2023 halftime report

6 hot topics to keep an eye on for the remainder of this year and into 2024.

By **DEBORAH ABRAMS KAPLAN**

Spread pricing. Medicare drug negotiations. Rising retail health. They have been fodder for healthcare headlines, hashtags and tweets so far this year. They are also likely to have some staying power during the second half of 2023 and spillover into 2024. Here's a look at six topics and developments in healthcare and how they might play out over the next six months and beyond.

1 The rollout of Medicare price negotiation

Pharmaceutical companies were not happy when the Inflation Reduction Act (IRA) allowed Medicare to negotiate prices on some drugs it covered. The process starts this year on Sept. 1, when CMS will publish its list for the first 10 Medicare Part D drugs. In March 2024, manufacturers will receive CMS' offer for a maximum fair drug price to accept or counter, and on Sept. 1, 2024, CMS is scheduled to publish the prices. These prices will not go into effect until Jan. 1, 2026. In a laddered approach, 15 more drugs will be selected in 2024 for 2027 implementation, another 15 drugs covered either under Medicare Part D or Part B for 2028, and another 20 drugs for 2029 and later years.

The timing assumes no disruption from litigation, according to Howard Deutsch, a principal at ZS Associates, a management consulting and technology company. Merck, which is expected to have one of the 2023 drugs listed, filed a lawsuit in early June against the government, claiming First and Fifth Amendment violations, which was followed by lawsuits filed by the U.S. Chamber of Commerce and Bristol Myers Squibb. Although CMS published draft guidance in March on the negotiation process, Deutsch says he read all 90-plus pages of guidance and still was unclear on how pricing will work.


DEUTSCH

Deutsch says the CMS price negotiation isn't really a negotiation. "For all practical purposes, the government will set a price, and it will allow the pharmaceutical company to accept that price or be ruined in penalties." The target drugs for 2023 have not been explicitly announced, but "it's not like people are waiting with bated breath," Deutsch says, given the CMS parameter. Lists predicting which 10 drugs CMS will select the first year have been published, and they have included Eliquis (apixaban), Januvia (sitagliptin) and Jardiance (empagliflozin).

It is unknown how the CMS pricing will impact commercial payers, although the pricing will carry through to Medicare Advantage.

"We expect (commercial) payers will try to use that as leverage of sorts, but fundamentally, there's no new market leverage they'd have that they didn't have before," says Deutsch. "There are no strong reasons to believe manufacturers will have to change their discounting behaviors."

2 The bipartisan appetite for pharmacy benefit manager legislation

Pharmacy benefit managers (PBMs) were in the spotlight — and not in a favorable way — during the first half of 2023, as Congressional hearings were held and bills were introduced that would increase oversight and ban or restrict certain of their business practices. There is a bipartisan appetite for the PBM issues, says Adam Colborn, J.D., director of

government affairs at the Academy of Managed Care Pharmacy. "We (have) a divide in Congress. I think this is something parties will be motivated to move on just because there's not a lot of other territory to agree on." Colborn says his organization is watching three bills in particular: the Pharmacy Benefit Manager Transparency Act and the Pharmacy Benefit Manager Reform Act that were introduced in the Senate, as well as the Protecting Patients Against PBM Abuses Act that was introduced in the House.


COLBORN

"The top-line thread for all these bills is that they're drilling down on behaviors labeled as anticompetitive," Colborn says. The sponsors' goal is to improve transparency and competition between payers, he explained. The bills mostly target spread pricing, the margin between what a plan sponsor is charged, and what the PBM pays pharmacies for a prescription. The bills also contain language about reporting to CMS.

So far, it's largely been a one-sided conversation, according to Colborn . "We haven't seen a ton of engagement from the payer community or from the other PBM folks in the space."

