CAPITOL STREET

July 12, 2026

Health Policy Peek: Week of July 13-17

Primary & Value-Based Care Event 7/14 w/ CMS Leaders, CDC Nomination, Patents & Innovation Hearings, CMS Lab Test Meeting

ANY DAY NOW

FDA Commissioner Nominee: The White House is set to announce a new FDA Commissioner imminently. Finalists include Heidi Overton, M.D., Ph.D., a current White House adviser; Jeffrey Vacirca, M.D., CEO and Chair of the Board of New York Cancer & Blood Specialists; and Stephen Ferrara, M.D., a Pentagon health official.

OUR TAKE: We note that the administration continues to focus on stability at the FDA. Dr. Heidi Overton is considered a “Makary protege” and the most political nominee who would likely continue his trajectory. Dr. Vacirca is likely pro-innovation, but politically aligns with MAHA and supported RFK Jr as HHS secretary nominee. Dr. Ferrara has a long, disciplined military career and experience in bureaucratic leadership, but limited private sector experience. All three candidates lack traditional regulatory experience at the FDA, but bring leadership skills.

340B Alternative Rebate Model Pilot: An updated 340B rebate model is coming any day now with a pending rule at the White House Budget office, or OMB here. Earlier this year, Health Resources and Services Administration (HRSA) issued a Request for Information (RFI) on how to implement a 340B alternative rebate model after the 2026 pilot was struck due to hospital (AHA) litigation. We note that the administration received a significant number of comments against implementation, but still intends to move forward with a 340B model.

OUR TAKE: With a potential start in 2027, the model will target Medicare negotiated products for 2026 and 2027. The structure of the new model is likely to be similar to the proposed 2026 pilot with manufacturers submitting their rebate plans for negotiated drugs, but could also include an effort to establish a 340B/IRA clearinghouse within HRSA to address duplicate discounts.

CMS CY 2027 Physician Fee Schedule (PFS): CMS will soon release its proposed CY 2027 physician payment rule.

OUR TAKE: The regulation will include the physician pay component for co-specific technologies outlined in our analysis of Medicare’s proposed CY 2027 Outpatient Hospital rule, or OPPS (here): ABT, CVRX, EBR, GKOS, INSP, LNTH, and NYXH. Recall, the July 2 OPPS rule also included a significant expansion of imaging site-neutral (our take here) and substantial reimbursement cuts for 340B drugs (ASP-33%) to hospitals (our take here). The PFS and OPPS final rules are expected in late October/early November and new policies are effective Jan. 1, 2027.

FTC Agreements w/ CVS & UNH: The FTC and Optum (UNH) on June 12 announced a settlement to resolve claims it engaged in anticompetitive activities that drove up the price of insulin. A proposed settlement with CVS Caremark was reached in March. Formal details of both agreements are likely to be announced soon and will likely be followed by the FTC's final 6B report later this summer.

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 the administration's priorities. We expect the FTC to continue to use these settlements to advance broader policy priorities as Trump looks to highlight wins with the upcoming mid-terms.

TUES, JUL 14

Senate Hearing on Patents (here): The Senate Judiciary Committee (Chair Grassley, R-IA) will hold a 10:15 a.m. hearing on "From Genes to Machines: the Patent Eligibility Debate." Witnesses include former USPTO Director Andrei Iancu and others representing industry and academia.

OUR TAKE: While biopharma IP is newly under scrutiny as a potential policy lever for drug pricing reforms, lawmakers are also discussing the limitations of the current patent system and the impact on innovation. The *Patent Eligibility Restoration Act (PERA)* is likely to be discussed and may undergo a markup this summer. This bill aims to address the gap in patent protection for gene therapies by narrowing judge-made exclusions for patent eligibility exceptions. Under current judicial interpretations (the Supreme Court's 2013 Myriad decision), merely isolating or modifying naturally occurring DNA is not patentable. But engineered gene therapy platforms are currently protected due to the appeals court decision in *Regenxbio v. Sarepta* in February.

