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Washington Healthcare

Legislative and Regulatory Update

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BofA SECURITIES

Trump Nominations for Key Healthcare Positions

HHS Secretary: RFK, Jr as HHS Secretary – Significant Uncertainty Regarding his Agenda

- **Confirmation Hearings to be held on January 19 (Senate Finance Committee) & January 20 (Senate HELP Committee)**
- **RFK has stated that his priority at HHS would be to "put an end to the chronic disease epidemic."**
- **Along with his outspoken vaccine skepticism, he has also suggested that FDA and other agencies have been corrupted by conflicts of interest and "corporate capture" by food and pharmaceutical industries.**
- **Unclear how RFK Jr. may approach Medicaid funding, Medicare reforms, or Revisions to IRA drug pricing**
- **RFK Jr. has called for several health-related reforms he would like to address, including:**
  - Significant restructuring and layoffs at FDA, NIH and CDC;
  - Revisions to vaccine data and oversight and public health reforms;
  - Revising FDA User Fee programs, stating that agency funding should not be "in the hands of the pharmaceutical industry";
  - Calls for banning direct-to-consumer pharmaceutical advertising on TV;
  - Questions the use of GLP-1 drugs for obesity;
  - Capping drug prices at levels paid in Europe; and
  - Overhauling food and nutrition regulations.
- **While most of these efforts would need support from Congress, several could be implemented through administrative efforts**

Source: BofA Global Research

Trump Nominations for Key Healthcare Positions (Continued)

CMS Administrator: Dr. Mehmet Oz

- **Confirmation Hearings: TBD**
- Supporter of Medicare Advantage, having suggested a "Medicare Advantage for All" to expand healthcare coverage in 2020
- Supports alternative medicine, including homeopathic medicine, and alternative therapies to treat COVID. Supporter of telehealth, digital therapeutics, and remote health monitoring.
- Critic of PBMs and high prescription drug costs, including high costs of insulin. While having criticized high costs of drugs, it is not clear how he will approach the implementation of IRA drug price negotiations.

FDA Commissioner: Dr. Marty Makary

- **Confirmation Hearings: TBD**
- Dr. Makary defended RFK Jr. on vaccines, and stated "he's not anti-vax, he's not going to remove or take away anyone's vaccines."
- Dr. Makary does have a more traditional background for being named FDA Commissioner, having been a surgeon and researcher at Johns Hopkins, a member of the National Academy of Medicine, and a former editor at Medpage Today.
- Makary is also a supporter for speeding FDA's review process, suggesting that the agency moves too slowly, and that the culture at the FDA should "promote scientific advancement, not hinder it." President Trump also suggested that Dr. Makary will work with RFK Jr. on food, nutrition, and the "childhood chronic disease epidemic."

NIH Director: Dr. Jay Bhattacharya

- **Confirmation Hearings: TBD**
- Trump stated that Bhattacharya would refocus NIH on chronic illness and diseases.
- During the COVID pandemic was a leading critic of NIH and public health efforts, having co-authored the "Great Barrington Declaration" that opposed COVID lockdowns.
- Dr. Bhattacharya and Congressional Republicans have called for major restructuring of NIH, seeking to reduce the number of research institutes down to 15. Trump's budget proposals have called for significant reductions in NIH funding.

Source: BofA Global Research

Unfinished Health Care Legislation in Congress From December

- **Congress Passed a Short-term CR to Fund the Government until March 14**
- **Outstanding Healthcare Issues Remain from December Healthcare Extender Package**
  - **Medicare/Medicaid Extenders & Other Provisions**
    - **Hospitals:** Delay Medicaid DSH payment cuts ($8 billion per year) / Extend Low-Volume and Medicare Dependent Hospital subsidies (delayed until March 31); Extend the Acute Care Hospital at Home Program
    - **Physician Payment Cuts:** Mitigate 2.8% Medicare payment cut in 2025 (took effect on January 1, 2025)
    - **Extend other Medicare payment provisions** including ambulance add-on payments, FDA pediatric cancer programs,
    - **Telehealth Flexibility extensions** (delayed until March 31)
  - **PBM Reform Provisions**
    - PBM Transparency/Reporting Requirements; Medicare "De-Linking" of PBM revenues from price of a drug/discount/rebate; Prohibition on spread pricing by PBMs in Medicaid; Pass-through of 100% of rebates to Employers and Health Plans
  - **Community Health Center Funding** (extended to March 31)
  - **Pandemic Preparedness Provisions (PAHPA)**
  - **SUPPORT Act programs to extend Substance Use prevention and Opioid Recovery and Treatment**
  - **Clinical Labs -** 1-year delay in Medicare payment cuts (until 2026), and delays reporting of commercial rates (was included in earlier CR)
  - **PAYGO Sequestration cuts** of 4% were eliminated
- **Provisions Not Included**
  - **Hospital Site Neutral Payment Reductions –** Congress had earlier considered $3.7 billion in cuts to physician-administered drug services
  - **Biosecure Act –** Prohibit federal government contracts/grants to biotech companies owned by foreign adversaries/CCP
  - **Extension of ACA Enhanced Subsidies** that expire at end of 2025
  - **Medicare Advantage Prior Authorization legislation**
  - **Additional Provider Transparency Provisions**

Source: CBO; BofA Global Research

Reconciliation Legislation to be Focus for First Half of 2025 (Extending 2017 Tax Cuts)

