TxSCO Update

August 8, 2024

ADVI & HillCo

Federal Updates

2024 Election: Polls in Flux, Though Latest Predictions Favor Republicans

Today

White House: Biden

Senate: Democrats Control (51D, 49R)

House: Republicans Control (217 R, 213 D, 5 vacant)

2024 Polls

Harris

226 D, 251 R, 61 Toss-up

Trump

Democrat-controlled Senate

48 D, 50 R, 2 Toss-up

Republican-controlled Senate

Must gain 1 seat (Trump wins) or 2 seats (Harris wins) to take control

Democrat-controlled House

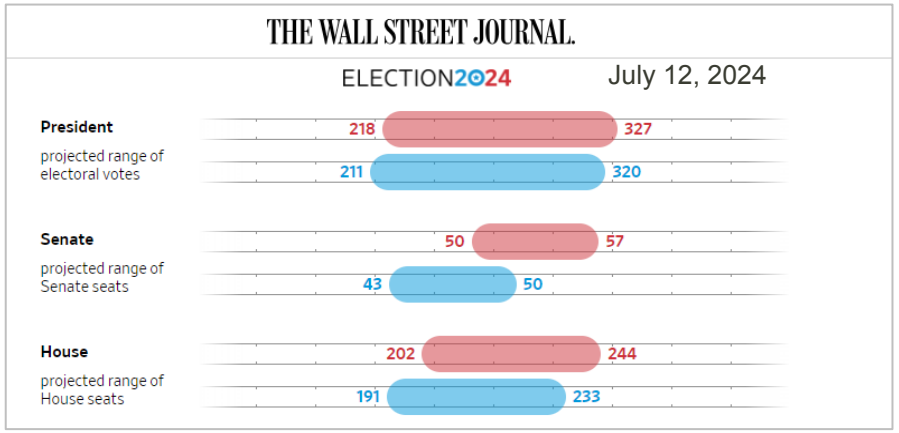
Must gain 4 seats to take control

201 D, 209 R, 25 Toss-up

Republican-controlled House

Polling source – as updated August 5, 2024: 270toWin Presidential (link); 270toWin Senate (link); 270toWin House (link)

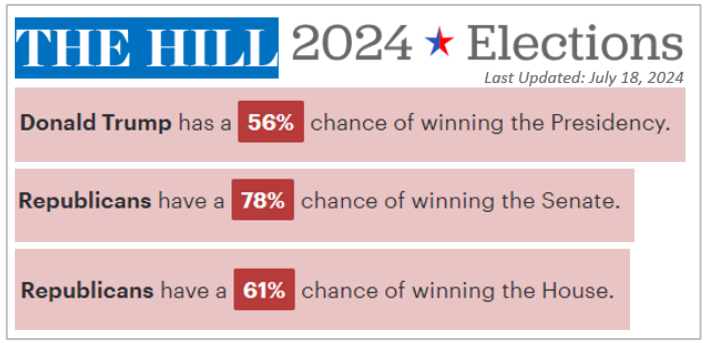
2024 Election: Polls in Flux, Latest Margins are Tight

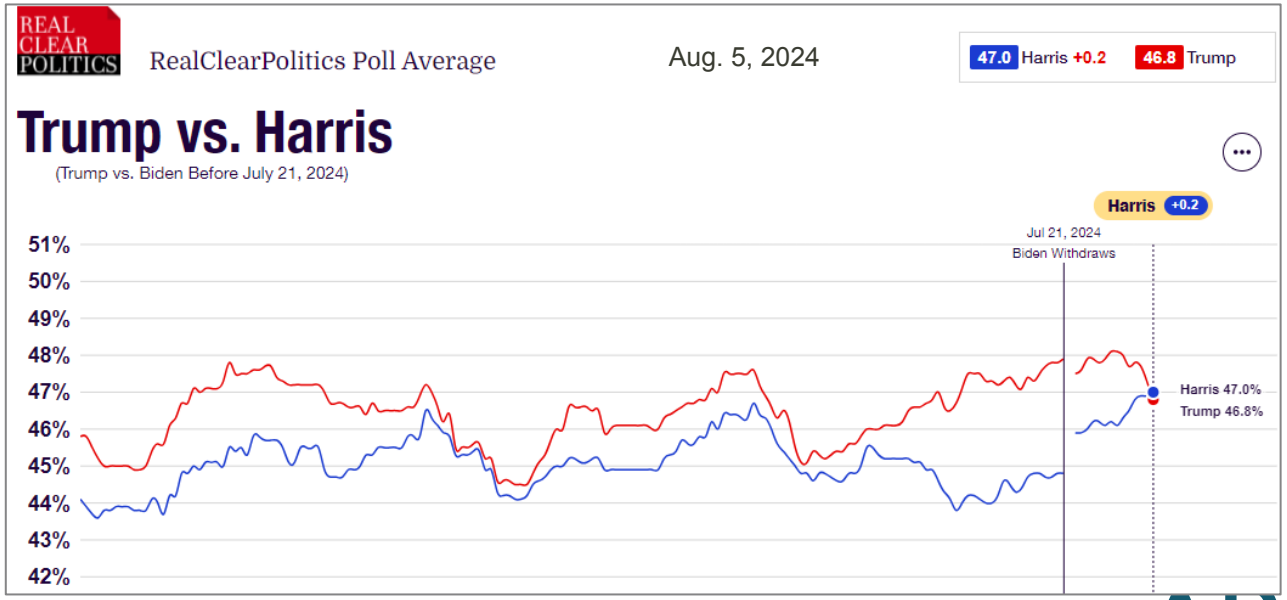


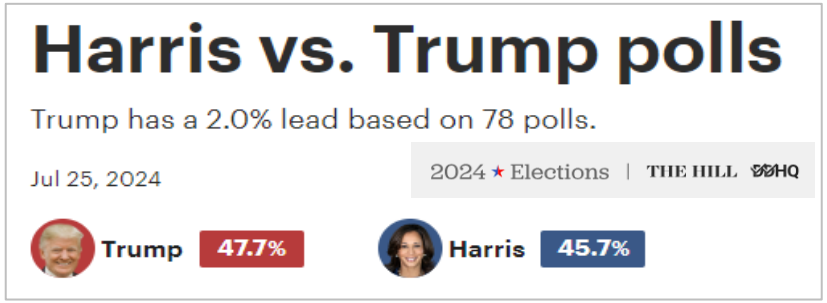
RealClearPolitics Election 2024
RCP Poll Averages Aug. 6, 2024

Election 2024	Trump	Harris	Spread
RCP Poll Average	46.8	47.0	Harris +0.2
5-Way RCP Average	44.3	44.7	Harris +0.4
Top Battlegrounds	47.8	46.3	Trump +1.5
Favorability Ratings	-7.4	-5.9	Harris +1.5
RCP Betting Odds	52.0	46.3	
Electoral College	**Trump**	**Harris**	**Toss Ups**
RCP Electoral Map	219	208	111
No Toss Up States	297	241	

Battlegrounds	Trump	Harris	Spread
Wisconsin	48.2	48.0	Trump +0.2
Pennsylvania	48.4	46.6	Trump +1.8
Michigan	46.3	48.3	Harris +2.0
Arizona	48.3	45.5	Trump +2.8
Nevada	47.5	43.5	Trump +4.0
North Carolina	48.0	45.0	Trump +3.0
Georgia	47.8	47.0	Trump +0.8
Battle for Congress	**GOP**	**Dems**	
U.S. Senate	50	43	7 TU
Generic Ballot	45.4	45.2	GOP +0.2







