June 22, 2021 | Number 4

Invitation to Complementary Webcast — Drug and Device Pricing and Reimbursement Landscape: Legal and Policy Trends Under the Biden Administration

Wednesday, June 30, 2021
11:00 a.m. Pacific | 1:00 p.m. Central | 2:00 p.m. Eastern

Join Latham's government price reporting and reimbursement lawyers for a discussion of recent legal and policy developments and trends, including initiatives by the Biden Administration and in Congress:

- H.R. 3 and the drug pricing debate
- Trends in government price reporting
- Coverage/reimbursement developments to watch

Christopher H. Schott, *Partner*, Washington, D.C.
Eric C. Greig, *Partner*, Washington, D.C.

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Supreme Court Upholds Affordable Care Act: On June 17, 2021, the Supreme Court ruled 7 to 2 to dismiss for lack of standing a challenge to the Affordable Care Act (ACA) brought by Texas and other states. The states had alleged that the elimination by Congress of the penalty for failing to comply with the mandate to buy insurance rendered that provision invalid, and that due to the significance of that provision, the whole law had to be struck down. Writing for the majority, Justice Breyer said that "[w]e proceed no further than standing," noting that "[n]either the individual nor the state plaintiffs have shown that the injury they will suffer or have suffered is 'fairly traceable' to the 'allegedly unlawful conduct' of which they complain."

Justices Alito and Gorsuch dissented, indicating that they would have let the suit proceed. They wrote that "[n]o one can fail to be impressed by the lengths to which this court has been willing to go to defend the ACA against all threats."

The case is *California v. Texas*, Nos. 19-840 and 19-1019, 2021 WL 2459255 (U.S. June 17, 2021).
Sources: Law360 (link, link), InsideHealthPolicy (link, link, link), Bloomberg Law (link, link, link, link, link), 340B Report

AHLA Annual Meeting Virtual Presentation: The annual meeting of the American Health Law Association (AHLA) will take place virtually this year from June 28 through June 30, providing nearly 1,500 health law professionals with the most current information and analysis on the legal issues facing the health care industry. Keynote speakers will include Dr. Anthony S. Fauci (Director, NIH, NIAID), the Honorable Christi A. Grimm (Principal Deputy Inspector General, HHS OIG), and Dr. Indu Subaiya (Co-Founder and President, Catalyst@Health 2.0). On June 30, 2021, Eric C. Greig (Partner, Latham & Watkins) will present an analysis of recent legal developments and opportunities for value-based arrangements in a session titled "Partnering with Life Sciences Companies in a Value-Based World."

MEDICAID DRUG REBATE PROGRAM (MDRP)

CMS Delays New Medicaid Price Reporting System for Manufacturers, but Not for States: The Centers for Medicare and Medicaid Services (CMS) announced to manufacturer technical and invoice contacts on June 15, 2021, that the replacement of the Drug Data Reporting for Medicaid (DDR) system, known as the Medicaid Drug Programs (MDP) system, will be delayed for manufacturers, but not for state Medicaid programs. CMS said that instead of "launching this new system [to manufacturers] in July 2021, we are delaying the transition to MDP until after the production of the third quarter 2021 rebate file," which "will be completed around November 5, 2021." State Medicaid programs, however, must begin using MDP to submit their second quarter 2021 state drug utilization data (SDUD) files to CMS "using the new file formats in August 2021." CMS also said it "will be sending the 2Q2021 Unit Rebate Amount (URA) and Unit Rebate Offset Amount (UROA) files to the states using the new file formats." Given the four-month difference in implementation dates for manufacturers and states, CMS suggests that "manufacturers and states work closely together to establish agreed upon field lengths in order to ensure that the Reconciliation of State Invoice (ROSI), the Prior Quarter Adjustment Statement (PQAS) and the State Invoice are able to be sent and received without interruption during this interim period."

Medicaid & Government Pricing Congress Concludes Virtually: The annual Medicaid & Government Pricing Congress, usually held in Orlando, concluded virtually on June 11, 2021. Themes from this year's Congress included developments in the 340B contract pharmacy space, safe harbor changes for pharmacy benefit manager (PBM) rebates, and Biden Administration policy priorities with respect to drug pricing. Featured speakers included current and former Department of Health and Human Services (HHS) and CMS officials, including Ruth Blatt of CMS' Division of Pharmacy. Christopher H. Schott (Partner, Latham & Watkins) participated in a panel discussion that concluded the Congress and covered notable legal and compliance developments.