- **Medicaid Cuts Targeted for Large Potential Offsets as Part of Reconciliation Package:**
  - **Per Capita Caps on Federal Medicaid Funding –** Savings of up to $900 Billion over 10 years
  - **Reduced FMAP matching rates for Expansion States** – Savings of $561 Billion over 10 years.
  - **Work requirements for Medicaid beneficiaries** – Savings of $100 Billion over 10 years – Potentially impacting 1.5 million beneficiaries
  - **Reduce Provider Taxes / Supplemental Payment / Directed Payment Programs** – Savings up to $200 Billion over 10 years.
  - **Reduce Medicaid FMAP Floor – Below 50%** - Savings of $387 Billion over 10 years – Particular impact to CA, CO, CT, MD, MA, NH, NJ, NY, WA
  - **Remove Temporary FMAP Increases for new Expansion States –** Savings of $18 Billion over 10 years
  - **Standardize Medicaid Administrative Matching Rates –** Savings of $69 Billion over 10 years

- **Medicare Reforms**
  - **Hospital Site Neutral Payment Reforms –** Savings of $146 Billion over 10 years
  - **Uncompensated Care Payment Reforms** – Savings of $229 Billion over 10 years
  - **Eliminate Medicare Bad Debt Payments** – Savings of $42 Billion over 10 years
  - **Extend Medicare 2% Sequestration Cuts** – Savings of $62 Billion over 10 years
  - **Reform Medicare GME Payments** – Savings of $75 Billion over 10 years
  - **Eliminate the Inpatient Only List for Medicare** – Savings of $10 billion over 10 years

Source: CBO; BofA Global Research

States with Triggers on Medicaid Expansion

- If Federal Matching Rates Drop Below 90%

States with Trigger to End Expansion	Medicaid Expansion Enrollment	ACA Enrollment (2025)
Arizona	698,000	423,000
Arkansas	302,000	167,000
Illinois	1,000,000	466,000
Indiana	604,000	359,000
Montana	117,000	77,000
New Hampshire	72,000	70,000
North Carolina	600,000	975,000
Utah	132,000	422,000
Virginia	758,000	379,000
States Required to Mitigate Financial Impact		
Iowa	250,000	137,000
Idaho	117,000	117,000
New Mexico	293,000	70,000

Source: BofA Global Research, Kaiser Family Foundation, CMS, Sirona Strategies

Reconciliation Legislation to be Focus for First Half of 2025 (Extending 2017 Tax Cuts)

- **Affordable Care Act Provisions**
  - **Recapture Excess Premium Tax Credits –** Savings of $46 Billion over 10 years
  - **Revise ACA Cost-Sharing Reductions** – Savings of $55 Billion over 10 years.
  - **Reform ACA Market Plan and Benefit Design** – Savings of $10 Billion over 10 years

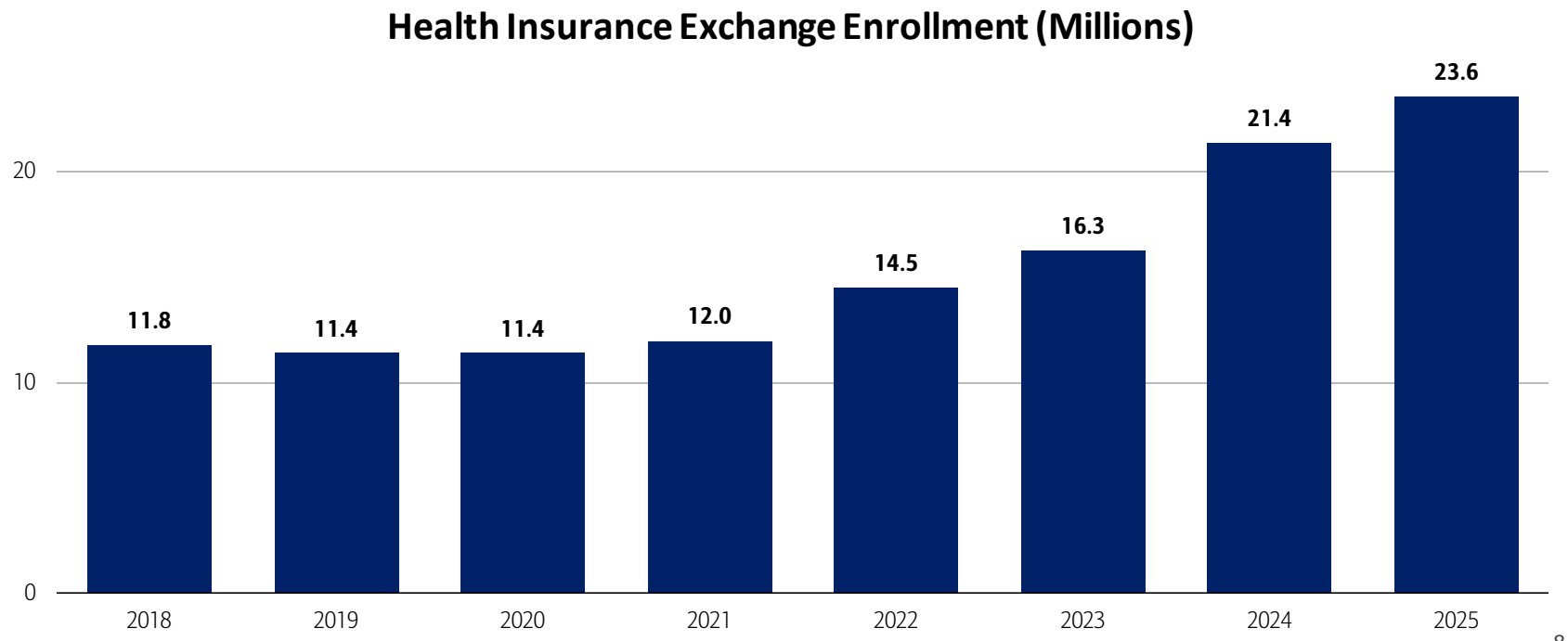
- **Repeal Major Biden-Era Healthcare Regulations**
  - **Repeal Nursing Home Minimum Staffing Regulation –** Savings of $22 Billion over 10 years
  - **Repeal Medicaid/CHIP Access Regulation** – Savings of $121 Billion over 10 years.
  - **Repeal Medicaid Eligibility Regulation** – Savings of $164 Billion over 10 years
  - **Repeal the ACA Family Glitch Revision Regulation** – Savings of $35 Billion over 10 years

