

CAPITOL STREET

November 3, 2025

Health Policy Peek: Week Of November 3-7

Gene Editing, MFN Deal(s), CMS Final ESRD, Outpatient & Home Health Rules, SCOTUS Orals on Tariffs

ICYMI

CY2026 Medicare Physician Pay Finalized: CMS finalized a specialist-friendly rule, similar to its proposed rule in July, with a new chronic disease CMMI pilot (our take [here](#)). For biopharma, ASP prices will be lower, along with reduced reimbursement for cell & gene and skin substitutes (our take [here](#)).

Two Overdue Medicare NCDs Finalized (MDT, BSX): CMS on Oct. 28 issued final National Coverage Determinations (NCDs) providing conditional coverage (Coverage with Evidence Development) for renal denervation procedures for uncontrolled hypertension (MDT and ReCor) and Cardiac Contractility Modulation for Heart Failure (Impulse Dynamics). Final NCDs can be found [here](#) and [here](#).

NDAA Negotiations Underway: According to *Politico* ([here](#)), staff from the House and Senate Armed Services Committees have begun the formal conference process to reconcile differences between the two chambers' versions of the annual defense authorization bill. Recall, the Senate version of the bill includes a watered-down version of the *BIOSECURE Act*, which we believe has a 70%+ chance of passage by year end (our take [here](#)).

USPSTF November Meeting Cancelled: According to *Axios* ([here](#)), HHS is cancelling its November meeting of the U.S. Preventive Services Task Force (USPSTF) due to the government shutdown.

WEEK AHEAD

Day 34 of Shutdown as ACA Open Enrollment Started 11/1: Rank-and-file senators from both parties appear to be shifting their tone in favor of a deal to end the government shutdown. Pressure points remain the extension of EPTCs and payments for the military and air traffic controllers. A federal judge ordered the Trump administration to deliver partial SNAP payments by Wednesday ([here](#)).

OUR TAKE: ACA open enrollment started Saturday (11/1). The shutdown may go through 11/10, as Republicans want to show premium sticker shock first before extending EPTCs. ACA premiums will double or triple for Americans and will be most severe for those aged 50-64 ([here](#)). We view one or two years as a likely extension timeline.

More MFN Deals Coming Soon: We expect additional MFN agreements to be announced as soon as this week, possibly from MRK, JNJ, LLY, REGN, or ABBV.

OUR TAKE: Pending CMMI demos (GLOBE, GUARD) likely exempt companies that agreed to voluntary MFN terms (PFE, AZN, EMD Serono). The three CEOs noted a sense of certainty on tariffs from MFN agreements

(our take [here](#)). We don't think the agreements will be cookie cutter; they are likely to be bespoke. What are MFN prices? We think G7 including Denmark + Switzerland.

CMS '26 Final Pay Rules (Outpatient Hospital, ESRD, & Home Health): CMS is expected to release more final rules with new policies and payment rates starting Jan 1, 2026.

OUR TAKE:

- **Hospital Outpatient:** We expect final rates similar to the proposal of +2.6% for proprietary hospitals ([here](#)). We expect there will be modifications to other policies: (a) site neutral for drugs, and (b) conducting a Medicare drug acquisition survey for 340B purposes likely moves forward ([here](#)). Our take on device-specific topics ([here](#)).
- **Home Health/DME Comp Bidding Coming:** We expect CMS to restart the DME competitive bidding program (CBP), with more color on timelines/product categories in a later announcement. We still think CGMs and insulin pumps are on the table for CBP, though we could see the agency narrowing the scope given pushback during the public comment period. We also expect some mitigation of proposed cuts of -6.5% for home health (our take [here](#)).
- **ESRD/Dialysis:** We expect final rates similar to the proposal of +2.1% for large dialysis organizations (LDOs) ([here](#)).

FDA Announcements on Non-Animal Testing & Gene-Editing: Commissioner Makary noted the agency will make an announcement on reducing animal testing (our take [here](#) and [here](#)). CBER Director Vinay Prasad also alluded to an announcement on speeding approvals of custom gene-editing treatments ([here](#)).

TUES, NOV 3

Election Day: Off-year elections, including governor's races in Virginia and New Jersey and mayoral contests in New York and Minneapolis.

