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Biden Administration Releases FY 2023 Budget: The Biden Administration's proposed Budget of the U.S. Government for FY 2023 (see also the accompanying fact sheet) includes proposals relevant to drug manufacturers. Department of Health and Human Services (HHS) Secretary Xavier Becerra issued a statement on the budget, and in recent testimony before Congress highlighted specific HHS goals, including reaffirming the President's agenda "to work to lower the costs of prescription drugs, such as by capping the cost of insulin at $35 per month, and to allow Medicare to negotiate payment for certain high-cost drugs." The budget itself proposes modification of the Medicaid Drug Rebate Program (MDRP) in the US territories. In its Budget in Brief, HHS identifies proposed technical changes to provide "flexibility" under the MDRP so that "territories ready to participate … may do so and achieve drug price savings without increasing drug prices in territories not ready to participate." HHS explains that its "proposal excludes sales from the manufacturer calculation of average manufacturer price and best price in territories to ensure continued discounted drug prices for territories," which "will support territories in continuing to provide medication access for vulnerable populations."

The Health Resources and Services Administration (HRSA), in its Justification of Estimates for Appropriations Committees, proposes a budget of approximately $17 million for the Office of Pharmacy Affairs and the 340B Program, which would provide an increase of $7 million over the FY 2022 enacted budget. HRSA states that this increase will allow the 340B Program to continue building on program integrity efforts, including implementation of the new administrative dispute resolution (ADR) process and establishment of an ADR claims intake system and security protocols for protecting proprietary information. As it has done in prior year budget justifications, HRSA proposes that Congress grant it "general rulemaking" authority — which the 340B statute currently does not provide — and asserts that it "continues to confront significant operational challenges caused by the lack of broader authority for overseeing the program." The agency also states that additional funding would increase audit and oversight functions, including the ability to conduct additional audits for FY 2023.
Sources: Bloomberg Law, Politico Pro (link, link), InsideHealthPolicy (link, link, link, link, link)

Drug Pricing Initiatives: The House of Representatives passed H.R. 6833 (the Affordable Insulin Now Act), which would cap the patient cost share for insulin under Medicare Part D at $35 for a 30-day supply. Meanwhile, Senators and stakeholders continue to discuss some of the drug price reform measures that were originally part of H.R. 5376 (the Build Back Better Act, or BBBA).
Sources: Bloomberg Law (link, link), InsideHealthPolicy (link, link), Politico Pro (link, link, link), Pink Sheet, 340B Report

MEDICAID DRUG REBATE PROGRAM (MDRP)

CMS Addresses Value-Based Purchasing Arrangements and Multiple Best Price Option: The December 2020 MDRP final rule created a regulatory definition of value-based purchasing (VBP) arrangements and addressed the price reporting treatment of such arrangements, specifically the qualification of VBP arrangements as bundled sales, consideration of pay-over-time arrangements in

average manufacturer price (AMP), and the option to report multiple best price (BP) figures for the same drug if subject to a VBP arrangement. The multiple BP pathway was then delayed until July 1, 2022. The Centers for Medicare and Medicaid Services (CMS) has now issued Manufacturer Release No. 116, providing further guidance regarding VBP arrangements.

- **Bundled Sales:** The final rule amended the bundled sale definition to indicate that VBP arrangements "may qualify as a bundled sale." Release 116 affirms that the manufacturer may elect to "allocate the price concessions provided under the VBP arrangement as provided in the definition of bundled sale," or may choose to report multiple BPs associated with the VBP arrangement. CMS also addresses the interplay between these two options, stating that "[i]f the manufacturer chooses to report multiple best prices associated with the price concessions provided under its VBP arrangement as provided in a bundled sale, the manufacturer is not required to allocate discounts or rebates associated with the VBP arrangement as a bundled sale to a single payer when determining the best price."
- **Pay-Over-Time Arrangements and AMP:** Release 116 repeats preamble guidance from the final rule, indicating that the full price for a drug, not just an installment payment, should be reflected in AMP, and that "it is appropriate that an installment payment not made because of a VBP arrangement outcome which would result in a significant discount, be treated as a lagged price concession."