- **Other Healthcare Proposals**
  - **Eliminate Not-For-Profit Status for Hospitals –** Savings of $260 Billion over 10 years
  - **Move Federal Employee Health Benefit Program to a Voucher Model** – Savings of $16 Billion over 10 years.
  - **Eliminate the Prevention and Public Health Fund** – Savings of $55 Billion over 10 years

Source: CBO; BofA Global Research

Health Care Exchange Enrollment Reaches Record Levels in 2025

- **Inflation Reduction Act Extended Enhanced ACA Premium Subsidies Expire at End of 2025**
  - Exchange enrollment increased by 2.2 million in 2025 (10% increase), after increasing 5 million (31% increase) in 2024
  - Strong Enrollment increases due to
    - Medicaid redetermination process continuing; Enhanced premium subsidies, with low or no-premium options for most exchange enrollees; and Strong support from Biden Administration to support ACA and HC exchange enrollment, with marketing and Navigators – which will be under pressure.
  - **Key issue:** Enhanced subsidies expire at end of 2025. Republicans generally oppose a full extension of the enhanced subsidies. CBO estimates a permanent extension would cost $335 billion (roughly $30 billion per year). CBO estimates that Exchange enrollment could fall by 6-7 million if enhanced subsidies expire.



Source: BofA Global Research, CMS

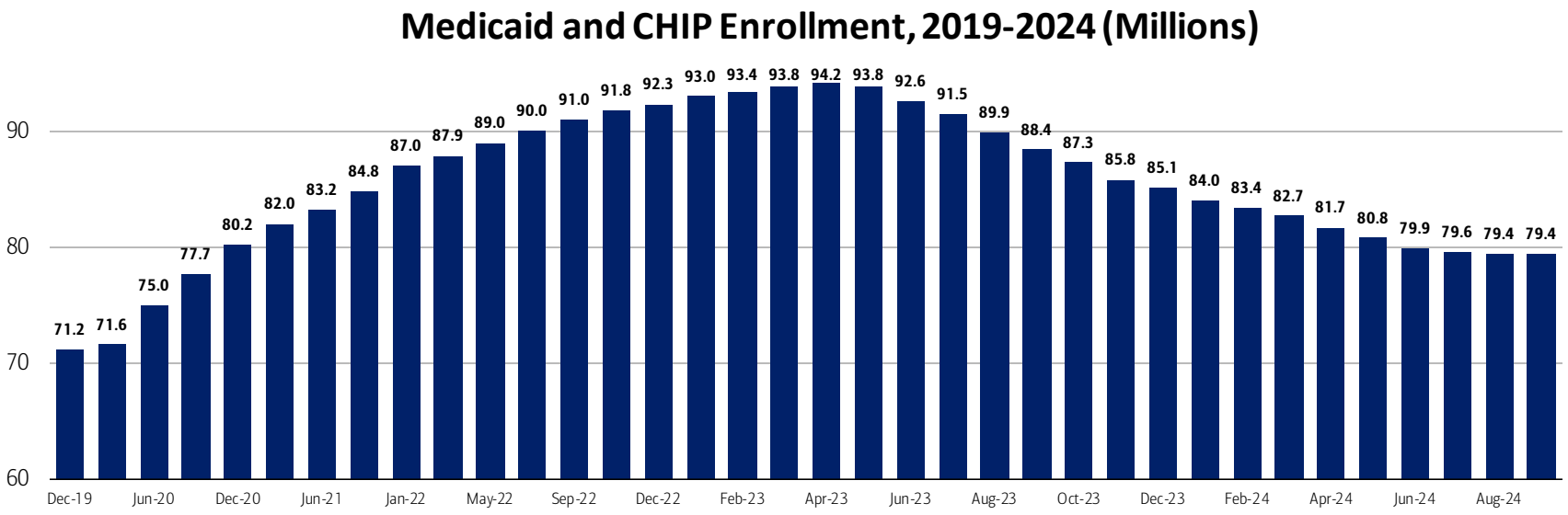
Additional 2025 Key Healthcare Priorities

- **Medicare Advantage**
  - Trump Administration was viewed positively for MA in first term
  - However, longer-term significant risks remain, given the size of MA, and the potential for payment reforms, and adjustments to risk model, coding intensity, star bonus payments, etc.
- **Drug Pricing Reforms**
  - Trump is more of a wildcard on drug pricing, given his past support of "Most-Favored Nations" pricing for Medicare drugs – which would be below IRA negotiated prices
- **Site Neutral Payment reforms**
  - May gain traction in 2025; Senators Cassidy (R-LA) and Hassan (D-NH) are working on a bipartisan proposal to ensure rural providers are protected
- **340B Drug Discount Program**
  - Range of Congressional proposals, some with bipartisan support look to both provide statutory support for 340B, and ensure there are some limitations on the program
- **NIH Reforms**
  - Republicans in Congress have proposed a framework for restructuring NIH, with fewer Institutes, folding ARPA-H into NIH, and redistributing funding
- **Medicare Coverage for Obesity Drugs**
  - CMS has proposed expanding coverage of Anti-Obesity Medications to Medicare and Medicaid beginning in 2026 – Significant cost of $40 Billion over 10 years.
  - CMS also included Ozempic in its list of 15 drugs for Medicare drug price negotiations (2027 cohort)

