May 9, 2022 | Number 27

Drug Pricing Initiatives: In advance of the midterm elections in November, discussion continues in Congress and among stakeholders of drug pricing reform measures, including those that were originally part of H.R. 5376 (the Build Back Better Act, or BBBA).
Sources: InsideHealthPolicy, STAT (link, link)

2023 Budget Hearings: On April 27, 2022, Xavier Becerra, Secretary of the Department of Health and Human Services (HHS), appeared at a congressional budget hearing, where he faced a broad discussion of HHS priorities and the agency's responsiveness to information requests from Congress.
Sources: BioWorld, Bloomberg Law, Politico Pro

Medicare Part D Rule Promises Beneficiary and Manufacturer Cost Savings: The Centers for Medicare and Medicaid Services (CMS) issued a final rule (with an accompanying fact sheet) implementing policy and technical changes for CY 2023 under the Medicare Advantage and Medicare Prescription Drug Benefit programs. CMS estimates that the final rule will result in $26.5 billion in Medicare Part D beneficiary savings and a reduction of $16.8 billion in manufacturer discounts required under the Part D coverage gap program.

The final rule redefines a Medicare Part D drug's "negotiated price" at the point of sale, which is the basis for establishing beneficiary cost-sharing obligations and generally used to adjudicate the Part D benefit. Beginning Jan. 1, 2024, the negotiated price will mean the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug. Previously, Part D plans could exclude certain price concessions, such as performance-based adjustments occurring after the point of sale, to the extent they could not "reasonably be determined" at the point of sale. Under the final rule, Part D plans must consider a larger universe of price concessions for determining the negotiated price, across all phases of the Part D benefit, including the coverage gap phase.

In connection with this change, CMS has finalized its definition of "price concession" to mean "any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor." Examples of price concessions include, but are not limited to, "discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind."
Sources: Pink Sheet, InsideHealthPolicy (link, link), Healthcare Finance

MEDICAID DRUG REBATE PROGRAM (MDRP)

PBM Program Becomes Focus of Litigation: On May 4, 2022, Johnson & Johnson Health Care Systems, Inc. (JJHCS), a subsidiary of Johnson & Johnson, filed a complaint against Save on SP, LLC (SaveOnSP) in the US District Court for the District of New Jersey, seeking damages and injunctive relief in connection with an alleged scheme by SaveOnSP to "inflate and misappropriate the funding

JJHCS provides for patients." JJHCS asserts that SaveOnSP, a company that partners with certain pharmacy benefit managers (PBMs) and payers, "enriches the payers with which it partners by (a) reducing the amount they pay to pharmacists for each prescription … and (b) increasing by a commensurate amount the costs to the JJHCS patient assistance program," in return for a 25% commission from the plans. JJHCS asserts that the SaveOnSP program has caused JJHCS to pay at least $100 million more in copayment assistance than otherwise, "depleting the support for patients who cannot afford their rising copays." JJHCS has brought specific claims of tortious interference with contract and deceptive trade practices under New York law. The case is *JJHCS, Inc. v. Save on SP, LLC*, 2:22-cv-02632-JMV-CLW (D.N.J.).

In the complaint, JJHCS identifies the SaveOnSP program as the latest in "a set of evolving schemes" that PBMs have "designed to capture the benefit of patient assistance funds," including the specific examples of copayment "accumulators" and "maximizers."

As discussed in Issues No. 2, No. 3, and No. 18 of this digest, CMS responded to such PBM programs in the 2020 Medicaid final rule by revising the criteria that must be met for manufacturer-sponsored copayment assistance to be excluded from price reporting. These provisions will become effective on Jan. 1, 2023. Litigation by the Pharmaceutical Manufacturers of America (PhRMA) challenging this portion of the final rule remains ongoing in the US District Court for the District of Columbia. The court held oral argument on May 4, 2022, to consider the parties' motions for summary judgment. The case is *PhRMA v. Becerra*, 1:21-cv-01395-CJN (D.D.C.).
Sources: Law360, STAT, Pink Sheet, Wall Street Journal

CMS Email Discusses Line Extension Criteria: On April 25, 2022, CMS sent an email to technical contacts addressing change requests relating to the "Line Extension Drug Indicator" field in the Medicaid Drug Programs (MDP) system. The email discusses the dates that are relevant to identify line extensions and original drugs and mentions that CMS is "noticing manufacturers requesting to identify a drug as a line extension when several strengths of the same dosage form of a drug were introduced to the market on the same date." In CMS's view, "such drugs are generally not line extensions of any initial or original or previous drugs." Instead, CMS explains that "for there to be 'a change to the drug' (as noted in the definition of new formulation), there must be a drug that was marketed earlier than the drug that is being evaluated to determine whether it is a line extension of that drug."

By way of example, CMS states that "if three strengths of a drug are all introduced with the same new active ingredient, in the same dosage form, at the same time, then none of those three drugs should be identified as a line extension of each other," noting that "if a new strength of one of these three drugs is introduced after these three drugs enter the market, then that drug that is introduced thereafter is a new formulation, and a line extension of an initial or original drug."

CMS Releases MDP System Demonstration Video of Multiple Best Price Features: CMS has posted a "Medicaid Drug Programs (MDP) Value Based Purchasing Demonstration" video, which introduces new functionality in the MDP system related to the multiple best price (BP) pathway. The video follows the recent publication of Manufacturer Release No. 116, which provides further guidance regarding value-based purchasing arrangements, as noted in Issue No. 25 of this digest.

340B PROGRAM

Federal Court Allows Intervenors in Arkansas 340B Litigation: On May 3, 2022, the US District Court for the Eastern District of Arkansas granted a motion by a 340B covered entity association and an individual covered entity hospital to intervene in pending litigation challenging an Arkansas state statute. As noted in previous issues of this digest (Issues No. 1, No. 9, No. 14, No. 20, No. 21, and No. 22), the Arkansas law purports to govern the relationship between manufacturers and 340B contract pharmacies. The case is *PhRMA v. McClain*, 4:21-cv-00864-BRW (E.D. Ark.).
Source: 340B Report

Contract Pharmacy Updates: With litigation related to manufacturer contract pharmacy policies continuing, the Health Resources and Services Administration (HRSA) sent a letter threatening enforcement action to another manufacturer, the first such letter since 2021.
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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