Proposed Changes to Best Price Could Shift Market Dynamics for Stakeholders

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December 2023

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Table of Contents

Funding for this research was provided by the Healthcare Leadership Council. Avalere retained full editorial control.

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Executive Summary

The 2023 proposed rule titled “Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (MDRP)” includes a provision to amend the definition of Best Price to require manufacturers determining Best Price to aggregate, or “stack,” all price concessions provided throughout the supply chain for a single unit of a drug. This policy change would increase Medicaid rebate liability for some drugs and have spillover effects into other markets and channels, including the commercial market and the 340B drug pricing program. Depending on market responses, changes in Best Price determination could shift market dynamics for stakeholders across the ecosystem, including manufacturers, payers, providers, pharmacies, wholesalers, and patients.

Avalere conducted an analysis to illustrate the potential direct and indirect impacts of the proposed Best Price stacking policy on Medicaid rebate liability across three drug classes: antipsychotics, multiple sclerosis (MS), and oncology. Specifically, Avalere used third-party discount data and internal market expertise to evaluate how an illustrative Medicaid basic rebate level for affected single source drugs could increase if a typical set of discounts (e.g., wholesaler discounts, pharmacy rebates, provider discounts) were required to be stacked in determining Best Price. Avalere found:

- The statutory basic rebate for single source drugs in antipsychotics, MS, and oncology classes could increase between 17%-21%.
- Increases in basic rebate liability would be directly applicable in Medicaid, which Avalere estimates could represent between 10%-35% of volume for some products in these classes.
- In addition, these increases would apply to the 340B ceiling price. Avalere estimates 340B could account for up to 20%-30% of volume for some products in these classes.

Revisions to Best Price determination and anticipated increases in Medicaid rebate liability could lead to changes in contracting arrangements and market strategy across stakeholders. Changes may include:

- **Commercial Payer Rebates.** Some manufacturers may re-evaluate commercial payer rebates, which could have downstream implications for formulary positioning, patient cost sharing, and access.
- **Channel Discounts and Strategy.** Manufacturers could restructure supply chain discounts or modify channel strategy, which could have financial implications for wholesalers, pharmacies, providers, and other supply chain stakeholders.
- **Medicaid and Innovative Arrangements:** The proposed change could reshape dynamics between manufacturers and state Medicaid programs, potentially limiting flexibility for supplemental rebate agreements and reducing incentives for innovative contracting arrangements where a substantial portion of a drug’s cost is at risk.

Any of these decisions would be weighed in combination with other policy and market forces for a given product, including payer mix, competitive dynamics, current rebate levels, and exposure to parallel policy changes (e.g., average manufacturer price [AMP] cap removal).

This policy is being advanced within a dynamic drug pricing environment, amid the implementation of the Medicare Drug Price Negotiation Program and the removal of the 100% AMP cap. Looking ahead, upcoming Centers for Medicare and Medicaid Services (CMS) decisions on finalization and implementation of policies affecting Best Price will shape eventual market impact, both within Medicaid and outside the program.