Source: CBO; BofA Global Research

Medicaid Redeterminations

- **Medicaid Redeterminations vary by State**
  - Enrollment down from a peak of 94.2 million in April 2023 to 79 million in September 2024
- **Medicaid Redeterminations were Significant as States Unwound Medicaid Enrollment in 2024**
  - As of September, 25.2 million disenrolled, and 56.4 million renewed
    - Texas with 2.5 million disenrolled & 2.2 million renewed;
    - New York with 2.0 million disenrolled & 4.7 million renewed;
    - California with 2.0 million disenrolled & 8.7 million renewed;
    - Florida with 1.9 million disenrolled & 3.1 million renewed;
    - Michigan with 1.1 million disenrolled & 1.9 million renewed;



Source: BofA Global Research, CMS, Kaiser Family Foundation

2023-2025 Medicare Provider Payment Updates

	2023 Payment Update	2024 Payment Update	Proposed 2025 Payment Updates	Final 2025 Payment Updates
Inpatient Hospital Operating Payments (FY)	+2.6%	+3.1%	+2.4%	+2.8%
Long-Term Acute Care Hospitals (FY)	+2.4%	-0.2%	+1.2%	+2.0%
Skilled Nursing Facilities (FY)	+2.7%	+4.0%	+4.1%	+4.2%
Inpatient Rehab Facilities (FY)	+3.2%	+4.0%	+2.5%	+2.8%
Inpatient Psych Facilities (FY)	+2.5%	+2.3%	+2.6%	+2.5%
Hospice (FY)	+3.8%	+3.1%	+2.6%	+2.9%
Home Health (CY)	+0.7%	+0.8%	-1.7%	+0.5%
Hospital Outpatient Payments (CY)	+4.7%	+3.3%	+2.4%	+3.2%
Ambulatory Surgical Centers (CY)	+3.8%	+3.1%	+2.6%	+2.9%
Physician Payments (CY)	-0.5%*	-1.25% / +0.43%*	-2.8%	-2.8%
Dialysis (CY)	+3.1%	+2.1%	+2.2%	+2.7%

Source: CMS, BofA Global Research

*+1.68% update is effective March 9, 2024, and Does not include budget neutrality adjustment, for 2024, CMS includes an additional a 2.20% budget neutrality adjustment for physicians, which will yield a -1.7% Conversion factor (vs. -3.37% conversion factor in effect from Jan. 1 to March 8, 2024)

Hospital Payment & Regulatory Highlights

- **Final FY2025 Hospital Inpatient Payment Regulation –** The FY2025 final regulation includes a net inpatient hospital operating payment increase of +2.8%. The proposed payment update includes the following:
  - +3.4% market basket update, less 0.5% productivity reduction, less 0.1% in expiration of Medicare Dependent Hospital program
  - CMS estimates that overall hospital payments would increase by $2.9 billion in FY2025.
  - DSH and uncompensated care payments decrease by of $236 million (-3.9%) in FY2025 – a significant reduction from the proposed +9.4% increase
  - New Technology add-on payments are expected to increase by $0.3 billion
- We view the final 2.8% operating payment increase as better than the proposed 2.4% update. However, lower uncompensated care payments (-3.9%) are a significant reduction from the +9.4% increase included in the proposed regulation.

- **Final 2025 Hospital Outpatient PPS Payment Regulation –** Net 3.2% increase in Medicare HOPD payments for 2025.
  - The Final 2025 payment update of +3.2% is an improvement over the proposed +2.4%.
  - For-profit hospitals are estimated to see a much better 4.9% increase in payments in 2025.
  - CMS projects total hospital outpatient payments will increase by $1.98 billion in 2025 due to the changes in the regulation and estimates that overall hospital-based outpatient department (HOPD) Medicare payments are projected to increase by $4.7 billion, to a total of $87.7 billion, when enrollment, utilization and case-mix are included.
- Overall, the final CY2025 payment update of +3.2 % is an improvement from the proposed increase of +2.4%. In addition, for-profit hospitals are expected to see an even better 4.9% increase in payments for 2025.

- **MedPAC Final 2026 Payment recommendations:** Current law (MB less Productivity) **+1% for 2026** and calls for a new Medicare Safety Net Index (MSNI) payment to redistribute DSH and Uncompensated Care payments, adding $4 billion in payments.
- **MedPAC projects Medicare hospital margins** were low at -13% in 2023 and **will remain at -13% in 2025**.

