

CAPITOL STREET

September 8, 2025

Health Policy Peek: Week Of September 8-12

Fall Health Package: ACA Subsidy Extension & Health Extenders

ICYMI

A House bill to extend enhanced ACA subsidies (EPTC) for one year (costs \$24 B) was released on Sept. 4 ([here](#)). We believe Congress is likely to extend subsidies for 1-2 years, but not to the full extent enrollees receive currently (subsidy limit possibly above 400%). (Our take [here](#)).

ANY DAY NOW

MAHA Report 2.0: The release of HHS Secretary RFK Jr.'s second MAHA report to President Trump is expected to be publicly released this week ([here](#)). A leaked version of the report ([here](#)) suggests the focus will be on vaccine safety, DTC advertising for pharma, and overprescribing for mental health. The report will also warn of a possible link between Tylenol use during pregnancy and autism, according to the *WSJ* ([here](#)).

More Rulings on Medicare Drug Negotiation: We are still waiting on decisions from the DC District Court for MRK and the 3rd Circuit on NVO and NVS. BMY and JNJ lost appellate challenges to Medicare drug price negotiation on Sept. 4 ([here](#)). The courts also ruled in the government's favor in cases brought by Boehringer Ingelheim, U.S. Chamber of Commerce and PhRMA (our take [here](#)).

OUR TAKE: The 3rd Circuit decision on NVO could be one that finally goes in industry's way. CMS could be required to issue new guidance or decrease the number of drugs that the negotiated price applies to if NVO wins their case on APA merits. However, we believe the Medicare Drug Negotiation program overall will likely remain intact (our take [here](#)).

SCOTUS Decision on Whether to Hear IEEPA Case: The Trump administration has requested that SCOTUS decide whether to hear the case by Sept. 10 to allow oral arguments to take place in early November. Recall, the US Appeals Court for the Federal District upheld a lower court's ruling that President Trump's IEEPA tariffs are unlawful, effective Oct. 14 ([here](#)).

OUR TAKE: The legal challenge does not impact pending Sec. 232 pharma tariffs. In our view, SCOTUS is more likely to restrict the use of IEEPA authority to impose tariffs, but the Trump Administration could use other legal authorities to implement them (our take [here](#)).

MON, SEPT 8

House Markup of NDAA (BIOSECURE) ([here](#)): The House version of the FY 2026 *National Defense Authorization Act* (NDAA) is scheduled for a 2 p.m. markup in the House Rules Committee (Chair Virginia Foxx, R-NC). The committee will decide whether the *BIOSECURE* amendment will be included in the final NDAA

package and voted on by the full House.

OUR TAKE: In our view, prospects for updated *BIOSECURE* language are strong (70%+) given mirroring amendments in both chambers. Both bills include companies named in the DoD [1260H list](#), a 5-year grandfather period, and protection from public release for new companies until a final determination. BGI/MGI is expected to be impacted due to their status on the 1260H list, while WuXi entities are not named at this time (our take [here](#)).

TUES, SEPT 9

House Markup of FY 2026 HHS Funding ([here](#)): The House Appropriations Committee (Chair Tom Cole, R-OK) is tentatively scheduled to hold an 11 a.m. markup of its FY 2026 House Appropriations Labor-HHS bill ([here](#)), which cleared the Labor-HHS Subcommittee on Sept. 1 (11-7). The bill funds NIH at \$48 B (flat), which compares to a +1% increase in the Senate Appropriations Committee bill approved in late July ([here](#)).

OUR TAKE: We have said there is bipartisan and bicameral support for NIH despite President Trump's FY 2026 budget request (40% cut). In our view, Congress will likely pass a short-term (1-3 month) Continuing Resolution (CR) keeping NIH funding flat. We believe a government shutdown will be averted ahead of the Sept. 30 deadline, but an additional CR will likely be needed at year-end and/or CROmnibus, where some agencies are funded and others kept at "current levels" (CR). (Our take [here](#)).

House Hearing on Children's Health ([here](#)): The House Oversight and Accountability Subcommittee on Health Care and Financial Services (Chair Glenn Grothman, R-WI) will hold a 2 p.m. hearing on "Better Meals, Fewer Pills: Making Our Children Healthy Again." Witnesses include Dr. Dorothy Fink, M.D. (HHS) and Dr. Eve Stoodly, Ph.D. (Department of Agriculture).

Senate Hearing on Vaccines ([here](#)): The Senate Oversight Permanent Subcommittee on Investigations (Chair Ron Johnson, R-WI) will hold a 2 p.m. hearing on "How the Corruption of Science has Impacted Public Perception and Policies Regarding Vaccines." No witnesses have been announced.

WED, SEPT 10

House Markup of Health Bills: According to *Politico* ([here](#)), a House Energy & Commerce Health Subcommittee (Chair Morgan Griffith, R-VA) markup is planned to consider health legislation in contention for a fall legislative package, including a modified Medicare coverage pathway for breakthrough devices (background [here](#)) and pan-cancer screening tests (background [here](#)). A House Ways & Means markup of health bills is also expected this month.

