Tuesday, December 14, 2021

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New Reports Issued on Drug Access and PBM Accountability

On December 1, the Institute for Clinical and Economic Review (ICER) released a new report, examining whether insurance plan coverage for certain drugs is fair for patients. On December 2, the PBM Accountability Project released a new report that found pharmacy benefit managers realized a 12% increase in gross profits between 2017 ($25 billion) and 2019 ($28 billion). **Read below.**

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Earlier today, the Senate Committee on Health, Education, Labor, and Pensions held a confirmation hearing with Dr. Robert Califf. **Read below.**

Oversight Committee Holds Final Hearing on Drug Pricing Probe

On December 10, the House Committee on Oversight and Reform held a hearing on the final report of its three-year investigation into pharmaceutical pricing and business practices for widely used prescription drugs. **Read below.**

FULL STORIES

President Biden Signs Medicare Payment Fix Into Law

On December 10, President Biden signed a bill into law averting Medicare physician payment cuts previously scheduled to begin on January 1, 2022. The Protecting Medicare & American Farmers from Sequester Cuts Act was passed through both the House and Senate last week, receiving bipartisan support.

The bill makes a number of welcomed changes to avert payment cuts of approximately 10% to oncology as finalized under the CY 2022 Physician Fee Schedule (PFS), including:

- An extension of Medicare sequestration relief through March 2022. From March through June 2022, a 1% sequester would be applied before returning to the pre-pandemic 2% sequester in July. This is paid for by increasing the sequester applied in 2030 – to 2.25% for the first half of the year and 3% for the second half.
- A 3% bump in the CY 2022 PFS conversion faction (CF). This will result in a net -0.75% CF reduction from the temporary increase enacted for CY 2021, but a 3% increase from CMS' final rule.
- A 1-year delay in CMMI's Radiation Oncology (RO) Alternative Payment Model, which will now begin on January 1, 2023.
- A provision preventing a new 4% Medicare sequester from taking effect. The bill advances FY 2022 PAYGO scorecard balances otherwise triggering a sequestration order into FY 2023, delaying the potential cuts.
- A 1-year delay in clinical lab reporting and payment cuts included in the Protecting Access to Medicare Act (PAMA) of 2014. The December 31, 2021 reporting deadline used to establish Medicare rates would be extended to December 31, 2022.

Action on the Medicare payment cuts comes after Congress failed to include a fix in a temporary spending bill passed on December 2, keeping the government funded through February 18, 2022. The Network immediately responded to this omission by sending a letter to Congressional leadership, urging legislation to fix the Medicare payment cuts before the end of the year.

To read the text of the bill, CLICK HERE.

To read a copy of the letter The Network sent Congressional leadership, CLICK HERE.

Senate Work Continues on Build Back Better Act

Since the November 19 House passage of the Build Back Better Act containing several drug pricing measures, the Senate has set an end-of-year goal to finish its work. Several Senate committees have reported modified language and updated cost estimates of the legislation from the Congressional Budget Office (CBO). However, it is still unclear whether the Senate can pass the bill before the end-of-the year and whether it has unanimous support from Senate Democrats.

The healthcare and drug pricing provisions reported by the Senate Finance and Health, Education, Labor & Pensions (HELP) Committees remain largely identical to the House-passed bill, including:

- Medicare drug pricing negotiation program for certain Part B & D products that lack competition. Negotiated prices (Maximum Fair Prices) would begin in 2025 for Part D and 2027 for Part B.
- Medicare rebates on manufacturers increasing list prices above the rate of inflation.

- Temporary, 5-year add-on payment increase for biosimilars (+8% instead of +6%).
- Part D benefit redesign and new $2,000 annual out-of-pocket max for beneficiaries.
- New transparency reporting requirements on PBMs.
- New $35 monthly coinsurance cap for insulin products.
- Permanent repeal of the Trump Administration's rebate rule.

As the Senate considers the legislation, healthcare industry stakeholders are expressing concern, particularly with the drug negotiation proposal. The Pharmaceutical Research Manufacturers of America (PhRMA) continues running advertisements pointing the finger at pharmacy benefit managers – "middlemen" who should be passing along savings to patients at the pharmacy counter. The proposal is also being opposed by the generic drug industry, which claims that if the bill is enacted as written, it could cause branded drugs to maintain their monopolies for longer and delay dozens of biosimilars from entering the market because negotiation could undercut generic drugs' competitive advantage. Finally, a recent Avalere analysis found the BBBA's negotiation program could lead to a 40% average cut to Medicare Part B providers, though some reporting has challenged the methodology of the research.

In response to the BBBA Medicare drug price negotiation provisions, The US Oncology Network issued a statement warning the proposal "could lead to unintended consequences in patient care." The Network called on Congress to consider the downstream impacts that price negotiation could have on community oncology practices and Americans with cancer.

To read about the generic drug industry's opposition to BBBA, CLICK HERE.

To read the report by Avalere, CLICK HERE.

To read the article challenging the Avalere analysis, CLICK HERE.

To read The Network's statement on the BBBA, CLICK HERE.

340B Case Proceeds to The Supreme Court

On November 30, the Supreme Court heard arguments in a lawsuit over Medicare reimbursement of 340B drugs that could impact how hospitals are reimbursed under the drug discount program in the future. The ruling could have wide-ranging implications on the 340B program and the bounds of administrative law – known as Chevron deference.