CMS's Proposed Change to Best Price

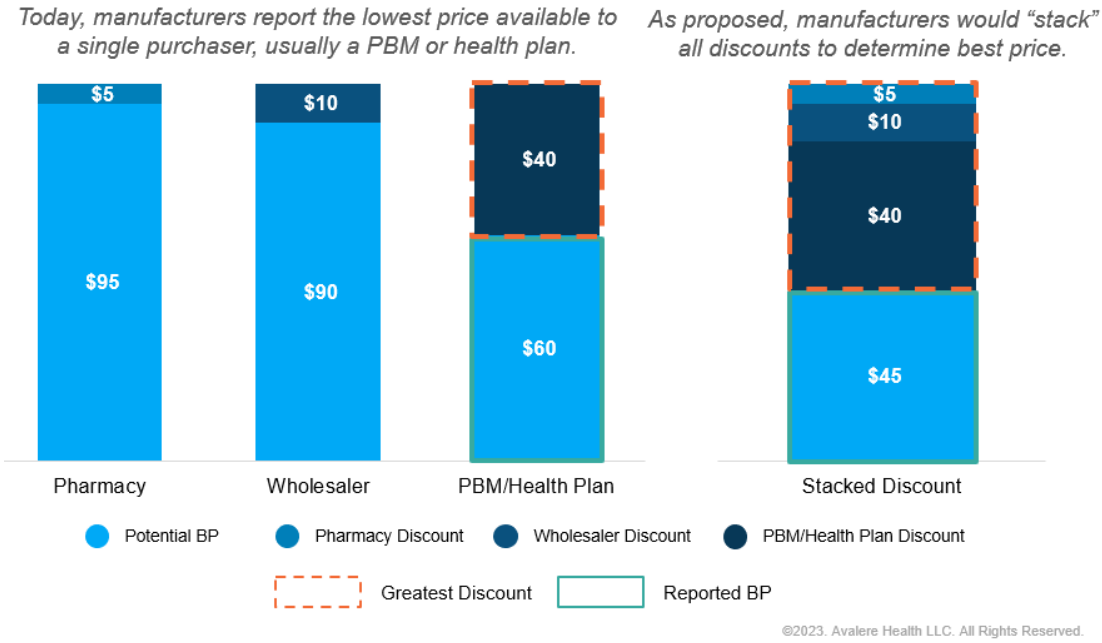
The MDRP is designed to ensure that state Medicaid programs receive the lowest, or Best Price, offered to any Best Price-eligible entity. Best Price is the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity (with some exceptions) in the US.[1] Best Price is inclusive of all prices, including applicable discounts, rebates, or other transactions that adjust prices, either directly or indirectly.[2] Best Price is also an input to arriving at the 340B ceiling price for a given product. Manufacturers that participate in the 340B drug discount program are required to offer covered entities access to drugs at a price that is equal to or less than the 340B ceiling price (i.e., AMP minus total Medicaid unit rebate amount [URA]).

On May 26, 2023, CMS released a proposed rule, "Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program." Among a series of other proposals, including adding transparency provisions and amending definitions within Medicaid, CMS proposes to change the definition of Best Price.

Specifically, CMS proposes revisions to add the following to the current regulatory definition of Best Price: "The manufacturer must adjust the best price for a drug for a rebate period if cumulative discounts, rebates, or other arrangements to best price eligible entities subsequently adjust the price available from the manufacturer. Cumulative discounts, rebates, or other arrangements must be stacked to determine a final price realized by the manufacturer for a covered outpatient drug, including discounts, rebates, or other arrangements provided to different best price eligible entities."[3] Effectively, this policy change would require manufacturers to "stack" all price concessions provided throughout the supply and payment chain on a unit of a drug, aggregating price concessions the manufacturer provides to multiple different entities. CMS states that "by stacking, best price reflects the lowest realized price at which the manufacturer made that drug unit available."[4] As illustrated in Figure 1, the proposed change could lead to increases in Medicaid rebate liability.[5]

1. 42 Code of Federal Regulations Section 447.505(a), Here
2. 42 Code of Federal Regulations Section 447.505(b), Here
3. 88 Federal Register 34238, Here
4. Ibid.
5. Avalere. *CMS Best Price Discount Stacking Proposal May Trigger AMP Cap.* Here

Figure 1: Illustration of Best Price Determination for a $100 Drug



If finalized, the provision would alter the mechanics of Best Price reporting for manufacturers under many scenarios. While additional manufacturer guidance from CMS would be expected if CMS finalizes this proposal, the proposed change would require manufacturers to establish methodologies and/or develop assumptions for tracking of a product through the supply chain to accurately identify discounts applied for a given unit (e.g., tablet, vial).

Since the MDRP's inception in 1990, legislation, regulation, and legal challenges have modified certain provisions of the MDRP, including the determination of Best Price. As a result, certain prices are excluded from the Best Price determination, including bona fide service fees paid to wholesalers and pharmacies, manufacturer-sponsored direct patient assistance, supplemental rebates offered to state Medicaid programs, free goods not contingent on purchase, nominal prices provided to some public and non-profit entities, certain discounts provided to pharmacy benefit managers (PBMs), and prices provided to specific government agencies (e.g., Indian Health Service), 340B drug pricing program covered entities, and Medicare Part D plans (both standalone and Medicare Advantage).[6]

A generally accepted practice when determining Best Price is to report the price associated with the single highest discount to any Best Price eligible entity. Manufacturers engaging in contract arrangements will evaluate the effect on Best Price and ensure alignment with overall business strategy. Manufacturers typically approach contractual arrangements with entities across different classes of trade separately (e.g., wholesaler discounts, payer rebates) and may not aggregate in determining Best Price.

