

CAPITOL STREET

April 26, 2026

Health Policy Peek: Week of April 27-May 1

More MFN Deals Coming, New CBER Director, Hospital CEO Hearing (HCA, NY Presby, Common Spirit, ECU Health), USPSTF Panel Changes

ICYMI

Regeneron, Final Holdout of 17, Secures MFN Agreement w/ White House (WH) ([here](#) and [here](#)): Gene therapy Otarmeni (pediatric hearing loss) will be free in the US (but not forever). WH announced it's (1) negotiating with hundreds of biotech companies, (2) negotiating international trade deals, and (3) pushing Congress to pass MFN into law (our take [here](#)).

OUR TAKE: Now what? Dozens of smaller companies -- Biomarin, Alkermes, many others -- have visited Washington, DC over the last few weeks to meet with the administration. We believe, per Chris Klomp's comments on Thursday, that more "deals" will be announced this Spring. The deals may be in the form of the GENEROUS model, which effectively is the MFN corporate deal in the form of a CMS pilot. CMMI details are [here](#) and our take on GENEROUS (2025) is [here](#). This will be the mid-term election "win" that the administration is pursuing. As a reminder Klomp said on Thursday in the White House that (1) negotiations with smaller pharma companies are ongoing, (2) negotiations are being pursued with other nations and (3) MFN codification is being sought.

CMS, FDA Announce RAPID Coverage Pathway for Breakthrough MedTech ([here](#)): The new pathway appears to be an incremental improvement from the current TCET pathway, but not as generous as the original MCIT proposal from the first Trump administration (our take [here](#)).

US Preventive Services Task Force Changes: HHS on April 23 solicited new USPSTF members ([here](#)). It's unclear if HHS will attempt to replace all 16 USPSTF members as it did with the CDC's Advisory Committee on Immunization Practices (our take [here](#)).

OUR TAKE: We have said that RFK Jr. is expected to target the USPSTF in reforming coverage of tests, but continue to expect cancer screening recommendations (EXAS, GH, MYGN) to stay largely intact (our take [here](#)). Additionally, RFK recently signaled ([here](#)) new USPSTF recommendations on early screening for Alzheimer's disease (Roche, Fujirebio).

ANY DAY NOW

NEW CBER Director: FDA Commissioner Makary will announce this week the new CBER Director. One potential candidate (among others) is Dr. Houman Hemmati. Hemmati has long been a fixture on the biotech scene, co-founding Optigo Biotherapeutics and holding positions at companies including Capricor Therapeutics,

Allergan and Noveome Biotherapeutics. He would be viewed favorably, if HHS Deputy Chris Klomp and others sign off.

CVS FTC Agreement/Settlement: A proposed [settlement](#) with CVS Caremark was reached in March, with formal details TBA imminently. The FTC final 6B report may be delayed to post CVS and UNH announcements, or Spring/Summer 2026.

OUR TAKE: We expect CVS and UNH settlements to mirror the CI agreement from [February](#), including transparency requirements, access to TrumpRx, focus on net pricing, and domestic onshoring of GPOs (for UNH), with compliance by Jan 1, 2028. We note that provisions included in the settlement reflect Administration priorities including expansion of TrumpRx, onshoring GPOs and formulary transparency. We expect the FTC to continue to use these settlements to advance broader policy priorities as Trump looks to highlight wins with the upcoming midterms.

TUES, APRIL 28

House Hearing w/ Health System CEOs ([here](#)): The House Ways and Means Committee (Chair Smith, R-MO) will hold a hearing on the role health systems play in rising healthcare costs.

