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Drug Pricing Initiatives: Discussion continues regarding pathways to Senate passage of H.R. 5376 (the Build Back Better Act, or BBBA). Potential approaches include a reduced or modified version of the BBBA, although details and timing remain unclear. In a speech on Feb. 10, 2022, President Biden urged passage of the drug pricing portions of the BBBA, stating that "bringing down the cost of prescription drugs is an easy thing for us to do" and could be "done legally with the stroke of a pen." Meanwhile, Senator Bernie Sanders and Senator Amy Klobuchar introduced the Cutting Medicare Prescription Drug Prices in Half Act, which would cap reimbursement under Medicare Part B and Part D for all drugs at the lower of the amount paid by the Secretary of Veterans Affairs to procure the drug, or the amount paid to procure the drug through the Federal Supply Schedule of the General Services Administration. ***Sources:*** Bloomberg Law, InsideHealthPolicy (link, link, link, link), Politico Pro (link, link, link), 340B Report

MEDICAID DRUG REBATE PROGRAM (MDRP)

CMS Manufacturer Release Discusses Line Extension Changes: On Feb. 3, 2022, the Centers for Medicare and Medicaid Services (CMS) issued an MDRP Program Notice for Participating Drug Manufacturers, Release No. 115. The manufacturer release discusses reporting modalities under the Medicaid Drug Program (MDP) system, including with respect to manufacturer reporting of line extensions, as well as the application of interest on state utilization adjustments, unit rebate amounts, and prior period adjustments. Other topics include manufacturer contact information and system access requirements and updated Division of Pharmacy email resource mailboxes.

With respect to reporting of drugs that are line extensions, CMS states that participating manufacturers should review each of their drugs "to ascertain whether it is impacted by either the regulatory changes made by the Final Rule or the operational changes made to the MDRP system," and specifically advises manufacturers to determine: (1) whether the drug must be identified as a line extension, and (2) whether the manufacturer needs to request a product data override from CMS to modify the current line extension status of a drug, which is documented in the "line extension drug indicator" field. CMS notes that changes to this field "may only be processed by CMS," and therefore, "if your NDC requires an override, you must submit an override request (and the justification for that request)" by using the MDRP change request email resource box, with instructions and templates available for this purpose.

Federal Appeals Court Addresses Best Price Stacking: The US Court of Appeals for the Fourth Circuit, in a 2-1 decision, affirmed dismissal of a *qui tam* (whistleblower) complaint brought against a drug manufacturer under the False Claims Act (FCA) in relation to the manufacturer's MDRP price reporting obligations. The whistleblower's complaint alleged that the manufacturer had violated the MDRP statute by not aggregating, or stacking, discounts given to separate customers when calculating Best Price (BP). The court held that the manufacturer did not act "knowingly" under the FCA, and therefore could not be held liable under the FCA, because the manufacturer's reading of the MDRP

statute as to the BP calculation "was at the very least objectively reasonable" and the manufacturer "was not warned away from that reading by authoritative guidance."

The court analyzed the MDRP statute and found that its plain language comported with the manufacturer's interpretation and "was not only objectively reasonable but also the most natural." In reaching this holding, the court applied the Supreme Court's scienter (knowledge) standard set forth in *Safeco Insurance Company of America v. Burr*, 551 U.S. 47 (2007), as other federal circuit courts have done. The one dissenting judge argued that *Safeco* should not apply to FCA claims, but that even under that standard, the whistleblower had plausibly alleged an FCA claim against the manufacturer. The case is *United States ex rel. Deborah Sheldon v. Allergan Sales, LLC*, No. 20-2330 (4th Cir. Jan. 25, 2022). ***Sources:*** InsideHealthPolicy, Bloomberg Law, Reuters

PhRMA Challenge to Co-Pay/Accumulator Portion of December 2020 Medicaid Rule: As noted in previous editions of this digest (Issues No. 2, No. 18, and No. 20), the Pharmaceutical Research and Manufacturers of America (PhRMA) is challenging in federal court provisions in the 2020 MDRP final rule that will become effective Jan. 1, 2023. The provisions stipulate that manufacturer-provided patient copayment assistance is excludable from price reporting under the MDRP only "to the extent that the manufacturer ensures the program benefits are provided entirely to the patient," which CMS asserts would not be the case when a pharmacy benefit manager (PBM) accumulator program is in place.

On Feb. 3, 2022, the federal government filed a brief in opposition to PhRMA's motion for summary judgment, asserting that the final rule "accords with the text, structure, and purpose of the MDRP statute," and that "[PhRMA's] arguments to the contrary lack merit." The case is *PhRMA v. Becerra*, No. 1:21-cv-1395 (D.D.C.).

340B PROGRAM

Vermont State Agency Report on 340B: The Vermont Department of Financial Regulation (DFR) issued a report on the 340B program, as required by Vermont's Act No. 74, which became law in 2021 and placed restrictions on PBMs in relation to the 340B program. The report, titled "National Activity Affecting Participation in the 340B Drug Pricing Program," addresses "340B controversies and their implications for Vermont stakeholders," including manufacturer contract pharmacy policies, PBM actions toward 340B covered entities, and how covered entities and other parties use 340B profits. The report states that the 340B program "lacks clarity, including with respect to contract pharmacy participation, covered entities' use of program savings, and the scope of HHS's authority," and that "[i]n the absence of clear federal guidance, it is up to the states to ensure that the 340B program works equitably to ensure access to prescription medication." The report concludes that "Vermont can best accomplish this goal by implementing a comprehensive regulatory scheme for PBMs" similar to Arkansas' HB 1881, the 340B Drug Pricing Non-Discrimination Act, enacted in 2021.

As noted in previous editions of this digest (Issues No. 1 and No. 3), the Arkansas law is more extensive than the Vermont law and also purports to govern the relationship between manufacturers and 340B contract pharmacies. The DFR report notes that the Arkansas law is currently subject to a federal court challenge by PhRMA (as discussed in Issues No. 9, No. 14, and No. 20). The case is *PhRMA v. McClain,* 4:21-cv-00864-BRW (E.D. Ark.).

Proposed 340B Legislation in California: On Feb. 8, 2022, proposed legislation (SB 939) was introduced in California that would seek to regulate PBMs in relation to their treatment of 340B covered entities and their contract pharmacies. Like the Arkansas law currently subject to legal challenge (see above), the California bill purports to govern the relationship between manufacturers and 340B contract pharmacies. Specifically, the law would not only require a drug manufacturer to comply with requirements of the federal 340B statute when selling covered outpatient drugs to covered entities in California, but also would require that a manufacturer "shall not impose any preconditions, limitations, delays, or other barriers to the purchase of covered drugs." The bill sets forth specific arrangements that

would be prohibited, including "[i]mplementation of policies or limitations that restrict the ability of covered entities or specified pharmacies to dispense covered drugs, including restrictions on the number or type of locations through which covered drugs may be dispensed by or on behalf of a covered entity."

Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continues.
Source: 340B Report

Meanwhile, various covered entity groups have publicly addressed the notion of seeking congressional action with respect to 340B contract pharmacy requirements.
Source: 340B Report (link, link, link)

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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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