Harris Administration: IRA Implementation, March-in Rights, Consolidation

Consolidation

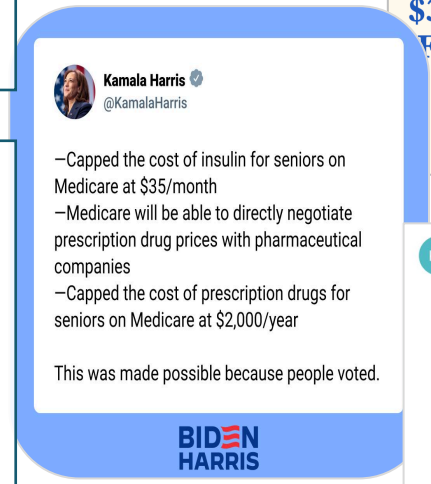
- Insurers: in 2016, as CA Atty General, sued to stop Anthem-Cigna merger
- Hospitals: in 2015, as CA Atty General, placed more than 300 conditions on a merger between for-profit hospital Prime Healthcare Services and a safety-net hospital
- PBMs: no past activity but potential for a Harris administration to scrutinize PBM consolidation

Medicare-for-All

- 2017: original co-sponsor of Sen. Sanders' (I-VT) "Medicare for All Act"
- 2019: introduced her own proposal that maintained a role for private insurers

Prescription Drugs

- IRA Implementation
  - Expect Harris to tout the IRA as a shared Biden-Harris achievement
  - Harris is generally viewed as more liberal than Biden, potential for a Harris administration to implement IRA government negotiation more aggressively (i.e., even lower MFPs) than Biden
- March-in Rights
  - 2019: cosponsored the *Prescription Drug Affordability and Access Act* to allow HHS to invalidate patents if manufacturers did not agree to an "appropriate" price determined by the government
  - 2019: included in her 2020 campaign platform
- Importation
  - 2019: included in her 2020 campaign platform
- International Reference Pricing
  - 2019: included in her 2020 campaign platform; called for limiting US prices to no more than 100% of the average price in OECD countries
  - Today: expect for Harris to shift focus to touting the IRA's government negotiation policy



Sources: Harris Medicare for All Plan (7/29/19, link); California AG Press Release (9/22/16, link) California AG Press Release (7/2/12, link); California AG Press Release (7/26/12, link); Politico (7/16/19, link); CNN (7/16/19, link); Stat (link); S.1804 (link); S.3166 (link)

Harris Selects Minnesota Governor Tim Walz as Vice Presidential Candidate

Gov. Walz has supported legislation related to healthcare during his time as Governor (2019-present) and as a Representative for MN-1 (2007-2019). Walz did not have any health-related committee assignments during his time in Congress, although he was the Chair of the Congressional Emergency Medical Services (EMS) Caucus.

July 29, 2024: “Don't ever shy away from our progressive values. **One person's socialism is another person's neighborliness**.”

Previous Healthcare-Related Activity

Drug Pricing

- PDAB
  - **Walz signed into law SF2744 in 2023, which established the Minnesota Prescription Drug Affordability Board**
- Transparency
  - Walz advocated for and passed the MN Prescription Drug Price Transparency Act in 2020, which requires manufacturers to report price increases and prices for newly launched drugs that meet a specified threshold.
    - As a result, Minnesota Department of Health has published a list of 364 drugs from 76 manufacturers that now require reporting from various healthcare entities.
- Government Negotiation
  - As a member of the House, **Walz supported Medicare drug price negotiation**

Hospital/Consolidation

- Minnesota is home to some of the largest healthcare entities, including the Mayo Clinic and United Health Group (Optum)
- **In 2023, Walz and MN Democrats proposed an affordability board that increased oversight over hospital and provider costs and staffing.**
  - As a result, Mayo Clinic threatened to withhold $4B in investments, and the state reintroduced and passed a weaker version of the bill.
- In 2023, Walz passed a bill that creates a “public interest standard” for mergers, blocking any mergers that may negatively impact patients, healthcare spending, or worker wages

Insurance

- As a member of the House, Walz voted for the Affordable Care Act
  - Walz also supported the Health Insurance Industry Fair Competition Act in 2010, which would have created antitrust protections against health insurers
  - In 2018, Walz introduced the Protect Medicare for Seniors Act, which would have extended Medicare cost reimbursement contracts through 2020
- **As Governor, in 2023, Walz signed into law a state-based public option** which has not yet been fully implemented but is planned to begin in 2027
- In 2024, Walz renewed restrictions preventing for-profit HMOs from securing managed care contracts with MN Medicaid

Insulin

- As Governor, Walz advocated for and passed an Insulin Affordability bill which allows patients to receive a 30-day insulin supply for a $35 copay once in a 12-month period, with a 90-day supply being capped at a $50 copay.
  - This bill was passed prior to the passage of the Inflation Reduction Act.
- In 2024, Minnesota reached a settlement agreement with Lilly and Sanofi that would cap all insulin prices in the state for at least five years at a $35 copay.

Other

- Veterans
  - As an Army veteran himself, Walz has supported numerous bills that support healthcare funding for Veterans, with an emphasis on mental health care.
- Provider Support
  - Health care professionals were top contributors to Walz campaigns, including support from the American Health Care Association and American Association of Orthopedic Surgeons.
- IVF/Fertility Preservation
  - Walz, who has a daughter via IVF, has been a vocal supporter of IVF and other reproductive technology.
  - Walz has voiced concern about Americans' access to IVF after the Alabama ”fetal personhood” Supreme Court ruling

Sources: Becker’s Hospital Review (8/6/24, link); MN Prescription Drug Transparency (link); Stat+ (8/6/24, link); MN SF2744 (5/24/23, link); Politico (5/30/23, link); MN Merger (5/26/23, link); H.R.6341 (7/11/2018, link); Insulin Affordability Act (4/15/20, link); CBS News (8/6/24, link)

Trump 2.0: JD Vance Selected as Vice President Candidate

Health care has not been a primary focus: Sen. Vance (R-OH) was elected in 2022 and has not served on any health care committees of jurisdiction (Finance or HELP), although he is a member of the Special Committee on Aging

Previous Healthcare-Related Activity

Drug Pricing

- Negotiation
  - In a 2022 interview with AARP (as part of Senate campaign), expressed support for allowing Medicare to negotiate prescription drug prices
- Importation
  - Also expressed support (in AARP interview) for allowing American companies and pharmacies to import drugs from overseas
- Insulin
  - Co-sponsored legislation (S.954) that would cap the price of insulin in the private health insurance market to the lesser of $35 or 25% of a plan's negotiated price

PBMs

- Legislation
  - Voted in favor of the PBM Transparency Act (S.127), which includes transparency provisions and would ban spread pricing
- FTC
  - While not specific to the ongoing PBM investigation, Vance has expressed support for the FTC's role in limiting anti-competitive behavior
    - He also previously praised Chair Lina Khan for her antitrust enforcement work and "building a more competitive marketplace"

FDA

- Legislation
  - Cosponsored the Promising Pathways Act (2.0) (S.1906), which would create a new time-limited conditional approval pathway at FDA
  - Introduced legislation (S.4232) to bar high-level officials at FDA (as well as CDC and NIH) from working in regulated industry for eight years

Cell and Gene Therapy

- Vance has previously invested in cell and gene therapy (CGT) companies, including AmplifyBio and Kriya Therapeutics (investments range from $50,000 to $100,000)
- *ADVI Insight:*
  - Vance's investment in CGT companies indicates some support for this evolving space
  - Generally, the Republican party has been supportive of CGT, so his public views of this space are unlikely to change

Opioids

- Co-sponsored *S.1271, the FEND Off Fentanyl Act*
  - Bill aims to enhance current law so government agencies can more effectively disrupt illicit opioid supply chains.
- Vance has personal connections to opioid abuse/addiction:
  - Vance's mother was addicted to OxyContin.
  - In 2016, Vance launched a nonprofit (Our Ohio Renewal) that he said would aim to develop opioid addiction treatments that might be "scaled nationally."

