

Healthcare & Life Sciences Practice

Drug Pricing Digest

July 6, 2021 | Number 5

Drug Pricing Initiatives: Debate continues regarding the drug pricing measures pending in Congress. On June 22, 2021, Senate Finance Committee Chair Ron Wyden released legislative principles that, among other things, would extend to commercial insurers the same drug prices that Medicare negotiates. At the same time, Democratic lawmakers are reportedly discussing which health policies to include in upcoming legislation as part of a reconciliation package. For example, House Energy and Commerce Health Subcommittee Chair Anna Eshoo reportedly wants to include policies that both close the Medicaid coverage gap and extend Medicare coverage to additional benefits.

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

MEDICAID DRUG REBATE PROGRAM (MDRP)

Becerra, Brooks-LaSure Address Medicaid Expansion in Comments to the Press: During a press briefing on June 18, 2021, Centers for Medicare and Medicaid Services (CMS) Administrator Chiquita Brooks-LaSure and Department of Health and Human Services (HHS) Secretary Xavier Becerra expressed a willingness to work with states interested in expanding their Medicaid programs, indicating that such states still could take advantage of the increased federal matching funds available pursuant to the American Rescue Plan. Becerra and Brooks-LaSure indicated that CMS is willing to consider allowing states to expand to only 100% of the federal poverty level, while noting the financial benefits that result from expanding to 138% of the federal poverty level pursuant to the Affordable Care Act.

Source: [InsideHealthPolicy](#)

340B PROGRAM

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

- On June 30, 2021, the US District Court for the District of Delaware rejected the government's contention that the withdrawal of its December 30, 2020, [advisory opinion](#) mooted AstraZeneca Pharmaceuticals LP's related lawsuit. Chief US District Judge Leonard Stark set aside and vacated the advisory opinion, stating that "although HHS withdrew the Opinion, HHS has made it clear that its position on the 340B statute has not changed," adding that because HHS and HRSA "intend to act in accordance with the withdrawn Opinion, this litigation is not moot." The parties have until July 6, 2021, to submit a joint status report with a proposed schedule for future filings and briefings. The case is *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027 (D. Del. filed Jan. 12, 2021). **Sources:** Bloomberg Law ([link](#), [link](#)), InsideHealthPolicy ([link](#), [link](#), [link](#)), 340B Report ([link](#), [link](#), [link](#))
- Certain of the manufacturers that have adopted contract pharmacy policies responded to the letters sent to them by the Health Resources and Services Administration (HRSA) on May 17, 2021, rejecting HRSA's assertions that their policies were in violation of 340B program requirements. **Source:** [340B Report](#)

- Boehringer Ingelheim announced on June 30, 2021, that it will adopt a contract pharmacy policy that will go into effect on August 1, 2021, becoming the seventh manufacturer to publicly announce such a policy. Under its policy, the company “will ship products purchased at the 340B price exclusively to locations registered as a 340B covered entity or their child site locations and will not facilitate shipment to commercial contract pharmacies.” The company noted that federal grantees are exempt from the policy, and “any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location to receive and dispense 340B purchased products.”
Source: [340B Report](#)

HRSA Announces Members of ADR Board: On June 24, 2021, HRSA published the administrative dispute resolution (ADR) board member names in the [Federal Register](#). The ADR regulation is subject to litigation from covered entity organizations and covered entities that sought to compel HRSA to issue the regulation, and from the Pharmaceutical Research and Manufacturers of America (PhRMA), which is seeking to strike down the ADR regulation and HRSA’s 1996 audit guidance.

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

MEDICARE PART B

New Hospital Litigation Challenges Reimbursement Cuts for 340B Drugs; Supreme Court Agrees to Hear Related Case: On June 18, 2021, multiple hospitals filed a new action in the US District Court for the District of Columbia against the HHS, challenging Part B reimbursement cuts for drugs acquired at the 340B ceiling price. The case is *Advocate Christ Medical Center v. Becerra*, No. 1:21-cv-01651 (D.D.C. filed June 18, 2021). Litigation filed by the American Hospital Association (AHA) about the same subject remains ongoing, as noted in the May 24 [issue](#) of this digest. On July 2, 2021, the Supreme Court agreed to hear that case after a split D.C. Circuit panel held that CMS used acceptable data and had authority to make the reimbursement cuts, *American Hospital Ass’n v. Azar*, 967 F.3d 818 (D.C. Cir. 2020), *cert. granted*, No. 20-1114 (U.S. July 2, 2021).

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

Supreme Court Rejects Hospital Challenge to 2018 Reimbursement Rule: On June 28, 2021, the Supreme Court refused to hear a case brought by a coalition of hospitals challenging a 2018 regulation that imposed cuts to outpatient Medicare reimbursements. The AHA, the Association of American Medical Colleges, and various hospitals challenged the rule and prevailed in district court, but that decision was reversed by the US Court of Appeals for the District of Columbia Circuit, which invoked so-called *Chevron* deference. The hospitals argued that reliance on the *Chevron* standard to defer to the government’s interpretation of the statute was inappropriate. The case is *American Hospital Ass’n v. Becerra*, 964 F.3d 1230 (D.C. Cir. 2020), *cert. denied*, No. 20-1113 (US June 28, 2021).

Sources: [Bloomberg Law](#), [Law 360](#), [InsideHealthPolicy](#)

CMS Announces July Schedule for Virtual HCPCS Public Meetings: On June 15, 2021, CMS published the July schedule for virtual public meetings for new revisions to the Healthcare Common Procedure Coding System (HCPCS) code set in the [Federal Register](#). Preliminary recommendation sessions will be held on July 7 and 8, while July 9 is set aside in case CMS receives more speaker registrations than can be accommodated on Wednesday and Thursday.

Source: [Medtech Insight Informa Pharma Intelligence](#)

STATE LAW DEVELOPMENTS

AHLA Issues White Paper on States Regulating PBMs: The American Health Law Association (AHLA) has issued a [white paper](#) discussing the legal background of state laws that address pharmacy benefit managers (PBMs). More recently, the interplay between the 340B program and these state laws was addressed in a [white paper](#) issued by individuals affiliated with covered entity organizations.

Source: [340B Report](#)

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