

CAPITOL STREET

November 9, 2025

ALERT: Shutdown Deal Includes Health Extenders & Clinical Lab (PAMA) Delay

Week of Nov 10-17: EPTC Vote Tabled, CMS Final ESRD, Outpatient & Home Health Rules, IRA 2027 Prices ASAP

WEEK AHEAD

Deal Reached & Votes This Eve... What's Included? Senate Republicans and Democrats cleared a procedural hurdle this evening, paving the way for a [deal](#) to reopen the federal government with a three-bill minibus (FY26 Ag-FDA, Leg Branch, & MilCon-VA) and a stopgap spending bill (Continuing Resolution) through Jan. 30, 2026 ([here](#)). A vote to extend Obamacare EPTCs would happen by the second week in December under the agreement.

- The bill renews healthcare extenders, such as maintaining pandemic-era telehealth flexibilities in Medicare, funding for Community Health Centers, and the Hospital at Home program.
- The CR also delays cuts to clinical labs (PAMA) and Medicaid DSH through Jan. 30, 2026.
- Payfors include a reduction in the Medicare Improvement Fund and a one-month extension of Medicare sequestration in the out-years.

OUR TAKE: Democrats agreed to a vote on ACA subsidies in December. President Trump posted on Truth Social ([here](#)) that subsidies ought to be given directly to Americans (via FSA/HSA) rather than insurance companies, per Sen. Cassidy's (R-LA) idea.

CMS '26 Final Pay Rules (Outpatient Hospital, ESRD, & Home Health): CMS will release more final CY 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](#)).

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.

More MFN Deals?: Last week saw deals with LLY and NVO (our take [here](#)). We expect additional MFN agreements to be announced as soon as this week, possibly from MRK, JNJ, REGN, or ABBV.

OUR TAKE: CMMI released a voluntary non-controversial model (starts Jan 2026), which implements MFN pricing in Medicaid through CMS negotiated supplemental rebates. See our analysis [here](#). On GLP-1 Medicare coverage, a voluntary pilot (BALANCE) is expected in Spring 2026 (Part D), which we will likely see before GUARD & GUIDE. We believe that Medicare drug pricing models (GLOBE, GUARD) are still forthcoming as a “stick” for the companies that don’t agree to a deal [here](#). Deals continue to follow the general framework laid out in the MFN letter, but future agreements are likely more tailored like the LLY and NVO deals.

FDA Announcements on Non-Animal Testing & Gene-Editing: FDA Commissioner Marty Makary noted the agency will soon make announcements 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](#)).

MON, NOV 10

HHS Announcement on Women’s Health: HHS has scheduled an 11 a.m. media briefing on "Advancing Women’s Health." HHS Secretary RFK Jr., FDA Commissioner Makary, and ARPA-H Director Alicia Jackson are among those expected to speak.

OUR TAKE: We believe that further investments in research on menopause and/or other women's health issues, given the speaker list includes ARPA-H along with two urologists.

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)**
- Oral Arguments in *American Academy of Pediatrics v. Kennedy* on vaccines **(Dec. 17, 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)**

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