The bulk of Release 116 focuses on the option for manufacturers to elect to report multiple BPs related to VBP arrangements. CMS addresses a number of key issues, including:

- **States Individually Opt In or Out:** The manufacturer must offer the VBP arrangement to all states, and each state has discretion in deciding whether to accept the VBP arrangement. In engaging with states, CMS encourages manufacturers to "make any minor adjustments to the arrangement to address the specific needs of the Medicaid program and the beneficiaries it serves," and also to "be mindful during negotiations that states do not necessarily operate like commercial payers."
- **Reporting of a Non-VBP BP:** Release 116 provides that "CMS will require that a manufacturer report a non-VBP best price when a manufacturer is also reporting multiple best prices … for the VBP arrangement being offered to states." The Medicaid rebate for states that opt out of the VBP will then be based on the "non-VBP" BP. Where the manufacturer does not "sell the covered outpatient drug commercially outside of a VBP arrangement," the manufacturer "could approximate the non-VBP best price by estimating a lowest price available to the payer/provider if no additional discounts based upon outcomes are made under the VBP arrangement."
- **MDP System Implementation:** CMS provides a detailed overview of how the Medicaid Drug Programs (MDP) reporting system will serve to implement the multiple BP reporting, as well as acceptance by the states of the VBP, and also indicates that many of the interactions between the manufacturer and the states under the multiple BP pathway will occur outside of the system. CMS conducted a demonstration of the related MDP functionality on April 7, 2022, for selected manufacturers and is expected to publish a recording of the demonstration.

CMS reminds manufacturers that they "may continue to make reasonable assumptions consistent with statute and regulation regarding the determination of AMP and best price," and states that such reasonable assumptions must be documented and maintained in writing. CMS notes that it "will monitor the implementation of this new [multiple BP] policy to ensure compliance with the new regulation and will consider making referrals to the [HHS] Office of Inspector General [(OIG)] in cases when we believe there are concerns with manufacturer price reporting under the MDRP."

340B PROGRAM

Seventh Circuit Sends Lilly Contract Pharmacy Appeal Back to District Court: On April 8, 2022, the US Court of Appeals for the Seventh Circuit issued an order remanding to district court pending litigation between Eli Lilly and Company (Lilly) and the federal government regarding Lilly's contract pharmacy policy. As reported in previous issues of this digest (Issues No. 2 and No. 14), the US District Court for the Southern District of Indiana held that a May 17, 2021, enforcement letter against Lilly from HRSA, which alleged that Lilly's contract pharmacy policies "have resulted in overcharges and are in direct violation of the 340B statute," was arbitrary and capricious and therefore in violation of the Administrative Procedure Act. The district court set aside and vacated the HRSA letter, but also held that the position HRSA expressed in the letter "neither exceeds the agency's statutory authority nor is contrary to law." The district court entered judgment in the matter, and Lilly appealed to the Seventh Circuit. The appellate court has now ordered that the case be remanded to the district court to "enter a judgment that fully and completely implements its decision, declaring specifically and separately the rights of the parties." Once that is done, the Seventh Circuit explained, the appeal will proceed with briefing. The district court matter is *Eli Lilly & Co. v. Becerra*, No. 21-cv-81 (S. D. Ind.), and the appellate matter is *Eli Lilly & Co. Lilly v. Becerra*, No. 21-3128 (7th Cir.).

Other Contract Pharmacy Updates: HRSA published a letter on its website addressed to Boehringer Ingelheim, one of the manufacturers that has implemented a contract pharmacy policy, informing the company that HRSA has referred it to the HHS OIG pursuant to the civil monetary penalties regulation for failure to offer its covered outpatient drugs "without restrictions" at or below the 340B ceiling price to covered entities "that dispense the discounted medications through their contract pharmacy arrangements." Boehringer Ingelheim is the sixth manufacturer that HRSA has referred to the OIG.
Sources: Bloomberg Law, 340B Report

State Regulation of PBM 340B Activity: Illinois has become the most recent state seeking to regulate pharmacy benefit manager (PBM) actions related to the 340B Program through state legislation, passing HB 4595. Meanwhile, the US District Court for the Western District of Oklahoma partially invalidated an Oklahoma statute seeking to regulate PBMs, holding that portions of the statute were preempted by the Medicare Part D program. The court rejected the argument that the entire statute was preempted by the Employee Retirement Income Security Act (ERISA). The case is *Pharmaceutical Care Management Association v. Mulready*, No. 5:19-cv-00977 (W.D. Okla.).
Sources: Law360 (link, link), 340B Report

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

Washington State Prescription Drug Affordability Board and Upper Payment Limit Law: On March 24, 2022, the Governor of Washington State signed SB 5532, which establishes a Prescription Drug Affordability Board that will study prescription drug costs and identify certain prescription drugs for potential "affordability review," based on certain cost thresholds. The Board will be empowered to establish an upper payment limit for such drugs, which will be applicable to "all purchases of the drug by any entity and reimbursements for a claim for the drug [by health carriers and health plans] when the drug is dispensed or administered to an individual in the state by person, by mail, or by other means." The manufacturer of a drug subject to an upper payment limit will not be permitted to "withdraw" the drug from sale or distribution in the state absent 180 days' notice, and upon any withdrawal will be prohibited from selling the drug in the state for a period of three years. The law becomes effective June 9, 2022.

If you have questions about the Drug Pricing Digest, please contact the Government Price Reporting team listed below or the Latham lawyer with whom you normally consult:

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