Source: BofA Global Research, CMS, MedPAC

340B Drug Discount Program

Program Growth has Led to Increased Scrutiny

- Manufacturers must offer 340B discounts to covered entities to have their drugs covered under Medicaid, DoD, and VA
- 340B entities (NFP hospitals, clinics, and affiliated pharmacies) receive 25-50% discounts on drugs
- As of October 1, 2023, 14,060 covered entities; In 2022, there were 3,467 participating hospitals, and over 10,000 340B locations with a least one contract pharmacy.
- Total number of contract pharmacies has grown from 1,872 in 2011 to 37,020 in 2023.
- **Total 340B drug discounts of $66 billion in 2023; 18% of outpatient branded drug sales were 340B in 2022.**

340B Program Regulations & Litigation

- Drug manufacturers have been seeking to limit 340B drug discounts to certain entities (contract pharmacies)
  - **In September 2024, HRSA challenged J&J revised discount program for 340B entities – calling to remove J&J from 340B program; and on Sept. 30, J&J backed off its rebate proposal**
  - **Manufacturers have called for allowing 340B discounts to be replaced with a rebate program to help mitigate duplication and diversion risks**
  - Hospitals/340B entities and Drug manufacturers have been engaged in litigation over 340B discount program
  - 3rd Circuit and DC Circuit ruled in favor of drug manufacturers (Sanofi vs. HHS; and Novartis v. HHS
  - South Carolina District Court ruled in favor of hospitals (Genesis Healthcare v. HHS)
  - Still awaiting decision in 7th Circuit (Lilly vs. HHS)

340B Legislative Activity in Congress in 2023-2024 – and Likely Ramping Up in 2025

- Senate HELP Committee Chairman Cassidy (R-LA) Reviewing 340B program since 2023
- February 2024, bipartisan group of Senators releases draft reform proposals (Sustain 340B Act)
- March 2024, bipartisan House members introduce legislation on contract pharmacies (340B Patients Act)
- May 2024, House members introduce broader 340B reform legislation (340B Access Act)
- Expect a bigger push for reforms in 2025

Source: BofA Global Research, CMS, HRSA

Medicare Physician Payment Issues

Final CY2025 Medicare Physician Payments

- **CMS Proposes a -2.93% payment cut in 2025, based on expiration of add-on payments, per Congress**
- Conversion Factor update of -2.8% after factoring in a budget neutrality adjustment
- We expect Congress will likely mitigate the 2.93% payment cut, as part of a lame-duck session of Congress
- Most physician specialties will see modest additional adjustments to payments in 2025 (+/-1%)

Congress Considering Additional Medicare Physician Payment Reforms

- Proposals in Congress to implement Medicare physician payment reforms and provide an annual payment update

Additional Physician Payment Issues

- **MedPAC 2026 recommendation** calls for increasing payments to Medicare Economic Index (MEI) less 1%
  - This would yield a 2026 payment increase of 1.3%, based on a 2.3% MEI update
- **MedPAC Also Recommends** a new physician add-on payment for services to low-income beneficiaries (15% for primary care providers, and 5% for specialists).
- **Advanced Payment Model (APM) bonus payments are set to decline:**
  - 5.0% bonus payment in 2024;
  - 3.5% bonus payment in 2025;
  - 1.88% bonus payment in 2026;
  - No bonus payments in 2027 or beyond.
  - Congressional would extend the incentive payments for qualifying physicians in advanced alternative payment models (APMs) through payment year 2027 based on performance year 2025, at an adjusted amount of 3.53%.

Source: BofA Global Research, CMS, MedPAC

Post-Acute Sector Regulatory Issues

Home Health Payment Reforms

- CMS finalized CY2025 Medicare Home Health payment update of +0.5%, a significant improvement from the proposed -1.7% cut
- CMS included half (1.8%) of the 3.6% reduction in CY2025 for permanent behavioral adjustment.
- CMS did not propose recouping additional $4.5 billion+ for overpayments in CY2020-2023, but these cuts may begin CY2026.
- Home Health industry continues to lobby for relief from Congress, as well as legal challenges to CMS' payment cuts.
- **MedPAC recommends a 7% payment reduction for CY2026**

Skilled Nursing Facility Payment Reforms

- Final FY2025 payment update includes a net +4.2% payment increase.
- It includes a 3.0% MB update, less 0.45% productivity factor reduction; CMS also includes a positive 1.7% forecast error adjustment from FY2023.
- **CMS final regulation (released in April 2024) mandating new minimum staffing requirements – opposed by the industry, and is being challenged in court**
- **MedPAC recommends a 3% payment reduction for SNFs in FY2026**

Inpatient Rehab Facility Payment Reforms

- CMS final regulation includes a net Medicare payment increase for FY2025 of 2.8%.
- **MedPAC recommends a 7% payment reduction for FY2026**

Long-Term Acute Care Hospital Payment Reforms

- Final FY2025 Payment Regulation includes a +2.0% increase in PPS fully qualified cases for LTCHs, including a -0.8% reduction due to outlier adjustments.
- Overall, CMS estimates that LTCH payments will increase by $58 million (+2.2%) in FY2025 to $2.6 billion.
- Payments for site-neutral cases estimated to increase by 4.2% in FY2025 versus 2.0% for fully qualified PPS cases.

Source: BofA Global Research, CMS, MedPAC

Other Provider Sector Regulatory Issues

Hospice Payment Update

- CMS final net payment increase for FY2025 of +2.9%
- CMS is implementing additional audit efforts for hospices to enroll in Medicare, after concerns of increased fraud
- **MedPAC recommends eliminating payment update for hospice for FY2026**
  - **MedPAC previously recommended revising the hospice aggregate cap and reducing the cap by 20%.**

Inpatient Psych Facilities

- CMS finalized a net Medicare payment increase of +2.5% for FY2025.
- CMS is considering potential future revisions to the IPF PPS and included an RFI for potential revisions to the PPS facility level adjustments, including variables for safety-net populations.

ASCs

- CMS final update of +2.9% in 2025, an improvement over the +2.6% proposed payment update.

Ambulance

- CY2025 Payment update is likely to be roughly 2.6% (3.0% CPI less 0.4% productivity factor reduction)
- Ground ambulance add-on payments is extended to December 31, 2024 (2% urban add-on, 3% rural, 22.6% super-rural)
- Ground Ambulance Advisory Committee held 3 meetings in 2023; with report/recommendations released in 2024
- VA finalized regulation to revise Ambulance rates down to Medicare rates – **but, VA has now delayed payment reforms until 2029**.

