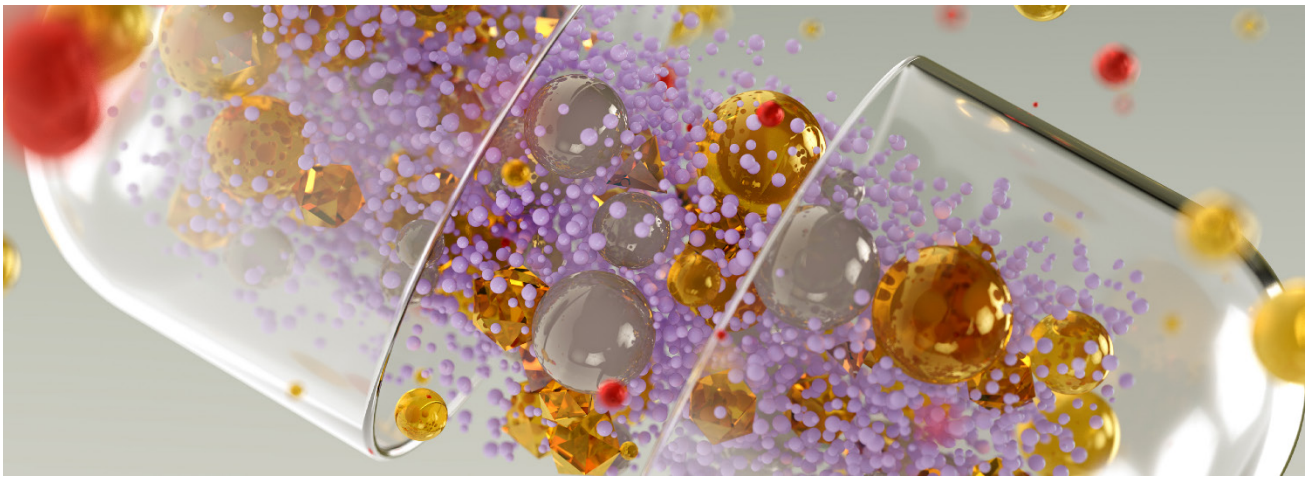

Healthcare & Life Sciences Practice April 7, 2025 | Number 43

Drug Pricing Digest

We are pleased to resume publication of the Latham & Watkins Drug Pricing Digest, which covers all things market access — including recent developments in the Medicaid Drug Rebate Program, Medicare Parts B and D, and the 340B drug pricing program, as well as the Inflation Reduction Act and healthcare reform generally. Latham's drug pricing and market access team provides a digest of reports from the trade press, government publications and releases, and court opinions. We intend to distribute the digest at the start of every other week.

I hope you will find this information useful.

Sincerely,

Chris

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Inflation Reduction Act, Healthcare Reform, and General Developments

Major Layoffs at HHS: The Department of Health and Human Services (HHS) announced major layoffs last week, which became effective as of April 2. The reorganization involves laying off 10,000 HHS employees, and the overall HHS workforce will decline by about 20,000 employees, amounting to a 20% reduction. These cuts affect the various agencies that are part of HHS, such as the Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), and the Health Resources and Services Administration (HRSA).

HRSA, through its Office of Pharmacy Affairs, has administered the 340B drug pricing program since its inception in 1992. HHS has announced that HRSA is being merged with four smaller agencies to create a new entity called the Administration for a Healthy America (AHA). It is unclear how this will impact 340B program administration.

The layoffs have prompted the Senate Committee on Health, Education, Labor & Pensions to invite HHS Secretary Robert F. Kennedy, Jr. to testify before the Committee on April 10 to "discuss your proposed reorganization" of HHS.

Stakeholder concerns as to the impact of the HHS layoffs and reductions may impact investments and transactions in the biotech and pharmaceutical sector.
Sources: New York Times, Washington Post, Law360, Pharma Intelligence (link, link), Bloomberg (link, link), FDLI SmartBrief (link, link, link), Politico (link, link), Inside Health (link, link, link, link, link, link, link, link), Bioworld (link, link), Stat+ (link, link, link), 340B Report.