The Supreme Court case was brought by the American Hospital Association (AHA) against the Department of Health and Human Services (HHS) after CMS cut hospitals reimbursement for 340B drugs by nearly 30 percent beginning in 2018, from average sales price (ASP) +6% to ASP -22.5%. A decision in the case is expected by June 2022.

A handful of other 340B cases made their way through federal courts, addressing the extent of the Health Resources and Services Administration's (HRSA) authority and its conflicting interpretation of the 340B statute. The cases largely concern the authority of HRSA to issue guidance related to the use of contract pharmacies, the validity of an HHS advisory opinion requiring drugmakers to include contract pharmacies in the program, and the validity of enforcement letters alleging pharmaceutical companies violated the law by implementing policies excluding contract pharmacies from participation.

Amgen recently became the tenth drug manufacturer to cut off contract pharmacy access to discounted drugs, potentially exposing the company to fines from the Biden Administration. Advocacy

group 340B Health is calling on the Biden Administration to do more to stop drugmakers from cutting off discounted sales to contract pharmacies as manufacturers continue to express concern that the program facilitates duplicate discounts.

To read the oral argument transcript in *AHA v. Becerra*, CLICK HERE.

To learn more about other 340B court decisions, CLICK HERE.

To learn more about drugmakers limiting 340B pharmacies, CLICK HERE.

New Reports Issued on Drug Access and PBM Accountability

On December 1, the Institute for Clinical and Economic Review (ICER) released a new report, "Assessment of Barriers to Fair Access," which examined whether insurance plan coverage for certain drugs is fair for patients.

The researchers created a set of new of appropriateness criteria to help policymakers and healthcare stakeholders understand where coverage aligns with the elements that determine if patients are gaining fair access to pharmaceuticals. The criteria include prescriber restrictions, eligibility based on clinical data, and step therapy requirements. In analyzing 28 drugs across 15 of the largest commercial formularies, the ICER report found that many health plans seem to provide access to medications in a fair way.

However, a major caveat to the report is that many health insurers are not transparent about how they implement their prescription drug policies, making it difficult for researchers—much less patients—to understand how fair the coverage was. In all, ICER was only able to assess fairness based on 7 of 20 total criteria it had previously identified to conduct its analysis. The report underscores the need to increase health insurance transparency.

On December 2, the PBM Accountability Project, released a new report that found pharmacy benefit managers realized a 12% increase in gross profits between 2017 ($25 billion) and 2019 ($28 billion). As the healthcare landscape changed over that time, PBMs shifted their sources of revenue in order to adapt to new competitive pressures, contracting practices, and scrutiny from the public. The report also found that high complexity and information asymmetry in the market prevent payers and patients from properly evaluating PBM decisions or drug costs. It also concluded that PBM growth is driven by a lack of meaningful PBM industry standards, limited transparency, and lack of regulatory oversight.

The researchers predicted that PBMs will continue to benefit from misaligned incentives – including list price increases – and utilize multiple avenues to derive revenue throughout all parts of the pharmaceutical supply chain.

To read the new ICER report, CLICK HERE.

To read the new PBM Accountability Project report, CLICK HERE.

FDA Nominee Califf Testifies to Senate HELP

Earlier today, the Senate Committee on Health, Education, Labor, and Pensions held a confirmation hearing with Dr. Robert Califf. The Committee questioned Califf on a variety of issues in order to better understand how he might set FDA policy if confirmed. In one exchange with Senator Bernie Sanders (I-VT), Califf expressed support for Medicare drug price negotiation as well as increased utilization of generics/biosimilars.

In early December, news outlets reported that President Biden's nominee to lead the Food and Drug Administration (FDA), Dr. Robert Califf, plans to keep Acting Commissioner Dr. Janet Woodcock on to continue playing a leadership role at the agency. While it is not clear what role she would play, if any, were Califf to be confirmed, insiders have speculated that Woodcock could serve as Principal Deputy Commissioner. Woodcock will continue to serve as Acting Commissioner until Califf is formally confirmed by the Senate.

To watch Dr. Califf's confirmation hearing, CLICK HERE.

Oversight Committee Holds Final Hearing on Drug Pricing Probe

On December 10, the House Committee on Oversight and Reform held a hearing on the final report of its three-year investigation into pharmaceutical pricing and business practices for widely used prescription drugs. The hearing, "Unsustainable Drug Prices: Findings from the Committee's Drug Pricing Investigation and the Need for Structural Reforms," called for implementing structural reforms to lower prescription drug prices, including allowing Medicare to negotiate prices for certain expensive drugs and placing a cap on out-of-pocket costs for patients.

In a press conference with Democratic leadership, Chairwoman Carolyn Maloney said the Committee's investigation highlights the need to pass the Build Back Better Act to lower prescription drug prices and make medication more affordable for millions of people in the United States. The report, which was drafted by the Committee majority, found that pharmaceutical companies increased the costs of common brand-name drugs during the past five years by nearly four times the rate of inflation. According to the lawmakers who drafted the report, the price hikes are substantially higher than investments in research and development (R&D), which the drug industry often points to justify increasing drug costs.

On the same day, the Republican minority of the Committee released its own report on pharmacy benefit managers (PBMs), claiming that they are a primary driver of the growth of drug spending. The report argues that PBMs use their market leverage to increase their profits – not reduce costs for consumers – and that pharmaceutical companies raise their prices due to PBM practices.

To watch the hearing, CLICK HERE.

To read Chairwoman Maloney's press release about the report, CLICK HERE.

To read the majority's report on drug pricing, CLICK HERE.

To read the minority's press release about their report, CLICK HERE.

To read the minority's report on PBMs, CLICK HERE.