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2022 Medicaid & Government Pricing Congress Concludes: The annual Medicaid & Government Pricing Congress took place in Philadelphia from May 23-25 and virtually from June 1-2. On May 25, Latham partner Christopher H. Schott spoke at three sessions: a fireside chat with external counsel; a presentation on Health Resources and Services Administration (HRSA) manufacturer audits under the 340B program; and a presentation on bona fide service fee and fair market value trends and updates.

A number of government officials also spoke at the conference. Among others, John Coster, director of the Division of Pharmacy in the Centers for Medicare and Medicaid Services (CMS), addressed the forthcoming option for manufacturers to report multiple best prices in connection with value-based purchasing (VBP) arrangements, as implemented by regulation to become effective July 1, 2022. He also addressed implementation of this option in the Medicaid Drug Programs (MDP) system.

Dr. Coster stated that CMS will sometime this year issue a notice of proposed rulemaking (NPRM) on drug misclassification, pursuant to statutory provisions enacted under Section 6 of the Medicaid Services Investment and Accountability Act of 2019 (MSIAA). Dr. Coster said this NPRM will include proposed penalties and other enforcement mechanisms concerning manufacturers that misclassify their drugs under the Medicaid Drug Rebate Program (MDRP) as well as "many other things," such as new program integrity and administrative provisions relating to the MDRP. Other representatives from CMS gave presentations on the MDP system and unit types under the MDRP.

David Tawes, a Regional Inspector General from the Department of Health and Human Services (HHS) Office of Inspector General (OIG), and others from HHS OIG discussed ongoing and future HHS OIG initiatives. They specifically addressed future HHS OIG publications, including a report that will provide a limited assessment of average sales price (ASP) information submitted by manufacturers under Medicare Part B and a report that will evaluate CMS efforts to ensure ASP reporting accuracy.

The HHS OIG representatives also reported that HHS OIG is developing a process to identify any new National Drug Codes (NDCs) added to CMS's Part B drug crosswalk that may meet the criteria for being "usually self-administered," from which HHS OIG will determine if they are included as part of the same HCPCS code as physician-administered drug presentations. Pursuant to recent statute, HHS OIG must conduct such periodic studies to determine whether there are self-administered drugs that should be excluded from Part B payment amount calculations.

Drug Pricing Initiatives: Congress and stakeholders continue to discuss drug pricing reform measures, including those that were originally part of H.R. 5376 (the Build Back Better Act, or BBBA), as well as other measures, such as imposing transparency obligations on pharmacy benefit managers (PBMs). ***Sources:*** Bloomberg Law, Pink Sheet (link, link), Generics Bulletin, Modern Healthcare, The Hill, BioWorld

FDA Issues Guidance on Drug Importation: The Food and Drug Administration (FDA) issued a guidance document with frequently asked questions related to a Trump-era final rule that permits importation of drugs from Canada. As noted in Issue No. 6 of this digest, on July 9, 2021, President Biden issued an Executive Order on Promoting Competition in the American Economy that, among other things, asked the FDA to work with states to import prescription drugs from Canada. The final rule remains subject to litigation. As noted in Issue No. 3, a lawsuit brought by the Pharmaceutical Research and Manufacturers of America (PhRMA) alleges 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." The case is *PhRMA v. HHS*, No. 1:20-cv-03402 (D.D.C. filed Nov. 23, 2020).
Sources: Bloomberg Law, BioWorld

HHS Finalizes Repeal of "Sunset" Regulation: On May 27, 2022, HHS published a final rule that withdraws a Trump-era regulation imposing expiration dates on HHS regulations. The so-called sunset regulation was published on Jan. 19, 2021, but HHS twice postponed its effective date, to Sept. 22, 2022 (as noted in Issues No. 14 and No. 23). 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: Law360, Bloomberg Law, InsideHealthPolicy, Politico Pro, BioWorld, Fierce Healthcare, Endpoint News

MEDICAID DRUG REBATE PROGRAM (MDRP)

MDP System Updates: CMS announced on the MDP system's alert page that it has completed MDP updates related to the implementation of the line extension regulation that became effective this year. CMS also indicated that the functionality related to the optional reporting of multiple best price figures for VBP arrangements is accessible in advance of the July 1, 2022, effective date, in order to allow "manufacturers the opportunity to access the system and begin entering the details of their VBP arrangements into MDP so that states can preview their various options." As noted in Issue No. 27, CMS has published a demonstration video of the VBP functionality.

340B PROGRAM

Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continues.
Sources: Law360, 340B Report

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

State law developments related to the 340B program and the regulation of PBMs and manufacturers have occurred in Maryland and California.
Source: 340B Report (link, link)

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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