Tune in to the most recent episode of the Latham drug pricing podcast for a discussion of possible impacts of the HHS reorganization on FDA.

Stakeholders Review Impact of Tariffs on the Pharmaceutical Industry: President Trump's announcement of significant tariffs was greeted with skepticism by stakeholders in the pharmaceutical and biotech sectors. Commentators noted that manufacturers will have to carefully examine how the tariffs will impact their products and supply chains. Reportedly, the Trump administration is considering conducting a Section 232 investigation of pharmaceuticals, which could form the basis for import duties in this area.
Sources: CNBC, Inside Health (link, link, link), Bioworld (link, link), Bloomberg, Politico.

Dr. Oz Confirmed as Head of CMS: The Senate confirmed Dr. Mehmet Oz as the head of CMS. In his confirmation hearing before the Senate Finance Committee, Dr. Oz responded to various questions about drug pricing. When asked whether he would continue to support the Medicare drug price negotiation program under the Inflation Reduction Act (IRA) in court challenges and commit to negotiating prescription drug prices, Dr. Oz said, "I'm going to look, as the president has instructed me, at every single way we can reduce drug prices, and there are lots of options available." Questioned about international reference pricing, Dr. Oz responded, "President Trump has been very clear that he wants me to reduce drug prices, not just for what the government pays, but also for beneficiaries. International reference pricing is a way of doing that."

At the same time, a Trump administration-aligned think tank, America First Policy Institute, issued a brief discussing most favored nation and international reference pricing policies that are in place in other countries, stating, "If other countries paid higher drug prices, drug manufacturers could invest in more R&D to develop additional medications or could lower prices for American patients."
Sources: Politico, Stat+, Bloomberg (link, link), Inside Health (link, link), Pink Sheet (link, link), StatNews, 340B Report (link, link).

To keep abreast of developments in the White House, visit the Trump Administration: First 100 Days blog, where Latham provides insights on the shifting regulatory and legal landscape.

Manufacturers Agree to IRA Negotiations: The second group of 15 drugs selected for Medicare price negotiations was announced by CMS shortly before the change in administration. CMS has recently stated that all of the manufacturers of these drugs have agreed to participate in the negotiation process.
Sources: CMS, 340B Report.

Check out the Latham roadmap to the IRA, which outlines the statutory provisions in a thoughtful order, while providing citations to the IRA for easy reference to the legislative text.

CMS Extends IRA Stakeholder Meetings Deadline: As part of implementing the IRA, CMS has conducted meetings with patients, researchers, and other stakeholders. CMS has extended the deadline for registering for these meetings.
Source: Inside Health.

Congress Continues to Discuss IRA Changes: Possible changes to the IRA statutory provisions remain a topic of discussion in Congress. Most recently, House lawmakers reintroduced the ORPHAN Cures Act, which would expand the scope of the exclusion of orphan drugs from IRA negotiations and would toll the seven- or 11-year negotiation clock for periods when the drug was an orphan drug.
Source: Law360.

Manufacturer Legal Challenges to the IRA Continue: Litigation challenging the IRA's drug pricing negotiation program continues, with various drug manufacturers filing briefs and oral argument taking place in the US Court of Appeals for the Second Circuit.
Sources: Law360, Bloomberg (link, link), SmartBrief.

The Cell and Gene Therapy (CGT) Access Model Continues: The Trump administration has cancelled two of the three prescription drug payment models that the Center for Medicare & Medicaid Innovation (CMMI) had announced in 2023 in response to a Biden executive order. The cancelled models are the "Medicare Two Dollar Drug List Model" and the "Accelerating Clinical Evidence Model." The third model, the CGT Access Model, was not subject to cancellation. According to CMS, "the two drug manufacturers of gene therapies for treating sickle cell disease…have each entered into separate agreements with CMS to participate." The enrollment period for states ended in March 2025.
Source: Inside Health.

