June 7, 2021 | Number 3

Biden Releases Federal Budget Proposal for 2022: On May 28, 2021, President Biden released the proposed budget for fiscal year 2022, which would increase health spending by 23%. The proposal urges Congress to enact drug pricing reform this year but leaves developing policy specifics to the legislators. Somewhat unexpectedly, the budget includes a proposal to amend the 340B statute to require covered entities to "permit the Secretary to audit, at the Secretary's expense, the records of the entity to determine how net income from purchases under this section [i.e., the 340B program] are used by the covered entity."
Sources: Bloomberg Law, BioWorld, InsideHealthPolicy, Pink Sheet (link, link), Medtech Insight, 340B Report

Chiquita Brooks-LaSure Confirmed as CMS Administrator: On May 25, 2021, the Senate confirmed Chiquita Brooks-LaSure as Administrator of the Centers for Medicare and Medicaid Services (CMS). Her confirmation vote had been delayed due to objections over a revoked Texas Medicaid waiver extension.
Sources: InsideHealthPolicy, Pink Sheet, Medtech Insight, 340B Report

Drug Pricing Initiatives: Debate continues regarding the drug pricing measure introduced by House Democrats, H.R. 3 (the Elijah E. Cummings Lower Drug Costs Now Act). Moderate House Democrats are reportedly preparing alternative legislation that would forgo some of the more drastic proposals of H.R. 3 in hopes of garnering broader support. At the same time, more than 155 House Democrats urged President Biden in a letter to add drug pricing provisions to the American Families Plan, such as lowering the Medicare age, capping annual spending for Medicare beneficiaries, adding further benefits to Medicare, and directing the program to negotiate drug prices.
Sources: Bloomberg Law, InsideHealthPolicy

Democratic Senators, meanwhile, wrote a letter to President Biden, calling for any health reform proposal to reduce the out-of-pocket costs for consumers, in addition to lowering premiums.
Source: InsideHealthPolicy

In a development that might help inform the drug pricing debate, the Institute for Clinical and Economic Review (ICER) will "evaluate the coverage policies of 28 drugs across the largest formularies (by covered lives) of the 15 largest commercial payers in the US" in a bid to determine whether the plans are providing "fair" access to the treatments.
Sources: Pink Sheet, Scrip, BioWorld

Drug Importation Litigation: The Department of Health and Human Services (HHS) moved to dismiss a suit brought in 2020 by Pharmaceutical Research and Manufacturers of America (PhRMA), which challenges a Trump-era final rule that permits importation of drugs from Canada. PhRMA alleged that the final rule will weaken the drug distribution system, undermine regulatory protections designed to protect consumers, and "violate manufacturers' First Amendment rights, and raise serious questions under the

Fifth Amendment Takings Clause." According to the May 28, 2021, filing by HHS, "the doctrines of standing and ripeness do not permit Plaintiffs to erase a Certification and Rule that have not yet affected their members in any concrete way and perhaps never will," with HHS noting that no importation plan has yet been approved. The case is *Pharmaceutical Research and Manufacturers of America v. HHS*, No. 1:20-cv-03402 (D.D.C. filed Nov. 23, 2020).
Sources: Pink Sheet (link, link), InsideHealthPolicy

MEDICAID DRUG REBATE PROGRAM (MDRP)

CMS Proposes to Delay Multiple Best Price Reporting, Inclusion of the Territories: On May 28, 2021, CMS published a proposed rule in the Federal Register (the May 24 issue of this digest noted OMB's review of the proposed rule). Comments are due on June 28, 2021. Key points of the proposed rule include:

- Multiple Best Price reporting for Value-Based Purchasing — This provision from the December 2020 Medicaid final rule would be delayed by six months, from January 1, 2022, to July 1, 2022. The delay is "warranted to assure that stakeholders have the ability to implement the new … policy in a manner that assures that patient access and quality of care is protected."
- Medicaid inclusion of the US Territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) — CMS proposes a two-year delay, from April 1, 2022 (the date established by a 2019 interim final rule with comment period), to April 1, 2024 (or in the alternative, to an earlier date, but not before January 1, 2023).
- COVID-19 public health emergency — The preamble notes that the declared public health emergency "is expected to last through 2021."

Sources: Bloomberg Law, InsideHealthPolicy, 340B Report

PhRMA Suit Challenges Co-Pay/Accumulator Portion of December 2020 Medicaid Rule: As discussed in the May 24 issue of this digest, on May 21, 2021, 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 alleges 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).
Sources: Bloomberg Law, Pink Sheet, 340B Report

340B PROGRAM

Contract Pharmacy Litigation Updates: As noted in the May 24 issue of this digest, on May 17, 2021, the Health Resources and Services Administration (HRSA) sent letters to six pharmaceutical manufacturers that have implemented contract pharmacy policies, requesting an update on each manufacturer's "plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by June 1, 2021." These letters and the June 1 deadline were the subjects of manufacturer filings in ongoing contract pharmacy lawsuits and also prompted new litigation.
Sources: InsideHealthPolicy, Bloomberg Law (link, link, link), Law360 (link, link), 340B Report (link, link, link, link, link, link, link)

MEDICARE PART B

Physician, Patient Groups Urge HHS to Reinstate Ban on Step Therapy for Part B Drugs: In a letter dated April 22, 2021, more than 50 physician and patient groups urge HHS Secretary Xavier Becerra to

reinstate a ban that would prevent Medicare Advantage plans from applying step therapy for Part B drugs. The ban had been in place since 2012 but was withdrawn by the Trump Administration in 2018.
Source: InsideHealthPolicy

STATE LAW DEVELOPMENTS

Vermont Joins States Regulating PBMs: On May 21, 2021, the Vermont legislature passed H.439, which, among other things, would prohibit pharmacy benefit managers (PBMs) from requiring a claims modifier to identify a 340B drug, unless the claim is for payment by Medicaid, or restricting access to a pharmacy network or adjust reimbursement rates based on a pharmacy's participation in a 340B contract pharmacy arrangement. As noted in the May 24 issue of this digest, a growing number of states have adopted legislation related to PBMs this year.
Source: 340B Report

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