Welcome and Opening Remarks

Matt Devino, MPH

Director of Cancer Care Delivery & Health Policy

Association of Community Cancer Centers

@ACCCBuzz | **#ACCCORM**

28,000+

multidisciplinary practitioners from every discipline in oncology

CANCER PROGRAM LEADERSHIP

Hospital Presidents
CEOs, COOs, CMOs
Vice Presidents
Department Directors

ADMINISTRATION

Oncology Program and Practice Administrators, Managers, and Service Line Executives
Program Administrative Staff

CLINICIANS

Medical
Radiation
Surgical
Pharmacy

PATIENT CARE

Allied Physicians
Oncology Nurses
Nurse Practitioners
Physician's Assistants

SUPPORTIVE CARE STAFF

Social Workers
Patient Navigators
Financial Advocates
Palliative Specialists

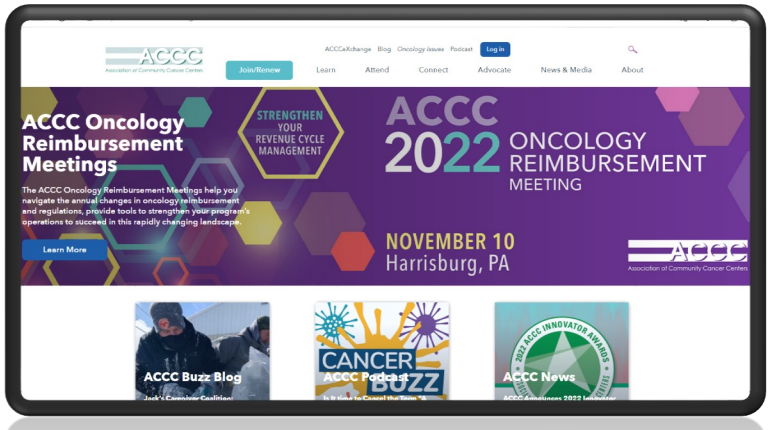
THE ENTIRE TEAM

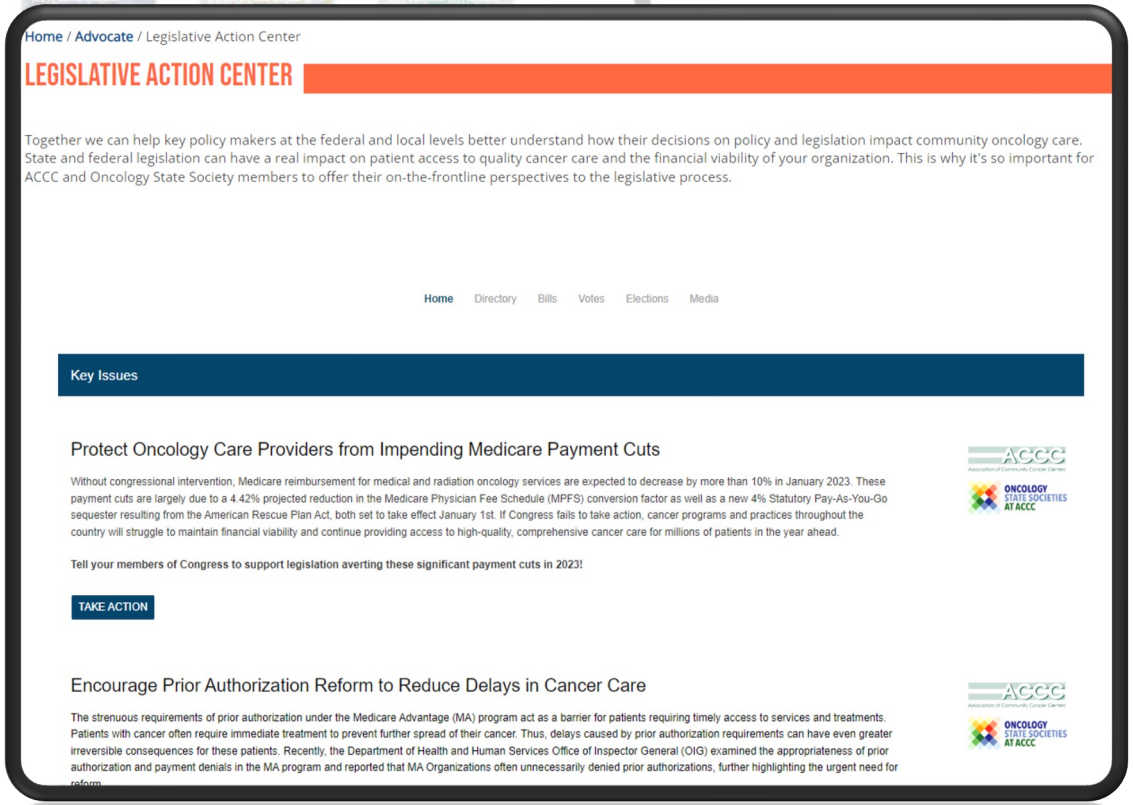
Genetic Counselors
Quality Officers
Data Manager/Registrars
Billers & Coders