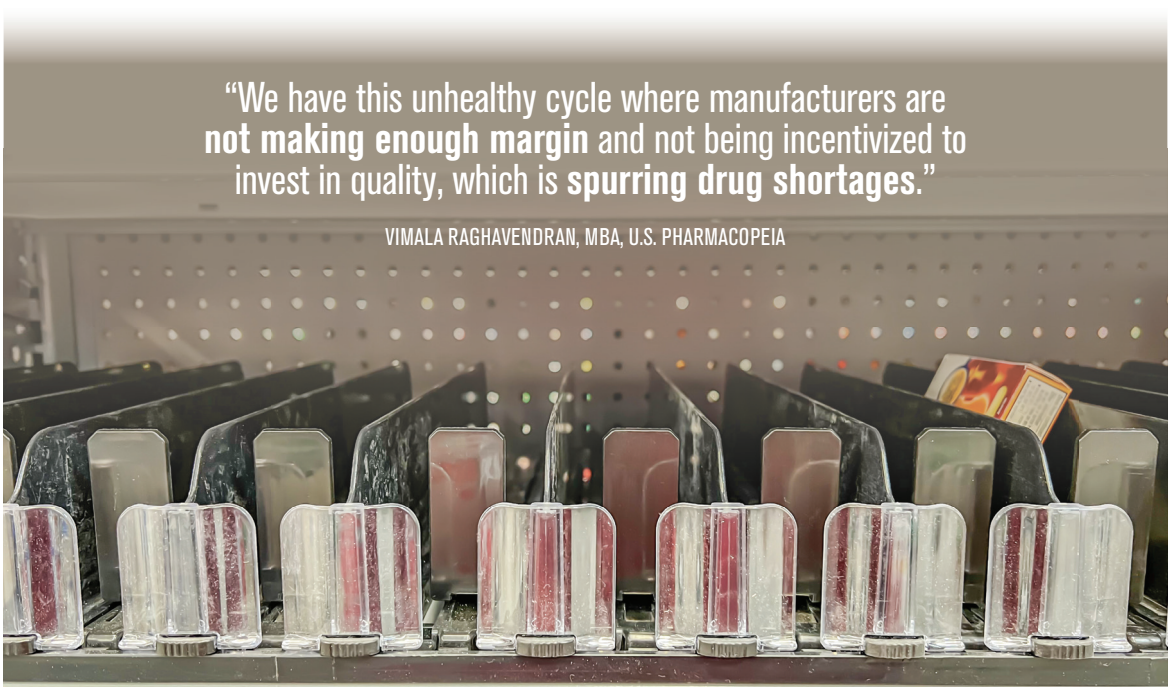
Eventually, the various PBM-related pieces of legislation are likely to be rolled into one bill, predicts Erin McKeon, associate director of federal advocacy at the Crohn's and Colitis Foundation. McKeon says she expects a bill to pass during this Congress, but that could mean sometime next year. Part of the current political dynamic is that the various committees and their chairs and ranking members are maneuvering to take credit for whatever law finally emerges, observes McKeon.

3 The empty medicine cabinet

Medication shortages are at their highest numbers since 2014 and have affected drugs for a wide range of conditions and medical purposes, including cancer treatment, ADHD and local anesthetics.

"We have seen this tremendous spike in drug shortages," says Vimala Raghavendran, MBA, vice president of informatics product development for U.S. Pharmacopeia (USP), an independent, scientific nonprofit organization. "These shortages have also been lasting longer, with more severe patient impact."


RAGHAVENDRAN



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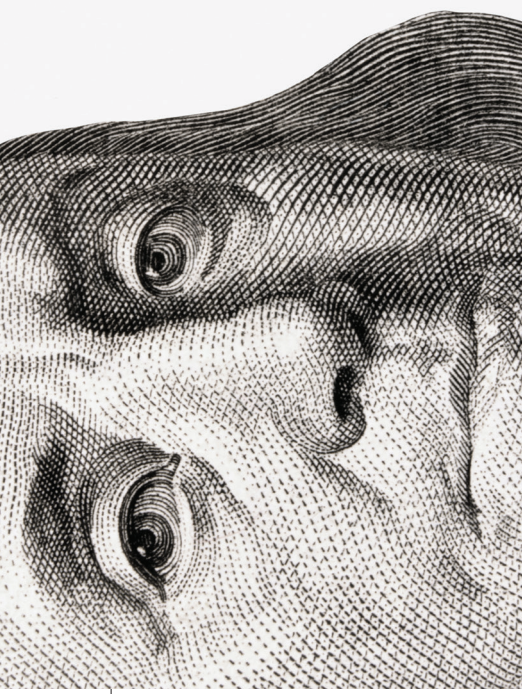
> FRANÇOIS DE BRANTES, M.S., MBA, HIGH VALUE CARE INCENTIVE ADVISORY GROUP



One reason for this shortage is "tremendous economic pressure on the generic industry over the (past) several years, driving down prices," she says. "We have this unhealthy cycle where manufacturers are not making enough margin and not being incentivized to invest in quality, which is spurring drug shortages." Some expensive brand-name drugs are also in short supply for other reasons.

The shortages are drawing government attention. Both the House and Senate held hearings this spring, and the White House is also looking into it. USP is advocating for an early warning system for drug shortages, coordinated with government and private sectors. They created a Medicine Supply Map to increase visibility into the supply chain.

4 Pulling back the curtain on prices

François de Brantes, M.S., MBA, senior partner at High Value Care Incentives Advisory Group and a member of the *Managed Healthcare Executive* editorial advisory board, says we'll look back in a decade and say that now through 2024 will be seen as a turning point for U.S. healthcare, with transparency replacing opacity when it comes to prices. As of July 1, 2022, group health plans had to begin posting pricing information for third parties, with additional milestones in 2023 and 2024. "The intent of the legislation is clear: Can we arm consumers with the information they need to make more informed choices?" de Brantes says.

