

CAPITOL STREET

October 11, 2024

A Week of Policy Headlines & Our Take

Harris Wants Homecare for Seniors, PBMs Ask 3 FTC Commissioners to Go, CBO GLP-1 Estimate, Oct 16 FDA Rare Disease Hub

HEALTH POLICY HOT TAKES THIS WEEK

Harris Proposes MORE Drug Price Negotiation to Expand Homecare, Vision, and Hearing to Non-MA Seniors: Vice President Kamala Harris introduced an Oct. 8 plan ([here](#)) to add homecare, vision, and hearing services to the Medicare program as a new campaign plank. The plan would be paid for by accelerating and expanding IRA drug price negotiation.

OUR TAKE: Harris' plan to expand Medicare benefits is expected to cost in excess of \$40B and would likely be extremely difficult to achieve, even if Democrats were able to gain full control of Congress. Dems are unlikely to maintain control of the Senate, and if they did, it would likely be a very narrow majority.

CBO Releases \$35 B Cost (over ten) Estimate for Expanding GLP-1 Obesity Coverage: Expanding Medicare coverage of GLP-1 drugs for obesity would cost \$35 B/10 years, according to an Oct. 8 CBO report ([link](#)). The report also finds that half of seniors who would qualify for obesity coverage already have access for other conditions.

OUR TAKE: We had already assigned low odds on legislation to extend Medicare coverage of GLP-1s for obesity (our analysis [here](#)) and the hefty price tag for doing so likely pours cold water on efforts to pass the *Treat and Reduce Obesity Act (TROA)* ([here](#)), in our view.

PBMs Ask Judge to Remove Lina Khan from FTC's Insulin-Price Lawsuit: UNH, CVS, and CI petitioned a federal judge to remove FTC Chair Lina Khan and two Dem commissioners (Alvaro M. Bedoya and Rebecca Kelly Slaughter) from the FTC's PBMS lawsuit.

OUR TAKE: This is a common tactic, most recently attempted by tech companies in a separate case. We don't expect Khan and others will be removed from the case, but either way, the lawsuit will likely take months, if not years to move. We believe the lawsuit has limited impact to PBMs due to the FTC's lack of empirical evidence and the potential to see the lawsuit withdrawn in 2025 under a Trump Administration. However, congressional scrutiny on PBMs will likely continue in 2025 (see our analysis [here](#)).

CMS Releases Preliminary \$2 Drug List: CMS on Oct. 9 released a preliminary list of generic drugs that would be made available to Medicare beneficiaries for \$2 out of pocket ([link](#)). The list includes drugs such as amoxicillin, buprenorphine, metformin, and prednisone - likely not much of a needle-mover. Our take [here](#) — this reminds us of Amazon RxPass.

WEEK AHEAD

Oct. 14, 2024

Columbus Day - Federal Holiday

House & Senate on Congressional Recess

NOTE: Members may be called back in to pass a disaster relief emergency funding plan

Oct. 16, 2024

FDA Rare Disease Hub Meeting: The [meeting](#) will bring together rare disease patient advocates, academic researchers, regulated industry, and other key stakeholders to discuss how the recently announced Rare Disease Innovation Hub can best engage with members of the rare disease community and prioritize its work.

OUR TAKE: While a fantastic idea to shepherd needed therapies that address orphan and ultra orphan conditions, this new “hub” will take resources and good staff to be successful. We look to the FDA user fee bill (next reauthorization due Sept. 30, 2027) as a place for funding to be requested as industry funds therapy review and often policy riders accompany the “UFAs”

Late October/Early November 2024

Final CY25 Medicare Provider Payment Rules: CMS is expected to release final CY2025 provider payment rules for ESRD, Home Health, OPPTS, and PFS.

OUR TAKE: In general, we expect most of the final rules will be similar to proposed rules from June/July. Our previews of final rules are forthcoming & proposed analysis can be found here (1) Home health [here](#) (2) ESRD [here](#) (3) Hospital Outpatient [here](#) and (4) Physician Fee [here](#).

Tuesday, November 5

Election Day

November-December

Lame Duck Session of Congress/PBM Reform, Telehealth Extension: Funding the federal government is one of several items likely to be addressed during the post-election lame duck session of Congress between mid-November and year-end.

OUR TAKE: We continue to believe certain PBM reforms will likely move as part of this package (see our analysis [here](#)) along with a two-year extension of Medicare telehealth benefits before expiring on Dec. 31, 2024 (see our analysis [here](#)). Also possible in a year-end package are hospital at home extension, funding extensions for Medicaid DSH and community health centers.

Other healthcare priorities in the mix for lame duck, but perhaps less certain, include (1) limited site-neutral payments, (2) physician payment reform/fix per PFS, (3) clinical workforce augmentation, (4) miscellaneous extenders (SUPPORT, PAHPA), (5) drug reforms (orphan fix, though unlikely due to price tag) and (6) addressing drug shortages, particularly sterile injectables.

ON THE HORIZON

- Final CY25 Medicare Provider Payment Rules - ESRD, Home Health, OPPTS, PFS (**Late October/Early November 2024**)
- Election Day 2024 (**Nov. 5, 2024**)

- CMS HCPCS Coding Meeting (**Nov. 6-8, 2024**)
- MedPAC meeting (**Nov. 7-8, 2024**)
- Veterans Day - Federal Holiday (**Nov. 11, 2024**)
- FDA Advisory Committee mtg on AI for use in devices (**Nov. 20-21, 2024**)
- Thanksgiving Day - Federal Holiday (**Nov. 28, 2024**)
- Defense Authorization: funding vehicle for a (tweaked) BIOSECURE Act (**December 2024**)
- CMS New Technology Town Hall (**Dec. 11, 2024**)
- MedPAC meeting (**Dec. 12-13, 2024**)
- CMS Draft NCD on Transcatheter Tricuspid Valve Replacement (**Dec. 20, 2024**)
- CMS Draft NCD on TTVR (Edwards Lifesciences) (**Dec. 20, 2024**)
- Christmas Day - Federal Holiday (**Dec. 25, 2024**)
- The Biosecurity Commission's report release on anti-China legislation (**Early 2025**)
- CMS Cell & Gene Therapy Model Launch (**Jan. 1, 2025**)
- MedPAC meeting (**Jan. 16-17, 2025**)
- Inauguration Day (**Jan. 20, 2025**)
- Medicare Advantage Rate Notice (**Late January/Early February 2025**)
- CMS unveils 2027 negotiated drug list (15 Part D drugs) (**Feb. 1, 2025**) **OUR TAKE ON Top 15** [here](#)
- CMS pricing justification for initial negotiated drug list (15 Part D drugs) (**March 1, 2025**) **See our take** [here](#)
- MedPAC meeting (**March 6-7, 2025**)
- CMS Draft NCD on Home Ventilators for COPD (**March 11, 2025**)
- CMS Final NCD on TTVR (Edwards Lifesciences) (**March 20, 2025**)
- Medicare Advantage Final Rates (**Early April 2025**)
- CMS Draft NCD on T-TEER (Abbott) (**April 3, 2025**)
- MedPAC meeting (**April 10-11, 2025**)
- CMS Final NCD on Home Ventilators for COPD (**June 9, 2025**)
- CMS Final NCD on T-TEER (Abbott) (**July 2, 2025**)
- CMS MFP Effective for Selected Drugs (**Jan. 1, 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

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