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**Drug Pricing Initiatives:** US lawmakers continue to debate the drug pricing measure introduced by House Democrats, H.R. 3 (the Elijah E. Cummings Lower Drug Costs Now Act). Among other things, H.R. 3 would empower the Department of Health and Human Services (HHS) to negotiate drug prices directly with manufacturers. On July 20, 2021, the Center for American Progress (CAP) published an analysis of the impacts of this provision, including details on how specific drugs may be affected.
***Sources:*** Bloomberg Law, Scrip

The Association for Accessible Medicine (AAM) issued a white paper, calling for a Part D redesign that would encourage adoption of generics.
***Source:*** Pink Sheet

Senators Richard Burr, Michael Bennet, Tom Carper, and Tim Scott reintroduced S. 2416 (the New Opportunities for Value to Extend Lives (NOVEL) Act), a measure first introduced in committee in 2019. The legislation aims to make cutting-edge technologies available to Medicare beneficiaries once they are approved by the Food and Drug Administration (FDA) and designated as "breakthrough" or "regenerative medicine advanced therapy" by updating coding, coverage, and payment processes employed by the Centers for Medicare and Medicaid Services (CMS).
***Source:*** Medtech Insight

**Drug Importation Remains a Topic of Discussion:** HHS withdrew two requests for proposals for the importation of insulin and the personal importation of prescription drugs due to lack of interest, after no proposals were received. However, in light of the Biden Executive Order that asks the FDA to work with states to import prescription drugs from Canada, Senator Amy Klobuchar and Senator Chuck Grassley urged the Biden Administration to enable Americans to personally purchase certain prescription drugs from Canada. (For more on the Executive Order, see the July 19 issue of this digest.) Senator Klobuchar had introduced S. 259 (the Safe and Affordable Drugs from Canada Act of 2021) in February.
***Sources:*** InsideHealthPolicy (link, link), Law360

**Infrastructure Bill Would Delay Part D Rebate Rule:** The bipartisan infrastructure deal as currently proposed would include two offsets related to drug pricing. First, it would delay implementation of the Part D drug rebate regulation promulgated by the Trump Administration. Second, it would require drug manufacturers of physician-administered drugs to refund Medicare for excess amounts of drug remaining in the vial.
***Sources:*** InsideHealthPolicy, Bloomberg Law

**FDA Approves First Interchangeable Biosimilar:** On July 28, 2021, the FDA approved a biological product as biosimilar to and, for the first time, as also interchangeable with the reference product. The new product is Semglee, by Viatris Inc., and the reference product is Lantus, by Sanofi SA.
***Sources:*** BioWorld, InsideHealthPolicy, Pink Sheet (link, link), Generics Bulletin, In Vivo, Law360, Bloomberg Law

## MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

## 340B PROGRAM

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

**Continuation of Reimbursement Cut for 340B-Purchased Drugs:** In the 2021 Hospital Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) proposed rule, which was released on July 19, 2021, CMS proposed to maintain the payment rate of Average Sales Price (ASP) minus 22.5% for certain separately payable drugs or biologicals acquired through the 340B Program, with exceptions for rural sole community hospitals, children's hospitals, and cancer hospitals that are exempt from the Medicare prospective payment system (PPS). This payment policy has been in place since issuance of the CY 2018 OPPS/ASC final rule. It remains subject to litigation, with the US Supreme Court recently agreeing to hear an appeal of lower court decisions upholding the payment rate established in prior years (as discussed in the July 6 issue of this digest).
***Source:*** 340B Report (link, link)

## MEDICARE PART B

No developments to report.

## STATE LAW DEVELOPMENTS

No developments to report.

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