The next 18 months are vital, given the long cycle for health plans and employer contracting. There is a latency between when employers publish their requests for proposals, get carrier quotes and implement those contracts. Last year, consultants had difficulty making sense of the large amount of plan data. Going into this fall, de Brantes says, they are more prepared.

"(For decades), employers have been unable to understand the differences in the price of healthcare. That means no control or accountability around rate increases," he said, adding that the law will continue creating appropriate tension in the market, including for employers. "It's based on the realization that (employers and employees) are getting a raw deal. And (although) people kind of know it, if it's not in your face, you can choose to ignore it. But when it's in your face, it's public and it's made simple and useful. As an employer, you can't ignore it. I think the difference between where we are today and where we will be a year from now is going to be quite significant."

5 Retailization of healthcare

The increasing reach of retail primary healthcare is a trend worth watching the rest of this year and beyond, according to industry observers who point to CVS Health's recent acquisitions of Oak Street Health and Signify Health. Oak Street Health is a primary care company, whereas Signify Health is a home health company. CVS' retail pharmacy chain rival, Walgreens Boots Alliance, is the majority owner of VillageMD, a primary care provider with several hundred locations that has made some major acquisitions, including the purchase of Summit Health-CityMD, a large

provider group and urgent care company. Amazon shut down its Amazon Care, its virtual care unit, last year, but the company has acquired One Medical, a concierge medical business.

"Patients want high-quality care, but they also want care on their terms," says Brad Younggren, M.D., chief medical officer for 98point6, a former virtual care provider that is now a software-as-a-service company.

The retailer-turned-primary-care-provider could further fragment U.S. healthcare delivery, Younggren warns. "If you show up in the emergency department at 2 in the morning with hypertension, it's probably not because it's an emergency; it's probably because you got a higher reading and you just didn't know what to do with it, and there's nowhere to go but the ED."

One benefit that retail health offers is more digital health options, which can lead to a better patient experience. Younggren's company currently provides services to health systems. He anticipates that in the next two years many of the larger ones will be putting greater emphasis on the digital patient experience to ensure that they don't become disintermediated from their traditional patient populations.

Virtual care is one type of digital healthcare, which is something that gained greater acceptance during the COVID-19 pandemic. As the pandemic wore on and the public health emergency ended, many health systems decreased the numbers of virtual care cases for a variety of reasons, Younggren says. Yet, at the same time, health system executives accept that they need a digital strategy to compete, in Younggren's opinion. "There's no going back to a nondigital approach to managing your regional population."

Health systems are trying to determine how to integrate digital technology with brick-and-mortar assets. That might include using technology to help doctors more efficiently chart, or to provide more comprehensive patient background before clinician visits. Digital tools can potentially enhance both the patient and provider experience, including administrative aspects.

For a whole set of interlocking reasons, health systems are feeling the pressure to improve the patient experience, including competition from One Medical and Carbon Health, a primary and urgent care company that emphasizes technology. "Health systems are now talking about patient experience, almost like a technology company would," Younggren says.

6 Medicaid best price and prescription digital therapeutics

The PBM legislation isn't the only game in town when it comes to federal legislation.

One bill that Colborn and others are keeping an eye on would codify the existing Medicaid best price rules that were revised to allow Medicaid programs to enter value-based contracts for drugs. "The goal of that is to incentivize further use of value-based contracting for high-cost medicines in Medicaid programs," Colborn says. Although the issues involved are important to Medicaid programs and pharmaceutical companies, they are technical and unlikely to garner little, if any, attention from interest that aren't affected. The Medicaid Valued-Based Purchasing for Patients Act has bipartisan support and was voted out of committee a month after it was introduced.

The Access to Prescription Digital Therapeutics (PDT) Act of 2023 is another bill that has bipartisan support and important consequences but is of limited interest to those not directly involved. The bill would create reimbursement categories for PDTs to be covered by Medicare. PDTs have been developed to treat insomnia, substance use disorders and attention-deficit disorder, although at this point they are new and don't have much of a track record behind them.

"Now Medicare can't cover them at all; there's no benefit category. It doesn't fit into any existing nondrug categories," Colborn says. Proponents of Medicare coverage note that commercial plans can choose to cover PDTs, leading to possible disparity between commercial payers increasing access to PDTs without a similar coverage under public plans.

Colborn acknowledges that the IRA is taking up most of the healthcare political bandwidth these days. "The main thing everyone is thinking about is the IRA implementation. It's probably 90% to 95% of what we hear about."

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