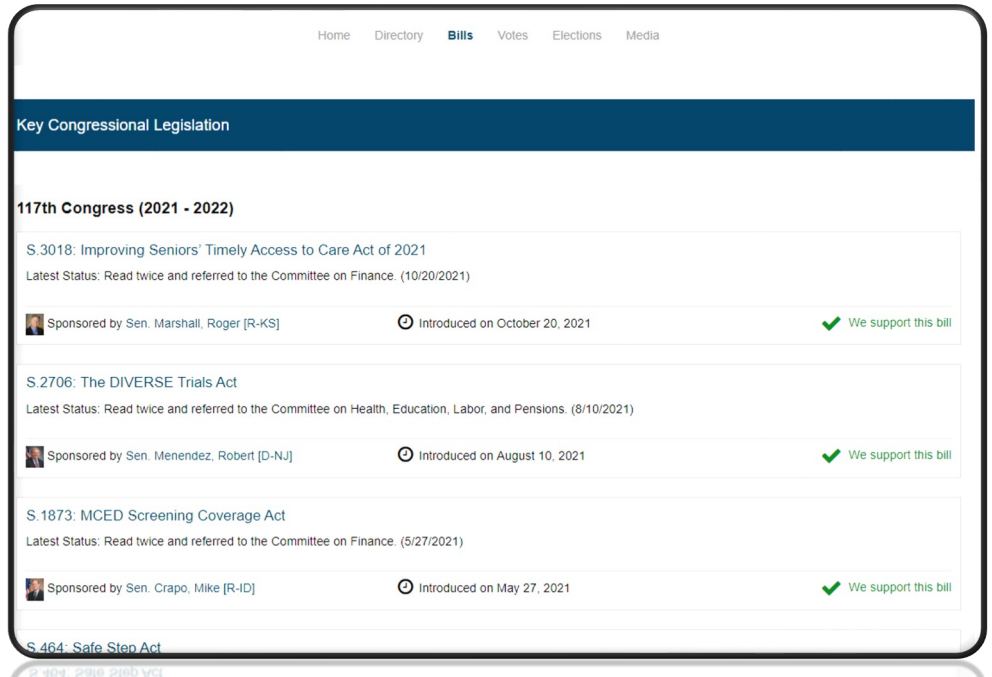
1,700

Private Practices, Hospital Cancer Programs, Healthcare Systems, & Major Academic Centers Nationwide

Stay Abreast of Key Congressional Legislation And Take Action In A Few Steps







ACCC Policy Update

Matt Devino, MPH
Director of Cancer Care Delivery & Health Policy
Association of Community Cancer Centers

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Calendar Year (CY) 2023 Medicare Physician Fee Schedule (MPFS) Final Rule[1]

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CY 2023 MPFS Conversion Factor (CF)[1]

TABLE 146: Calculation of the CY 2023 PFS Conversion Factor

CY 2022 Conversion Factor		34.6062
Conversion Factor without CY 2022 Protecting Medicare and American Farmers from Sequester Cuts Act		33.5983
Statutory Update Factor	0.00 percent (1.0000)	
CY 2023 RVU Budget Neutrality Adjustment	-1.60 percent (0.9840)	
CY 2023 Conversion Factor		**33.0607**

- Difference of -4.5% from the finalized CY 2022 CF
- Does not include relative value unit (RVU) changes, sequestration (-2%), or the statutory PAYGO sequester triggered by the American Rescue Plan Act[2] (-4%)

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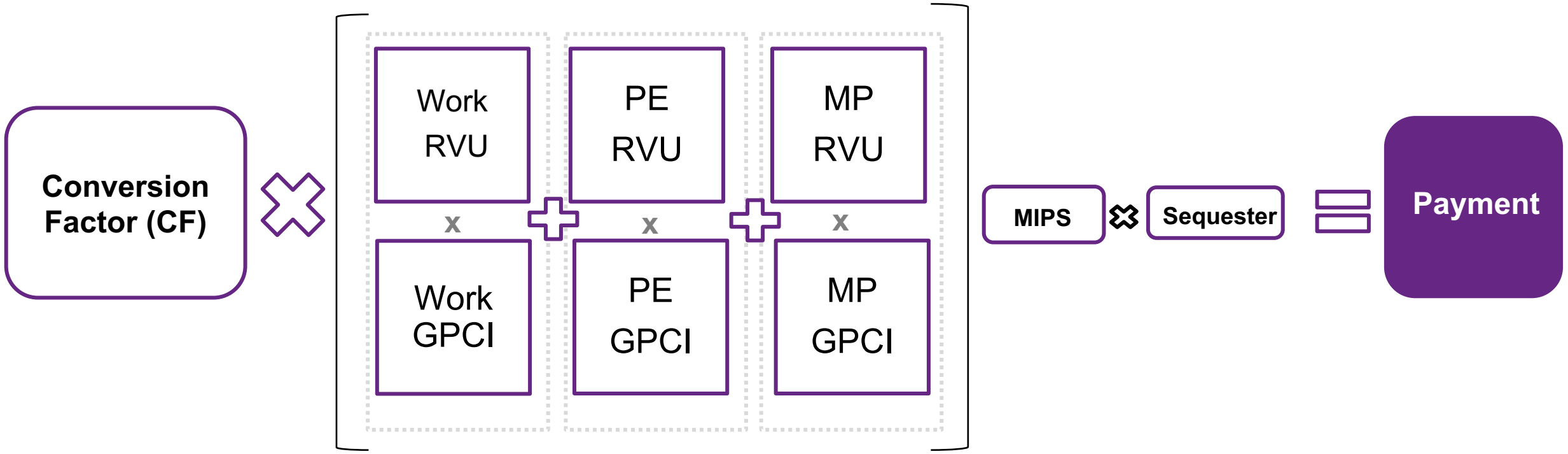
Medicare Service Payment Calculation[1]



