

Healthcare & Life Sciences Practice

Drug Pricing Digest

October 11, 2021 | Number 12

Join Latham's Government Price Reporting Lawyers at the 2021 Medicaid Drug Rebate Program Conference

The live portion of this hybrid live/virtual [conference](#) will take place October 11-13 at the Hyatt Regency in New Brunswick, NJ, with the virtual portion following October 18-20. We look forward to connecting in person at the Latham booth or through the conference's virtual platform.

Drug Pricing Initiatives: The fate of the reconciliation package that contains many of President Biden's domestic policy initiatives, including with respect to drug pricing, remains in limbo as Democrats continue to debate the scope of the package. Competing approaches and priorities regarding drug pricing reform are a source of controversy within the Democratic party and face opposition from the Republican party. It is currently unclear when the reconciliation package will come to a vote.

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

MEDICAID DRUG REBATE PROGRAM (MDRP)

Medicaid Drug Programs System Will Launch November 8: On October 8, 2021, the Centers for Medicare and Medicaid Services (CMS) announced to technical contacts via email that the last day to access the Drug Data Reporting for Medicaid (DDR) system will be November 1, after which the new Medicaid Drug Programs (MDP) system will be accessible for manufacturers on November 8. CMS will migrate manufacturer data from DDR to MDP.

Important points from the email include:

- MDP will support "new features and larger pricing values"
- Updates include "[a]dditional locked fields including Unit Type and Units Per Package Size (UPPS)"
- CMS urges manufacturers to "[c]heck unit types and UPPS and make any necessary changes or corrections in DDR"
- Manufacturers should "[s]ubmit a change request once MDP is live if Unit Type is millicurie or microcurie"

CMS promises to provide "more detailed direction from us" in a follow-up email, as well as instructions for making an appointment during one of four one-hour "office hour" windows.

340B PROGRAM

Contract Pharmacy Updates: Litigation continues in connection with manufacturers that have adopted contract pharmacy policies.

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

The Health Resources and Services Administration (HRSA) has assigned Administrative Dispute Resolution (ADR) panels to address ADR petitions by covered entities against certain of the drug manufacturers that have adopted contract pharmacy policies.

Source: [340B Report](#)

Kalderos, Inc., a healthcare technology company that offers a platform for exchanging data related to 340B contract pharmacy transactions, filed a complaint in the U.S. District Court for the District of Columbia challenging HRSA's "new policy prohibiting the conditioning of 340B prices on the provision of claims data by covered entities." The case is *Kalderos, Inc. v. United States*, Case No. 1:21-cv-02608 (D.D.C.).

Source: [Law360](#)

HHS Rescinds Regulation Mandating Pass-Through of 340B Ceiling Price: The Department of Health and Human Services (HHS) issued a [final rule](#) on October 1, 2021, rescinding the Implementation of Executive Order on Access to Affordable Life-Saving Medications final rule that was published on December 23, 2020, but never became effective. The 2020 final rule would have conditioned grants to federally qualified health centers (FQHCs) on the requirement that the FQHC pass through the 340B ceiling price for insulin and injectable epinephrine to certain eligible patients. HHS stated that it is "rescinding the 2020 Rule due to the excessive administrative costs and burdens that implementation would have imposed on health centers," and that its decision was "informed, in part, by the demands on health centers resulting from the COVID-19 pandemic."

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

On September 23, 2021, Senator John Kennedy introduced [S. 2814](#), the Vital Medication Affordability Act, which would make the requirements of the Executive Order on Access to Affordable Life-Saving Medications binding through legislation.

Source: [340B Report](#)

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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