

## Healthcare & Life Sciences Practice

### Drug Pricing Digest

May 23, 2022 | Number 28

#### Join Latham's Government Price Reporting Team at the 2022 Medicaid & Government Pricing Congress

The live portion of this hybrid live/virtual [conference](#) will take place May 23-25 at the Sheraton Philadelphia Downtown in Philadelphia, Pa., with the virtual portion following June 1-2. Latham partner Christopher H. Schott will speak at three [sessions](#) on May 25. We look forward to connecting in person at the Latham booth or through the conference's virtual platform.

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

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

#### MEDICAID DRUG REBATE PROGRAM (MDRP)

**Co-Pay/PBM Accumulator Regulation Struck Down:** On May 17, 2022, the US District Court for the District of Columbia vacated and set aside the portions of the December 2020 Medicaid [final rule](#) related to the price reporting treatment of manufacturer-sponsored patient programs, including co-pay assistance programs, when the patient's health plan, or its pharmacy benefit manager (PBM), has implemented a so-called "accumulator adjustment program." The case is *PhRMA v. Becerra*, No. 1:21-cv-01395 (D.D.C.).

As we have reported (Issues [No. 2](#), [No. 3](#), [No. 18](#), and [No. 27](#)), the Pharmaceutical Research and Manufacturers of America (PhRMA) brought the underlying litigation against the government, alleging that the final rule "treats financial assistance manufacturers provide to patients as if such assistance were a price discount that the manufacturer instead provided to the patients' health plans, unless the manufacturer somehow 'ensures' that no health plan retroactively takes the benefits that the manufacturer intended for and provided to patients through the imposition of an accumulator adjustment program." PhRMA asserted that this approach "contradicts the Medicaid rebate statute's plain text," specifically with respect to the statute's best price definition.

The court agreed with PhRMA, explaining: "A manufacturer's financial assistance to a patient does not qualify as a price made available *from* a manufacturer *to* a best-price-eligible purchaser. Rather, a manufacturer's financial assistance is available *from* the manufacturer *to* the patient. And a patient is not a best-price-eligible purchaser." The court added that "[f]easibility concerns support this conclusion," as the rule "would make the calculation of the best price turn on information often in the sole possession of commercial health insurers" and that "manufacturers would need to conduct transaction-by-transaction investigations into the operations of accumulator adjustment programs even though manufacturers have

no control over (and sometimes no information) concerning those programs.” The government has 60 days to file an appeal.

**Sources:** [Law360](#), [Bloomberg Law](#), [STAT](#), [BioWorld](#), [Reuters](#), [Endpoints News](#)

## 340B PROGRAM

**Contract Pharmacy Updates:** Litigation related to manufacturer contract pharmacy policies continued, with the government filing an appeal in *United Therapeutics Corp. v. Espinosa*, No. 21 cv 1686 (DLF) (D.D.C.) and *Novartis Pharm. Corp. v. Espinosa*, No. 21-cv-1479 (DLF) (D.D.C.). For more information on the court decision in these cases, see [Issue No. 14](#) of this digest.

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

## MEDICARE PART B

No developments to report.

## STATE LAW DEVELOPMENTS

State law developments related to the 340B program and the regulation of PBMs and manufacturers occurred in Colorado, Michigan, and Connecticut.

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

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