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Welcome to the first issue of the Latham & Watkins Drug Pricing Digest. Here, Latham's government price reporting team provides a digest of recent developments, as reported in the trade press or published directly by government bodies, which we intend to distribute at the start of every second week. In this digest, we cover general developments, followed by sections focusing on the Medicaid Drug Rebate Program, the 340B Drug Pricing Program, Medicare Part B, and state law developments.

We hope you will find this information useful.

Sincerely,

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Drug Pricing Initiatives: On April 28, 2021, President Biden delivered his first full address to a joint session of Congress, which included a call to allow Medicare to negotiate prices for prescription drugs, and asked Congress to "get it done this year." Despite being pitched as a "top priority" for the Biden administration, drug pricing was not addressed in either of the two multi-trillion dollar legislative packages announced by the White House — the American Jobs Plan, which focused on infrastructure or the American Families Plan, which focused on the social safety net. President Biden reiterated his support for drug pricing reform in a "Proclamation on Older Americans Month" issued on May 3, 2021.
Sources: Bloomberg Law, Pink Sheet, and InsideHealthPolicy

President Biden's remarks followed legislative initiatives by both parties:

- House Democrats introduced H.R. 3 (the Elijah E. Cummings Lower Drug Costs Now Act), an updated version of the legislation passed by the House in December 2019 (link). H.R. 3 includes far-reaching proposals, such as allowing the Secretary of the Department of Health & Human Services (HHS) to negotiate prescription drug prices for Medicare and capping the prices of certain Part B and Part D drugs based on an international price index. The President has stated that "[w]e pay the highest prescription drug prices of anywhere in the world right here in America," and according to a recent Government Accountability Office report, retail drug prices

are two to four times higher in the US than in Australia, Canada, and France.
Sources: Bloomberg Law (link, link, link) and Pink Sheet

- Progressive Democrats, including Senator Bernie Sanders and more than two dozen colleagues in the House, introduced their own legislative package of drug pricing bills. Their package includes: (1) the Prescription Drug Price Relief Act (S. 909), which would peg the price of prescription drugs in the United States to the median price in Canada, the United Kingdom, France, Germany, and Japan; (2) the Medicare Drug Price Negotiation Act (S. 908), which would direct the Secretary of HHS to negotiate lower prices for prescription drugs under Medicare Part D; and (3) the Affordable and Safe Prescription Drug Importation Act (S. 920), which would allow patients, pharmacists, and wholesalers to import medicine from Canada and other major countries.
Source: Bloomberg Law
- The competing Republican legislation, H.R. 19 (the Lower Costs, More Cures Act of 2021), summarized here, also proposes significant changes, but seemingly follows a more incremental approach than H.R. 3. House Republicans argue that "[if]f H.R. 3 were the law of the land before the pandemic, it would have hindered America's private sector medical innovators from stepping up to help us beat the virus."
- Of particular relevance for the 340B program, Section 204 of H.R. 19 would limit payment to pharmacies for drugs dispensed to Medicaid Managed Care Organization (MCO) beneficiaries to ingredient cost and a dispensing fee, which 340B covered entities "say would foreclose all remaining profits on 340B-purchased drugs billed to state Medicaid agencies."
Source: 340B Report
- The Pharmaceutical Research and Manufacturers of America (PhRMA) responded to the legislative initiatives by releasing its "Better Way" agenda, "paired with a seven-figure advertising campaign that will run in national print media and on social and digital platforms."
Source: Pink Sheet
- Notably, even if neither H.R. 3 nor H.R. 19 is adopted wholesale, individual provisions from the proposed legislation could still become law. For example, various provisions from the never-adopted Prescription Drug Pricing Reduction Act of 2019 (S. 2543) have been enacted over the years. Most recently, H.R. 1319 (the American Rescue Plan Act of 2021) eliminated the cap on the Medicaid rebate, effective January 1, 2024.

Antitrust Bills Focusing on the Pharmaceutical Industry: On April 29, 2021, the House Judiciary Antitrust Subcommittee issued a set of bills targeting specific anticompetitive tactics that lawmakers allege pharmaceutical companies often employ. In some cases the bills would make the practices presumptively illegal.
Source: Law 360

OIG Advisory Opinion 21-01: On March 23, 2021, the HHS Office of Inspector General (OIG) released Advisory Opinion 21-01, which addresses an arrangement under which a pharmaceutical manufacturer of an autologous therapy provides free drug to patients who satisfy specific criteria, such as being uninsured and earning below an annual household income threshold. OIG concluded that "(i) although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the Arrangement," and "(ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements" civil monetary penalty provision.

