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Drug Pricing Initiatives: Late on Nov. 5, 2021, the House of Representatives passed H.R. 3684 (the Infrastructure Investment and Jobs Act). This $1 trillion infrastructure bill, which was passed earlier by the Senate, is part of the reconciliation package that contains many of President Biden's domestic policy initiatives.

The other bill in the reconciliation package, H.R. 5376 (the Build Back Better Act, or BBBA), is the $1.85 trillion social safety net, climate, and tax bill that includes measures related to drug pricing and healthcare. It has not yet been passed by either chamber. Centrist Democrats had delayed a vote on the BBBA while negotiating changes to various provisions, but have now reportedly agreed to a compromise bill. The BBBA nevertheless did not come to a vote on Nov. 5 because centrist Democrats reportedly want to wait for final scoring by the Congressional Budget Office (CBO). A vote is expected the week of Nov. 15. If the BBBA is passed in the House, Senate Democrats will likely seek to further revise the legislation, which is strongly opposed by Republicans. The budget reconciliation process allows passage in both chambers of Congress by a simple majority, which would require all 50 Democratic and Independent Senators' votes, with Vice President Harris casting the tie-breaking vote.
Sources: New York Times, Washington Post, Politico Pro (link, link, link, link)

Among other things, the BBBA reportedly mandates drug price negotiations with Medicare, but in a more limited scope than originally provided in H.R. 3 (the Elijah E. Cummings Lower Drug Costs Now Act). The BBBA would also impose rebates under Medicare Part B and Part D, triggered by price increases that outpace inflation, and would block the rebate rule proposed by the Trump Administration.
Sources: Bloomberg Law (link, link, link), Pink Sheet, BioWorld, InsideHealthPolicy, 340B Report

A preliminary review by the CBO assigned a value of approximately $100 billion to the BBBA's drug price controls, and approximately $150 billion to repealing the rebate rule.
Source: InsideHealthPolicy

CMS Issues Series of Final Rules Implementing Expanded ASP Reporting Requirement and Maintaining Medicare Payment Rate for 340B Drugs: The Centers for Medicare and Medicaid Services (CMS) recently issued the following final rules:

- CY 2022 End Stage Renal Disease (ESRD) Prospective Payment System final rule
- CY 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System final rule with comment period
- CY 2022 Medicare Physician Fee Schedule (PFS) final rule
- CY 2022 Home Health Prospective Payment System final rule
- Medicaid and Medicare Omnibus COVID-19 Health Care Staff Vaccination interim final rule with comment period

Notably, the Medicare PFS final rule implements portions of the Consolidated Appropriations Act of 2021, which requires that manufacturers *without* Medicaid rebate agreements in effect report Average Sales Price (ASP) for drugs or biologicals payable under Medicare Part B for calendar quarters beginning Jan. 1, 2022. CMS explained that it "sought to preserve the status quo to the extent possible" in implementing this expansion of the ASP reporting requirement. CMS also modified the regulatory definition of "drug" subject to ASP reporting to include any item, service, supply, or product that is payable under Medicare Part B as a drug or biological.

The OPPS/ASC final rule maintained a Medicare payment rate of ASP minus 22.5% for certain separately payable drugs or biologicals purchased under the 340B Drug Pricing Program at or below the ceiling price (while continuing to exempt rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the policy). CMS originally implemented this policy with the CY 2018 OPPS/ASC final rule, and the government has so far prevailed in the face of legal challenge, with the US Court of Appeals for the District of Columbia Circuit ruling on July 31, 2020, that the policy as implemented for CY 2018 and CY 2019 rested on a reasonable interpretation of the Medicare statute. The US Supreme Court agreed to review the case and set oral argument for Nov. 30, 2021. *See Am. Hosp. Ass'n v. Azar*, 967 F.3d 818 (D.C. Cir. 2020), *cert. granted sub nom. Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2883 (2021).
Sources: CMS Press Releases (link, link, link, link), CMS Fact Sheets (link, link, link, link), InsideHealthPolicy, Bloomberg Law (link, link, link), Politico Pro, 340B Report

HHS Proposes to Repeal "Sunset" Regulation: On Oct. 29, 2021, the Department of Health and Human Services (HHS) published a proposed rule that would withdraw a Trump-era regulation imposing expiration dates on HHS regulations. Comments are due Dec. 28, 2021.

