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PhRMA Suit Challenges Co-Pay/Accumulator Portion of December 2020 Medicaid Rule: On May 21, 2021, Pharmaceutical Research and Manufacturers of America (PhRMA) filed suit in the US District Court for the District of Columbia, challenging the portions of the December 2020 Medicaid final rule related to the price reporting treatment of manufacturer-sponsored patient co-pay assistance programs when the patient's health plan has implemented a so-called "accumulator adjustment program." PhRMA explains that the final rule "treats financial assistance manufacturers provide to *patients* as if such assistance were a price discount that the manufacturer instead provided to the patients' *health plans*, unless the manufacturer somehow 'ensures' that no health plan retroactively takes the benefits that the manufacturer intended for and provided to patients through the imposition of an accumulator adjustment program," which PhRMA asserts "contradicts the Medicaid rebate statute's plain text." The case is *Pharmaceutical Research and Manufacturers of America v. Becerra*, No. 1:21-cv-01395 (D.D.C. filed May 21, 2021).

RFI on Methods to Advance Equity in Public Programs: The Office of Management and Budget (OMB) is soliciting public comments on ways federal agencies can advance equity and support underserved communities, and the Centers for Medicare & Medicaid Services (CMS) is encouraging stakeholders to use this opportunity to provide feedback. OMB's Request for Information (RFI) follows on Executive Order 13985, issued in January 2021, which mandates that OMB and federal agencies assess barriers in accessing benefits under federal programs and allocate resources to invest in underserved communities. The RFI asks for comment on a variety of topics that are potentially relevant to manufacturers, including approaches that would improve access to public benefits and provide financial assistance to underserved communities. The RFI provides an opportunity for stakeholders to engage in dialogue with the Biden Administration around this important issue through the submission of written comments, which are due July 6, 2021.
Source: InsideHealthPolicy

Drug Pricing Initiatives: The drug pricing measure introduced by House Democrats, H.R. 3 (the Elijah E. Cummings Lower Drug Costs Now Act) continues to be a focus of debate. In a letter dated May 3, 2021, House Democrats urged Speaker Nancy Pelosi to work "collaboratively in a bipartisan manner with our colleagues in the Senate and with the Biden Administration to develop healthcare policies that will deliver on President Biden's promise to defend and build upon the Affordable Care Act, to ensure that patients are able to afford their medicine at the pharmacy counter, and to enhance the United States' innovation ecosystem that delivers treatments and cures when we need them most, as we've seen throughout the COVID-19 pandemic." Some commenters view the letter as focusing on affordability for patients, rather than on drug prices, and as raising doubts over the fate of the bill. Richard Neal, Chair of the House Ways and Means Committee, indicated in recent remarks that he does not plan to hold a hearing on H.R. 3 for a few weeks, and instead is focused on infrastructure legislation. At the same time, President Biden's support for international talks on waiving patent protections for COVID-19 vaccines is

seen by some as a way to increase pressure on pharmaceutical manufacturers in the context of the drug pricing debate.
Sources: InsideHealthPolicy (link, link), Bloomberg Law, Pink Sheet

Department of Health and Human Services (HHS) Secretary Xavier Becerra testified in Congress on May 12, 2021, regarding the President's fiscal year 2022 discretionary budget request for HHS. Various lawmakers asked questions related to H.R. 3, as well as to the competing Republican legislation, H.R. 19 (the Lower Costs, More Cures Act of 2021). In response to questions from lawmakers about the 340B contract pharmacy policy that multiple manufacturers are challenging (see the 340B Program section below), Becerra stated: "We are on this one, as we know that vulnerable populations are at risk. And so, everyone, I've been saying all along: We have to follow the law, and everyone has to follow the law."
Sources: InsideHealthPolicy, 340B Report

The Senate Finance Committee has retained Anna Kaltenboeck to focus on drug pricing. In her previous role as program director and senior health economist at Memorial Sloan Kettering Cancer Center's Center for Health Policy and Outcomes, she supported measuring drug value through cost per quality adjusted life year (QALY) metrics, while voicing skepticism about whether value-based contracting could control pricing.
Sources: Pink Sheet, InsideHealthPolicy

BioMed Conference Concludes Virtually: The 19th National Life Science & Technology Week, which ordinarily takes place in Israel, concluded virtually on May 13, 2021. Various sessions focused on proposed and anticipated Biden Administration policies. For example, Stephen J. Ubl, president and CEO, PhRMA, and Sarah Pitluck, head of Global Pricing & Reimbursement, Spark Therapeutics, discussed Food and Drug Administration (FDA) and CMS policy priorities for life sciences companies on a panel moderated by Latham & Watkins.