Other

- Alzheimer's
  - Co-sponsored three bills (S.133, S.134, S.626) to
    1. Extend the National Alzheimer's Project,
    2. Require budget estimates for recommendations from the National Alzheimer's Project; and
    3. Recommend CMS test dementia care models
- 340B and Medicaid
  - Co-sponsor of legislation (S.3578) that calls for a government report on health benefits provided to noncitizens, including covered outpatient drugs provided through 340B and Medicaid

Sources: AARP Interview (9/28/22, link); 340B Report (1/23/24, link); Stat (7/15/24, link), PinkSheet (7/15/24, link); Reason (7/16/24, link); S. 127 (link); S.1906 (link); S.4232 (link); S.954 (link); S. 3578 (link); S. 133 (link); S.134 (link); S.626 (link)

CY 2025 Physician Fee Schedule Proposed Rule

On July 10, 2024, CMS released the CY 2025 Medicare Physician Fee Schedule (PFS) Proposed Rule. Comments are due by September 9, 2024.

Calculation of the CY 2025 PFS Conversion Factor

CY 2024 Conversion Factor		33.2875
Conversion Factor without the CAA, 2024 (2.93 Percent Increase for CY 2024)		32.3400
CY 2025 Statutory Update Factor	0.00 percent (1.0000)	
CY 2025 RVU Budget Neutrality Adjustment	0.05 percent (1.0005)	
CY 2025 Conversion Factor		**32.3562 (-2.80%)**

Specialty Impact

Specialty	Combined Impact
Hematology/Oncology	0%
Radiation Oncology and Radiation Therapy Centers	0%

E/M Services

- Use of G2211 (complexity add-on code): Expanded to be used at the same time as an annual wellness visit, vaccine administration, or any Part B preventive service

Telehealth Services

- Permanent allowance of audio-only telehealth services
- Allowance of direct supervision via telehealth through CY 2025
  - Permanent allowance of direct supervision via telehealth for subset of services: provided by auxiliary personnel employed by the physician and working under his or her direct supervision and for which the underlying HCPCS code has been assigned a PC/TC indicator of 5

Global Surgery

- Requirement of the existing modifiers (-54, -55, and -56) for all 90-day global surgical packages in any case when a practitioner (or another practitioner from the same group practice) expects to furnish only the pre-operative (-56), procedure (-54), or post operative portions of a global package
- Creation of new add-on code GPOC1 for post-operative care services

Source: ADVI Instant (7/10/24, link); CY 2025 PFS Proposed Rule (7/10/24, link)

CY 2025 PFS Proposed Rule

On July 10, 2024, CMS released the CY 2025 Medicare Physician Fee Schedule (PFS) Proposed Rule. Comments are due by September 9, 2024.

Colorectal Cancer (CRC) Screening*

- Removal of coverage for barium enema procedures
- Addition of coverage for the computed tomography colonography (CTC) procedure
- Expansion the definition of “complete colorectal cancer screening” to include a follow-on colonoscopy after a Medicare covered blood-based biomarker CRC screening test

Caregiver Training Services

- Creation of three HCPCS codes for direct care caregiver training services, focused on specific clinical skills that will allow the caregiver to effectuate hands-on treatment, reduce complications, and monitor the patient
  - GCTD1: Initial 30 min. of caregiver training
  - GCTD2: Each additional 15 min. of caregiver training
  - GCTD3: Group caregiver training
- Creation of two HCPCS codes for caregiver behavior management and modification training
  - GCTB1: Initial 30 min. of caregiver training in behavior management/modification
  - GCTB2: Each additional 15 min. of caregiver training in behavior management/modification

2024 CAA Implementation

- Codification of the 12-month continuous coverage mandate for people aged 19 or younger who are enrolled in Medicaid or CHIP

*Note: These provisions are repeated in the CY 2025 OPPS proposed rule
Source: ADVI Instant (7/10/24, link); CY 2025 PFS Proposed Rule (7/10/24, link)

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CY 2025 PFS Proposed Rule: Health Equity Provisions

On July 10, 2024, CMS released the CY 2025 Medicare Physician Fee Schedule (PFS) Proposed Rule. Comments are due by September 9, 2024.

RFI on the Community Health Integration (CHI), Principal Illness Navigation (PIN), and SDOH Risk Assessment Codes

- Any related services that may not be described by the current coding and that are medically reasonable and necessary "for the diagnosis or treatment of illness or injury"
- Barriers to furnishing services related to HRSNs; can include barriers specific to certain populations
- Other types of auxiliary personnel, other certifications, and/or training requirements that aren't adequately captured in current coding/payment
- Whether the incident to billing construct is appropriate for CBOs to supplement pre-existing staffing arrangements and the CBO/provider interface
- CBOs' roles in the use of these codes (contracting with practitioners, incident to billing, etc.)
- Barriers or opportunities to increase coding of Z codes

RFI for Future Ambulatory Specialty Care Model

- Replacement for traditional MIPS
- Model where participants receive payment adjustment based on:
  - Clinically relevant, mandatory MVP measures
  - Comparison of participant performance with other cohort members

Source: ADVI Instant (7/10/24, link); CY 2025 PFS Proposed Rule (7/10/24, link)

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CY 2025 PFS Proposed Rule: Other Relevant Provisions

On July 10, 2024, CMS released the CY 2025 Medicare Physician Fee Schedule (PFS) Proposed Rule. Comments are due by September 9, 2024.

New MVPs

- Complete Ophthalmologic Care
- Dermatological Care
- Gastroenterology Care
- Optimal Care for Patients with Urologic Conditions
- Pulmonology Care
- Surgical Care

QP Thresholds

- Full QP threshold
  - Increase from 50% to 75% of payments
  - Increase from 35% to 50% of patients
- Partial QP threshold
  - Increase from 40% to 50% of payments
  - Increase from 25% to 35% of patients

Source: ADVI Instant (7/10/24, link); CY 2025 PFS Proposed Rule (7/10/24, link)

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AMA Calls for Physician Payment Reform

On July 26, the AMA and 150+ other organizations wrote to Congress, calling for four major types of physician reform.