PLEASE JOIN US on Tuesday, July 14 in Washington, DC at the National Press Club for Primary Care for America's *PrimaryCare: See the Possibilities* Event. Panels will feature CMS leadership including Abe Sutton, Joe Albanese, and Stephanie Carlton, along with industry leaders, and patient advocates covering primary care innovation and value-based care. The full agenda is here and the link to register is here.

JUL 14-15

CMS Meeting on Lab Test Reimbursement (here): We will attend. CMS will hold its first of two advisory panel meetings on Clinical Diagnostic Laboratory Tests (CDLTs) to make recommendations regarding crosswalking and gapfilling for new and reconsidered lab tests discussed during the June 10 CLFS meeting (here). Companies on the agenda include ABT, BDSX, CSTL, LH, NTRA, TMO, VCYT, VITR, AIM: VRCI, WGS, and ZBH.

OUR TAKE: CMS meetings this summer (July 14-15) and fall (Sept. 15-16) are unlikely to address Advanced Diagnostic Laboratory Tests (ADLTs), supporting our view that ADLTs face limited risk of near-term structural changes (our take here). The PAMA data reporting period for CDLTs goes from May 1 to July 31, followed by data analysis and proposed & finalized pay determinations in the fall and new rates effective Jan. 1, 2027 (timeline here).

WED, JUL 15

Senate Hearing on HHS, CDC Nominations (Erica Schwartz, MD) (here): The Senate HELP Committee (Chair Cassidy, R-LA) will hold a 10 a.m. hearing on the nomination of Sean Kaufman, M.P.H., to be Assistant Secretary for Preparedness and Response (ASPR) for the U.S. Dept. of Health and Human Services (HHS) and Erica Schwartz, M.D., to be Director of the Centers for Disease Control and Prevention (CDC).

House Hearing on Biomedical Innovation (here): The House Energy & Commerce Health Subcommittee (Chair Griffith, R-VA) will hold a 10:15 a.m. hearing on "Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development."

OUR TAKE: The hearing is likely to focus on reforms that can be enacted in the next PDUFA user fees to streamline the FDA approval process. We note that the FDA is moving forward on multiple initiatives that aim to reduce the regulatory burden for novel therapies (plausible mechanism pathway, expedited IND pilot, one pivotal trial).

FRI, JULY 17

PLEASE JOIN US on Friday, July 17 at 10 a.m. ET for a fireside chat with Mark Newsom, President and Founder of Health Evaluations on "Medicare Advantage & Stars Litigation: Outlook." Mark will unpack the Clover Health decision, what it signals for CMS's next moves, and what it means for plans heading into 2027 and beyond. The link to register is here.

ON THE HORIZON

- CVS & UNH FTC Agreements/Settlements **(Summer 2026)**
- FTC PBM 6B study final report **(Summer 2026)**
- HRSA 340B rebate pilot **(Summer 2026)**
- DOL final rule on PBM **(Summer 2026)**
- CMS announces DME CBP timeline and launches bidder education **(Summer 2026)**
- CMS proposed CY27 PFS rule **(Early July 2026)**
- CMS Advisory Panel on Clinical Diagnostic Laboratory Tests **(July 14-15, 2026)**
- CMS final FY27 Inpatient Hospital/LTCH, Psych, IRF, SNF, & Hospice rules **(August 2026)**
- FDA Medical Device User Fee Amendments public meeting **(Aug. 5, 2026)**
- CMS Advisory Panel on Hospital Outpatient Payment **(Aug. 24, 2026)**
- CMS DME CBP bidder registration and bid submission open **(Summer/Fall 2026)**
- CMS Advisory Panel on Clinical Diagnostic Laboratory Tests **(Sept. 15-16, 2026)**
- USTR hearing on Sec. 301 Germany investigation **(Sept. 22, 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)**
- Commerce Dept. Section 232 Report on MedTech **(Fall/Winter 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 GUARD model in Medicare Part D **(Jan. 1, 2027)**
- CMS MFP Effective for 2027 Selected Drugs **(Jan. 1, 2027)**
- CMS DME CBP contracts awarded and payment rates announced **(Summer/Fall 2027)**

- FDA PDUFA and MDUFA reauthorization deadline **(Oct. 1, 2027)**
- CMS DME CBP new contracts and rates take effect **(Jan. 1, 2028)**

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