Dialysis

- Final 2025 Medicare dialysis payment regulation includes a net 2.7% payment update – an improvement over the 2.2% proposed increase. CMS also includes oral drugs in the bundle payment for 2025 (pending legislation to delay this provision).
- **MedPAC recommends maintaining current law dialysis payment update for 2026**
- Marietta Hospital Health Plan v. Davita – Supreme Court decision in June 2022; potential impact over next several years.
  - Dialysis industry supports legislation in Congress to reverse the Supreme Court, but not much movement.

Source: BofA Global Research, CMS, MedPAC

Medicare Advantage Issues

Medicare Advantage Enrollment Now at 53% of Medicare Beneficiaries

- Rebates have now increased to 17% of MA payments, yielding significant additional benefits for MA beneficiaries

Medicare Advantage Rate Updates

- For 2026, CMS preliminary update includes a reduction of +2.23%; After adding 2.1% in MA risk score trends, CMS estimates **increase payments of +4.33% in 2026, resulting in $21 billion increase in payments**.
- 2026 is year 3 of 3-year phase-in of new risk model revisions
- CMS did not include any revisions to the 5.9% coding intensity adjustment for 2026

Medicare Advantage Prior Authorization

- Legislation in Congress called new electronic program for prior authorizations and reporting on number of denials and expedited requests for prior authorization of services within 24 hours.
- CMS finalized regulations in January 2024 to streamline prior authorizations for MA, Medicaid, and HC Exchange plans, AHA notes that prior authorization leads to patient delays in care, reduced quality of care, lack of transparency and consistency from health plans

MedPAC Recommendations on MA Reforms & Growing Pressure from Congress on Medicare Advantage Payments

- MedPAC estimates favorable selection and coding results in MA payments being 18% higher than FFS payments ($50 billion per year)
- Current coding intensity adjustment is set at 5.9%, but MedPAC estimates actual coding intensity of 20% (difference of 14%)
  - Estimated $47 billion in excess MA payments in 2023, and increasing to $54 billion in 2024
- MedPAC suggests that MA plans benefit from favorable selection, which increases payments by 9% (or $36 billion in 2024)

Quality Bonus Program (QBP) – worth $13 billion per year – Potential need for reforms

- CMS announced that for 2025, 40% of MA plans qualify for 4 or 5 stars (representing 62% of enrollment), down from 45% in 2024 (representing 77% of enrollment in 2024
- Humana disclosed significant reductions in Quality Bonus Payments (impact in 2026), as several plans failed to reach 4 Stars in 2025.

Source: BofA Global Research, CMS, MedPAC

Other Key Recent Regulations

Nursing Home and Long-Term Care Facility Staffing Regulation

- April 22, CMS finalized its proposal to mandate minimum staffing levels for long-term care facilities
- Final Regulation includes 3.48 hours per resident day (HRPD) with RNs (0.55) and NAs (2.45); and requires an RN 24/7
- Final regulation phases-in over 3 years (non-rural); and 5 years (rural)
- Total cost to the industry estimated at **$43 billion over 10 years**
- **Industry is now challenging the regulation in Federal District Court (TX)**

Medicaid Home and Community Based Care (HCBS)

- On April 22, CMS finalized regulations including reforms for Medicaid access to care.
- CMS includes new oversight, monitoring, improvements for HCBS programs, including requirement that at least 80% of Medicaid payments for personal care, homemaker, and home health services spent on paying direct care workers.
- New 80% rule will become effective in 6 years (vs. 4 years in proposed regulation).

FDA Laboratory Developed Tests (LDT) Regulation

- April 29, FDA finalized new regulatory authority over laboratory developed tests (LDTs), with a phase-in over 4 years.
- Congress had sought legislation to provide this regulatory authority through the VALID Act over last several years but has not been able to get to a final vote; and FDA Commissioner Califf stated his intention to move forward on regulations.
- **ACLA Industry group is now challenging the regulation in court (TX)**

Proposed Transitional Medicare Coverage for Emerging Technologies

- In June 2023, CMS released a proposed notice outlining a new Medicare coverage pathway for new medical technologies.
- The TCET coverage attempts to: 1) facilitate early, predictable, and safe beneficiary access to new technologies; 2) reduce manufacturers' uncertainty on coverage; and 3) encourage evidence development if evidence gaps exist.
- Coverage under the TCET would continue for as long as needed to facilitate evidence for patient and clinician decision making. CMS would coordinate with manufacturers and FDA, and issue transitional coverage decisions within six months.
- Bipartisan Congressional proposals would require broader coverage for emerging technologies.

Prohibition on Non-Compete Agreements

- On April 23, FTC issued final regulations banning most non-compete agreements
- Impactful for hospitals and physicians, however, Hospital Groups and Chamber of Commerce have challenged rules in Court

Source: BofA Global Research, CMS

Inflation Reduction Act Major Healthcare Provisions

- **Drug Pricing Reforms**
  - Includes Drug Price Negotiation Authority for HHS for 10 drugs starting in 2026 (Part D); 15 in 2027 (Part D); 15 in 2028 (Part B and D); and 20 in 2029 (Part B and D)
  - Inflationary rebates on drug price increases greater than inflation (beginning in 2023)
  - Medicare Part D Benefit Redesign (includes $2,000 out of pocket cap)
  - Also includes further delay in PBM Rebate Rule until 2032 – savings of $122 billion over 10 years
  - Overall, a modest negative for Pharma
  - **CMS Announced Maximum Fair Prices (MFP) for first 10 Medicare Drugs on August 15, 2024 with a 22% net savings, or $6 billion estimated savings in first year**
  - **List of 2nd set of 15 Medicare Part D drugs up for negotiation were announced on January 17, 2025 – with negotiation process through November 2025.**