GPCI = geographic practice cost indices; MIPS = Merit-based Incentive Payment System; MP = malpractice; PE = practice expense

RVU Changes: Specialty Impact by Setting[1]

Specialty	Total Non-Facility/Facility	Allowed Charges (million)	Combined Impact
Hematology/Oncology	**TOTAL**	**$1,713**	**-1%**
	Non-facility	$1,134	**-2%**
	Facility	$579	**1%**
Radiation Oncology and Radiation Therapy Centers	**TOTAL**	**$1,615**	**-1%**
	Non-facility	$1,545	**-1%**
	Facility	$69	**-2%**

“Other” Evaluation and Management (E/M) Services[1]

Medical decision making (MDM) & time-based

Inpatient and observation, emergency department (ED), nursing facility, domiciliary or rest home, home visits, and cognitive impairment assessment

CMS accepting most of the American Medical Association’s (AMA’s) guidelines

Clarified initial and subsequent

Different criteria for prolonged services

E/M Split (or Shared) Visit Definitions[1]

CMS finalized its decision to maintain the 2022 definition of the "substantive portion" of an E/M service performed by both a physician and a non-physician practitioner in a facility setting through 2023.

E/M Visit Code Family	2022 & 2023 Definition of Substantive Portion	2024 Definition of Substantive Portion
Outpatient facility*	History, or exam, or MDM, or more than half of total time	More than half of total time
Inpatient/observation/hospital/nursing facility	History, or exam, or MDM, or more than half of total time	More than half of total time
Emergency department	History, or exam, or MDM, or more than half of total time	More than half of total time
Critical care	More than half of total time	More than half of total time

***Non-facility office visits will not be billable as split (or shared) services.**

Status of the COVID-19 Public Health Emergency (PHE)[1,3,4]

PHE Extended October 13, 2022

↓

Extension beyond January 11, 2023?

↓

Biden administration will provide 60 days' notice

↓

Some waivers/extensions will end 152 days after PHE ends

Medicare Telehealth After the COVID-19 PHE[1]

Temporary Codes	• End day 152 post-PHE to align with Consolidated Appropriations Act of 2022, **including audio-only E/M codes 99441-99443**
Modifiers and POS Codes	• Modifier 95 no longer applies • Use place of service (POS) codes – 02 & 10
Location of Patient Telehealth Services	• Telehealth no longer allowed in any geographic area or any originating site, including the beneficiary's home, except for a select subset of services/illnesses
Physician Supervision	• Returns to "direct supervision," virtual presence ends Dec. 31, of year PHE ends • Seeking comments on the possibility allowing virtual supervision for a select subset of services

Expanded Coverage for Dental Services[1]

- The Social Security Act excludes Medicare coverage of routine dental services.
- Dental services are covered by Medicare in only a limited number of circumstances, including when treatment is medically necessary, the dental service requires hospitalization because of an individual's underlying medical condition and clinical status, or the dental service is an integral part of a covered primary procedure or service furnished by another physician treating the primary medical illness.
- CMS finalized its proposal to pay for dental exams and necessary treatments **prior to the treatment for head and neck cancers starting in CY 2024**.
- It also finalized a process in CY 2023 to review and consider public recommendations for Medicare payment for dental service in other potentially analogous clinical scenarios.

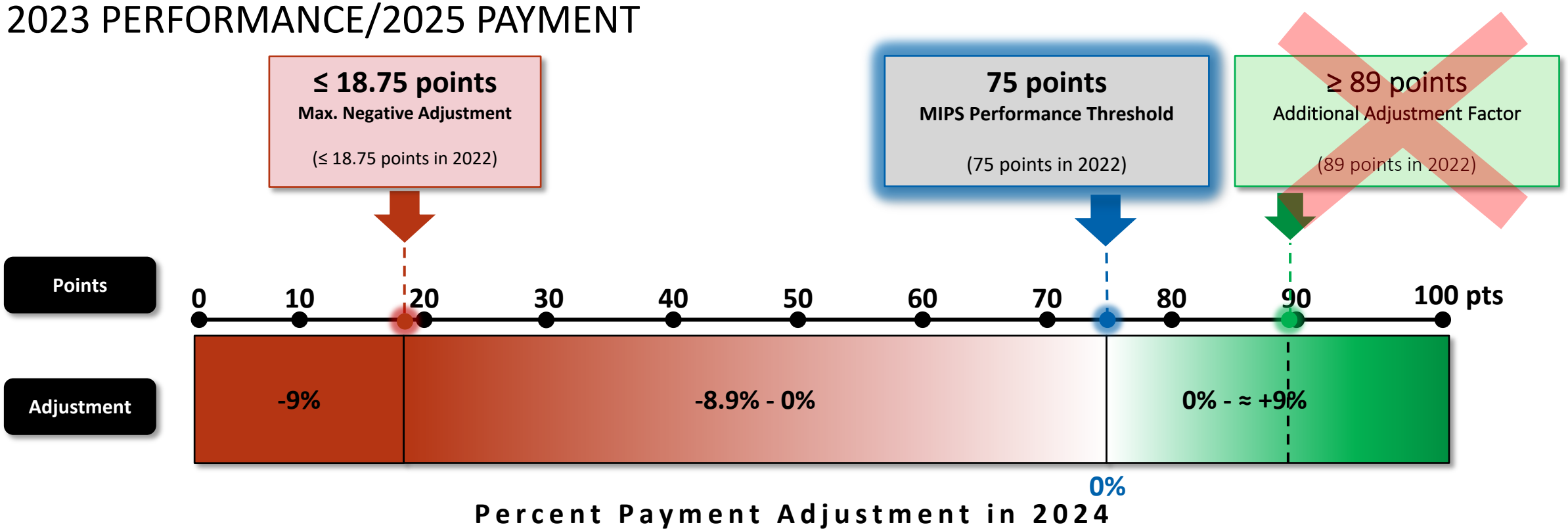
Expanded Coverage for Colorectal Cancer Screening[1]

