

Healthcare & Life Sciences Practice

Drug Pricing Digest

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CMS Releases Proposed Physician Fee Schedule for 2022: On July 13, 2021, the Centers for Medicare and Medicaid Services (CMS) released the proposed Physician Fee Schedule (PFS) for 2022 ([link](#)). Among other issues, the PFS addresses Medicare reimbursement for drugs approved under the 505(b)(2) pathway, after CMS withdrew a related proposal during last year's rulemaking cycle. CMS again discusses price and utilization differences between 505(b)(2) drugs and "corresponding" multiple source drugs. As CMS considers potential future policymaking, the agency published a potential framework through which it would determine if a 505(b)(2) drug could be assigned to an existing multiple source (generic) drug code rather than receive its own billing code.

CMS is not proposing to adopt this framework for 2022, but is soliciting comments from stakeholders on (i) whether the framework aligns with statutory criteria for single/multiple source drugs, (ii) whether CMS is proposing the correct criteria to distinguish 505(b)(2) drugs from "corresponding" multiple source drugs, and (iii) the impact the framework could have on patients and other stakeholders. Comments are due no later than September 13, 2021.

Source: [Bloomberg Law](#)

Senate Budget Committee Democrats Agree on \$3.5 Trillion Budget: The draft budget proposal addresses many of the Biden Administration's policy priorities. Among other initiatives, it would add dental, hearing, and vision benefits for Medicare beneficiaries. It is unclear if the proposal would lower the Medicare eligibility age, or if it would include additional proposals related to drug pricing, which some lawmakers are calling for. Any drug pricing provisions in the proposal would come in the context of ongoing debate of the drug pricing measure introduced by House Democrats, [H.R. 3](#) (the Elijah E. Cummings Lower Drug Costs Now Act), as well as related measures. [H.R. 4311](#), introduced earlier by House Ways and Means Health Subcommittee Chair Lloyd Doggett, would also add dental, hearing, and vision benefits to Medicare.

Sources: Bloomberg Law ([link](#), [link](#)), InsideHealthPolicy ([link](#), [link](#), [link](#), [link](#)), [Pink Sheet](#), [Law360](#)

Biden Executive Order Addresses Drug Pricing: On July 9, 2021, President Biden issued an Executive Order on Promoting Competition in the American Economy ([link](#)) that calls for multiple federal initiatives to address drug pricing. Among other things, the Order (i) asks the Food and Drug Administration (FDA) to work with states to import prescription drugs from Canada, (ii) instructs the Federal Trade Commission (FTC) to examine instances in which brand manufacturers allegedly pay generic manufacturers to delay market entry of generic drugs, and (iii) directs the Department of Health and Human Services (HHS) to submit a "plan" within 45 days to address prescription drug prices and "enhance domestic pharmaceutical supply chains" and "to reduce the prices paid by the federal government for such drugs."

Sources: Law360 ([link](#), [link](#)), [Bloomberg Law](#), Pink Sheet ([link](#), [link](#)), InsideHealthPolicy ([link](#), [link](#), [link](#)), [Scrip](#), [340B Report](#)

International Generic and Biosimilar Medicines Association Releases Strategic Whitepaper:

The International Generic and Biosimilar Medicines Association (IGBMA) issued a [white paper](#) that reviews the generics and biosimilar industry and sets forth a “2030 Vision” for the industry.

Sources: [Pink Sheet](#), [Generics Bulletin](#)

MEDICAID DRUG REBATE PROGRAM (MDRP)

Lawmakers Discuss Fix to Medicaid Coverage Gap: The Affordable Care Act permitted states to expand Medicaid coverage to individuals earning 138% of the federal poverty level, but currently, 12 states have declined to do so. Democratic lawmakers have been discussing different approaches to extend coverage to the approximately 2 million individuals left without access to coverage as a result of this coverage gap. One potential approach is to address the coverage gap in the overall budget (discussed above).

Source: InsideHealthPolicy ([link](#), [link](#), [link](#), [link](#), [link](#))

340B PROGRAM

Another Manufacturer Files Suit Defending Its Contract Pharmacy Policy: United Therapeutics Corporation became the sixth manufacturer to file suit against HHS in defense of a contract pharmacy policy. The case is *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686-DLF (D.D.C. filed June 23, 2021).

A related suit against HHS seeks an order requiring the agency to release documents requested under a Freedom of Information Act (FOIA) request, which the agency failed to address within the 20 business days required by FOIA. The case is *Latham & Watkins v. HRSA*, No. 1:21-cv-01862-DLF (D.D.C. filed July 13, 2021).

Source: 340B Report ([link](#), [link](#))

Other contract pharmacy lawsuits remain ongoing.

Source: 340B Report ([link](#), [link](#), [link](#))

MEDICARE PART B

International Reference Pricing Discussion Continues: Senate Finance Committee Chair Ron Wyden is reportedly considering proposing domestic reference pricing in lieu of the international reference pricing approach proposed in [H.R. 3](#) (the Elijah E. Cummings Lower Drug Costs Now Act).

Meanwhile, on July 7, 2021, the Office of Management and Budget began its review of a [proposed rule](#) titled “Most Favored Nation (MFN) Model (CMS-5528).” It is unclear whether this proposed rule would modify or withdraw the 2020 MFN [model](#) initiated by the Trump Administration. That regulation was vacated following multiple lawsuits: *Association of Community Cancer Centers v. Azar*, No. 1:20-cv-03531 (D. Md. filed Dec. 4, 2020); *Biotechnology Innovation Organization v. Azar*, No. 20-cv-08603 (N.D. Cal. filed Dec. 4, 2020); *Regeneron Pharmaceuticals, Inc. v. U.S. Dep’t of Health and Human Services*, No. 7:20-cv-10488 (S.D.N.Y. filed Dec. 11, 2020); and *Community Oncology Alliance, Inc. v. U.S. Dep’t of Health and Human Services*, No. 1:20-cv-03605 (D.D.C. filed Dec. 11, 2020).

Source: InsideHealthPolicy ([link](#), [link](#))

STATE LAW DEVELOPMENTS

No developments to report.

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