The so-called sunset regulation was published on Jan. 19, 2021, but HHS postponed its effective date to March 22, 2022. The 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.
Sources: BioWorld, InsideHealthPolicy, Bloomberg Law, Informa Pharma Intelligence, 340B Report

MEDICAID DRUG REBATE PROGRAM (MDRP)

DDR System Off-Line; Release of MDP System Delayed: As previously announced by CMS, the Drug Data Reporting for Medicaid (DDR) system is no longer accessible. CMS notified technical contacts on Nov. 7, 2021, that the release of the replacement Medicaid Drug Program (MDP) system, which was scheduled for Nov. 8, 2021, has been delayed until Nov. 15, 2021, to "ensure the most successful transition." On Nov. 15, "you can begin adding, editing, and certifying products in MDP," and "you will receive instructions for logging into MDP with the announcement email."

CMS also indicated that the Nov. 9, 2021, "office hours" session will be canceled and replaced with an additional session on Dec. 7, 2021.

340B PROGRAM

Contract Pharmacy Updates: On Nov. 5, 2021, the US District Court for the District of Columbia issued an opinion in the litigation filed by United Therapeutics and by Novartis Pharmaceuticals, in connection with those companies' respective contract pharmacy policies. The court granted partial summary judgment in favor of the manufacturers, holding that their respective policies do not violate the 340B statute under the positions advanced in the Health Resources and Services Administration (HRSA) violation letters to the companies and developed in the litigation, which rested on "an erroneous reading" of the statute. The court concluded: "The [340B] statute's plain language, purpose, and structure do not *prohibit* drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies. Nor do they *permit* all conditions." The court found that the government had presented no evidence of a 340B violation under the companies' policies, and added that any future enforcement

action would have to rely on "a new statutory provision, a new legislative rule, or a well-developed legal theory that Section 340B precludes the specific conditions here." The cases are *United Therapeutics Corp. v. Espinosa*, No. 21 cv 1686 (DLF) (D.D.C.) and *Novartis Pharm. Corp. v. Espinosa*, No. 21-cv-1479 (DLF) (D.D.C.).
Source: 340B Report

Also on Nov. 5, 2021, the US District Court for the District of New Jersey issued an opinion in the litigation filed by Sanofi Aventis and by Novo Nordisk, in connection with those companies' respective contract pharmacy policies. Among other things, the court held that the 340B statute permits contract pharmacy arrangements, that the companies' respective policies violate the 340B statute, as manufacturers "may not attach strings to 340B offers," and that the companies' respective policies resulted in impermissible overcharges to covered entities. The court also denied Sanofi's motion to set aside the Administrative Dispute Resolution (ADR) final rule. At the same time, the court partially vacated HRSA's violation letters to the companies and remanded them to the agency for consideration, declining to decide whether the 340B statute permits covered entities to use multiple or unlimited contract pharmacies. The cases are *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 21-000634 (FLW) (D.N.J.) and *Novo Nordisk Inc. v. U.S. Dep't of Health & Human Servs.*, No. 21-00806 (FLW) (D.N.J.).
Source: 340B Report

On Oct. 29, 2021, the US District Court for the Southern District of Indiana issued an opinion in litigation filed by Eli Lilly and Co. in connection with the company's contract pharmacy policy. The court held that the May 17 enforcement letter that HRSA sent to Lilly — which alleged that Lilly's contract pharmacy policies "have resulted in overcharges and are in direct violation of the 340B statute" — was arbitrary and capricious and therefore in violation of the Administrative Procedure Act. The court set aside and vacated the HRSA letter, but also held that the position HRSA expressed in its letter "neither exceeds the agency's statutory authority nor is contrary to law." The case is *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs.,* No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021).
Sources: BioWorld, Pink Sheet, InsideHealthPolicy, 340B Report (link, link)

An eighth manufacturer, Boehringer Ingelheim, has filed suit against HRSA in defense of its contract pharmacy policy. The case is *Boehringer Ingelheim Pharm., Inc. v. Becerra*, No. 1:21-cv-02826-DLF (D.D.C. filed Oct. 25, 2021).
Sources: Bloomberg Law, 340B Report (link, link, link)

Contract pharmacy litigation filed by other manufacturers remains pending.
Sources: 340B Report (link, link)

Related litigation challenging the ADR process remains pending.
Source: 340B Report

Litigation regarding an Arkansas state law that purports to govern the relationship between manufacturers and 340B contract pharmacies also remains pending.
Source: 340B Report

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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