modernization as our healthcare system shifts from volume-based care to increasing the value of care. Modernization of federal fraud and abuse laws will enable pro-patient, value-focused collaboration among payers, providers, and manufacturers."[27] HHS' Office of Inspector General (OIG) evidently considered and addressed this issue in relation to the pharmaceutical industry in its recent AKS Final Rule (Rule), which was published in the November 30, 2020 *Federal Register*.[28] The OIG modified the existing discount safe harbor to close a loophole that had enabled PBMs to take advantage of the rebate schematic without liability.

The provision of the Rule addressing drug rebates, entitled *Removal Of Safe Harbor*

Protection For Rebates Involving Prescription Pharmaceuticals And Creation Of New Safe Harbor Protection For Certain Point-Of-Sale Reductions In Price On Prescription Pharmaceuticals And Certain Pharmacy Benefit Manager Service Fees, clarifies and amends the AKS discount safe harbor (42 C.F.R. § 1001.952(h)) so that "rebates paid from drug manufacturers to Medicare Part D prescription drug plan sponsors or their pharmacy benefit managers (PBMs) are not protected from liability under the discount safe harbor."[29] This provision highlights two key issues: (1) expressly reiterating that PBMs and the prescription drug plan sponsors are included in the rebates related to best price; and (2) if the relevant safe harbor is not met and/or not satisfied, then it is likely that there is a violation of the AKS. The October 1, 2015 version of 42 C.F.R. § 1001.952(h) contained no express language related to PBMs or Medicare Part D.

In the Rule, the OIG specifically points out that the change to the safe harbor does not change best price obligations:

> The Department recognizes that the final rule has the potential to affect calculations of AMP, Best Price, and Federal Upper Limits in ways and to an extent that may be difficult to anticipate. However, we are not finalizing the changes to the discount safe

> harbor with respect to Medicaid MCOs. We reiterate that the final rule does not alter obligations under the statutory provisions for Medicaid prescription drug rebates under section 1927 of the [Social Security] Act, including AMP, Best Price, and Federal Upper Limits.[30]

The text of the Rule is clear – best price is not affected. While all of the implications cannot be projected, the door remains open for government enforcement action and/or Congressional inquiries related to a company's misapplication of best price – a lesson which should have been learned from Mylan.[31]

Conclusion

The healthcare sector in America is in the midst of interesting times – a pandemic that is ravaging the hospital and nursing home ecosystem (not to mention the economy); the cost of pharmaceutical drug prices and the underlying conduct is costing both the government and patients more money; and the transition to a new Presidential Administration, which brings (as a normal course of change), different views and priorities. There is no doubt that the bipartisan nature of the Report and the need to curtail both the exponentially increasing drug prices and the underlying alleged impermissible conduct

between various companies will lead to changes. The caveat remains that the Rule and best price as it is implemented today, as well as the AKS safe harbor, remain "wild cards" that need to be watched closely to see if value-based initiatives are viewed in the same light

1 Center on Budget and Policy Priorities, *Reducing Medicaid and Medicare Drug Costs Could Help Pay for Health Reform* (June 11, 2009), https://www.cbpp.org/research/reducing-medicaid-and-medicare-drug-costs-could-help-pay-for-health-reform.

2 *Id.*

3 KFF, *How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?* (May 20, 2019), https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/.

4 *See* DOJ, *Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates* (Aug. 17, 2017) (noting that Mylan

misclassified its brand name drug, EpiPen, to profit at the expense of the Medicaid program.).

5 Kaiser Permanente Institute for Health Policy, *The Medicaid Drug Rebate Program and the impact of "best price" rules*, https://www.kpihp.org/wp-content/uploads/2020/10/Best_Price_101.pdf (last visited Jan. 18, 2021).

6 Fein, A., *JAMA: Withdraw This Flawed and Inaccurate Article about the 340B Program and Drug Prices* (July 16, 2019) (quoting several sources, including a leading health law expert at King & Spalding, which confirmed that including PBMs rebates in best price is industry custom).

7 *See supra* n. 4 (noting that the price of EpiPen was increased by approximately 400 percent yet paid only a fixed 13 percent rebate to Medicaid during the same period); *see also* U.S. Securities and Exchange Commission, *Mylan to Pay $30 Million for Disclosure and Accounting Failure Relating to EpiPen* (Sept. 27, 2019), https://www.sec.gov/news/press-release/2019-194.