MEI update

Pass the Strengthening Medicare for Providers and Patients Act (H.R. 2474)

- Provides an annual physician pay update tied to the MEI

Budget neutrality reform

Pass the Provider Reimbursement Stability Act (H.R. 6371)

- Establishes a look-back adjustment to prospectively correct misestimates
- Updates the $20M budget neutrality threshold to adjust for inflation (would be $57M)
- Prevents the conversion factor from increasing/decreasing more than 2.5% each year

MIPS reform

Implement the AMA's Data-Driven Performance Payment System

- Temporarily freezes performance thresholds
- Replaces payment adjustments with a percentage of statutorily mandated payment updates
- Requires CMS to provide timely feedback
- Allows cross category credit for measures

APM reform

Pass the Value in Health Care Act (S. 3503/H.R. 5013)

- Extends the original 5% advanced APM incentives
- Maintains the QP revenue threshold at 50% for two years

Source: AMA (7/26/24, link)

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UnitedHealthcare Launches Gold Card Program for Prior Authorizations

Starting October 1, 2024, UHC will launch a national Gold Card program, which will allow qualifying practices to submit advance notifications instead of prior authorization requests

Program Details	Practices with Gold Card status would complete an advance notification for the services covered under the Gold Card, rather than a prior authorization request The advance notification would confirm member eligibility and coverage for the service(s) requested
Plan Applicability	Commercial Individual Exchange Medicare Advantage Community Plans
Program Eligibility	In-network participation with one of the above plans Minimum annual volume of 10 eligible prior authorizations for 2 consecutive calendar years Prior authorization approval rate of 92% or higher for two consecutive years
Other Details	Practices do not need to apply; UHC will determine each practice's eligibility A list of services eligible for Gold Card will be published on September 1, 2024

Source: UHC (8/1/24, link)

FTC: Judges Continue to Rule on Noncompete Final Rule

Ryan LLC v. FTC

- July 3, 2024: Judge Ada E. Brown rules against FTC in preliminary injunction
- Judge Brown writes that the FTC does not have authority to set rules governing competition issues
  - In preliminary injunction, postpones effective date of the final rule for the plaintiffs only (Chamber of Commerce, Business Roundtable, Texas Association of Business, Longview Chamber of Commerce, Ryan LLC)
- July 26, 2024: AHA and American Federation of Hospitals file amicus brief, asking the court to vacate the final rule
- Final ruling expected by August 30

ATS Tree Services, LLC v. FTC

- July 23, 2024: Judge Kelley Hodge rules in favor of FTC
- Judge Hodge writes that the FTC acted within its authority to prohibit noncompetes as part of its mandate to foster competition
  - "The plain text of the statute provides no express limitations on the FTC's rulemaking authority and the Court will not read in such limitations"

Source: Politico (7/3/24, link; 7/23/24, link)

FTC Releases Interim Report on PBMs

On July 9, 2024, the Federal Trade Commission released an interim report summarizing findings in its investigation into pharmacy benefits managers and their practices.

Background & Delays

- In June 2022, the FTC launched in inquiry into the "prescription drug middleman industry, specifically targeting the six largest PBMs:
  - CVS Caremark
  - Express Scripts, Inc.
  - OptumRx, Inc.
  - Humana Inc.
  - Prime Therapeutics LLC
  - MedImpact Healthcare Systems, Inc.
- Despite requiring data and documents around business practices that year and again in 2023, some have yet to comply and submit the required materials
- FTC notes the lack of responses as reason for the study's delay, and that it may take legal action to compel compliance
- FTC published the interim report based on its findings to date


FEDERAL TRADE COMMISSION

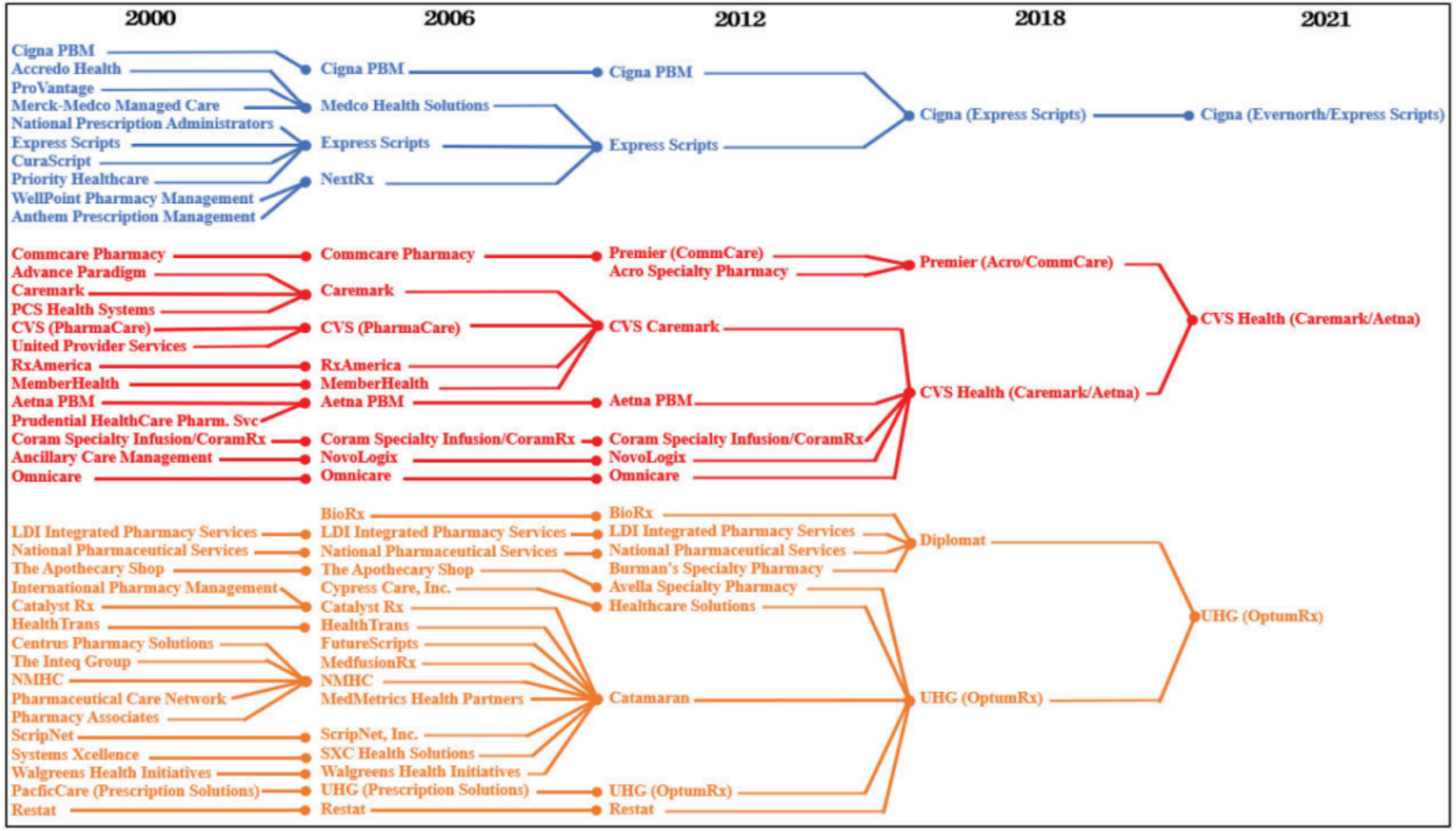
Pharmacy Benefit Managers:
The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies

Interim Staff Report
July 2024
U.S. Federal Trade Commission
Office of Policy Planning

Source: FTC PBM Interim Report (link)

FTC Interim Report on PBMs: Highlights

Figure 3. PBM Parent Entity Consolidation[21]