- To be consistent with updated U.S. Preventive Services Task Force guidance, CMS finalized its proposal to expand Medicare coverage for certain colorectal cancer screening tests by reducing the **minimum age limitation from 50 years to 45 years**.
- CMS also expanded its regulatory definition of colorectal cancer screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive, stool-based colorectal cancer screening test returns a positive result.
- For most beneficiaries, **cost sharing will not apply** for either the initial stool-based test or the follow-on colonoscopy.

Quality Payment Program Updates[1]

Final Merit-Based Incentive Payment System (MIPS) Thresholds[1]

2023 PERFORMANCE/2025 PAYMENT



In CY 2022, there was an additional MIPS payment adjustment for exceptional performance above 89 points. These percentages are multiplied by a scaling factor to proportionally distribute statutorily allocated funds of $500 million. **By statute, the 2024 payment year will be the final year for an additional performance threshold/additional MIPS adjustment for exceptional performance.**

MIPS Value Pathways (MPVs)[1]

MIPS Value Pathways (MVPs)

Aligning measures across performance categories to be more relevant to practice specialty

Guiding principles for MVPs:

- Cohesion between performance categories and measures, reducing reporting burden
- Focused participation around pathways that are meaningful to clinician's specialty/practice or public health priority
- Clinicians report fewer measures and activities based on specialty and/or outcome within a pathway
- Measures selected using meaningful measures approach, considering the patient voice
- Support the transition to digital quality measures

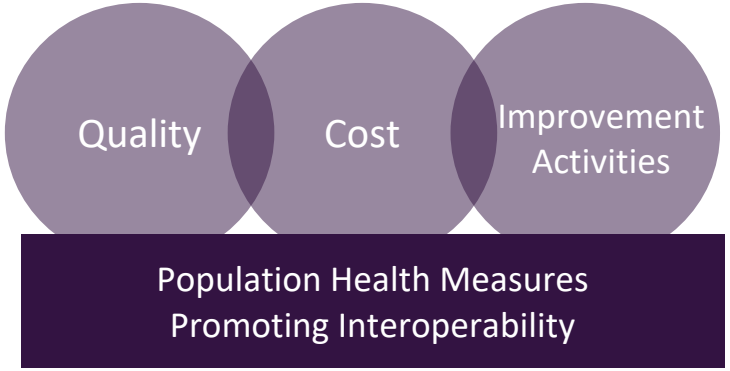
MVP Reporting Requirements:

Reporting Across all MVPs:

- **Population Health Measures:** Report on 1 selected population health measure
- **Promoting Interoperability:** Report on same promoting interoperability measures as required under traditional MIPS

MVP Specific Performance Category Reporting:

- **Quality:** Report on 4 selected quality measures, one must be an outcome measure
- **Improvement Activities:** Report on either 2 medium-weighted or 1 high-weighted
- **Cost:** Performance calculated only using cost measures in the MVP using administrative claims data



MVPs Implementation Timeline[1]

In the CY 2022 MPFS final rule, CMS created seven MVPs available for reporting in the 2023 performance year (PY) and introduced the proposed transition timeline from traditional MIPS reporting to MVPs.

In the CY 2023 MPFS rule, CMS finalized an additional five new MVPs for reporting in PY 2023:

1. **Advancing cancer care**
2. Optimal care for kidney health
3. Optimal care for neurological conditions
4. Supportive care for cognitive-based neurological conditions
5. Promoting wellness.

Proposed MVP Implementation Timeline (*Performance Years*)

Medicare Advanced Alternative Payment Model (APM) Incentive Payments[1]

- Originally authorized under the Medicare Access and CHIP Reauthorization Act (MACRA), these 5% advanced APM incentive payments support providers transitioning to value-based arrangements.
- Only Advanced APM participants who meet the "QP threshold" will receive the payment incentive. To qualify, an Advanced APM must receive either 50% of their Part B payments or see 35% of their Medicare patients through the APM entity. **This payment threshold is set to increase from 50% to 75% at the end of 2022**.
- **Moreover, absent congressional action, these payments will expire at the end of 2022.**
- Section 4 of the **Value in Health Care Act** (H.R. 4587)[5] would extend these payments for an additional six performance years, allowing oncology groups participating in advanced APMs, including the new Enhancing Oncology Model, to qualify for these incentives.