8 CMS, *CMS Issues Final Rule to Empower*

States, Manufacturers, and Private Payers to Create New Payment Methods for Innovative New Therapies Based on Patient Outcomes (Dec. 21, 2020), https://www.cms.gov/newsroom/press-releases/cms-issues-final-rule-empower-states-manufacturers-and-private-payers-create-new-payment-methods.

9 *See supra* n. 6.

10 *See supra* n. 5.

11 *Id.*

12 *Id.*

13 82 Fed. Reg. 1229 (Jan. 5, 2017), https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol1/xml/CFR-2017-title42-vol1-part10.xml.

14 Georgia Department of Public Health, *340B Information*, https://dph.georgia.gov/office-pharmacy/340b-information (last visited Jan. 18, 2021).

15 HRSA, 340B Drug Pricing Program, https://www.hrsa.gov/opa/index.html (last visited Jan. 18, 2021). *See also* Office web site of the U.S. Health Resources & Services Administration,

https://www.hrsa.gov (last visited Mar. 1, 2021) (providing that HRSA was established in 1982 and is the primary federal agency tasked with improving healthcare for three specific categories of individuals: geographically isolated, economically disadvantaged, or medically vulnerable).

16 *See* Senate Hearing 116-267, *Drug Pricing in America: A Prescription for Change, Part I* (Jan. 29, 2019), https://www.congress.gov/event/116th-congress/senate-event/LC65345/text?s=1&r=30 (quoting Dr. Douglas Holtz-Eakin as stating that "340B came about because of Medicaid best price.").

17 *See* Senate Hearing 116-39, *Drug Pricing in America: A Prescription for Change, Part II* (Feb. 26, 2019), https://www.finance.senate.gov/imo/media/doc/37143.pdf.

18 *See* https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL).pdf (Jan. 14, 2021).

19 *See supra* n. 12.

20 Lidgett, A., *3 Takeaways From Senate Insulin Pricing Probe*, *Law360* (Jan. 14, 2021),

https://www.law360.com/articles/1345004/print?section=health.

21 *Id.*

22 *See supra* n. 14 at 6.

23 *Id.*

24 *Id.* at 7.

25 *See supra* n. 14 at 56.

26 *See supra* n. 14 at 68.

27 *See* https://www.congress.gov/event/116th-congress/senate-event/LC65345/text?s=1&r=41 (Jan. 27, 2019). *See also* Rose, R.V., New Stark Law and Anti-Kickback Statute Final Rules: Part 1 – Key Items (Dec. 3, 2020), *https://www.physicianspractice.com/view/new-stark-law-and-anti-kickback-statute-final-rules-part-1-key-items* (providing an overview of two separate Final Rules related to value-based arrangements under the Stark Law and the AKS).

28 HHS-OIG, *Final Rule: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New*

Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 85 Fed. Reg.76666 (Nov. 30, 2020); *see also* HHS-OIG, *Final* Rule, 85 Fed. Reg. 77684 (Dec. 2, 2020); CMS, *Final Rule*, 85 Fed. Reg. 77492 (Dec. 2, 2020).

29 *OIG Finalizes Rebate Rules: Removal of Safe Harbor Protections for Rebates and Creation of Safe Harbors for Other Discounts and Service Fees, The National Law Review* (Dec. 2, 2020), https://www.natlawreview.com/article/oig-finalizes-rebate-rules-removal-safe-harbor-protections-rebates-and-creation-new. *See also* 85 Fed. Reg. 76666, 76667. The rule also adds a new safe harbor for point-of-sale reductions in price that are passed on to a defined "buyer" and an additional safe harbor for PBM service fees paid by drug manufacturers. The final rule "removed[ed] safe harbor protection for reductions in price in connection with the sale or purchase of prescription pharmaceutical products from manufacturers to plan sponsors under Part D, either directly or through PBMs acting under contract with them, unless the reduction in price is required by law.

30 85 Fed. Reg. 76666, 76776 (Nov. 30, 2020), https://www.govinfo.gov/app/details/FR-2020-11-30/2020-25841.

31 *See supra* n. 7.

About the Author

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