

CAPITOL STREET

December 12, 2025

Health Policy Peek: Dec 15-19

Capitol Street “FDA 2026 Outlook” Webinar, House Vote on Healthcare Bills, Final Vote on *BIOSECURE (NDAA)*

WEEK AHEAD

House Vote on Healthcare Bills Next Week - Deal In The Making?: House GOP leaders plan to bring a health care package to the floor next week to address the looming Obamacare cliff ([here](#)). The Republican bill would likely mirror the growing bipartisan bill that includes: a 2-year extension, HSAs, CSRs and association health plans with significant fraud safeguards ([here](#)). On the short list for inclusion are PBM reforms and site-neutral hospital payment changes ([here](#)). House GOP leaders may allow a vote on extending ACA subsidies without Hyde Amendment restrictions to ease concerns from moderates.

OUR TAKE: We still anticipate a late December/January bill with a one- or two-year EPTC extension (plus health extenders) - this will be clearer after next week’s vote. A compromise proposal will likely include income caps, anti-fraud protections, modest cost-sharing, and a transition to a HSA-type platform (2027 at the soonest, as this is likely not feasible for early 2026 implementation) (our take [here](#)). We’ll also be on the lookout for PBM reform and potential pay-fors (MA, site-neutral) on what appears to be a pricey package (our take [here](#)).

Final Vote on *BIOSECURE (NDAA)*: The *BIOSECURE Act* is expected to undergo a final vote in the Senate as part of the *National Defense Authorization Act (NDAA)*, after clearing the House on Dec. 10 by a vote of 312-112 ([here](#)).

OUR TAKE: Recall, the House-passed bill includes a watered-down version of the *BIOSECURE Act*, which we have said has a 70%+ chance of passage by year end. The provision bars federal agencies from contracting with Chinese biotech companies of concern, but no longer names certain entities like WuXi (our take [here](#)). Though the Pentagon recently recommended Congress add WuXi and seven other Chinese firms to the 1260H risk list ([here](#)).

More MFN Deals?: A “batch” of new drug pricing deals may be announced this month, according to CMS Administrator Mehmet Oz ([here](#)). So far the Trump Administration has secured most-favored nation (MFN) deals with five of 17 drug companies it called upon to take action on drug prices – PFE, AZN, EMD Serono, LLY and NVO.

OUR TAKE: We are on the lookout for deals with MRK, JNJ, REGN, and ABBV. Deals continue to follow the general framework laid out in the MFN letters, but future agreements are likely more tailored like the LLY and NVO deals. 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 (our take [here](#)).

MON, DEC 15

HHS Roundtable on Lyme Disease ([here](#)): According to HHS, the agency is taking action to advance the evaluation and care of Lyme Disease patients in line with the Trump Administration's commitment to addressing chronic and often unseen illnesses that affect millions of Americans.

WED, DEC 17

PLEASE JOIN US: Capitol Street Webinar at 3 pm ET on FDA: 2026 Outlook for Commissioner Pathways, Agency Leadership & Reviews ([Register here](#)): Please join team Capitol Street for a webinar with Dan Kracov and Eva Temkin, partners at Arnold & Porter, to explore FDA hot topics. We will discuss recent leadership changes (Makary announcements, Pazdur's retirements), updates on reviews and functionality at the agency, AI & non-animal model initiatives, and the CNPV program.

Oral Arguments in Vaccines/Prevention Case ([here](#)): In *American Academy of Pediatrics v. Kennedy*, plaintiffs including physician groups challenge recent HHS actions on vaccines and prevention, arguing that while HHS Secretary RFK Jr. has authority over ACIP and USPSTF, that power can't be used in an arbitrary or capricious way ([here](#)).

OUR TAKE: The administration continues to pressure vaccine manufacturers with shifting recommendations, claims of autism and other side effects, and a push for individually administered vs. combo vaccines (our take [here](#)). According to *Politico*, HHS is also considering adding autism to the vaccine injury table ([here](#)), which we said was a distinct possibility ([here](#)), along with a stricter approach to vaccine regulation at FDA ([here](#)). Other potential near-term targets are the USPSTF (reconfiguration of panel and priorities) and Vaccine Injury Compensation Program (legal liability changes) (our prior take [here](#)).