CY 2023 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule[6]

Change to 340B Drug Reimbursement as a Result of Supreme Court Decision[6]

CY 2018-2022

- Average sales price (ASP) ***minus*** 22.5% for separately payable drugs and biosimilar biologicals acquired through the 340B Program
- Drugs not purchased under the 340B program continue to be paid at ASP+6%

CY 2023

- ASP ***plus*** 6% for separately payable drugs and biosimilar biologicals acquired through the 340B Program
- CMS will address the remedy for 340B drug payments for CYs 2018-2022 in future rulemaking prior to the CY 2024 OPPS/ASC proposed rule
- Claims for 340B-acquired drugs paid after the U.S. District Court's September 28, 2022, ruling are being paid at the default rate (generally ASP+6%)

The Centers for Medicare & Medicaid Services (CMS) Finalized Increases to HOPPS Payments for 2023 – *But* There's a Catch…[6]

3.8% increase to Outpatient Department (OPD) fee schedule overall…

But a **3.09% reduction** in all *non-drug services* to achieve budget neutrality for the 340B rate change

→ Different types of hospitals will be impacted differently by the combination of the payment increases in the OPD fee schedule and 340B drugs and the budget neutrality adjustment

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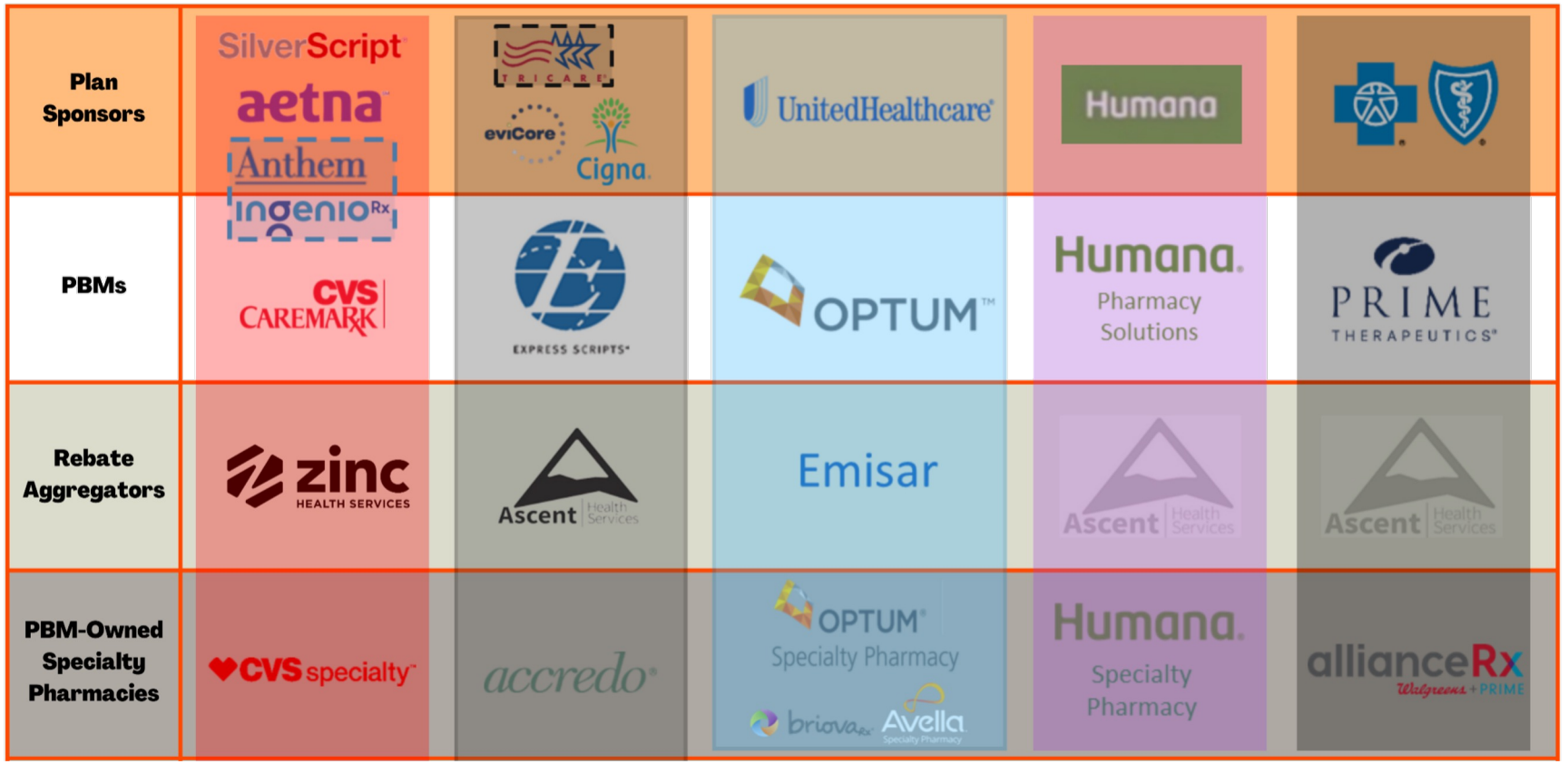
Pharmacy Benefit Manager (PBM) Reform Efforts

Increasing Vertical Integration of Health Plans with PBMs and PBM-Owned Entities



→ Increasing utilization management, site of service restrictions, white/brown bagging, co-pay accumulators, single-source contracting, and non-medical switching

→ **Decreasing patient access and affordability**

FTC Inquiry Into PBM Business Practices[7,8]

- On Feb. 24, the Federal Trade Commission (FTC) announced a request for information soliciting public comments on PBM "business practices" that affect drug affordability and access, including contract terms, rebates, fees, pricing policies, steering methods, conflicts of interest, and consolidation.
- In response to more than 24,000 public comments received, the FTC voted unanimously to launch an inquiry into the PBM industry and send compulsory orders to CVS Caremark, Express Scripts, OptumRx, Humana, Prime Therapeutics (BCBS), and MedImpact Healthcare Systems (Kaiser).
- The inquiry is aimed at shedding light on a variety of PBM practices, including:
  - Fees and clawbacks charged to unaffiliated pharmacies;
  - Methods to steer patients towards pharmacy benefit manager-owned pharmacies;
  - Potentially unfair audits of independent pharmacies;
  - Complicated and opaque methods to determine pharmacy reimbursement;
  - Prevalence of prior authorizations and other administrative restrictions;
  - Use of specialty drug lists and surrounding specialty drug policies;
  - Impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

