

Healthcare & Life Sciences Practice

Drug Pricing Digest

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Drug Pricing Initiatives: With no clear pathway to Senate passage of [H.R. 5376](#) (the Build Back Better Act, or BBBA), Democrats are considering whether to separately adopt individual BBBA drug price reform measures. One such measure, introduced as the [Affordable Insulin Now Act](#), would cap patient cost share for insulin under Medicare Part D at \$35 for a 30-day supply.

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

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: On Feb. 16, 2022, the US District Court for the District of Delaware issued an order and an opinion in the ongoing contract pharmacy litigation involving AstraZeneca, with the court vacating, setting aside, and remanding the May 17, 2021, violation letter issued by the Health Resources and Services Administration (HRSA) against AstraZeneca in connection with the manufacturer's 340B contract pharmacy policy. This decision follows a previous decision of the same court vacating a governmental advisory opinion issued from the US Department of Health and Human Services (HHS) Office of General Counsel (later [withdrawn](#)), which had asserted that the 340B statute requires manufacturers to honor contract pharmacy arrangements. In its more recent decision, the court requested that the parties submit a joint status report describing what relief the court should grant on claims brought by the manufacturer in a second amended complaint, and how, if at all, the case should proceed. The parties submitted their joint status report on Feb. 23, 2022, with the manufacturer generally seeking broader declaratory and injunctive relief from the court and the government requesting that the court limit relief to what was granted in the Feb. 16 decision, which would result in remanding the matter back to HRSA.

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

Meanwhile, another pharmaceutical manufacturer has implemented contract pharmacy policies, bringing the number of manufacturers with a published policy to 14.

Sources: [Politico Pro](#), [340B Report](#)

SEC Filing Alludes to Materiality of Contract Pharmacy Arrangements: In its [Annual Report](#) on Form 10-K filed Feb. 9, 2022, CVS Health Corporation stated that "a number of pharmaceutical manufacturers began programs that limited Covered Entities' participation in the [340B] program through contract pharmacies arrangements." The company stated that a "reduction in Covered Entities' participation in contract pharmacy arrangements, as a result of the pending enforcement actions or otherwise, a reduction in the use of the Company's administrative services by Covered Entities, or a

reduction in drug manufacturers' participation in the program could materially and adversely affect the Company.”

Source: [Drug Channels](#)

ADR Panel Rejects Manufacturer Motion to Stay Proceedings: In a decision issued Feb. 11, 2022, an HHS Administrative Dispute Resolution (ADR) panel rejected the motions by respondents Sanofi-Aventis and AstraZeneca to stay the ADR proceedings brought by the National Association of Community Health Centers (NACHC). The ADR panel stated that “neither the various pieces of litigation pending before the federal courts nor the possibility, or even the likelihood that HHS will choose to replace the current ADR Rule weigh in favor of a stay here.” The matter is *NACHC v. Sanofi-Aventis U.S. LLC*, Case No. 210112-2 (Dep’t of Health and Human Servs. Feb. 11, 2022).

Source: [340B Report](#)

Ongoing Antitrust Litigation Related to Contract Pharmacy Policies: Litigation related to allegations that four pharmaceutical manufacturers' contract pharmacy policies violate federal and state antitrust laws continues. As described in a prior edition of this digest ([Issue No. 19](#)), the case is *Mosaic Health, Inc. v. Sanofi Aventis U.S., LLC*, No. 6:21 cv 6507-EAW (W.D.N.Y.).

Source: [340B Report](#)

Arkansas Proposes Regulation Pursuant to 340B Law: The Arkansas Insurance Commissioner issued a [proposed regulation](#) pursuant to the state's 340B Drug Pricing Nondiscrimination Act. The Arkansas law is subject to legal challenge, as reported in previous editions of this digest ([Issue No. 1](#), [Issue No. 3](#), [Issue No. 9](#), [Issue No. 14](#), [Issue No. 20](#), and [Issue No. 21](#)). The public comment period regarding the proposed regulation will end with a [public hearing](#) scheduled for April 14, 2022.

Michigan Joins States Regulating PBMs: On Feb. 23, 2022, Michigan's governor signed into law the [Pharmacy Benefit Manager Licensure and Regulation Act](#), which regulates pharmacy benefit managers (PBMs) and includes a specific provision prohibiting PBMs from differential treatment and reimbursement of 340B covered entities and contract pharmacies. The bill includes PBM transparency requirements, including the reporting of aggregate manufacturer rebates. As reported in previous editions of this digest ([Issue No. 1](#), [Issue No. 2](#), [Issue No. 3](#), [Issue No. 5](#), [Issue No. 11](#), and [Issue No. 19](#)), a number of other states have introduced and enacted similar legislation.

Sources: [Fierce Healthcare](#), [Michigan Radio \(NPR\)](#), [The Detroit News](#), [340B Report](#)

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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