Highmark's Weekly Capitol Hill Report

Issues for the week ending November 29, 2024

Federal Issues

Regulatory

Fourth Drugmaker Pushes for 340B Rebates

The drugmaker Bristol Myers Squibb (BMS) is asking a federal court to enable the company to impose a 340B rebate model for one of its drugs. BMS follows Johnson & Johnson (J&J), Eli Lilly, and the drug industry vendor Kalderos in suing the government over the 340B rebate issue. Sanofi also is pursuing its own model but to date has not filed a lawsuit regarding its attempt to require rebates.

BMS said it informed the Health Resources & Services Administration (HRSA) last month that it planned to replace upfront discounts for its anticoagulant drug *Eliquis* with back-end rebates for all covered entities (CEs) starting in early 2025. The agency rejected that plan, as it did with similar rebate proposals from J&J and Lilly, because the drugmaker had not received approval from the Health and Human Services (HHS) secretary for the model. The BMS lawsuit asks the U.S. District Court for the District of Columbia to declare that HRSA is taking an unlawful position, set aside the agency's

In this Issue:

disapproval of BMS's rebate plan, and block any federal enforcement actions against the drugmaker for pursuing rebates.

In its complaint, BMS makes similar arguments to those of the other drug companies attempting to impose 340B rebates. The drugmaker claims the 340B drug discount program is "rife with abuse" and that the rebates are necessary to combat diversion, duplicate discounts, and instances in which multiple CEs claim 340B pricing on the same unit. BMS also says the only way to ensure nonduplication of 340B pricing and the maximum fair price (MFP) under the Inflation Reduction Act (IRA) would be to implement rebates.

Hospitals and other covered entities believe the BMS legal arguments, like the others, are completely meritless, and strongly deny the program abuse allegations, and instead insist the drug manufacturers are simply putting profits over patients.

Why this matters: Bristol Myers Squibb, like J&J, Eli Lilly and Sanofi, does not have the legal authority to change how the 340B payment model works. Moving to a rebate scheme would violate the 340B statute's requirement that drugmakers provide eligible drugs 'for purchase at or below the applicable ceiling price' and would conflict with HRSA's longstanding interpretation of that language as requiring upfront discounts.

This unlawful rebate scheme undermines the very foundation of the 340B program, which is designed to provide discounted pricing at the time of purchase. What's more, this shift would impose massive financial and administrative burdens on 340B hospitals, which serve vulnerable patients and underserved communities.

Hospitals will continue to strongly oppose drugmaker 340B rebates and advocating

- **CMS Publishes Marketplace 2025 Open Enrollment Period Report: National Snapshot**

that HRSA use its enforcement authority to block any such rebates from taking effect.

CMS Establishes New Model for Kidney Transplant Programs
The Centers for Medicare & Medicaid Services (CMS) last week finalized a rule establishing a new, six-year mandatory model that aims to increase access to kidney transplants, improve quality, and reduce disparities among patients undergoing the process to receive a kidney transplant. The program begins on July 1, 2025.

Background: The Biden administration released a new mandatory model for transplant hospitals that seeks to "spur innovation nationwide by evenly distributing the model's effects across the nation while engaging more specialists in value-based care."

The administration has stated it wants to update the transplant model, with nearly 90,000 people on the waiting list and only 28,000 organs procured. Key priorities include care coordination, building "patient-centeredness in the process of being waitlisted for and receiving a kidney transplant," and greater access.

The new model provides "two-sided risk management," offering an incentive to perform more transplants and a disincentive to perform fewer. It also includes performance measures around efficiency (rates of accepting organs offered) and post-transplant outcomes.

CMS is selecting half of the donation service areas (DSA) in the country and all eligible kidney transplant hospitals within those DSAs to participate in the model, for a total of 103 kidney transplant hospitals.

Why this matters: Following feedback on the proposed rule—including comments from the hospital community—CMS delayed the model start date to July and increased the maximum amount a transplant hospital can receive through its upside risk payment from $8,000 to $15,000 per Medicare kidney transplant.

