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Drug Pricing Initiatives: Senators, Representatives, and stakeholders continue to discuss some of the drug price reform measures that were originally part of H.R. 5376 (the Build Back Better Act, or BBBA). ***Sources:*** InsideHealthPolicy (link, link), Pink Sheet

MEDICAID DRUG REBATE PROGRAM (MDRP)

Second Manufacturer Legal Challenge to "Line Extension" Regulation: On April 21, 2022, Vanda Pharmaceuticals Inc. (Vanda) filed a complaint in the US District Court for the District of Maryland challenging the 2020 MDRP final rule provisions on "line extensions." This action follows a separate challenge by Incyte Corporation in the US District Court for the District of Columbia, as previously reported in this digest (Issue No. 20).

The provisions at issue became effective Jan. 1, 2022. Under the MDRP, a drug that qualifies as a line extension of an initial drug is potentially subject to an alternative Medicaid rebate formula. This formula generally results in higher rebate obligations, as it applies the inflation penalty from the initial drug to the line extension. The concept was introduced to the MDRP by the Patient Protection and Affordable Care Act (ACA) in 2010. After a decade of issuing guidance, the 2020 MDRP final rule marked the first time the Centers for Medicare and Medicaid Services (CMS) addressed line extensions in regulation.

In its complaint, Vanda asserts that the final rule "oversteps its statutory authority, undermines Congress's intent, and contains several arbitrary and capricious inconsistencies." The company requests that the relevant provisions be set aside and declared void and unlawful, and that the court enjoin the government from enforcing, applying, or implementing the provisions as to two of the company's drugs. The case is *Vanda Pharmaceuticals Inc. v. CMS*, Case No. 22-977 (D. Md.).

340B PROGRAM

Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continues. ***Source:*** 340B Report (link, link)

MEDICARE PART B

MedPAC Discusses Part B Drug Payment Reform: At a recent Medicare Payment Advisory Commission (MedPAC) public meeting, MedPAC staff presented three proposals to address "high prices of drugs covered under Medicare Part B." MedPAC believes the proposals could generate savings for beneficiaries and taxpayers and improve Medicare's financial sustainability. The proposals are expected to be included in MedPAC's June report to Congress. They include:

- **Payment cap for certain drugs approved under the accelerated pathway.** CMS would collect clinical evidence about first-in-class drugs approved by the Food and Drug Administration (FDA)

under the accelerated pathway, and then cap their payment using a combined approach of evaluating information about comparative clinical effectiveness and cost-effectiveness.

As noted in previous editions of this digest, drugs approved under the accelerated pathway have been the focus of recommendations by MedPAC (Issue No. 13) and the Medicaid and CHIP Payment and Access Commission (MACPAC) (Issue No. 1).

- **Domestic reference pricing.** Medicare would implement "domestic reference pricing," under which each Part B drug would remain in its own billing code, but would be placed in a "reference group" of drugs with "similar health effects" that would be subject to a related payment rate tied to the Average Sales Price (ASP) figures of the drugs in the group.

- **Modification of ASP add-on payment.** Under existing law, separately payable Part B drugs and biologicals are generally reimbursed at ASP plus 6%. MedPAC is concerned that the existing add-on percentage "creates incentives for providers to choose higher-price drugs," and therefore proposes modifying this reimbursement methodology, with suggested options including a cap to the add-on payment and a reduced add-on payment, or a combination of these approaches limited to drugs above a certain ASP threshold.

Source: InsideHealthPolicy

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:

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