Source: FTC PBM Interim Report (link)

FTC Interim Report on PBMs: Highlights

- FTC compared proportions of specialty prescriptions based on 30-day equivalents and dispensing revenue through affiliated and unaffiliated pharmacies between 2017 – 2022
- **PBMs are less able to steer prescriptions in Part D likely due to "any willing pharmacy" requirements**
  - Part D plans are required to contract with any interested pharmacy that meets plan standard terms and conditions
- The report notes that one of the ways PBMs steer fulfillment to affiliated pharmacies is by designating products as "specialty" and requiring the use of specialty pharmacies
- FTC calculated the number of drugs characterized by PBMs as specialty between 2017 – 2022
- **FTC notes the trend does not appear to only relate to the number of new specialty drugs brought to market, as 45% of specialty drugs were unique to a single PBM**
- FTC also notes that PBMs designate a portion of generic drugs as "specialty generics
  - Most PBMs added generics to their specialty drugs lists at a faster rate than brand drugs

Figure 8. Proportion of Specialty Prescriptions Filled by Affiliated and Unaffiliated Pharmacies For Members of Commercial and Medicare Part D Plans Managed By Two of the Big 3 PBMs, 2017-2022[175]

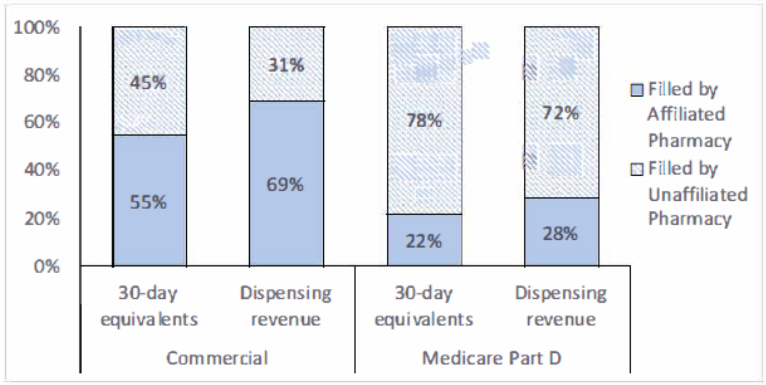


Figure 9. Number of Specialty Drugs Covered by PBMs, 2017-2021[186]

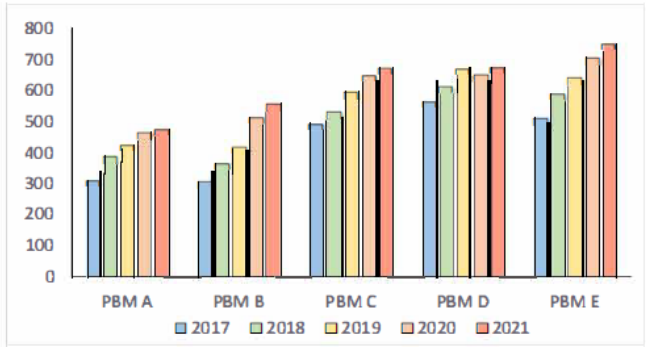


Figure 10. Growth and Mix of Specialty Drugs Covered by PBMs for Commercial Members, 2017-2021[189]

	Growth in Number of Drugs Covered, 2017-2021		Specialty Generic As Percent of Total, 2021
	Specialty Brand	Specialty Generic	
PBM A	70%	268%	13%
PBM B	44%	233%	11%
PBM C	41%	94%	13%
PBM D	31%	73%	15%
PBM E	20%	19%	15%

Source: FTC PBM Interim Report (link)

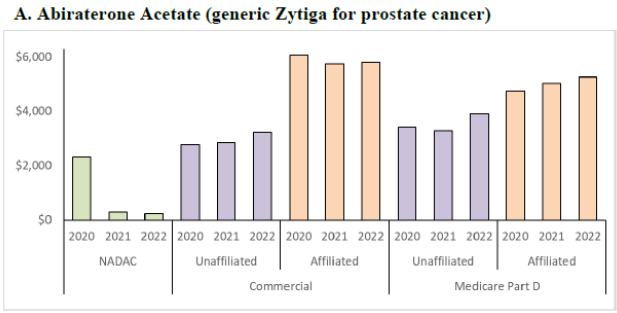
FTC Interim Report on PBMs: Highlights

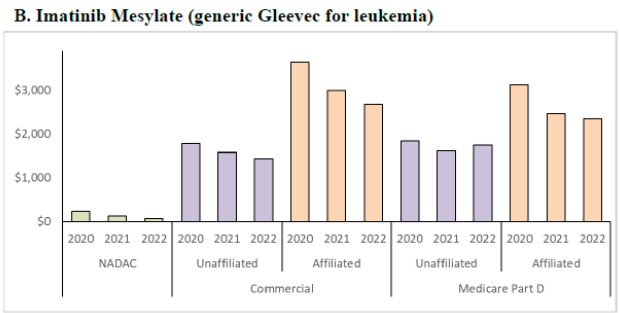
Generic Zytiga

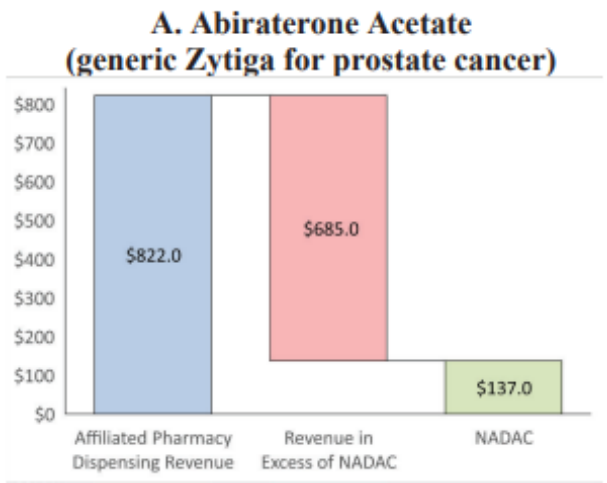
- 232,000 prescriptions
  - 31% commercial
  - 69% Part D
- **Part D plans paid PBM-affiliated pharmacies 23x the acquisition cost on average**

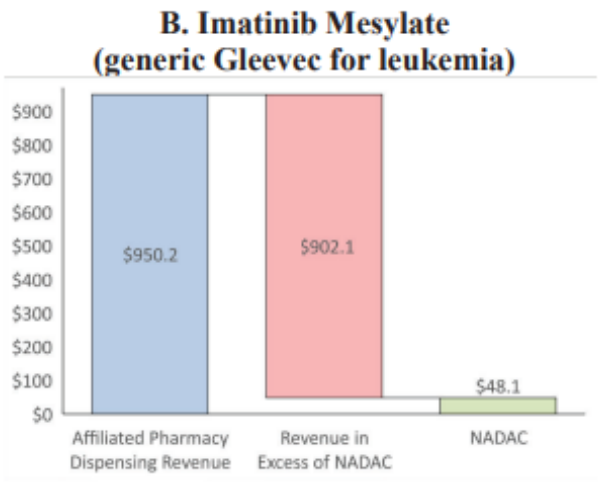
Generic Gleevac

- 182,000 prescriptions
  - 50% commercial
  - 50% Part D
- **Part D plans paid PBM-affiliated pharmacies 36x the acquisition cost on average**









