

Healthcare & Life Sciences Practice

Drug Pricing Digest

November 7, 2022 | Number 40

Inflation Reduction Act and Health Reform: The Centers for Medicare & Medicaid Services (CMS) is continuing its efforts to staff the new Medicare Drug Rebate and Negotiations group and has [posted](#) various related job openings. According to CMS Administrator Chiquita Brooks-LaSure, CMS has also begun conversations with stakeholders, such as “health plans who are trying to figure out how are they going to incorporate what we’re doing into the benefits for people” and “companies and how are they going to submit the data.”

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

Meanwhile, commentators are reviewing the potential impact of the Nov. 8 midterm elections on the pharmaceutical industry, and manufacturers expressed concerns that the Inflation Reduction Act (IRA) jeopardizes cancer drug innovation.

Sources: [BioWorld](#), [Scrip](#)

To learn more about the IRA’s key provisions regarding the pharmaceutical industry, please see this Latham & Watkins [Client Alert](#). It provides a roadmap to the legislation that presents the topics in a thoughtful order, while providing citations to the IRA for easy reference to the legislative text.

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: Oral arguments took place in two of the contract pharmacy lawsuits brought by manufacturers:

- On Oct. 24, 2022, a three-judge panel of the US Court of Appeals for the District of Columbia Circuit heard oral argument in *United Therapeutics Corp. v. Johnson*, No. 21-5304 (D.C. Cir.) and *Novartis Pharmaceuticals Corp. v. Johnson*, No. 21-5299 (D.C. Cir.). Much of the judges’ questioning was focused on what constitutes a true offer of the 340B price by the manufacturer. **Source:** 340B Report ([link](#), [link](#))
- On Oct. 31, 2022, a three-judge panel of the US Court of Appeals for the Seventh Circuit heard oral argument in *Eli Lilly & Co. v. Becerra*, No. 21-3128 (7th Cir.). The main issue raised in the judges’ questioning was whether the court has jurisdiction or whether Eli Lilly’s challenge to the government’s enforcement letter is premature.

Sources: [Bloomberg Law](#), [Law360](#), 340B Report ([link](#), [link](#))

The US Court of Appeals for the Third Circuit is scheduled to hear oral argument on Nov. 15 in three consolidated cases, brought by Sanofi Aventis, Novo Nordisk, and AstraZeneca.

Source: [Law360](#)

Medicare 340B Reimbursement Policy Litigation Updates: See the discussion of the 2023 Hospital Outpatient Prospective Payment System (OPPS) final rule in the Medicare Part B section below.

Covered Entity's "Patient" Definition Challenge Continues: Litigation continues related to Genesis Healthcare Inc.'s challenge to the "patient" definition set forth under guidance from the Health Resources and Services Administration (HRSA). The litigation is discussed in more detail in Issue [No. 31](#) of this digest.

Source: [340B Report](#)

MEDICARE PART B

CMS Releases Slew of Final Rules: CMS has issued the following final regulations and Healthcare Common Procedure Coding System (HCPCS) decisions:

- **2023 Physician Fee Schedule (PFS) Final Rule:** This regulation is set to reduce payments to various medical providers, while expanding access to various healthcare services, such as behavioral health and dental care.
Sources: [Bloomberg Law](#), [InsideHealthPolicy](#) ([link](#), [link](#))
- **2023 Hospital Outpatient Prospective Payment System (OPPS) Final Rule:** This regulation will increase payment rates for hospital outpatient departments and ambulatory surgical centers, while imposing a reduction in payments on hospitals that do not meet the outpatient quality reporting requirements.
Sources: [Bloomberg Law](#), [InsideHealthPolicy](#), [BioWorld](#)

In connection with the court-mandated change of the Medicare reimbursement rate for drugs purchased under the 340B program from Average Sales Price (ASP) minus 22.5% to ASP plus 6%, CMS states that it will address repayments to hospitals for periods from 2018 to 2022 in a separate rulemaking.

Sources: [InsideHealthPolicy](#), [340B Report](#) ([link](#), [link](#), [link](#))

- **Q3 2022 HCPCS Level II Coding Decisions for Drugs and Biologicals:** Pursuant to these coding decisions, CMS will, among other things, establish 36 new HCPCS Level II codes to separately identify products approved under the 505(b)(2) New Drug Application (NDA) or the Biologics License Applications (BLA) pathways that are not rated as therapeutically equivalent (TE) to their reference listed drug by the Food and Drug Administration. CMS is treating drug products that are not TE-rated as "single source drugs" pursuant to section 1847A(c)(6) of the Social Security Act, stating that "there is a programmatic need for each product to have a unique billing and payment code."
- **Revisions to Medicare Enrollment and Eligibility Criteria:** This final rule implements certain provisions of the Consolidated Appropriations Act of 2021, providing for Part B coverage of immunosuppressive drugs for end-stage renal disease (ESRD) patients, while also providing for Medicare coverage the month after enrollment and making other enrollment and eligibility changes.
Source: [Bloomberg Law](#)
- **2023 ESRD Prospective Payment System Final Rule:** This regulation will, among other things, increase payments to hospital-based dialysis centers, as well as freestanding dialysis centers. These facilities treat ESRD patients.
Source: [Bloomberg Law](#)

- [2023 Home Health Prospective Payment System Rate Update](#): This final rule updates Medicare payment policies and rates for home health agencies.
Source: [BioWorld](#)

STATE LAW DEVELOPMENTS

No developments to report.

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