Medicaid Drug Rebate Program (MDRP)

Dr. John Coster Retires From CMS: After a long and distinguished career in government service, Dr. John Coster retired from CMS on February 27. In connection with his most recent role as a senior technical advisor to the IRA's Medicare Drug Rebate Negotiation program, Dr. Coster acknowledged that duplication of the 340B discount and the Maximum Fair Price could pose a problem. He stated that handling deduplication "would be a huge undertaking" and that the 340B program is "very complex." He noted that CMS "would probably need the authority to compel 340B entities to report claims data to the agency" and acknowledged that "I understand the manufacturers' frustration… It's in everybody's interest to reduce the 340B duplication or eliminate it, ideally" and that the "ideal solution" would be "at the time of dispensing to put a modifier on the claim indicating it's 340B."
Sources: Pink Sheet, LinkedIn.

340B Program

Additional States Adopt Contract Pharmacy Laws: Various states recently adopted or introduced legislation that would bar drug manufacturers from restricting contract pharmacy access, with some bills also requiring 340B pricing to be available at the time of sale as opposed to as a rebate. These states are Colorado, Idaho, Kansas, Maine, Massachusetts, New Mexico, North Carolina, North Dakota, Oklahoma, Utah, Vermont, and Virginia. We note that legislative action related to 340B may have occurred in other states but has not yet been reported in the trade press.
Sources: Law360, 340B Report (Colorado, Idaho, Kansas, Maine/Massachusetts, New Mexico (link, link), North Carolina, North Dakota, Oklahoma, Utah, Vermont, Virginia, Other States).

Arkansas took action to enforce its 340B contract pharmacy law enacted in 2021 by ordering one manufacturer to restore access to 340B drugs at all contract pharmacy "delivery locations" in the state.
Sources: 340B Report.

Litigation Regarding 340B Rebate Models Continues: Some drug manufacturers' attempts to provide the 340B discount as a rebate and not at the time of sale has led to litigation in the face of government threats of enforcement. In its first filing under the Trump administration, the HHS continued to oppose rebate models.
Sources: Bloomberg, Law360, 340B Report (link, link).

Manufacturer Contract Pharmacy Policies Continue to Evolve: Manufacturers continue to modify their contract pharmacy policies in response to state laws and other developments.
Source: 340B Report (link, link).

Nevada Covered Entity Challenge of STD Clinic Terminations Continues: A Nevada healthcare system earlier filed suit against HRSA challenging the agency's termination of some its STD clinics from the 340B program. In a public letter from December 2024, HRSA stated that the "sites failed to comply with this statutory eligibility requirement and failed to provide documentation to demonstrate receipt of section 318 funding or support." But during a recent court hearing, HRSA reportedly acknowledged that certain sites were in fact eligible for the 340B program, prompting the judge to delay ruling on emergency relief sought by the covered entity.
Sources: Bloomberg, 340B Report.

These and other STD sites are the subject of a lawsuit brought by manufacturers in December 2024, alleging that HRSA permitted certain STD clinics to participate in the 340B program without satisfying all statutory eligibility requirements.
Sources: Bloomberg, 340B Report.

Medicare Part B

No developments to report.

Medicare Part D

Government Report Highlights Reduction of Beneficiary Burdens Under IRA Redesign: A report from the Assistant Secretary for Planning and Evaluation (ASPE), the principal advisor to the Secretary of HHS on policy development, highlights how the IRA's redesign of the Part D benefit is expected to reduce beneficiary burdens. According to the report, the IRA's Part D spending cap is projected to help beneficiaries save $7 billion on prescription drugs. Each enrollee is expected to save $600 annually, with those who do not receive the low-income subsidy saving closer to $1,100 annually.
Source: Pink Sheet.

State Law Developments

No developments to report.

Contacts

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