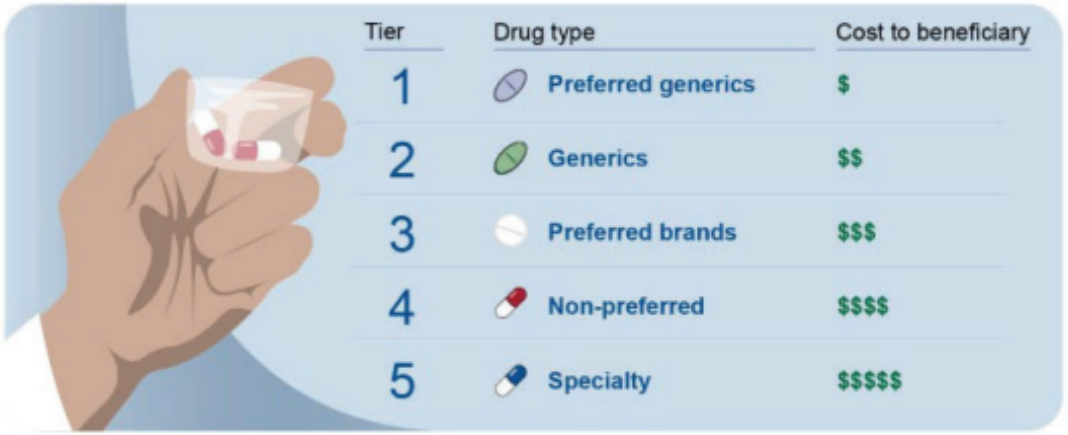
"[Y]ou can get the drug [imatinib mesylate] at a non-preferred pharmacy (Costco) for $97, at Walgreens (preferred) for $9000, and at preferred home delivery for $19,200. CMS expects that plans that offer preferred pharmacy constructs have lower pricing in the preferred channel. Compounding the challenge/optics is the fact that we've created plan designs to aggressively steer customers to home delivery where the drug cost is ~200 times higher. The optics are not good and must be addressed."

- Quote from PBM Parent Company Executive (name redacted)

Source: FTC PBM Interim Report (link)

FTC Interim Report on PBMs: Highlights

- PBM + Manufacturer Contract Implications
  - Rebate structures may impede/impair competition and patient access to affordable medicines
    - Examples of
      - Preferred formulary positioning over competitor products
      - Additional rebates to exclude competitors
        - Incl. NDC blocks
      - Additional rebates to step through products before competitors



Source: GAO; GAO (illustrations). | GAO-23-105270

Figure 17. Rebate Contract Excerpt

A-4 Lantus and Lantus SoloSTAR

REBATES FOR LANTUS® and LANTUS SoloSTAR® [1] (INCLUDES ALL NDCs, STRENGTHS & PACKAGE SIZES)						
Formulary Type		1 of 1 Manufacturer Status**	1 of 2 Manufacturer Status**	1 of 3 Manufacturer Status**	1 of 4 Manufacturer Status	Listed Formulary Status
Non-Exclusion Formulary*	No Cost Share Differential	63.0%	58.0%	56.0%	N/A	N/A
	Cost Share Differential	63.0%	58.0%	56.0%	N/A	N/A
Exclusion Formulary*		63.0%	58.0%	56.0%	N/A	N/A
ACF / ACSF Closed Plans*		63.0%	58.0%	56.0%	N/A	N/A

*CVS/caremark Clients with sixty percent (60%) or more of their Plan lives that qualify for a higher Formulary Type Rebate rate shall earn the higher rate on all Client utilization. Clients that do not meet this threshold shall be evaluated on a Plan by Plan basis. Additionally, for clarity, open Plans (i.e. Plans which do not otherwise qualify as Closed Plans), will receive Closed Plan Rebate rates for any Competitive Category which qualifies as Closed.

[1] **Plan must have all NDCs, strengths, package sizes of Lantus, Lantus SoloSTAR and Toujeo on the Preferred Brand Tier without restrictions to be eligible for this Rebate.**

**Within the Long-Acting Insulin Category as defined in Section O.

INCREMENTAL ADDITIONAL BASE REBATE FOR ADOPTION OF EXCLUSIONS*:	
One Manufacturer of Competitive Products Excluded	2.0%
Two Manufacturers of Competitive Products Excluded	3.0%
Three Manufacturers of Competitive Products Excluded	N/A

*The incremental rebates above may be used for any current or future PBM exclusions. For avoidance of doubt, incremental additional Base Rebate for adoption of Exclusions shall not apply to Non Preferred Brand Tier Status Rebates.

NON-PREFERRED BRAND TIER STATUS FOR LANTUS® and LANTUS SoloSTAR®
N/A

Incremental Additional Base Rebate For Adoption of Brand Step Therapy Program:	
*Implementation of Brand Step Therapy Program***	2.0%

Source: FTC PBM Interim Report (link)

House Oversight Committee Holds Hearing With PBM Executives

On July 23, 2024, the House Committee on Oversight and Accountability held a hearing entitled, "The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part III: Transparency and Accountability."

Background

- The House Committee on Oversight and Accountability has now held three hearings related to PBMs in the past 10 months
  - The hearing comes after the FTC released its Interim Report on PBM practices on July 9, 2024

Summary

- Representatives from both parties expressed their frustrations with PBM practices
  - Chair James Comer (R-KY-1) claimed that PBMs lack transparency and called out PBMs use of foreign subsidiaries to avoid oversight from the US government
  - Comer also stated that transparency focused bills do not go far enough and noted his support for action from the FTC to "break up" the major PBMs
- **Representative questions also focused on PBM approaches to independent pharmacy contracting, PBM preference of brand name products over generics or biosimilars, CEO compensation, and the benefactors of rebates and administrative fees**
  - Chair Comer and Rep. Jamie Raskin (D-MD-8) expressed frustration with the witness' answers or refusal to answer certain questions
  - Comer said to the witnesses, "*You have refused to answer questions from members on both sides of the aisle… You point the finger at manufacturers even though PBMs are at the center of the problem. You've taken no ownership or role in the rise of prescription drug costs*"

Adam Kautzner (ExpressScripts)

- Kautzner noted that ExpressScripts has supported independent pharmacies by launching "IndependentRx" to increase reimbursement to independent rural pharmacies
- Kautzner also claimed that patients spent less on average OOP from 2022 to 2023, despite manufacturer price increases

David Joyner (CVS Caremark)

- Joyner insisted that CVS puts patient access and care first, highlighting the newly announced TrueCost program
- Joyner claimed that TrueCost and other initiatives have contributed to increased transparency and accountability
- Joyner cited Humira as an example of how manufacturers "stretch the limits" of their sales rights through patent thickets

Patrick Conway (OptumRx)

- Conway claimed that high list prices from manufacturers are the main driver behind prescription drug costs
- Conway claimed that 98% of discounts are passed through to patients
- Conway was the only witness to disclose his compensation, which he stated was over $4 million
- He noted that OptumRx has been fully compliant with the FTC

Source: Hearing (7/24/24, link)

House Oversight Committee Releases PBM Report

On July 23, 2024, the House Committee on Oversight and Accountability released a report on PBM practices entitled, “The Role of Pharmacy Benefit Managers in Prescription Drug Markets.”