OUR TAKE: We expect a "Minibus" or "CR-omnibus" may include the following (1) EPTCs (short term), (2) telehealth extension, (3) community health center funding extension, (4) clinical lab payments (PAMA moratorium), (5) Medicaid DSH and other hospital extenders. POTENTIAL OFFSETS: PBM Reform: saves [\\$2 B/10](#); Site Neutral: saves up to [\\$170 B/10](#); Medicare Advantage (*No UPCODE Act*): saves between \$125B - [\\$260 B/10](#) (our take [here](#)).

SEPT 18-19

Two-day Advisory Committee on Immunization Practices (ACIP) Meeting ([here](#)). Potential headwinds

include recommendation changes for COVID-19 and childhood vaccines. Recall, HHS Secretary RFK Jr. defended vaccine policies at a SFC hearing on Sept. 4 ([here](#)).

OUR TAKE: Other potential targets for RFK include the USPSTF (reconfiguration of panel and priorities), Vaccine Injury Compensation Program (legal liability changes), and preliminary study results on environmental causes of autism (potential vaccine links). (Our take [here](#)).

FALL 2025

PBM 6B Study Final Report & Fresh Congressional Oversight: FTC is working on completing their 6B study following two interim reports on (1) PBM rebating practices and (2) dispensing and pricing of specialty generics (our take [here](#) and [here](#)). On the legislative side, the House Oversight Committee (Chair Comer, R-KY) is investigating PBM (CI, UNH) use of group purchasing organizations (GPOs) that are headquartered abroad with [letters](#) sent requesting info on contracting practices and corporate communications.

IRA Drug Pricing: 2027 Negotiated Prices and Final 2028 Guidance: We believe 2027 Medicare negotiated prices are likely to be lower than net prices seen in 2026, based on comments from Trump (our take [here](#)). We are also expecting to see the final Medicare Negotiation Program Guidance for 2028. As a reminder, 2028 is the first year of Part B drug inclusion and the first opportunity to renegotiate selected drugs for 2026 and 2027. CMS may look to group SubQ products with their IV versions despite an additional ingredient if it is only added for bioavailability purposes and is not therapeutically active (see our draft 2028 guidance analysis [here](#)).

ON THE HORIZON

- Announcement of pharmaceutical tariffs (**ASAP**)
- FTC PBM 6B study final report (**TBD**)
- CMS proposed rule on “Medicaid Managed Care-State Directed Payments” (**TBD**)
- CMS Draft MA & Part D technical rule (**TBD**)
- SCOTUS oral arguments on IEEPA tariffs (**TBD**)
- CMS 2028 final IRA drug price negotiation guidance (**Early Fall**)
- HHS preliminary autism study results (**September 2025**)
- FDA CEO Forum, Raleigh, NC (**Sept. 15, 2025**)
- CDC Advisory Committee on Immunization Practices (ACIP) meeting (**Sept. 18-19, 2025**)
- FDA Workshop on Advancing the Development of Interchangeable Products (**Sept. 19, 2025**)
- FDA CEO Forum, Atlanta, GA (**Sept. 26, 2025**)
- Deadline for MFN commitments from pharma manufacturers (**Sept. 29, 2025**)
- Expiration of Continuing Resolution/health extenders - telehealth, DSH, CHCs (**Sept. 30, 2025**)
- FDA Onshoring Manufacturing of Drugs and Biological Products meeting (**Sept. 30, 2025**)
- Deadline to pass the National Defense Authorization Act (**Sept. 30, 2025**)
- OIG report on Medicare pricing for CGM (**FY 2026**)
- ICER inaugural report on drug list prices & access (**October 2025**)
- Start of FY2026 (**Oct. 1, 2025**)
- CMS New Technology town hall meeting (**Oct. 7, 2025**)
- MedPAC meeting (**Oct. 9-10, 2025**)
- CDC Advisory Committee on Immunization Practices (ACIP) meeting (**Oct. 22-23, 2025**)
- Deadline for trade agreement with Mexico (**Oct. 29, 2025**)
- CMS Final FY26 Outpatient Hospital/ASC, Hospice, PFS, & ESRD rules (**Early November, 2025**)

- Mid-term elections (**Nov. 3, 2025**)
- MedPAC meeting (**Nov. 6-7, 2025**)
- CMS MFN rulemaking (**Nov. 8, 2025**)
- Deadline for trade agreement with China (**Nov. 9, 2025**)
- Deadline for CMS to publish 2027 negotiated maximum fair prices (**Nov. 30, 2025**)
- MedPAC meeting (**Dec. 4-5, 2025**)
- Expiration of APTCs and CLFS pay cut moratorium (PAMA) (**Dec. 31, 2025**)
- CMS MFP effective for selected drugs (**Jan. 1, 2026**)
- Effective date for Arkansas law banning PBM-owned pharmacies from operating within the state - injunction currently in effect (**Jan. 1, 2026**)
- CMS Medicare Advantage (MA) Rate Notice '27 (**Early January, 2026**)
- MedPAC meeting (**Jan. 15-16, 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 Final NCD on CCM for Heart Failure (**Oct. 8, 2025**)
- CMS Final NCD on Renal Denervation (Medtronic) (**Oct. 11, 2025**)

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