MEDICAID DRUG REBATE PROGRAM (MDRP)

MACPAC Recommends Higher Medicaid Rebates for Accelerated Approval Drugs: On April 9, 2021, the Medicaid and CHIP Payment and Access Commission (MACPAC) approved two recommendations designed to address high-cost specialty drugs, both focused on the "accelerated approval" pathway. As MACPAC explains, accelerated approval under Section 506(c) is based on a "surrogate endpoint that is reasonably likely to predict a clinical benefit," and requires conducting "postmarketing" clinical trials to confirm the clinical benefit. MACPAC recommends (1) raising the basic Medicaid rebate percentage for accelerated approval drugs by an unspecified amount until completion of the postmarketing confirmatory trial and "traditional" FDA approval has been obtained, and (2) raising the additional (or inflation) Medicaid rebate for accelerated approval drugs if the manufacturer has not conducted confirmatory trials and obtained traditional approval within a specified number of years.
Sources: Pink Sheet (link, link) and 340B Report

The Institute for Clinical and Economic Review (ICER) issued a white paper on April 26, 2021, endorsing the MACPAC recommendations, but also proposing other measures, such as limiting the price for accelerated approval drugs to "marginal or average cost of producing and delivering the drug" until "confirmatory evidence is produced."
Source: Pink Sheet (link, link)

340B PROGRAM

Contract Pharmacy Litigation Updates: In a court filing, HHS has indicated that it is considering "recommended new appointments" to the Administrative Dispute Resolution (ADR) board to "correct for shortcomings in the prior slate of appointments" made by the Trump administration. The filing states that once the appointments are made, HHS "will be able to 'move forward with implementing the current ADR Rule'," and that HHS "is also actively considering additional options for agency enforcement of the 340B statute." The case is *Nat'l Ass'n of Community Health Centers v. Azar, et al.*, No. 1:20-cv-03032 (D.D.C.).
Sources: Bloomberg Law and 340B Report

Various developments occurred in *AstraZeneca Pharmaceuticals LP v. Azar, et al.*, No. 1:21-cv-000027-LPS (D. Del.):

- Aaron Vandervelde, business development lead for 340B ESP and Managing Director of consulting firm Berkeley Research Group (BRG), filed a friend of the court brief, stating that the 2010 guidance allowing an unlimited number of contract pharmacies "led to high rates of diversion and duplicate discounts" and that although audits demonstrated this non-compliance, "covered entities experienced little to no consequences for their failure to comply with the 340B statute."
  Source: 340B Report
- The court denied the request by six hospital groups to intervene in the litigation, suggesting they file a friend of the court brief instead, which the groups then did on May 4, 2021. The groups are the American Hospital Association (AHA), 340B Health, America's Essential Hospitals, the Association of American Medical Colleges (AAMC), Children's Hospital Association (CHA), and ASHP (American Society of Health-System Pharmacists).
  Source: 340B Report (link, link, link)

Arkansas Legislation Addresses Contract Pharmacies: Arkansas House Bill 1881, the "340B Drug Pricing Nondiscrimination Act," was enacted on May 4, 2021. The law includes many provisions related to the 340B program. It also specifically addresses pharmaceutical manufacturers, stating they shall not "(1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or

(2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing."
Source: 340B Report (link, link)

Vermont Civil Investigative Subpoenas: Novartis Pharmaceuticals Corporation, Eli Lilly and Company, and AstraZeneca Pharmaceuticals LP disclosed in their respective Q1 financial filings that they have received civil investigative subpoenas from the Office of the Attorney General of the State of Vermont, requesting information about each company's participation in the 340B program as it relates to Vermont. Sanofi had disclosed receipt of a similar subpoena in its Annual Report on Form 20-F in March.
Source: 340B Report (link, link)

Kalderos Annual Report Discusses Duplicate Discounts: Kalderos, provider of a "drug discount management platform," issued its first annual report, which includes an analysis of duplicate discounts in the 340B program. Its "findings suggest that 3-5% of 340B discounts and Medicaid rebates are duplicates," and that as of "2019, that 3-5% adds up to at least $933 million in duplicate discounts, potentially as high as $1.6 billion." Further, Kalderos "estimates that around 68% of that stems from Medicaid managed care organizations (MCOs)."
Source: 340 Report

Stakeholder Letters to HHS Secretary Becerra: Six hospital groups — AHA, 340B Health, America's Essential Hospitals, AAMC, CHA, and ASHP — sent a letter dated April 20, 2021 to HHS Secretary Becerra, asking him to "immediately take steps" to prevent Eli Lilly and Company, Sanofi-Aventis U.S. LLC, AstraZeneca PLC, Novartis Pharmaceuticals Corporation, United Therapeutics Corporation, and Novo Nordisk, Inc./Novo Nordisk Pharma "from refusing to provide statutorily required drug discounts" to 340B hospitals on contract pharmacy transactions.
Source: 340B Report

In a separate letter to Secretary Becerra, 24 health systems outlined steps HHS could take to "stabilize" the 340B program without involvement of Congress.
Source: 340B Report

MEDICARE PART B

Medicare Exemption from Sequestration Extended Through End of 2021: On April 14, 2021, President Biden signed into law H.R. 1868, now Public Law No. 117-7. Among other things, the law continues to exempt Medicare from sequestration until December 31, 2021.
Source: Bloomberg Law

STATE LAW DEVELOPMENTS

West Virginia Enacts Law Requiring Pharmacy Benefit Managers (PBMs) to Pass Savings to Patients: West Virginia has enacted House Bill 2263 which, among other changes, now requires PBMs to pass their savings to the patient. The law provides that "[a] covered individual's defined cost sharing for each prescription drug shall be calculated at the point of sale based on a price that is reduced by an amount equal to at least 100% of all rebates received, or to be received, in connection with the dispensing or administration of the prescription drug. Any rebate over and above the defined cost sharing would then be passed on to the health plan to reduce premiums." PhRMA welcomed the legislation, stating that "[t]his common sense policy could help lower what patients pay out of pocket by hundreds of dollars a year."
Source: Pink Sheet

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