Anticompetitive Behavior

- The report focuses on consolidation, noting that the three largest PBMs (CVS, Optum, and ExpressScript):
  - Control 80% of the market
  - Are vertically integrated with insurers
- The report argues that:
  - Patient steering practices and retroactive fees are harming independent and community pharmacies
  - PBMs are creating group purchasing organizations in foreign countries to avoid US regulation

Rebates, Fees, Spread Pricing

- The report states that PBMs regularly engage in spread pricing to increase revenue at the expense of plans, pharmacies, and patients
  - The report notes that this can occur with across payer types (commercial, Medicare, Medicaid)
- The report claims that rebates play a direct role in increasing list prices, arguing that PBMs shift patients to higher priced drugs to collect larger rebates
  - Humira was cited as an example; the report states that ExpressScripts kept the drug at parity with its biosimilars to maintain high rebates

Patient and Policy Impact

- The report states that PBM preference of high-priced, brand name drugs over biosimilars and generics leads to delays in uptake of these alternatives
  - Prior authorization and step therapy are characterized as tools used to “prevent or delay patients from accessing the medicines they need”
- The committee cited a recent OIG report which found that ExpressScripts had been overcharging the Postal Service Union $45 million from 2016-2021
  - The committee claims that PBMs have also been overcharging Medicare and other federal health plans

Legislative Reforms

- The report highlights the following bills:
  - DRUG Act (H.R. 6283)
  - Lower Costs, More Transparency Act (H.R. 5378)
  - Pharmacy Benefit Manager Transparency Act of 2023 (S. 127)
  - Medicare PBM Accountability Act (H.R. 5385)
  - PBM Reporting Transparency Act (S. 2493)
  - Pharmacy Benefit Manager Sunshine and Accountability Act (H.R. 2816)
  - Pharmacy Benefits Manager Accountability Act (H.R. 2679)
- The report also discusses state PBM reform

Source: House Oversight Report (7/23/24, link)

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Appendix

CMS Releases OPPS Proposed Rule

On July 10, 2024, CMS released the CY 2025 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System Proposed Rule (link) and fact sheet (link). Comments are due by September 9, 2024. Select highlights are summarized herein.

Payment for Drugs/Devices Being Studied in Clinical Trials with a Medicare CED NCD

- For CY 2025, CMS proposes to develop alternative payment methods under Medicare Part B for drugs and devices studied in clinical trials under a CED NCD
  - CMS proposes to make a blended payment representing the frequency with which the study drug and placebo (or comparator) are used
    - CMS would use ASP payment amounts for study drugs and zero-dollar amounts for placebo/ comparators
      - If ASP data is not available, CMS proposes to pay according to the existing payment hierarchy for non-passthrough separately payable drugs in OPPS
    - CMS provides an example of a 1:1 study design where the study drug is $1, blended payments would be $0.50
  - CMS notes that a new, or revised, HCPCS code would be created for the drug and placebo/ comparator
- CMS seeks comment on other instances where Medicare payment methodologies could interfere with the scientific validity of a trial

Radiopharmaceuticals

- CMS proposes the following changes to the existing policy which packages the payment of diagnostic radiopharmaceuticals with nuclear medicine tests:
  - Pay separately for diagnostic radiopharmaceuticals with per day costs above $630
    - Diagnostic radiopharmaceuticals with per-day costs equal to or below the threshold would continue to be policy-packaged
    - Beginning in 2026 and annually thereafter, update the $630 threshold by the Producer Price Index (PPI) for Pharmaceutical Preparations
    - Base payments for separately payable diagnostic radiopharmaceuticals on their Mean Unit Cost (MUC) derived from OPPS claims (CY 2025 payments would be based on CY 2023 MUC data)
  - CMS seeks comments on basing payments on ASP in future years, acknowledging that radiopharmaceuticals are not required to report ASP under Section 1847A of the Social Security Act

Drug Packaging Threshold

- CMS proposes to raise the threshold to $140 per day for CY 2025. This is a $5 increase from the CY 2024 threshold of $135 per day. Items with a per day cost greater than $140 are identified as separately payable unless they are policy-packaged.

Proposed Drugs and Biologicals with Forthcoming Expirations of Pass-Through Payment Status

- The Proposed Rule includes:
  - 25 products for which pass-through payment status expires before CY 2025 (Table 62)
  - 28 products for which pass-through payment status expires during CY 2025 (Table 63)
  - 57 products for which pass-through payment status expires after CY 2025 (Table 64)

Source: ADVI Instant (7/11/2024, link)

CMS Releases OPPS Proposed Rule

On July 10, 2024, CMS released the CY 2025 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System Proposed Rule (link) and fact sheet (link). Comments are due by September 9, 2024. Additional highlights are detailed below.

Other Notable Proposals

Invoice drug pricing proposal: CMS proposes to adopt an invoicing pricing policy beginning in CY26 for novel drugs and biologics which do not have sufficient WAC, AWP, sales, and MUC information for CMS to assign a payable status indicator. Medicare Administrative Contractors would use the provider invoice amount to set a payment rate for separately payable drugs, biologics, or radiopharmaceuticals until their payment amount is available to CMS. For CY 2025, impacted drugs and biologics would continue to be assigned a non-payable status indicator until the implementation of the proposed policy.

Add-on payment for high-cost drugs provided by Indian Health Service (IHS) and Tribal Facilities: For CY2025, CMS proposes to pay IHS and tribal hospitals separately for high-cost Part B drugs (daily costs over 2x the lower 48 AIR - $1,334 in CY 2024) furnished in hospital payment departments through and add-on payment in addition to the All-Inclusive Rate (AIR). The add-on payment would be the ASP of the drug (if no ASP: WAC; if no WAC: 89.6% AWP).

Colorectal cancer (CRC) screening: CMS proposes the following changes to coverage of CRC screening services:

Remove coverage and discontinue codes for barium enema procedures (HCPCS codes G0106 and G0120) due to the procedures no longer being recommended in clinical guidelines and add coverage for the computed tomography colonography (CTC) procedure (HCPCS code 74263), and expand the existing definition of a “complete colorectal cancer screening” to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3).

Quality measures: CMS proposes to adopt several measures across the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs, including:

Hospital Commitment to Health Equity (HCHE) (CY 2025 reporting period/CY 2027 payment or program determination) and Screening for SDOH and Screen Positive Rate for SDOH (voluntary reporting for the CY 2025 reporting period)

Beginning CY 2025, CMS proposes to modify the Immediate Measure Removal policy for adopted OQR and ASCQR Program measures.

Implementation of provisions from the Consolidated Appropriations Act (CAA) of 2023: CMS proposes to revise Medicaid and CHIP regulations to codify the requirement that states provide 12 months of continuous eligibility to children under the age of 19 and CMS proposes to implement Section 4135 of the CAA, which will provide temporary additional payments for certain non-opioid pain treatments from January 1, 2025, through December 21, 2027. CMS states that seven drugs and one device qualify as non-opioid pain treatments and proposes that these products will be separately paid beginning in CY 2025 and requests comments on other products that may qualify.

Cell and Gene Therapy: For CY 2025 only, CMS proposes not to package payment for certain cell and gene therapies into the payment for the primary Comprehensive Ambulatory Payment Classification (C-APC) service when they appear on the same claim as primary C-APCs services.

Source: ADVI Instant (7/11/2024, link)

CMS Releases the FY 2025 Inpatient Prospective Payment System Final Rule

On August 1, 2024, CMS issued the fiscal year 2025 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule (link) and accompanying fact sheet (link).