340B PROGRAM

Contract Pharmacy Litigation Updates: Litigation developments in connection with the six manufacturers that have adopted contract pharmacy policies include:

- On May 31, 2021, Novartis Pharmaceuticals Corporation became the fifth manufacturer to file suit related to its contract pharmacy policy. The action was in part prompted by the Health Resources and Services Administration's (HRSA's) May 17 letters, in which the agency notified each of the six manufacturers that HRSA viewed their contract pharmacy policies as violating the 340B statute.
  Source: 340B Report
- On June 9, 2021, HHS Secretary Xavier Becerra stated in testimony before the Senate Appropriations subcommittee that HHS had sent "a clear message" to the six drug manufacturers that have adopted contract pharmacy policies "that we believe that they are violating the law," adding that "[y]ou violate the law, you pay the consequences."
  Source: 340B Report

- On June 16, 2021, the US District Court for the District of Delaware denied the government's request to dismiss the AstraZeneca PLC lawsuit seeking to overturn the December 30, 2020, advisory opinion, in which HHS had stated that the 340B statute requires manufacturers to honor contract pharmacy orders.
  Sources: Pink Sheet, Law360, InsideHealthPolicy, Bloomberg Law, 340B Report (link, link)
- On June 19, 2021, HHS withdrew the December 30, 2020, advisory opinion.
  Sources: Bloomberg Law, Law360, 340B Report

340B Purchases in 2020 Increased by 27% Over 2019: Purchases at the 340B ceiling price "reached at least $38 billion in 2020," an increase of 27% compared to 2019, and "more than quadruple the value of discounted purchases in 2014."
Source: Drug Channels

HHS Proposes to Rescind Regulation Mandating Pass-Through of 340B Ceiling Price: HHS issued a proposed rule on June 16, 2021, that would rescind the "Implementation of Executive Order on Access to Affordable Life-Saving Medications" final rule that was published on December 23, 2020, but has not yet become effective. The final rule would condition grants to federally qualified health centers (FQHCs) on the requirement that the FQHC pass through the 340B ceiling price for insulin and injectable epinephrine to certain eligible patients. HHS stated that it is "proposing the rescission due to undue administrative costs and burdens that implementation would impose on health centers."
Sources: Bloomberg Law, 340B Report

MEDICARE PART B

MedPAC Releases Report to Congress: On June 15, 2021, the Medicare Payment Advisory Commission (MedPAC) released its June 2021 report to Congress, which includes a chapter on separately payable drugs in the Hospital Outpatient Prospective Payment System (OPPS) system. The chapter includes two recommendations: (1) Congress should direct the Secretary to modify the OPPS pass-through drug policy so that it includes only drugs and biologics that function as supplies to a service and applies only to drugs and biologics that are clinically superior to their packaged analogs; and (2) the Secretary should specify that the OPPS separately payable non-pass-through policy applies only to drugs and biologics that are the reason for a visit and meet a defined cost threshold. The recommendations reflect MedPAC's concerns that "the criteria for drugs to be eligible for separate payment under the OPPS do not strike an appropriate balance between promoting access to high-cost innovative treatments and maintaining pressure on providers to be efficient."
Sources: BioWorld, 340B Report

Appointment of Two MedPAC Commissioners: On June 2, 2021, the GAO announced the appointment of two new MedPAC Commissioners (Lynn Barr, MPH, and Stacie B. Dusetzina, PhD). Ms. Dusetzina has published research on drug pricing and previously served as a committee member for the National Academies of Sciences, Engineering and Medicine on the topic "Ensuring Patient Access to Affordable Drug Therapies." Ms. Barr has been described as "the founder and executive chair of a company that helps health systems implement value-based payment models and maximize 340B savings."
Source: 340B Report

GAO Issues Report on Medicare Spending on Drugs With Direct-to-Consumer Advertising: In a new report, the Government Accountability Office (GAO) found that between 2016 and 2018, Medicare spent $560 billion on prescription drugs, with almost 60% of that amount spent for drugs that were advertised directly to consumers. The GAO noted that factors other than advertising "likely contributed to a drug's Medicare beneficiary use and spending, making it difficult to isolate the relationship between drug advertising, use and spending."
Source: Bloomberg Law

STATE LAW DEVELOPMENTS

Louisiana Law Addresses "White Bagging" Requirements for Physician-Administered Drugs: Louisiana Senate Bill No. 191, which was signed into law on June 1, 2021, addresses the practice of "white bagging," under which health insurers require physicians to acquire physician-administered drugs from particular specialty pharmacies, which then ship the drugs to the physician's office. Among other things, the Louisiana law provides that "[a] health insurance issuer shall not condition, deny, restrict, refuse to authorize or approve, or reduce payment to a participating provider for a physician-administered drug when all criteria for medical necessity are met, because the participating provider obtains physician-administered drugs from a pharmacy that is not a participating provider in the health insurance issuer's network."
Source: 340B 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