6. 42 Code of Federal Regulations Section 447.505(c), Here

In recent years, CMS regulatory statements and litigation have sought to provide clarifications around the definition of Best Price and offer context for CMS's recent proposal. These include a 2016 response to comment by CMS[7] and a 2022 opinion in the ongoing *United States ex. rel. Sheldon vs Allergan* case issued by the U.S. Court of Appeals for the Fourth Circuit.[8] CMS's proposed rule would address interpretations offered in these statements and opinions, proposing regulatory changes to the definition of Best Price.

Evolving Medicaid Drug Pricing Policy Landscape

In addition to the MDRP proposed rule, there are several additional policies being implemented that may alter Best Price determination and/or manufacturer rebate liability under the MDRP.

VBP Rule and Multiple Best Prices: The December 2020 Value-Based Purchasing (VBP) final rule creates new Best Price flexibilities to support the use of VBP agreements in both commercial and Medicaid markets.[9] VBP arrangements are those "intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population," and may include evidence-based or outcomes-based measures.[10] The rule's Best Price provisions, effective in July 2022, allow manufacturers to report multiple Best Prices for a product if 1) the prices are associated with a VBP arrangement, and 2) the VBP arrangement is offered to all state Medicaid programs. Alternatively, manufacturers may classify VBP rebates as part of a bundled sale, which allows price concessions to be spread in the bundle to mitigate impact on Best Price.[11]

AMP Cap Removal: The American Rescue Plan Act of 2021 removes the cap that limits mandatory Medicaid rebates (basic and additional rebates) to 100% of AMP, beginning January 1, 2024. This change will allow total mandatory manufacturer Medicaid rebates to exceed 100% of a drug's AMP. For certain products, this change could result in a substantial increase in Medicaid rebate liability, particularly for drugs whose prices have increased.[12]

Medicare Drug Price Negotiation: The Inflation Reduction Act (IRA) grants CMS the authority to negotiate prices for selected prescription drugs in Medicare and set a Maximum Fair Price (MFP) to apply to all Medicare sales of those drugs (subject to the 340B nonduplication clause). Single-source Part B and Part D drugs that have been on the market a minimum number of years and represent the highest total Medicare program expenditures, with some exceptions, will be eligible to be selected for negotiation. CMS selected 10 Part D drugs to be negotiated for an MFP effective in 2026, will select an additional 15 Part D drugs for 2027, and will select additional Part B and Part D drugs in 2028 and beyond. The MFP established by the Medicare negotiation process for a drug will factor into Best Price determination and has the potential to

7. Federal Register 5169, Here
8. Sheldon v. Allergan Sales, LLC, 24 F. 4th 340, 348 (4th Cir. 2022.), Here
9. 85 Federal Register 87000, Here
10. 42 Code of Federal Regulations Section 447.502, Here
11. 85 Federal Register 87000, Here
12. American Rescue Plan Act of 2021, Pub. L. No. 117-2 Section 9816 Here

set a new Medicaid Best Price.[13] As a result, manufacturers of drugs for which MFPs are established may face increased Medicaid rebate and 340B discount liability as the MFP is effectuated.

Therapeutic Area Impact Analysis

Approach

To estimate the potential changes in Medicaid basic rebates under the proposed rule, Avalere selected single-source brand drugs generally distributed through pharmacies (i.e., self-administered) in three therapeutic areas: antipsychotics, multiple sclerosis (MS), and oncology.[14] These therapeutic areas were selected to create a sample representative of a range of drug types (i.e., retail vs. specialty), Medicaid utilization, channel discount structures, and price points, with antipsychotics generally lower cost and MS and oncology generally higher cost.

Avalere estimated a representative Best Price for drugs in each class by using third-party data[15] and applying assumptions based on market expertise to arrive at an illustrative discount off AMP. While certain drugs in the class are likely to have a higher or lower Best Price, Avalere's estimate is intended to illustrate a payer rebate level that is representative of dynamics for single-source drugs in that class but not one specific drug.