The agency also removed three quality measures and adjusted the transplant target to reflect the average number of deceased or living donor transplants during the baseline years rather than the highest count. It also removed the requirement for providers to review organ offers declined on behalf of the attributed patient.

The **final rule** and a **fact sheet** are available online.

CMS' 2026 Medicare Advantage/Part D Proposed Rule Includes Coverage of Anti-Obesity Medications & New Prior Authorization Requirements

CMS released the Contract Year (CY) 2026 Medicare Advantage (MA) and Part D proposed rule.

Key proposals include:

- **Anti-obesity medication coverage** – Reinterprets the statute to provide Part D coverage of anti-obesity medications when used for weight loss or chronic weight management for the treatment of obesity. This reinterpretation would also apply to the Medicaid program.

- **Prior Authorization rules** – Establishes additional requirements for Medicare Advantage plans, including restrictions on reopening approved authorizations for inpatient hospital admissions.

Next steps: Comments are due to CMS by January 27, 2025. The rule was proposed under the Biden Administration, but the Trump Administration will make the decision on what, if any, provisions will be finalized.

Go deeper: View the proposed rule, CMS fact sheet, and CMS press release.

DEA Extends Tele-Prescribing of Controlled Substances through 2025

The Drug Enforcement Agency (DEA) announced it would extend flexibilities that allow for tele-prescribing of certain controlled substances through December 31, 2025.

Background: The flexibilities, which have been in place since 2020, allow for Schedule II - V controlled substances to be prescribed by a practitioner without the need for an in-person medical evaluation.

Why this matters: The flexibilities allow prescribing of medications, including those to treat opioid use disorder (OUD). AHIP submitted comments to DEA in support of expanding access to care through telehealth, with appropriate guardrails. The extension enables the DEA and HHS to continue to consider public feedback and permanent rulemaking.

CMS Payment Year 2018 Risk Adjustment Data Validation (RADV) Audits

On Nov. 15, CMS released its audit methods and instructions for MAOs with contracts selected for a PY 2018 contract-specific RADV audit. CMS also published a Q&A document to address general and payment year specific questions about the MA RADV program and the current audit process.

Why this matters: Included in the Q&A is a full listing of plans selected for the audits. Plans selected should expect to be issued a formal notice from CMS. These notices

follow the issuance of CMS's final rule (88 Fed. Reg. 6643 (Feb. 1, 2023), amending 42 C.F.R. 422.310(e). Pursuant to the rule, CMS has the authority to extrapolate audit findings for PY 2018 and beyond. CMS has noted the extrapolation methodology it adopts for RADV audits will be focused on MAO contracts that, through statistical modeling and/or data analytics, are identified as being at the highest risk for improper payments. If imposed, CMS will share with MAOs its extrapolation methodology.

DOL, Treasury, and HHS Extend Certain ERISA-Related Deadlines for Helene and Milton Impacted Areas

On November 8, 2024, the Departments of Labor (DOL) and Treasury issued guidance extending deadlines (through May 1, 2025) related to retirement, health, and welfare plans in response to recent hurricanes and tropical storms. The Department of Health and Human Services (HHS) followed with a similar bulletin on November 14, 2024. The guidance covers the following:

- EBSA Disaster Relief Notice 2024-01 extends the time for plans to furnish required notifications and provides that a plan will not be in violation of the Employee Retirement Income Act of 1974 (ERISA) if there is a good faith effort to furnish the documents as soon as possible.

- Final Regulations suspends participant Consolidated Omnibus Budget Reconciliation Act (COBRA), Health Insurance Portability and Accountability Act (HIPAA) special enrollment, and claims/appeal-related deadlines.

- FAQs for Participants and Beneficiaries aids participants impacted by the storms in understanding their rights under ERISA.

- Insurance Standards Bulletin Series encourages health insurance issuers and non-federal governmental plans to also extend participant deadlines and provides non-enforcement relief.

Industry Trends

Policy / Market Trends

Data Show Two Years of Cuts to MA Cause Higher Costs, Reduced Benefits for Seniors

Two consecutive years of cuts to MA payment rates have resulted in fewer options, higher out-of-pocket costs and reduced supplemental benefits for seniors and individuals with disabilities in 2025, according to several recent analyses highlighted by AHIP.