New Technology Add-On Payments (NTAP)

- **CMS received 23 applications for new technology add-on payments for FY 2025 under the NTAP alternative pathway.**
  - 7 were not eligible for consideration for NTAP and 5 withdrew their applications
  - Of the remaining 11, 12 of the technologies received a Breakthrough Device designation.
- **CMS awarded 5 NTAP applications for technologies under the traditional pathway.**
- CMS finalized the **change the April 1 cutoff to October 1 for determining whether a technology would be within its 2- to 3-year newness period.**
- CMS also finalized proposal to **no longer consider a hold status to be an inactive status** for eligibility for the NTAP.

NTAP for Gene Therapies

- CMS finalized a proposal to the NTAP percentage **from 65% to 75% for the newly approved gene therapies indicated to treat severe sickle cell disease.**
  - 2 gene therapies are eligible for increased payments upon being awarded NTAP in this final rule.
- **CMS received a request to expand MS-DRG 018's title, Chimeric Antigen T-cell therapies and Other T-cell Immunotherapies, to include autologous gene therapies.** CMS shared that they do not agree with the MS-DRG request's basis and will continue with the current titling of MS-DRG 018. CMS solicits feedback on MS-DRG 018 for future consideration.

Payment for Establishing & Maintaining Access to Essential Medicines

- CMS finalized the proposal to establish a separate payment for small, independent hospitals(<100 beds) for the IPPS shares of the additional costs to voluntarily establish and maintain a 6-month buffer stock of one or more essential medicines.
  - A drug will be considered an essential medicine if it is included in the Essential Medicines Supply Chain and Manufacturing Resilience Assessment report (the ARMI List).
  - A hospital that newly establishes a buffer stock of the medicine while in shortage will not be eligible for the separate payment.
- Separate payment would be for IPPS share of additional cost of procuring and maintaining the buffer stock.
  - Payment adjustments would begin on or after October 1, 2024, and could be provided biweekly or as a lump sum at cost report settlement.

Source: ADVI Instant (link)

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Applications Approved Under Alternative Pathways

- 12 technologies received a Breakthrough Device designation:
  - Annalise Enterprise Computed Tomography Brain (CTB) Triage – Obstructive
  - Hydrocephalus (OH)
  - ASTar® System
  - cefepime-taniborbactam
  - Edwards EVOQUETM Tricuspid Valve Replacement System (Transcatheter Tricuspid
  - Valve Replacement System)
  - GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)
  - LimFlow™ System
  - Paradise™ Ultrasound Renal Denervation System
  - PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter
  - restor3d TIDAL™ Fusion Cage
  - Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter
  - Transdermal Glomerular Filtration Rate (GFR) Measurement System utilizing Lumitrace
  - TriClip™ G4
  - VADER® Pedicle System
  - ZEVTERA™ (ceftobiprole medocaril)

Applications Awarded for Technologies Under the Traditional Pathway

- CASGEVY™ (exagamglogene autotemcel) for the indication of sickle cell disease
- HEPZATO™ KIT (melphalan for injection/ hepatic delivery system)
- LYFGENIA™ (lovotibeglogene autotemcel)
- ELREXFIO™ (elranatamab-bcmm)
- TALVEY™ (talquetamab-tgvs)

- CMS is **not** approving the NTAP application for the following:
  - Casgevy™ (exagamglogene autotemcel) for the indication of transfusion dependent β-thalassemia
  - DuraGraft® (Vascular Conduit Solution)
  - FloPatch FP120
  - Lantidra™ (donislecel-jujn (Allogeneic Pancreatic Islet Cellular Suspension for hepatic portal vein infusion))
  - AMTAGVI™ (lifileucel)
  - Quicktome Software Suite (Quicktome Neurological Visualization and Planning Tool)

CMS is discontinuing NTAP for the following technologies

- Intercept® Fibrinogen Complex (PRCFC)
- Rybrevant® (amivantamab)
- StrataGraft®
- aprevo® Intervertebral Body Fusion Device (TLIF indication)
- Hemolung Respiratory Assist System (RAS) (nonCOVID-19 related use)
- Livtencity™ (maribavir)
- Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor

CMS is continuing NTAP for the following technologies

- Thoraflex™ Hybrid Device
- ViviStim® Paired VNS System
- GORE® TAG® Thoracic Branch Endoprosthesis
- Cerament® G
- iFuse Bedrock Granite Implant System
- CYTALUX® (pafolacianine) (ovarian indication)
- CYTALUX® (pafolacianine) (lung indication)
- EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamabgxbm)
- Lunsumio™ (mosunetuzumab)
- REBYOTA™ (fecal microbiota, livejslm) and VOWST™ (fecal microbiota spores, live-brpk)
- SPEVIGO® (spesolimab)
- TECVAYLI™ (teclistamab-cqyv)
- TERLIVAZ® (terlipressin)
- Aveir™ AR Leadless Pacemaker
- Aveir™ Dual-Chamber Leadless Pacemaker
- Ceribell Status Epilepticus Monitor
- DETOUR System
- DefenCath™ (taurolidine/heparin)
- EchoGo Heart Failure 1.0
- Phagenyx® System
- REZZAYO™ (rezafungin for injection)
- SAINT Neuromodulation System
- TOPS™ System
- XACDURO® (sulbactam/durlobactam)

Source: ADVI Instant (link)

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Payment Rates

- **The finalized increase in operating payment rates for acute care hospitals paid under IPPS that successfully participate in Hospital IQR and meaningfully use EHRs is projected to be 2.9%.**
  - This reflects a projected FY 2025 hospital market basket percentage increase of 3.4%, reduced by a 0.5 percentage point productivity adjustment.
- Overall, for FY 2025, CMS expects the changes in operating and capital IPPS payment rates will generally increase hospital payments by $2.9 billion.
  - Operating and capital IPPS payment rates will increase hospital payments in FY 2025 by approximately $3.2 billion.
  - CMS projects Medicare uncompensated care payments to DSH will decrease in FY 2025 by approximately $0.2 billion.
  - CMS also estimates additional payments for inpatient cases involving new medical technologies will increase by approximately $0.3 billion in FY 2025, primarily driven by the approval of NTAP for several technologies.
- Under current law, additional payments for Medicare-Dependent Hospitals (MDHs) and the temporary change in payments for low-volume hospitals are set to expire December 31, 2024.
  - payments have previously been extended by legislation, but if they were to expire, CMS estimates that payments to these hospitals would decrease by $0.4 billion in FY 2025.

Other

- CMS finalized several changes to:
  - Hospital Inpatient Quality Reporting (IQR) Program
  - PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program
  - Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals.
    - CMS also has issued an RFI on the Medicare Promoting Interoperability Program's Public Health and Clinical Data Reporting objective.
- CMS finalized a new mandatory episode-based alternative payment model, titled Transforming Episode Accountability Model (TEAM), running from January 1, 2026, to December 31, 2030.
- CMS is finalizing proposal to change the severity designation of the seven ICD-10-CM diagnosis codes that describe inadequate housing and housing instability from non-complication or comorbidity (Non-CC) to complication or comorbidity (CC).
  - CMS is finalizing proposal to require Long-Term Care Hospitals to collect additional information to standardize patient assessment data elements under the SDOH category.

Source: ADVI Instant (link)

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