October 25, 2021 | Number 13

2021 Medicaid Drug Rebate Program Conference Concludes: The conference took place in New Brunswick, N.J., Oct. 11-13 and virtually Oct. 18-20. Christopher H. Schott spoke in person as part of the "Fireside Chat: External Counsel Roundtable" and on a panel titled "Manufacturer Best Practices for Managing 340B Overcharges and Refunds."

Other speakers included John Coster, Director of the Division of Pharmacy at the Center for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services (CMS); and David Tawes, a Regional Inspector General at the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS).

Dr. Coster spoke on several topics, including implementation of the recent MDRP final rule on value-based purchasing (VBP) arrangements, line extensions, and patient program exclusions from pricing calculations. He also addressed the impending launch of the Medicaid Drug Program (MDP) system for price reporting, which is set to replace the Medicaid Drug Data Reporting (DDR) system. Dr. Coster spoke broadly regarding a notice of proposed rulemaking to be issued this fall that will address penalties on manufacturers for misclassification of drug types, new program integrity and administration provisions, and possible VBP patient protections.

Mr. Tawes provided an overview of recent OIG work in connection with price reporting and announced forthcoming OIG reports on (i) the use of biosimilars and Hepatitis C drugs under Medicare Part D and (ii) the accuracy of manufacturer-reported Average Sales Price (ASP) figures for payment of drugs and biologicals under Medicare Part B.

Drug Pricing Initiatives: Democrats continue to debate the scope of the reconciliation package that contains many of President Biden's domestic policy initiatives, including with respect to drug pricing. It remains unclear when the reconciliation package will come to a vote, though some commentators have suggested a vote may be possible by the end of October.
Sources: Politico (link, link, link, link, link), Bloomberg Law, InsideHealthPolicy (link, link, link, link, link), In Vivo, BioWorld

MEDICAID DRUG REBATE PROGRAM (MDRP)

CMS Provides Additional Details Regarding the MDP System: On Oct. 15, 2021, CMS sent an email to technical contacts discussing additional details regarding the MDP system. The last day to access the DDR system will be Nov. 1, and the MDP system will become available on Nov. 8. Details provided by CMS include:

- **Unit Type Field** — CMS states that "[a]though you are currently able to change your Unit Type field values in DDR, you will not be able to change Unit Type values in MDP," and that "[o]nce data is migrated to MDP, Unit Type changes may only be made via a manual product override process that CMS must approve."

- **New Unit Types** — MDP will include two new Unit Types, millicurie (MCI) and microcurie (UCI). To "change your Unit Type to either of these values in MDP, you will need to request a product override once MDP goes live."
- **File Formats and Data Definitions** — Updated MDP file formats and data definitions are available on a dedicated webpage.
- **New Rebate Agreements and Reinstated Rebate Agreements** — A new "Rebate Agreement" module in MDP will serve to collect product data for manufacturers newly entering into a National Drug Rebate Agreement and will also handle reinstatement of terminated agreements.

MDRP data guides for state and manufacturer users will be combined into a single document that will be available for download in MDP. CMS will also share a link to a recorded "demonstration of MDP's key features" prior to its Nov. 8, 2021, implementation date.

Litigation Challenging Treatment of Radiopharmaceuticals as Covered Outpatient Drugs Continues: On Oct. 14, 2021, a panel of the US Court of Appeals for the District of Columbia Circuit heard arguments in a case brought by the Council on Radionuclides and Radiopharmaceuticals (CORAR) to determine if CORAR has standing in the matter. CORAR is appealing a November 2019 decision that granted summary judgment to HHS in CORAR's challenge to CMS's determination that radiopharmaceutical products are "covered outpatient drugs" under the MDRP. The lower court determined that CORAR did not have standing because it did not show any injury resulting from the 2016 CMS regulation at issue. The case is *Council on Radionuclides v. Becerra*, No. 20-5346 (D.C. Cir. argued Oct. 14, 2021).
Source: Law360

340B PROGRAM

Contract Pharmacy Updates: Litigation continues in connection with manufacturers that have adopted contract pharmacy policies.
Sources: Law360, 340B Report (link, link)