Fewer Options: Following the cuts to MA, seniors have fewer MA offerings to choose from and, in some cases, MA plans have had to exit the market, causing over 1 million

beneficiaries to lose their current coverage and forcing them to choose new coverage for 2025.

Higher Out-of-Pocket Costs: While national average premiums will fall slightly in 2025 (to $17, down from $18.23 in 2024, according to CMS), enrollees in some states will see significant premium increases. Cost sharing for services will also increase.

Reduced Supplemental Benefits: The vast majority of plans will continue to include dental, vision, and hearing coverage. However, payment cuts have resulted in reductions in other supplemental benefit offerings for 2025.

Go deeper: Click here to view the full data and click here to view an infographic highlighting the value of MA over fee-for-service Medicare.

Interactive Map: Positive Impact of Enhanced Tax Credits by State, Congressional District

More than 21 million Americans – including families, entrepreneurs, early retirees, gig workers and farmers – choose to enroll in affordable, high-quality health care coverage through the Marketplace. The broad-based coalition Keep Americans Covered launched an interactive map with state- and congressional district-level data demonstrating the positive impact of enhanced premium tax credits that help millions of Americans afford coverage through the individual market.

What's included:

- The **number of enrollees** currently receiving premium tax credits.
- How much higher, on average, **premiums** would be this year without enhanced tax credits.
- **One-pagers** for each congressional district with localized data that shows how premiums would increase on average without enhanced tax credits.

Why this matters: Without action by Congress, the enhanced tax credits will expire at the end of 2025.

Go deeper: Learn more about how the tax credits are helping deliver health, security and peace of mind for individuals with chronic conditions, Americans living in rural communities, and entrepreneurs and small business owners.

Health Equity Index Part C & D User Group Call

On Nov. 20, CMS held a Part C & D user group call to discuss the methodology of the health equity index reward factor being implemented for 2027 Star Ratings. While

materials weren't shared, a recording of the call was posted here. Key takeaways from our perspective are:

- There is no intention to publish HEI industrywide data, but CMS committed to sharing updated contract-level reports using data from the 2024 and 2025 Star Ratings in HPMS by the end of the year; they also mentioned sharing additional guidance via HPMS.

- Other FAQs were addressed including CMS' confirmation that the percentage of enrollees with social risk factors (SRFs) is determined using December enrollment for the most recent of the two measurement years (MYs); how the two years of data will be combined; the most up to date measures to be included in the HEI are already posted on HPMS but will be noticed annually in the Advance Notice/Rate Announcement; and other questions submitted in advance.

- CMS shared findings from their HEI simulation summary citing that,
  - Most contracts had no change in their highest Star rating (up or down) - 83% of MA-PD and 80% of PDP contracts had no change

  - Roughly the same number of contracts qualified for a hypothetical HEI reward as qualified for the current reward factor in the 2024 Star Ratings - 32% of MA-PD contacts qualified for a hypothetical HEI reward compared to 36% that qualified for the historical reward factor

  - The average HEI reward was similar for large (>1.5 enrollees across a contract) and small parent organization

  - CMS' conclusion slide included the statement that this is an upside-only reward

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CMS Publishes Marketplace 2025 Open Enrollment Period Report: National Snapshot

On November 22, 2024, CMS published a fact sheet highlighting open enrollment data so far for plan year (PY) 2025. They report that 496,000 consumers without current health care coverage and more than 2.5 million existing consumers have signed up for coverage in 2025. The fact sheet provides further breakdowns by state and platform.

If you have any questions regarding information included in Government Affairs *Capitol Hill Report*, please contact any of the following individuals:

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Delaware State Legislation: **http://legis.delaware.gov/.**
New York Legislation: **https://nyassembly.gov/leg/**
Pennsylvania Legislation: **www.legis.state.pa.us.**
West Virginia Legislation: **http://www.legis.state.wv.us/**
For copies of congressional bills, access the Thomas website – **http://thomas.loc.gov/.**