Federal PBM Reform Legislation: The PBM Transparency Act of 2022 (S. 4293)[9]

- Introduced by Senators Chuck Grassley (R-IA) and Maria Cantwell (D-WA) on May 24 to empower the FTC to increase drug pricing transparency and hold PBMs accountable for unfair and deceptive practices that drive up the costs of prescription drugs at the expense of consumers.
- Advanced by Senate Committee on Commerce (19-9) on June 22 to full Senate vote.
- Specifically, this legislation:
  - Prohibits spread pricing; arbitrarily, unfairly or deceptively reducing or clawing back drug reimbursement payments to pharmacies; and charging pharmacies more to offset federal reimbursement changes;
  - Incentivizes fair and transparent PBM practices by providing exceptions to liability for PBMs that pass along 100 percent of rebates to health plans
  - Requires PBMs to report the amount of money they obtain from spread pricing, pharmacy fees and claw backs; report any differences in the PBMs' reimbursement rates or fees PBMs charge affiliated vs. non-affiliated pharmacies; report whether and why they move drugs in formulary tiers to increase costs;
  - Enhances enforcement by authorizing the FTC and state attorneys general to enforce the legislation and hold bad actors accountable.

Trending PBM Reform at the State Level

PBM Licensure

Licensure bills require pharmacy benefit managers to apply for a license to operate in a state. Licensure bills may require a PBM to follow specific requirements and guidelines in order to obtain a license and may institute fees and penalties for PBMs. Licensure bills may also establish revolving funds to continue oversight.

PBM Transparency

Transparency bills vary widely. Some require pharmacy benefit managers to report to a state agency or other regulatory body on an annual or biannual basis, disclosing information concerning rebates, formulary changes, pharmacy ownership information, and contract information. Other bills prohibit PBMs from imposing gag clauses on pharmacists.

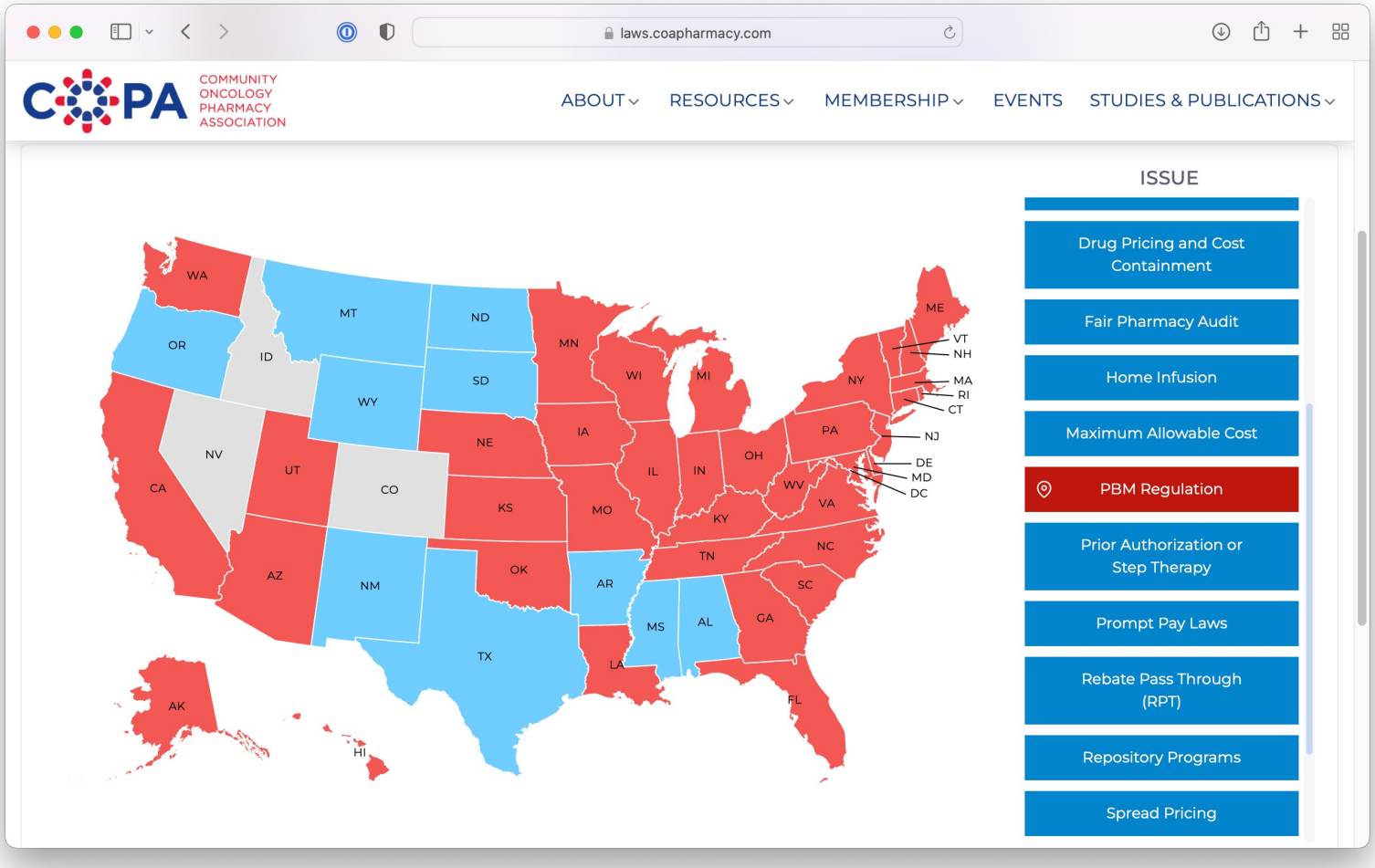
Co-Pay Accumulator Adjustment Program (CAAP) Bans