MEDICAID DRUG REBATE PROGRAM (MDRP)

OMB Reviews Medicaid Proposed Rule: On May 11, 2021, OMB received a proposed rule under the same Regulation Identifier Number (RIN) and title as the Medicaid final rule issued by CMS in December 2020. The final rule addressed areas including line extensions, value-based contracting, and copay assistance programs. OMB completed its review of the proposed rule "Consistent without Change" on May 12, 2021. The content of the proposed rule is unknown, and it is unclear if and how it might relate to the final rule.

340B PROGRAM

HRSA Letters Tell Manufacturers Their Contract Pharmacy Policies Violate the 340B Statute: On May 17, 2021, Health Resources and Services Administration (HRSA) Acting Administrator Diana Espinosa sent letters to six pharmaceutical manufacturers that have implemented contract pharmacy policies. HRSA publicized its action on the main page of the 340B website, stating that it "has determined that their policies that place restrictions on 340B Program pricing to covered entities that dispense medications through pharmacies under contract have resulted in overcharges and are in direct violation of the 340B statute." HRSA published the complete letters on the website's Program Integrity page. The letters inform the manufacturers that they "must immediately begin offering … covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy," and that failure to do so may result in civil monetary penalties.
Sources: Bloomberg Law, Politico, InsideHealthPolicy, Pink Sheet, 340B Report (link, link, link)

Contract Pharmacy Litigation Updates: The HRSA letters prompted filings by multiple manufacturers in the ongoing contract pharmacy litigation.
Source: 340B Report (link, link)

Earlier, Eli Lilly and Company, in its challenge to the December 2020 advisory opinion by HHS, responded to a motion for summary judgment or dismissal by HHS. The advisory opinion states that "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." In its May 10, 2021, filing, Lilly argued that the advisory opinion must be reviewed as a final agency action and invalidated because it is contrary to law. The case is *Eli Lilly & Co. v. Cochran*, S.D. Ind., No. 21-cv-81.
Sources: Bloomberg Law, 340B Report

HHS Proposes to Rescind Regulation Requiring 340B Pricing Pass-Through to Patients: OMB is reviewing a proposed rule entitled "Rescission of the Final Rule 'Implementation of Executive Order on Access to Affordable Life-Saving Medications'" under RIN 0906-AB25. The rule being rescinded would have implemented one of the Trump Executive Orders regarding drug pricing by requiring federally qualified health centers, as a condition of their grant, to pass 340B pricing on insulin and epinephrine through to qualifying patients. HHS previously delayed the effective date of the Trump rule to July 20, 2021.
Sources: Bloomberg Law, InsideHealthPolicy, 340B Report

MEDICARE PART B

HHS Urges Supreme Court Not to Hear Challenge to Part B Regulation: In a legal brief first reported on May 13, 2021, HHS urged the Supreme Court not to take up lawsuits challenging Part B reimbursement cuts for drugs purchased at the 340B price and payment cuts for outpatient clinic visits at certain off-campus hospital facilities. Hospital groups had brought legal action against HHS, challenging the reduction of the Part B reimbursement rate for 340B-purchased drugs from Average Sales Price (ASP) plus 6% to ASP minus 22.5%, but suffered a defeat in the US Court of Appeals for the District of Columbia. The May 13 brief argues that the Supreme Court should not take up the lawsuits, in part because there is no split among circuit courts as to the issues presented, stating that the lower court's decision "does not warrant further review." The case is *American Hospital Association v. Azar*, 967 F.3d 818 (D.C. Cir. 2020), *petition for cert. filed*, ___ U.S.L.W. ___ (U.S. Feb. 10, 2021) (No. 20-1114).
Sources: InsideHealthPolicy, Law360, Bloomberg Law (link, link), 340B Report

STATE LAW DEVELOPMENTS

Additional States Regulate PBMs: North Dakota enacted H.B. 1492 on April 21, 2021, which, among other things, prohibits Pharmacy Benefit Managers (PBMs) from discriminating against 340B covered entities or "a pharmacy under contract with a covered entity … to provide pharmacy services on behalf of the covered entity," which "includes refusing to contract with a pharmacy." Montana also recently enacted a law regulating PBMs, SB 395. More than half a dozen states have passed laws regulating PBMs this year, following a unanimous Supreme Court decision in December 2020 that upheld an Arkansas law regulating PBMs and rejected the PBM's argument that the state law was preempted by the federal Employee Retirement Income Security Act (ERISA). The case is *Rutledge v. Pharmaceutical Care Management Association*, 141 S. Ct. 474 (2020). The Pharmaceutical Care Management Association, a trade group representing PBMs, is challenging the North Dakota statute in the US Court of Appeals for the Eighth Circuit on the grounds that it goes beyond the Arkansas statute that the Supreme Court upheld in 2020. The case is *Pharmaceutical Care Management Association v. Wilke*, No. 18-2926 (8th Cir. filed Sept. 7, 2018).
Sources: Law360 (link, link), 340B Report (link, link)

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