Next, Avalere leveraged its market expertise to identify a set of channel discounts that are typical within each drug class, including discounts provided to wholesalers, pharmacies, and/or providers. Identified channel discounts for oncology include medically integrated dispensing provider discounts via a group purchasing organization, for MS include specialty pharmacy discounts, and for antipsychotics include community pharmacy discounts. With these data points, Avalere assessed the increases in basic rebate liability expected if the channel discounts are required to be stacked with payer rebates today to arrive at a new base rebate level. For this illustration, only the statutory basic rebate (i.e., the difference between AMP and Best Price or (if higher) 23.1% of AMP for most drugs) is considered; any additional inflationary rebates are excluded.

Findings

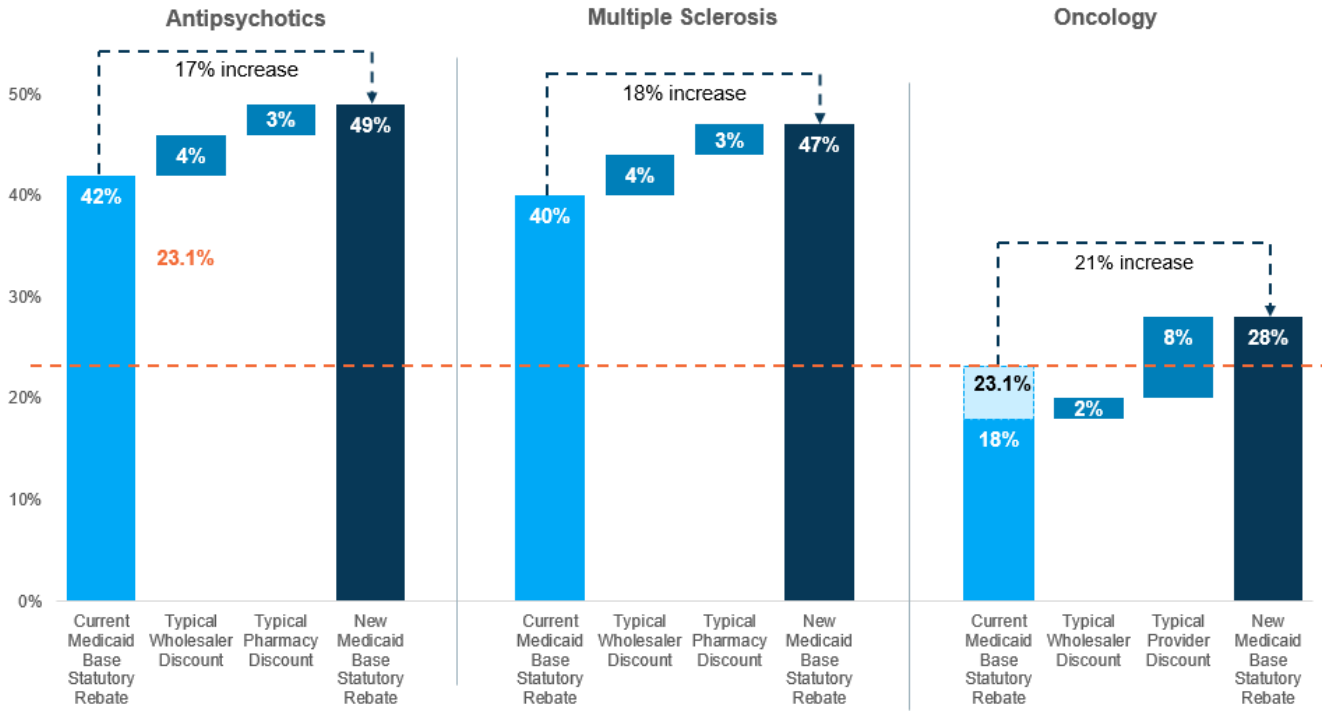
Avalere's analysis estimated potential changes in Medicaid basic rebates in three therapeutic areas selected to represent a range of drug types, Medicaid utilization, channel discount structures, and price points. As illustrated in Figure 2 below, Avalere found that statutory basic rebate levels may increase between 17%-21% across antipsychotics, MS, and oncology classes, compared to current Medicaid rebate levels. These increases would be directly applicable in the Medicaid market, which Avalere estimates may represent between approximately 10%-35% of patient volume within each therapeutic area, with MS and oncology therapies towards the lower end and antipsychotics at the upper end. In addition, increases in