CAAP bills require PBMs to recognize copay assistance programs, waivers, and third-party payments for prescriptions as part of a patient's deductible and annual out-of-pocket costs.

The Issue of Co-Pay Accumulators

- A **Co-Pay Accumulator Adjustment Program** (CAAP) is a strategy used by PBMs to stop manufacturer-sponsored co-payment cards or other manufacturer-assistance programs from counting toward a patient's deductible and/or annual out-of-pocket maximum.
- By using CAAPs, PBMs reduce the value of manufacturer-assistance programs by exhausting such funds and also requiring patients to pay deductibles and coinsurance up to their out-of-pocket maximums (and effectively double-dipping in the process).
- States have been reinvigorated to challenge PBMs following two policy changes at the federal level:
  1. The 2019 CMS Notice of Benefits and Payment Parameters Final Rule (45 CFR § 156.130h)[10] expressly allowing co-pay accumulators to be used for drugs that have a generic equivalent.
  2. The 2020 Supreme Court Decision in *Rutledge v. PCMA* ruling[11] that the Employee Retirement Income Security Act (ERISA) does prevent state law from regulating PBMs.

State Policy: Community Oncology Pharmacy Association's (COPA's) Legislative Tracking Tool[13]



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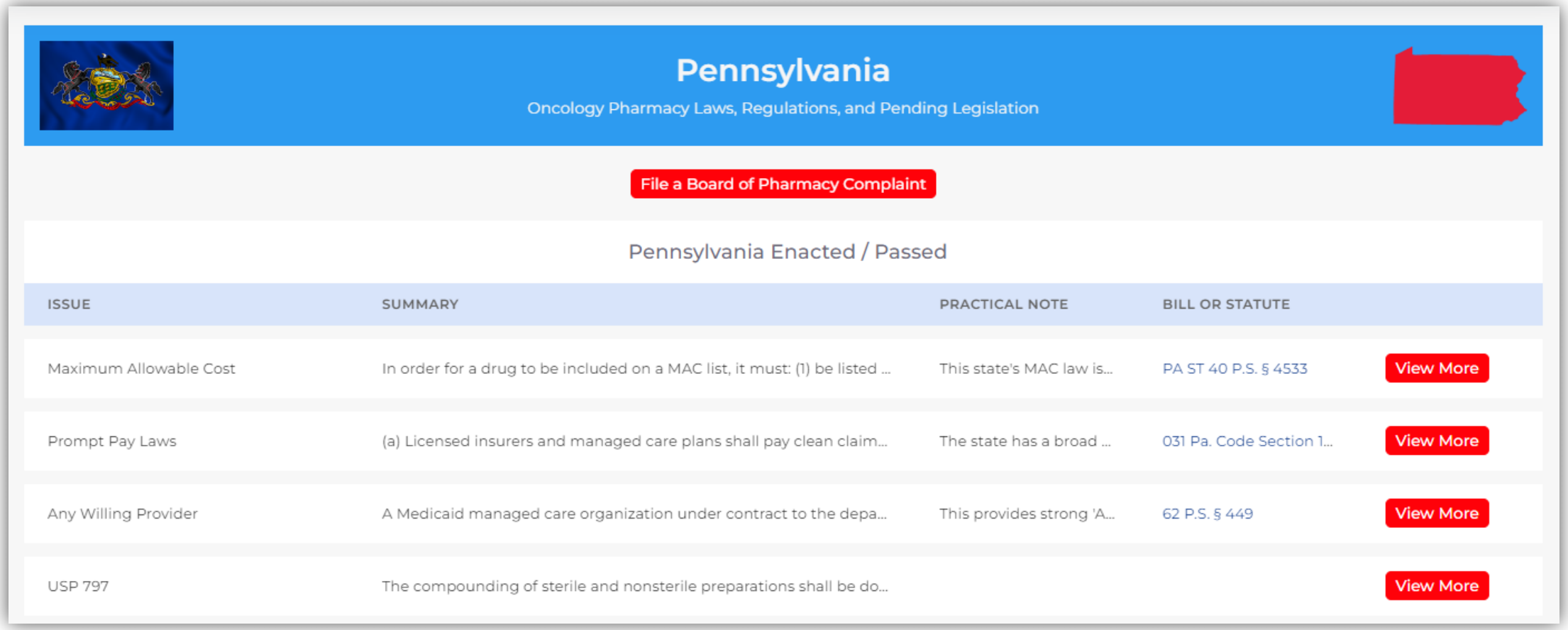
State Policy: COPA's Legislative Tracking Tool[13]