- **Extend ACA Healthcare Premium Subsidies – For 3 or more years**
  - Current Premium Subsidy Increases expire at end of 2025
  - Modest positive for managed care and hospitals

- **Not Included in Inflation Reduction Act**
  - Commercial Drug Pricing Inflationary Rebates (stripped out due to Byrd Rule)
  - Caps on Insulin Out-of-Pocket Costs ($35 per month) for Commercial Beneficiaries (also stripped out due to Byrd Rule)

Source: CBO; House Rules Committee; BofA Global Research

Major Drug Pricing Provisions

Medicare Drug Price Negotiations – First 10 Drugs

- **CMS first 10 Drugs part of negotiation – Effective in 2026**
  - Overall CMS estimates Net Savings of 22% if Negotiated Prices were in Effect in 2023
  - Discounts vs. List Price ranged from 38% to 79%
  - Overall Negotiated Prices were in-line with expectations, and manageable for drug manufacturers

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30-day Supply for CY2026	List Price for 30-day Supply, CY2023	Discount of Negotiated Price from 2023 List Price	Total Part D Gross Covered Prescription Drug Costs, CY2023 ($Billion)	Number of Medicare Part D Enrollees Who Used the Drug, CY2023
Januvia	Merck Sharp Dohme	Diabetes	$113	$527	79%	$4.1	843,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk	Diabetes	$119	$495	76%	$2.6	785,000
Farxiga	Astra	Diabetes; Heart Failure; Chronic Kidney Disease	$179	$556	68%	$4.3	994,000
Enbrel	Immunex Corp.	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	$2,355	$7,106	67%	$3.0	48,000
Jardiance	Boehringer Ingelheim Diabetes	Diabetes; Heart failure; Chronic kidney disease	$197	$573	66%	$8.8	1,883,000
Stelara	Janssen Biotech	Psoriatic arthritis; Crohn's disease; Ulcerative colitis	$4,695	$13,836	66%	$3.0	23,000
Xarelto	Janssen Pharmaceutical	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	$197	$517	62%	$6.3	1,324,000
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	$231	$521	56%	$18.3	3,928,000
Entresto	Novartis Pharmaceutical	Heart failure	$295	$628	53%	$3.4	664,000
Imbruvica	Pharmacyclics LLC	Blood cancers	$9,319	$14,934	38%	$2.4	17,000
Total						**$56.2**	**10,509,000**

Source: CMS, BofA Global Research

Major Drug Pricing Provisions

- **Medicare Drug Price Negotiations – Second 15 Drugs for 2027 Implementation**
  - **CMS Announced Next 15 Drugs for Negotiation on January 17, 2025**
    - Negotiations to take place through November 2025, with new prices taking effect in 2027
    - Not clear how Trump Administration will Approach the IRA Drug Price Negotiation Process

Drug Name	Manufacturer	Conditions	Total Part D Gross Covered Prescription Drug Costs from Nov. 2023-Oct. 2024 ($ Billion)	Number of Medicare Part D Enrollees Who Used the Drug from Nov. 2023-Oct. 2024
Ozempic; Rybelsus; Wegovy	Novo Nordisk	Type 2 Diabetes; Cardiovascular Disease, Obesity	$14.40	2,287,000
Trelegy Ellipta	GlaxoSmithKline	Asthma; Chronic obstructive pulmonary disease	$5.10	1,252,000
Xtandi	Astellas Pharma	Prostate Cancer	$3.20	35,000
Pomalyst	Celgene/BMS	Kaposi Sarcoma; Multiple Myeloma	$2.10	14,000
Ibrance	Pfizer	Breast Cancer	$2.00	16,000
Ofev	Boehringer Ingelheim	Idiopathic pulmonary fibrosis	$2.00	24,000
Linzess	Abbvie/Ironwood	Chronic idiopathic constipation; irritable bowel syndrome	$1.90	627,000
Calquence	AstraZeneca	Chronic lymphocytic leukemia/small lymphocytic lymphoma; Mantle cell lymphoma	$1.60	15,000
Austedo; Austedo XR	Teva	Chorea in Huntington's disease; Tardive dyskinesia	$1.50	26,000
Breo Ellipta	GlaxoSmithKline	Asthma; Chronic obstructive pulmonary disease	$1.40	634,000
Tradjenta	Boehringer Ingelheim	Type 2 Diabetes	$1.10	278,000
Xifaxan	Salix Pharmaceutical	Hepatic encephalopathy; irritable bowel syndrome with diarrhea	$1.10	104,000
Vraylar	Abbvie	Bipolar I disorder; Major depressive disorder; Schizophrenia	$1.10	116,000
Janumet; Janumet XR	Merck	Type 2 diabetes	$1.10	243,000
Otezla	Amgen	Oral ulcers in Behçet's Disease; Plaque psoriasis; Psoriatic arthritis	$1.00	31,000

Source: CMS, BofA Global Research

Inflation Reduction Act Litigation

Lawsuits Challenging Drug Price Negotiation Provisions in IRA Have Not Been Successful (to date)