Related litigation challenging the Administrative Dispute Resolution (ADR) process remains pending.
Source: 340B Report (link, link, link)

HHS Proposes to Repeal Trump Regulations Regarding Agency Guidance: On Oct. 20, 2021, HHS published a notice of proposed rulemaking in the Federal Register that would repeal two final rules: "Department of Health and Human Services Good Guidance Practices," published in the Federal Register on Dec. 7, 2020, and effective Jan. 6, 2021, and "Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions," published in the Federal Register on Jan. 14, 2021, and effective Jan. 12, 2021. These regulations implemented two Executive Orders (EOs) issued by President Trump on Oct. 9, 2019, both of which were withdrawn by President Biden on Jan. 20, 2021:

- EO 13891, "Promoting the Rule of Law Through Improved Agency Guidance Documents," 84 Fed. Reg. 55,235 (Oct. 15, 2019), which "required agencies to treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract; take public input on guidance documents into account; and make all guidance documents available on a single website."
- EO 13892, "Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication," 84 Fed. Reg. 55239 (Oct. 15, 2019), which "imposed a number of procedural hurdles on agencies engaged in civil administrative enforcement or adjudication."

In accordance with President Biden's revocation of the EOs, in which he "directed agencies to promptly take steps to rescind any rules and policies implementing or enforcing" the revoked EOs, HHS has "reconsidered these rules and now believes that they create unnecessary hurdles that hinder the

Department's ability to issue guidance, bring enforcement actions, and take other appropriate actions that advance the Department's mission." The status of guidance is particularly significant for the 340B program, but the regulations HHS now proposes to repeal are relevant for the Food and Drug Administration's guidance process as well.

Comments regarding the proposed rule are due Nov. 19, 2021.
Sources: InsideHealthPolicy, 340B Report

Study Finds That Participation in the 340B Program Is Not Associated With Increased Uncompensated Care: A study published by the *American Journal of Managed Care* evaluated "whether hospital entry into the 340B Drug Pricing Program…is associated with changes in hospital provision of uncompensated care" and did "not find evidence that hospitals increased provision of uncompensated care after entry into the 340B program differentially more than hospitals that never entered or had not yet entered the program." The study concluded that "[r]elying on hospitals to invest surplus into care for the underserved without marginal incentives to do so or strong oversight may not be an effective strategy to expand safety-net care."
Source: 340B Report

MEDICARE PART B

Medicare Payment Advisory Commission (MedPAC) Hearing Focuses on Part B: At its Oct. 7, 2021, hearing, MedPAC discussed "concerns about trends in drug pricing and spending" under Medicare Part B. The MedPAC proposals discussed include:

- Applying a value-based payment approach for products approved under the FDA's accelerated approval pathway, based on "a comparison of the incremental costs and …outcomes…of two or more technologies," while also applying "coverage with evidence development."
- Utilizing "internal reference pricing" by setting "a maximum payment rate for a group of drugs with similar health effects," such as "based on minimum, median, or average price," through a "transparent process for establishing and updating drug payment groups and rates." Beneficiaries who select a higher-priced treatment would be required to pay the "difference in higher cost sharing," subject to an "exceptions process for medical need."
- Modifying the ASP plus 6% reimbursement rate by reducing the percentage add-on, converting "all or part of the percentage add-on to a fixed fee," or placing a "dollar cap" on the percentage add-on payment.

Source: Pink Sheet (link, link)

STATE LAW DEVELOPMENTS

No developments to report.

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:

Christopher H. Schott
chris.schott@lw.com
+1.202.637.2208
Washington, D.C.

Stuart S. Kurlander
stuart.kurlander@lw.com
+1.202.637.2169
Washington, D.C.

Eric C. Greig
eric.greig@lw.com
+1.202.637.3330
Washington, D.C.

James M. Deal
jamie.deal@lw.com
+1.202.637.2290
Washington, D.C.

Ali Lakhani
ali.lakhani@lw.com
+1.202.637.2271
Washington, D.C.

Maria Malas
maria.malas@lw.com
+1.202.637.2334
Washington, D.C.

Lee B. Staley
lee.staley@lw.com
+1.617.880.4663
Boston