Pennsylvania

Oncology Pharmacy Laws, Regulations, and Pending Legislation

File a Board of Pharmacy Complaint

Pennsylvania Enacted / Passed

ISSUE	SUMMARY	PRACTICAL NOTE	BILL OR STATUTE	
Maximum Allowable Cost	In order for a drug to be included on a MAC list, it must: (1) be listed ...	This state's MAC law is...	PA ST 40 P.S. § 4533	View More
Prompt Pay Laws	(a) Licensed insurers and managed care plans shall pay clean claim...	The state has a broad ...	031 Pa. Code Section 1...	View More
Any Willing Provider	A Medicaid managed care organization under contract to the depa...	This provides strong 'A...	62 P.S. § 449	View More
USP 797	The compounding of sterile and nonsterile preparations shall be do...			View More

ACCC 2022

Congressional Updates

The Inflation Reduction Act of 2022[14]

- This budget reconciliation bill encompasses key pieces of the Biden administration's "Build Back Better" social and environmental agenda
- It is a significantly paired-down version of the *$2.2 trillion Build Back Better Act*, which originally that passed the House in November 2021.
- In early July 2022, the Senate Finance Committee released legislative text outlining the prescription drug provisions of the reconciliation package, largely aligned with the House version.
- On July 27, Senators Manchin and Schumer announced they had reached a deal on a broader package including deficit reduction, tax reform, domestic energy and climate, and healthcare provisions, intending to bring it to the Senate floor the following week
- **The $740 billion Inflation Reduction Act of 2022 (IRA) passed by the Senate on August 7 and the House on August 12. It was signed into law by President Biden on August 16.**

IRA: Key Healthcare Provisions[14]

Extension of Enhanced ACA Subsidies	• Increases the duration of financial assistance for those already eligible to buy subsidized Affordable Care Act (ACA) Marketplace plans and expanded subsidies to more middle-income individuals through 2025 • Originally set to expire at the end of 2022

Medicare Part D Redesign	• Eliminates the 5% coinsurance requirement above the catastrophic threshold in 2024 and implements a $2,000 cap on out-of-pocket drug spending in 2025
	  • Allows the option to spread the annual out-of-pocket costs into monthly payments
	  • Limits Part D premium growth to no more than 6% per year through 2030
	• Eliminates cost sharing for adult vaccines and limits copayments to $35/month for Part D insulin products

Prescription Drug Price Negotiation	• Requires Department of Health and Human Services (HHS) to negotiate prices for a set number of high-cost prescription drugs covered by Medicare Parts B and D • Negotiation-eligible drugs include brand-name drugs or biologics that are without generic or biosimilar equivalents that are 9 or more years (small-molecule drugs) or 13 or more years (biologics) from U.S. Food and Drug Administration (FDA) approval • Would establish a negotiated “Maximum Fair Price” for Medicare and impose a financial penalty in the form of an excise tax on drug manufacturers that do not negotiate with HHS

Implementation Timeline of IRA Prescription Drug Provisions[14]

2023	2024	2025	2026	2027	2028	2029
Rebates required if drug companies increase drug prices faster than the rate of inflation The rebate is assessed only on units sold in Medicare; commercial units are excluded	Eliminates the 5% coinsurance requirement above the Part D catastrophic threshold Expands income eligibility for Part D Low-Income Subsidy full benefits up to 150% FPL	Caps Part D out-of-pocket spending at $2,000 annually and implements other Part D Benefit Changes	HHS is authorized to negotiate the price of 10 high-cost Part D drugs	Expanded HHS authority to negotiate prices for an additional 15 Part D drugs Delays implementation of Trump Administration's Rebate Rule to 2032	Price negotiation for 15 more Part D *and* Part B drugs	Price negotiation expands to 20 additional Part B *and* Part D drugs (Cumulatively up to 60 Part D drugs and 35 Part B drugs)

Medicare prescription drug price negotiation

Part D premium growth capped at 6% per year through 2030

Continuation of Telehealth Flexibilities[4]

Advancing Telehealth Beyond COVID-19 Act of 2021 (H.R. 4040)

- Would extend many Medicare telehealth flexibilities and waivers through December 31, 2024, regardless of when the COVID-19 PHE ends, including:
  - The ability for beneficiaries to continue to receive telehealth services from any site including their homes
  - The provision of E/M and behavioral health services via audio-only technology
- Passed the House by a vote of 416 to 12 on July 27

Prior Authorization Reform in Medicare Advantage[15]

Improving Seniors' Timely Access to Care Act of 2021 (H.R. 3173/S. 3018)

- Would streamline and standardize prior authorization processes within the Medicare Advantage program by requiring these plans to:
  - Establish an electronic prior authorization program, including the ability to provide real-time decisions in response to requests for items and services that are routinely approved;
  - Annually publish specified prior authorization information, including the percentage of requests approved and the average response time; and
  - Meet other standards relating to the quality and timeliness of prior authorization determinations.
- House passed by unanimous voice vote on Sept. 14

Medicare MPFS CF & Budget Neutrality[16]

Supporting Medicare Providers Act of 2022 (H.R. 8800)

- On Sept. 13, 2022, Reps. Ami Bera, M.D., (D-CA) and Larry Bucshon, M.D., (R-IN) introduced bipartisan legislation to mitigate CMS' proposed PFS conversion factor cuts for CY 2023, effectively putting the cuts on hold for a year.
- While the lawmakers recognized that physicians face payment cuts of more than 8% in 2023, this piece of legislation would negate only the 4.5% reduction to the CF for CY 2023.
- Gaining lots of momentum for inclusion in end-of-year legislative package.

OPEN FOR QUESTIONS

Thank you!
Please reach out and stay in touch:

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Association of Community Cancer Centers

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