- Merck (District of Columbia) - briefs filed in September through November – Awaiting decision
- US Chamber of Commerce (Ohio) – On August 8, Judge dismissed case based on standing, on Appeal at 6th Circuit
- Bristol-Myers Squibb (New Jersey) - BMS and J&J suits were combined in New Jersey, Decision in April 2024 – Judge dismissed case with summary judgment; BMS appealed to the 3rd Circuit – Awaiting Decision.
- PhRMA & National Infusion Center Association (Texas) – In Feb. 2024, Judge dismissed case. PhRMA appealed to the 5th Circuit – which reversed the District Court in September 2024 on the question of standing, now remanded to District Court Again
- Teva (DC District Court) – Filed January 15, 2025 – TEVA's drug Austedo is included in 2nd round of negotiations
- Johnson & Johnson (New Jersey) – combined with BMS suit – In April 2024, Judge ruled in favor of DOJ with a summary judgment. J&J appealed to the 3rd Circuit – Awaiting Decision.
- Boehringer Ingelheim (Connecticut) – In July 2024– Judge rules in favor of DOJ with a summary judgement and denying drug manufacturers motions. Appeal filed in 2nd Circuit – Ongoing briefing
- AstraZeneca (Delaware) – In March 2024, Judge Connolly upheld the IRA drug pricing reforms - AZ appealed to the 3rd Circuit – Awaiting Decision.
- Novartis (New Jersey) – In October 2024, Judge ruled in favor of DOJ with summary judgement. Novartis appealed to the 3rd Circuit – Ongoing briefing
- Novo Nordisk (New Jersey) – In July 2024, Judge ruled in favor of DOJ with a summary judgement denying drug manufacturer motions. Novo Nordisk has appealed to 3rd Circuit. Ongoing briefing

- **Suits generally make the following legal challenges:**
  - 1st Amendment (Compelled Speech); 5th Amendment (Uncompensated Takings/Due Process); 8th Amendment (Excessive Fines/Taxes)
  - Administrative Procedures Act (APA) violations / No Statutory or Legislative Authority (CMS did not follow statutory language)

Source: BofA Global Research O'Neill Institute Healthcare Litigation Tracker

Major Drug Pricing Provisions

Medicare Drug Price Negotiations

- **Special Rule for Biologics – Up to a 2-year delay if a biosimilar is ready to enter the market**
- **Maximum Fair Prices for Drugs is the lesser of:**
  - First set of 10 drug prices announced in August 2024 – taking effect in 2026, with average 22% net savings, and $6 billion in first year savings – larger than CBO estimates
  - Part D Average Net Price (after concessions received by Part D plans), or for Part B drugs the ASP
  - Percentage of 2021 non-Federal Average Manufacturer's Price (FAMP), increased by CPI:
    - 75% of 2021 non-FAMP for small molecule drugs from 9-11 years since approval ("short-monopoly")
    - 65% of 2021 non-FAMP for drugs 12-15 years since approval ("extended monopoly")
    - 40% of 2021 non-FAMP for drugs 16 years or more since approval ("long-monopoly")
- **Excise Tax on drugs that do not Enter into Negotiations**
  - Excise tax starts at 65% in first 90 days, ramping up to 95% tax after 270 days.
- **Congressional Budget Office (CBO) Estimates**
  - Estimated savings of $98 billion from 2026-2031
  - CBO also estimates impact on drug development (15 fewer drugs over the next 3 decades vs. industry estimate of 135 fewer new drugs)
- **Industry Concerns**
  - **Concerns over limiting access for patients –** CMS Plans Formulary Review of Selected Drugs – Formulary Flexibility
  - **Potential to disincentivize innovation and post-approval research:** Particularly for small molecule drugs including cancer therapies, heart disease, and mental illness
  - **Differential impact on small molecules versus biologics (9 years versus 13 years)**
  - **Impact on Orphan drug market – as only orphan drugs treating 1 disease are exempt from negotiation**

Source: BofA Global Research

Major Drug Pricing Provisions (Continued)

- **Medicare Part B and Part D Inflationary Caps**
  - Part B Manufacturer rebates due 6 months after end of each quarter – However, for 2023 and 2024 Rebates, HHS expected to delay payment until September 2025; Part D Rebate payments to HHS delayed until December 2025
  - As of Q4 2024, there were 54 Medicare Part B drugs impacted by the inflationary rebates (vs. 64 in Q3 2024)
  - CBO estimated Medicare direct savings of $56 billion over 10 years (plus an additional $7 billion in Revenue effects)
- **Medicare Part D Benefit Re-Design**
  - **Cost-Sharing and Benefit Reforms**
    - Out-of-Pocket cap of $2,000, effective in 2025
    - Eliminates the current Medicare Coverage Gap ("Donut hole") and removes 70% mfg. discount; New manufacturer discount of 10% in the initial benefit phase; Beneficiary liability reduced from 25% to 23%
    - Plan sponsor liability revised from 75% to 67% for Brands/Biologics/Biosimilars and 77% for Generics
  - **Catastrophic Benefit Reforms**
    - In 2024: 5% beneficiary cost-sharing eliminated
    - In 2025: Part D Plan risk increases from 15% to 60% in 2025; New 20% drug manufacturer discount; Government Re-Insurance decreases from 80% to 20%
  - **Medicare Part D Premium Stabilization**
    - Medicare Part D premium stabilization – Caps premiums at 6% per year through 2029 (CBO estimates cost of $40 billion)
    - Additional Part D premium stabilization demo (announced in late July) – Estimated to cost $5 billion in 2025
  - **Other Reforms**
    - Cap on Insulin cost-sharing at $35 per month – began in 2023 (CBO est. cost of $5 billion over 10 years)
    - Medicare Part D Low Income Subsidies (LIS) expanded in 2024 from 135% of FPL to 150% of FPL (CBO est. of $2.2 billion)

Source: BofA Global Research, CMS

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