13. Inflation Reduction Act of 2022, Pub. L. No. 117-169 Section 139001, Here
14. The oncology products are oral kinase inhibitors indicated for blood cancers and solid tumors.
15. SSR Health Net's US Prescription Brand Net Pricing Data

the basic rebate would also apply in calculating the 340B ceiling price. For these therapeutic areas, Avalere estimates 340B could account for up to 20%-30% of patient volume for some products in these classes.

Figure 2: Illustrative Examples of Changes in Medicaid Basic Rebates

The aggregation of all channel discounts in the determination of Best Price could lead to increases in rebate liability across therapeutic areas. In therapeutic areas where the Medicaid base statutory rebate is currently set by Best Price (e.g., antipsychotics, multiple sclerosis), the aggregation of channel discounts could substantially increase rebate liability. In therapeutic areas where the typical maximum payer rebate is below 23.1% (e.g., oncology), the aggregation of channel discounts could cause Best Price to exceed 23.1%, increasing the Medicaid basic rebate above the statutory minimum.



Note: Wholesaler, pharmacy, and provider discounts represent typical arrangements in each therapeutic area based on Avalere market expertise. Specific discount arrangements and levels vary by drug.

Spectrum of Potential Market Responses

As illustrated above, the impact of Best Price discount stacking is likely to vary by therapeutic area. Manufacturers are more likely to adjust strategies to respond to the stacking proposal in therapeutic areas highly affected by channel discounts, the additional inflationary component of the total URA, and the combination of policies affecting Medicaid.

If the proposed Best Price change were finalized, manufacturers would not view it in isolation, but would consider Best Price stacking in combination with other policy and market forces for a given product. Market forces include payer mix, competitive dynamics, and current total Medicaid rebate levels (both the basic rebate and additional inflationary rebate). Manufacturers would first evaluate whether their current rebate liability is tenable or action is needed. The degree of increase in Medicaid rebate liability and a drug's Medicaid payer mix relative to other channels (i.e., commercial, Medicare) are likely to be important factors in shaping this decision. The mitigation options may present varying levels of stakeholder disruption.

Commercial Payer Rebates. Some manufacturers may focus on the current set of discounts available to Best Price-eligible entities as one lever to lessen the influence of stacked discounts. If payer rebates are a significant driver of the Medicaid basic rebate level, a manufacturer may choose to reduce or eliminate commercial payer rebates (e.g., rebates to PBMs and health plans). However, rebate agreements between manufacturers and payers are a tool to inform formulary positioning, which influences patient access. Changes to the commercial rebate environment could affect formulary positioning, patient cost sharing, and access.

Channel Discounts and Strategy. In addition to payer arrangements, manufacturers could consider adjusting channel discounts offered throughout the supply chain, such as to wholesalers, pharmacies, and providers. Amending contracts with these stakeholders could be burdensome operationally and have financial implications for the affected stakeholder. Outside of adjustments to channel discount levels, manufacturers could consider broader restructuring of their channel strategies for affected drugs to minimize Best Price impact.

Innovative Contracting. Additions to Best Price exposure as a result of stacking could reduce incentives for innovative contracting arrangements across markets, especially those where a substantial portion of a drug's cost is at risk. CMS has offered options to ease the effect of value- and outcomes-based contracts on Best Price through the VBP rule.

Medicaid Supplemental Rebates. Within Medicaid, increases to mandatory rebate levels may limit flexibility and feasibility for supplemental rebate agreements or value-based contracting with state Medicaid programs.

List Prices. Manufacturers may also choose to adjust list prices, however, this approach would need to be carefully evaluated given cross-market effects. Changes to pricing strategy may have market-wide implications, including access and formulary placement in Part D and for commercial payers, depending on contracting terms with plans and PBMs.