OUR TAKE: Hospitals have increasingly come under scrutiny in the healthcare affordability debate (our take [here](#)). In January, the nation's largest insurers pointed to hospitals as a primary driver of high health costs (our take [here](#)). The upcoming hearing will likely focus on consolidation incentives and whether hospital mergers improve care or reduce costs, along with the PE ownership angle. Site-neutral payment policy is moving along as CMS implemented site-neutral for physician administered drugs in 2026 (our take [here](#)). We could see additional site-neutral policy on the table in a 2027 payment rule (Rad Onc, Imaging). Invited CEOs represent **HCA, NY Presbyterian, CommonSpirit and ECU Health, Protect Our Care.**

WED, APRIL 29

House Hearing on Food Oversight ([here](#)): The House Energy & Commerce Health Subcommittee (Chair Griffith, R-VA) will hold a 2 p.m. hearing on "Healthier America: Legislative Proposals on the Regulation and Oversight of Food."

OUR TAKE: The subcommittee will discuss 28 bills related to regulation and oversight of food as part of the WH and GOP pivot toward less controversial aspects of the MAHA movement ahead of the mid-term elections (our take [here](#)).

Senate Hearing on COVID Vaccines ([here](#)): The Senate Homeland Security Permanent Subcommittee on Investigations (Chair Johnson, R-WI) will hold a 2:30 p.m. hearing titled "Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals." Witnesses include Karl Jablonowski (Children's Health Defense), David Wiseman (Synechion, Inc.) and Maria Young (COVID-19 Survivor).

ON THE HORIZON

- NBPP (Notice of Benefit and Payment Parameters) final rule 2027 (**any day now**)
- CMS IRA drug negotiation proposed rule for 2029 (**imminent**)
- CVS & UNH FTC Agreements/Settlements (**1H 2026**)

- FTC PBM 6B study final report (**may not be released for some time due to pending FTC settlements with CVS & UNH**)
- DOL final rule on PBMs (**late Spring/Summer 2026**)
- CMS launch of BALANCE model in Medicaid (**May 2026**)
- Trump trade talks w/ Xi Jinping in China (**May 14-15, 2026**)
- ITC Hearing on Chinese state support and pricing practices in biotech (**May 27-28, 2026**)
- Sec. 232 report on medical devices due to White House (**May 30, 2026**)
- Deadline for CMS to send an initial offer for 2028 selected drug (**June 1, 2026**)
- CMS first biannual HCPCS coding meeting (**June 1, 2026**)
- FDA hearing on Commissioner's National Priority Voucher (CNPV) Pilot Program (**June 4, 2026**)
- CDC ACIP meeting (**June 24-26, 2026**)
- CMS proposed CY27 Outpatient Hospital/ASC, PFS, Home Health, & ESRD rules (**Early July 2026**)
- CMS launch of Medicare GLP-1 Bridge in Medicare (**July 1, 2026**)
- USMCA joint review (**July 1, 2026**)
- CMS final FY27 Inpatient Hospital/LTCH, Psych, IRF, SNF, & Hospice rules (**August 2026**)
- Start of FY 2027 (**Oct. 1, 2026**)
- CMS launch of GLOBE model in Medicare Part B (**Oct. 1, 2026**)
- CDC ACIP meeting (**Oct. 21-23, 2026**)
- CMS final CY27 Outpatient Hospital/ASC, PFS, Home Health, & ESRD rules (**Early-Nov, 2026**)
- Deadline for CMS to publish 2028 negotiated maximum fair prices (**Nov. 30, 2026**)
- Mid-term elections (**Nov. 3, 2026**)
- CMS CY2027 Clinical Lab Fee Schedule (**Late-December 2026**)
- CMS launch of BALANCE model in Medicare Part D (**January 2027**)
- CMS launch of GUARD model in Medicare Part D (**Jan. 1, 2027**)
- CMS MFP Effective for 2027 Selected Drugs (**Jan. 1, 2027**)
- FDA PDUFA and MDUFA reauthorization deadline (**Oct. 1, 2027**)

CMS Coverage Decisions

- CMS Final NCD on Biomarker Tests for Colorectal Cancer Screening (**June 8, 2026**)
- CMS Draft NCD on TAVR for Asymptomatic Patients (EW) (**June 15, 2026**)
- CMS Final NCD on TAVR for Asymptomatic Patients (EW) (**Sept. 13, 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 2026 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