

Healthcare & Life Sciences Practice

Drug Pricing Digest

July 6, 2022 | Number 31

Drug Pricing Initiatives: Congress and stakeholders continue to discuss drug pricing reform measures, including those that were originally part of [H.R. 5376](#) (the Build Back Better Act, or BBBA).

Sources: STAT ([link](#), [link](#)), [Pink Sheet](#)

A new bill introduced in the Senate focuses on the cost of insulin.

Sources: [Pink Sheet](#), [Politico](#), [STAT](#), [The Hill](#), [340B Report](#)

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Appeals Court Revives Covered Entity’s “Patient” Definition Challenge: On July 1, 2022, the US Court of Appeals for the Fourth Circuit issued an [opinion](#) holding that Genesis Healthcare Inc., a 340B covered entity, may pursue a lawsuit against the federal government challenging the “patient” definition set forth under guidance from the Health Resources and Services Administration (HRSA). The US District Court for the District of South Carolina had ruled that Genesis could not maintain the suit because HRSA had rendered the controversy moot, voiding adverse audit findings that had applied the “patient” definition and reinstating Genesis as an eligible covered entity following an initial sanction of termination from the 340B program. The Fourth Circuit reversed, concluding that a “live controversy” remains because Genesis “continues to be governed by a definition of ‘patient’ that, it maintains, is illegal and harmful to it,” as Genesis remains subject to HRSA’s audit authority and, according to the case record, would still have to comply with HRSA’s “patient” definition guidance going forward. The case has been remanded to the lower court for further proceedings. The Fourth Circuit decision is *Genesis v. Becerra*, No. 20-1701 (4th Cir. July 1, 2022), *rev’g Genesis v. Azar*, No. 4:19-cv-01531-RBH, 2019 WL 6909572 (D.S.C. Dec. 18, 2019).

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

Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continued. Meanwhile, HRSA sent a [letter](#) threatening enforcement action to another manufacturer.

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

An additional manufacturer announced the implementation of a contract pharmacy policy, bringing the total number of manufacturers that have done so to 18.

Source: [340B Report](#)

Administrative Dispute Resolution (ADR) Regulation: The Office of Management and Budget (OMB) [updated](#) the release date of a proposed ADR regulation to June 2022. Litigation challenging the [current](#) ADR process remains pending.

Source: [340B Report](#)

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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