WED, NOV. 5

SCOTUS Oral Arguments on IEEPA Tariffs ([here](#)): The Supreme Court will hear oral arguments on tariffs imposed under IEEPA authority, including those targeting Canada, Mexico, and China (fentanyl and illegal immigration), as well as global and reciprocal tariffs (trade imbalances). The legal challenge does not impact potential Sec. 232 tariffs on pharma or med tech.

OUR TAKE: In our view, SCOTUS is more likely to restrict the use of IEEPA authority to impose tariffs, despite the high court's 6-3 conservative majority. However, the Trump Administration could utilize another legal authority to implement tariffs (our take [here](#)). For example, 232 investigations on Pharma and MedTech could serve as a hedge should IEEPA tariffs be struck down by SCOTUS (our take [here](#) and [here](#)).

THURS, NOV. 6

MedPAC Meeting ([here](#)): The Medicare Payment Advisory Commission's (MedPAC) two-day meeting is contingent upon the status of the government shutdown. Discussion would include Medicare payment issues

and potential recommendations. As a reminder, yearly payment recommendations will be discussed at MedPAC's December meeting and voted on in January.

FDA Meeting on Generative AI-enabled Devices ([here](#)): The FDA's Digital Health Advisory Committee will make recommendations on generative AI-enabled digital mental health medical devices.

NOV 2025

IRA Drug Pricing - 2027 Negotiated Prices: CMS is expected to publish 2027 negotiated prices well before Nov. 30. As a reminder, 2027 selected Part D drugs (15 total) range from medicines for Type 2 diabetes to treatments for bipolar disorder & cancer.

OUR TAKE: 2027 prices are expected to vary and are likely to be lower (40%+ discounts) than prices for 2026 ([here](#)). MFN prices were likely in mind when initial offers were sent by CMS to manufacturers. There will be one negotiated price for selected drugs that share active moiety (Ozempic/Wegovy). We note that manufacturers have lost their appeals cases that challenged the grouping selection process by CMS (our take [here](#)). BI and AZN have appealed to the Supreme Court.

ON THE HORIZON

- FTC PBM 6B study final report **(TBD)**
- CMS proposed rule on "Medicaid Managed Care-State Directed Payments" **(TBD)**
- CMS proposed rule on "Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model" **(TBD)**
- CMS proposed rule on "Global Benchmark for Efficient Drug Pricing (GLOBE) Model" **(TBD)**
- CMS Draft MA & Part D technical rule **(Fall)**
- OIG report on Medicare pricing for CGM **(FY 2026)**
- CMS Final CY26 HOPD/ASC, Home Health & ESRD rules **(Early November 2025)**
- U.S. Trade Representative Public Meeting on USMCA joint review **(Nov. 17, 2025)**
- Deadline for CMS to publish 2027 negotiated maximum fair prices **(Nov. 30, 2025)**
- MedPAC meeting **(Dec. 4-5, 2025)**
- CMS New Technology Town Hall **(Dec. 10-11, 2025)**
- Expiration of APTCs and CLFS pay cut moratorium (PAMA) **(Dec. 31, 2025)**
- Deadline to pass the National Defense Authorization Act **(Dec. 31, 2025)**
- CMS MFP effective for selected drugs **(Jan. 1, 2026)**
- Initial date for Arkansas law banning PBM-owned pharmacies from operating within the state - delayed indefinitely due to injunction currently in effect **(Jan. 1, 2026)**
- CMS Medicare Advantage (MA) Rate Notice '27 **(January 2026)**
- MedPAC meeting **(Jan. 15-16, 2026)**
- CDC Advisory Committee on Immunization Practices (ACIP) meeting **(Feb. 25-26, 2026)**
- CMS pricing justification for 2027 negotiated drug list (15 Part D drugs) **(March 1, 2026)** See our take [here](#)
- MedPAC meeting **(March 2-3, 2026)**
- CMS MA Final Rate Notice '27 **(Early April 2026)**
- MedPAC meeting **(April 9-10, 2026)**
- FDA PDUFA and MDUFA reauthorization deadline **(Oct. 1, 2027)**

CMS Coverage Decisions

- CMS Draft NCD on Biomarker Tests for Colorectal Cancer Screening (**March 10, 2026**)
- CMS Final NCD on Biomarker Tests for Colorectal Cancer Screening (**June 8, 2026**)

Ipsita Smolinski
Managing Director | Capitol Street
ipsita@capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

202.250.3741 | www.capitol-street.com

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