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Drug Pricing Initiatives: President Biden referred to some of the drug price reform measures originally part of H.R. 5376 (the Build Back Better Act, or BBBA) in his State of the Union address on March 1, 2022. Senator Manchin, one of the Democratic Senators who previously opposed the BBBA, responded to the President's speech by issuing his views of drug price reform and other BBBA measures. Discussions continue among Senators and stakeholders, but there appears to be no clear path to passage of comprehensive drug price reform measures in Congress.
Sources: Bloomberg Law, InsideHealthPolicy (link, link, link), Politico Pro (link, link, link), Pink Sheet (link, link), 340B Report

HHS Further Delays "Sunset" Regulation: On March 4, 2022, the Department of Health and Human Services (HHS) published a final rule that further postpones the effective date of the so-called sunset regulation from March 22 until September 22, 2022. The Trump-era sunset regulation would have required regulations to expire on the latest of (i) five years after the sunset regulation first became effective, (ii) 10 years after the year a regulation was initially promulgated, or (iii) 10 years after the last year in which a regulation was assessed.

As noted in Issue No. 14 of this digest, HHS previously published a proposed rule that would withdraw the sunset regulation, but to date HHS has not yet finalized the withdrawal.
Sources: Bloomberg Law, Politico Pro

MEDICAID DRUG REBATE PROGRAM (MDRP)

***Streck* False Claims Act Litigation:** On Feb. 28, 2022, the US District Court for the Northern District of Illinois ruled on several motions involving whistleblower allegations against Eli Lilly and Company (Lilly) in connection with MDRP price reporting. The whistleblower, who brought this litigation against Lilly and other manufacturers, alleged specifically as to Lilly that the company violated the federal False Claims Act and state false claims provisions by failing to accurately consider service fees in the reporting of average manufacturer price (AMP), resulting in reducing the company's Medicaid rebate obligations. Among other things, the court granted the whistleblower partial relief on his motion for summary judgment, holding that "Lilly's AMP calculations and related certifications were factually and legally false," but rejected the whistleblower's arguments as to the elements of scienter (knowledge), materiality, and causation, allowing these issues to proceed to the jury. The decision is *United States ex. rel. Ronald J. Streck v. Takeda Pharms. Am., Inc., et al.*, Case No. 14-cv-9412 (Feb. 28, 2022), ECF No. 374. Beginning in 2008, Streck filed various lawsuits on similar grounds against multiple pharmaceutical manufacturers, some of which have resulted in settlements.
Sources: Reuters, FiercePharma

PhRMA Challenge to Co-Pay/Accumulator MDRP Rule: As noted in previous editions of this digest (Issues No. 2, No. 18, No. 20, and No. 21), the Pharmaceutical Research and Manufacturers of America (PhRMA) is challenging in federal court certain 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 MDRP price reporting 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 March 7, 2022, PhRMA filed a combined opposition to the government's cross-motion for summary judgment and reply in support of PhRMA's motion for summary judgment. The case is *PhRMA v. Becerra*, No. 1:21-cv-1395 (D.D.C.).

Oregon Seeks Authority to Exclude Accelerated Approval Drugs From Medicaid Coverage: In its recent Section 1115 waiver renewal application, Oregon "seeks the ability to more closely manage pharmacy costs in its Medicaid program" through the "authority to allow exclusion of accelerated approval drugs with limited or inadequate evidence of clinical efficacy" from coverage. As the Food and Drug Administration (FDA) explains on its website, accelerated approval is intended "to allow for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint [which] can considerably shorten the time required prior to receiving FDA approval." Accelerated approval requires conducting "postmarketing" clinical trials to confirm the anticipated clinical benefit. The Oregon waiver, if approved, would make Oregon the first state with this authority.
Source: Pink Sheet

As noted in previous editions of this digest, drugs approved under the accelerated approval pathway have been the focus of recommendations by the Medicare Payment Advisory Commission (MedPAC) (see Issue No. 13) and the Medicaid and CHIP Payment and Access Commission (MACPAC) (see Issue No. 1).

340B PROGRAM

Contract Pharmacy Updates: As reported in the last issue of this digest (see Issue No. 22), on Feb. 16, 2022, the US District Court for the District of Delaware issued an order and an opinion in the contract pharmacy litigation involving AstraZeneca, vacating, setting aside, and remanding the May 17, 2021, violation letter issued by the Health Resources and Services Administration (HRSA) against AstraZeneca in connection with the manufacturer's 340B contract pharmacy policy. The court asked the parties to submit filings addressing whether further relief is warranted and how the case should proceed, if at all. The parties submitted those filings, and the court has now issued an order and final judgment in the case, dated March 11, 2022. The court confirmed the relief it granted in previous orders, but declined to grant further requested relief to AstraZeneca. The case is *AstraZeneca Pharmaceuticals LP v. Becerra*, C.A. No. 21-27-LPS (D. Del.).

Litigation related to other manufacturer contract pharmacy policies continues, as do related proceedings before an HHS Administrative Dispute Resolution (ADR) panel.
Source: 340B Report (link, link)

HRSA Announces New Head of OPA: In a letter addressed to "colleagues" and dated Feb. 28, 2022, HRSA announced the appointment of Dr. Emeka Egwim as director of the Office of Pharmacy Affairs (OPA) within HRSA's Office of Special Health Initiatives (OSHI). OPA oversees the 340B drug pricing program. According to the letter, Lieutenant Commander Egwim's long career in government service includes assignments with OPA and the Centers for Medicare and Medicaid Services (CMS), where he supported the MDRP. The letter is signed by Assistant Surgeon General, Rear Admiral Krista Pedley, who herself was director of OPA until her 2021 appointment as director of OSHI. Michelle Herzog, who served as acting OPA director, will continue in her prior role as deputy director of OPA. See Issue No. 9 of this digest for a discussion of the recent HRSA reorganization.
Source: 340B Report (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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