



A Publix Supermarket pharmacy manager in Miami retrieves a bottle of antibiotics from the shelf.
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Federal, State Drug Pricing Plans Prompting Deeper Challenges

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Latham & Watkins' Christopher Schott shares how the policy and regulatory environment is likely to continue being hostile to pharmaceutical manufacturers.

The pharmaceutical industry faced pressure and uncertainty in 2023 and that will likely continue in 2024, partially because of the implementation and evolution of the Inflation Reduction Act. Meanwhile, states are expected to continue their increasingly aggressive attempts to regulate drug pricing.

The industry has responded with a greater willingness to challenge overreach in court. Pharmaceutical manufacturers will also face even greater scrutiny because of the 2024 campaign season.

The Centers for Medicare & Medicaid Services began to implement the health-care law's Medicare price control program in 2023 with the selection of the first drugs subject to forced negotiation.

CMS will publish the so-called maximum fair prices for these drugs by September. Its 2023 implementation guidance revealed an agency broadly asserting the powers it received under the health-care law. It will be instructive to see if that approach carries through in the published prices.

Pharmaceutical stock trends in 2023 suggest the market may not yet have fully embraced the law's possible impact, which could change in 2024. Multiple pharmaceutical manufacturers challenged the health-care law in court in 2023, largely on constitutional grounds.

These suits will continue through 2024, and it's likely the constitutional claims will be supplemented with as-applied challenges as the law begins to have real-world effects.

The law's Part D redesign and new manufacturer discounting program will largely take effect in 2025, but it will be important to monitor how Part D plans begin addressing the changes that impact them—and how the plans' reactions will flow through to the pharmaceutical industry.

CMS' new authority under the law is limited to the Medicare program, but the agency took a similarly bold approach when it proposed a Medicaid regulation in 2023 that, among other things, would allow CMS to publish what amounts to a "shame list" of the most expensive drugs in Medicaid.

The regulation is now listed on the Office of Management and Budget [website](#) with an action date of June 2024, but the election will likely be a factor in CMS' decision whether and when to publish the regulation in final form.

States Embrace Requirements

Uncertainty appears to be on the rise in the [340B program](#), under which participating manufacturers sell drugs to enrolled providers at a steeply discounted price. A district court invalidated the program's longstanding "patient" definition, and the multiple manufacturer challenges of the 340B contract pharmacy policy will continue into 2024.

The agency overseeing the 340B program, the Health Resources and Services Administration, has long sought greater authority to administer the program, but it's unclear if Congress will act on 340B in an election year.

States have become more interested in the 340B program. Arkansas, for example, has adopted a state law that mandates 340B contract pharmacy. This and similar laws have been challenged on preemption and other constitutional grounds, and these lawsuits also will continue.

States are also pursuing their own initiatives aimed at the pharmaceutical industry. After establishing so-called drug pricing transparency laws in recent years, states are progressing from disclosure requirements to potential price caps, such as Colorado with its Prescription Drug Affordability Review Board. While apparently focused at the state level, such initiatives could indirectly impact the federal programs, and legal challenges [are likely](#).

Election Season

Drug prices in the US have traditionally been set in the free market, and federal health-care programs have linked reimbursement rates to market prices, through the mechanism of manufacturer price reporting. In contrast, the Biden campaign is touting the government-imposed drug pricing model embodied by the Inflation Reduction Act.

The outcome of the 2024 election may determine whether the US keeps supporting aggressive drug pricing policies and moves further toward a European-style redistribution model with price controls. The Biden administration just took another step in this direction with the proposal to aggressively use march-in rights to override pharmaceutical patents.

There may even be bipartisan support for some measures, such as setting reimbursement levels for a therapeutic class rather than for a particular drug, and introducing an international reference pricing mechanism.

Outlook

A key industry challenge for 2024 will be responding to newly applicable legal requirements while tracking and responding to developments in Congress and at the state level.

But challenges can bring opportunities. A well-rounded team of business leaders and other internal and external experts can help formulate a commercial strategy that maximizes patient access while fostering the therapeutic innovation that has been the hallmark of the US pharmaceutical industry.

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