CMS Coding (Drugs/Devices) Meeting ([here](#)): CMS is hosting (in person & virtual) its second biannual meeting of 2025 to discuss CMS' preliminary changes to the Healthcare Common Procedure Coding System, Medicare benefit category, and Medicare payment determinations ([here](#)). CMS finalizes coding decisions on a quarterly and annual basis. Technologies to be discussed are manufactured by Medtronic, Smith and Nephew, and dozens of small private companies.

FRI, DEC 19

Oral Arguments on 340B Rebate Pilot ([here](#)): In *American Hospital Association v. Kennedy*, plaintiffs are suing over the new 340B pilot program for negotiated drugs, arguing it breaks federal rules. AHA has asked for a temporary restraining order to delay 340B rebate pilot program implementation (set to start Jan. 1, 2026). The judge could rule on delaying the program within the next 2 weeks.

OUR TAKE: Outcomes could vary but the judge could rule on delaying the program within the next 2 weeks. As a reminder, 340B entities (hospitals and providers) are entitled to either lower of the MFP or the 340B ceiling price. However, CMS will not be responsible for preventing duplication of discounts. The pilot is intended to prevent duplication of discounts for negotiated drugs by shifting up-front discounts to after-the-fact rebates. Within the model, covered entities would buy 2026 negotiated drugs at WAC and submit claims data to manufacturers to receive a rebate.

LATE-DECEMBER

CY 2026 Clinical Lab Fee Schedule (CLFS): CMS will issue the CLFS for CY 2026 later this month, which should factor in the postponement of cuts to clinical labs (PAMA) through Jan. 30, 2026 from the recent stopgap spending bill (our take [here](#)).

OUR TAKE: PAMA cuts of up to 15% have been postponed five times since 2021 and the Continuing Resolution likely sets a template for further delays into 2026. Meanwhile, stakeholders are lobbying for passage of the *RESULTS Act*, which would provide a more favorable data reporting and rate-setting methodology and would institute new limits for rate increases and decreases in future years (our take [here](#)).

DECEMBER-FEBRUARY

SCOTUS Decision on IEEPA Tariffs: We believe the Supreme Court (SCOTUS) may limit the use of IEEPA tariffs, with a decision likely coming between December and February. SCOTUS officially has until the end of June to make a decision.

OUR TAKE: 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 (our take [here](#)).

ON THE HORIZON

- Expiration of EPTCs (**Dec. 31, 2025**)
- Deadline to pass the National Defense Authorization Act (**Dec. 31, 2025**)
- CMS CY2026 Clinical Lab Fee Schedule (**Late-December 2025**)
- SCOTUS Decision on IEEPA Tariffs (**December 2025-February 2026**)
- FTC PBM 6B study final report (**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**)
- IRA MFPs effective for selected drugs (**Jan. 1, 2026**)
- Initial date for Arkansas law banning PBM-owned pharmacies - delayed indefinitely due to injunction (**Jan. 1, 2026**)
- CMS Medicare Advantage (MA) Rate Notice ‘27 (**January 2026**)
- MedPAC meeting (**Jan. 15-16, 2026**)
- Expiration of Continuing Resolution & Healthcare Extenders (CHCs, DSH, Telehealth, Labs) (**Jan. 30, 2026**)
- CDC ACIP meeting (**Feb. 25-26, 2026**)
- CMS proposed rule on a voluntary pilot on GLP-1s (BALANCE) (**Spring 2026**)
- CMS pricing justification for 2027 negotiated drug list (15 Part D drugs) (**March 1, 2026**)
- 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

202.250.3741 | www.capitol-street.com

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

CAPITOL STREET

Copyright 2025 Capitol Street.

This communication, including this broadcast and any attachments hereto, is intended solely for the original recipient(s) and may not be redistributed without the written consent of Capitol Street. This communication is for informational purposes only and is not intended as an offer or solicitation for the purchase or sale of any financial instruments, nor is it intended as advice to purchase or sell such instruments