Looking Ahead

Upcoming CMS decisions on finalization and implementation of policies affecting Best Price will shape eventual market impact, both within Medicaid and outside the program. The impact of the policy and downstream responses to any changes that CMS adopts in its final rule has the potential to disrupt markets for stakeholders across the ecosystem including payers, manufacturers, pharmacies, supply chain entities, and patients. Stakeholders should start to anticipate scenarios of potential market impact as CMS advances a final rule.

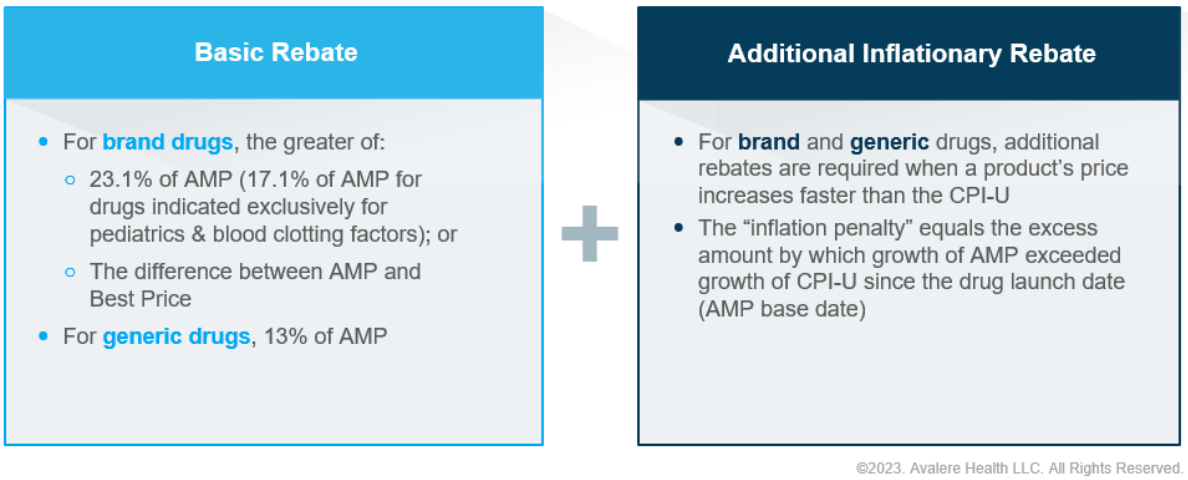
Appendix

MDRP Background

The MDRP governs coverage of and payment for prescription covered outpatient drugs in Medicaid. The MDRP requires participating manufacturers to provide rebates on covered outpatient prescription drugs to state Medicaid agencies and, in return, state Medicaid programs must cover all covered outpatient drugs marketed by participating manufacturers.[16] The MDRP's provisions apply to covered outpatient drugs, which are defined as prescribed drugs approved by the Food and Drug Administration that are not bundled as part of to the payment for other health services (e.g., physician, outpatient hospital, nursing facility).

The MDRP rebate formula is designed to ensure that state Medicaid programs receive the lowest, or Best Price, offered to certain entities. Manufacturers are also required to pay additional rebates if the AMP of their drug increases faster than the rate of inflation, as measured by the consumer price index for all urban consumers (CPI-U). The total unit rebate amount (URA) is calculated as shown in Figure 3:[17]

Figure 3: Medicaid URA Calculation



For most drugs, AMP is defined as the average price paid to a drug's manufacturer by wholesalers and retail pharmacies, inclusive of associated discounts and rebates to those entities. The AMP calculation excludes bona fide service fees, manufacturer-sponsored direct patient assistance, and sales to entities other than wholesalers and retail pharmacies.[18] AMP for drugs that are not generally dispensed through retail community pharmacies is calculated differently.[19]

17. 42 U.S. Code Section 1396r-8(a), Here
18. 42 U.S. Code Section 1396r-8(c), Here
19. 42 Code of Federal Regulations Section 447.504(b), Here
20. AMP for drugs that are not generally dispensed through retail community pharmacies and are inhaled, infused, instilled, implanted, or injected is inclusive of sales to insurers, PBMs, providers (e.g., physicians, hospitals), mail order pharmacies, and other entities that do not conduct business as a wholesaler or retail community pharmacy.

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