



**STRENGTHEN
YOUR
REVENUE CYCLE
MANAGEMENT**

ACCC
2022 ONCOLOGY
REIMBURSEMENT
MEETING

DECEMBER 6
Richmond, VA



Welcome!

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

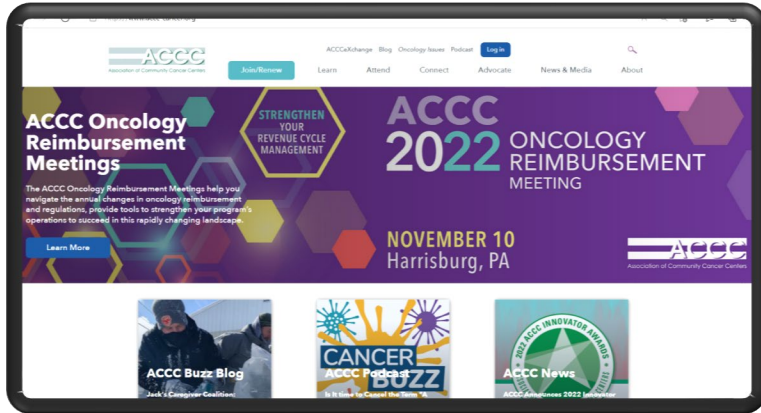
THE ENTIRE TEAM

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



Home / Advocate / Legislative Action Center

LEGISLATIVE ACTION CENTER

Together we can help key policy makers at the federal and local levels better understand how their decisions on policy and legislation impact community oncology care. State and federal legislation can have a real impact on patient access to quality cancer care and the financial viability of your organization. This is why it's so important for ACCC and Oncology State Society members to offer their on-the-frontline perspectives to the legislative process.

Home Directory Bills Votes Elections Media

Key Issues

Protect Oncology Care Providers from Impending Medicare Payment Cuts


Without congressional intervention, Medicare reimbursement for medical and radiation oncology services are expected to decrease by more than 10% in January 2023. These payment cuts are largely due to a 4.42% projected reduction in the Medicare Physician Fee Schedule (MPFS) conversion factor as well as a new 4% Statutory Pay-As-You-Go sequester resulting from the American Rescue Plan Act, both set to take effect January 1st. If Congress fails to take action, cancer programs and practices throughout the country will struggle to maintain financial viability and continue providing access to high-quality, comprehensive cancer care for millions of patients in the year ahead.

Tell your members of Congress to support legislation averting these significant payment cuts in 2023!

TAKE ACTION

Encourage Prior Authorization Reform to Reduce Delays in Cancer Care

The strenuous requirements of prior authorization under the Medicare Advantage (MA) program act as a barrier for patients requiring timely access to services and treatments. Patients with cancer often require immediate treatment to prevent further spread of their cancer. Thus, delays caused by prior authorization requirements can have even greater irreversible consequences for these patients. Recently, the Department of Health and Human Services Office of Inspector General (OIG) examined the appropriateness of prior authorization and payment denials in the MA program and reported that MA Organizations often unnecessarily denied prior authorizations, further highlighting the urgent need for reform.




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Key Congressional Legislation

117th Congress (2021 - 2022)

S. 3018: Improving Seniors' Timely Access to Care Act of 2021 Latest Status: Read twice and referred to the Committee on Finance. (10/20/2021)	Sponsored by Sen. Marshall, Roger [R-KS]	Introduced on October 20, 2021	<input checked="" type="checkbox"/> We support this bill
S. 2706: The DIVERSE Trials Act Latest Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (8/10/2021)	Sponsored by Sen. Menendez, Robert [D-NJ]	Introduced on August 10, 2021	<input checked="" type="checkbox"/> We support this bill
S. 1873: MCED Screening Coverage Act Latest Status: Read twice and referred to the Committee on Finance. (5/27/2021)	Sponsored by Sen. Crapo, Mike [R-ID]	Introduced on May 27, 2021	<input checked="" type="checkbox"/> We support this bill
S. 464: Safe Step Act			



ACCC Policy Update

Matt Devino, MPH

Director of Cancer Care Delivery & Health Policy

Association of Community Cancer Centers



Calendar Year (CY) 2023 Medicare Physician Fee Schedule (MPFS) Final Rule¹

CY 2023 MPFS Conversion Factor (CF)¹

TABLE 146: Calculation of the CY 2023 PFS Conversion Factor

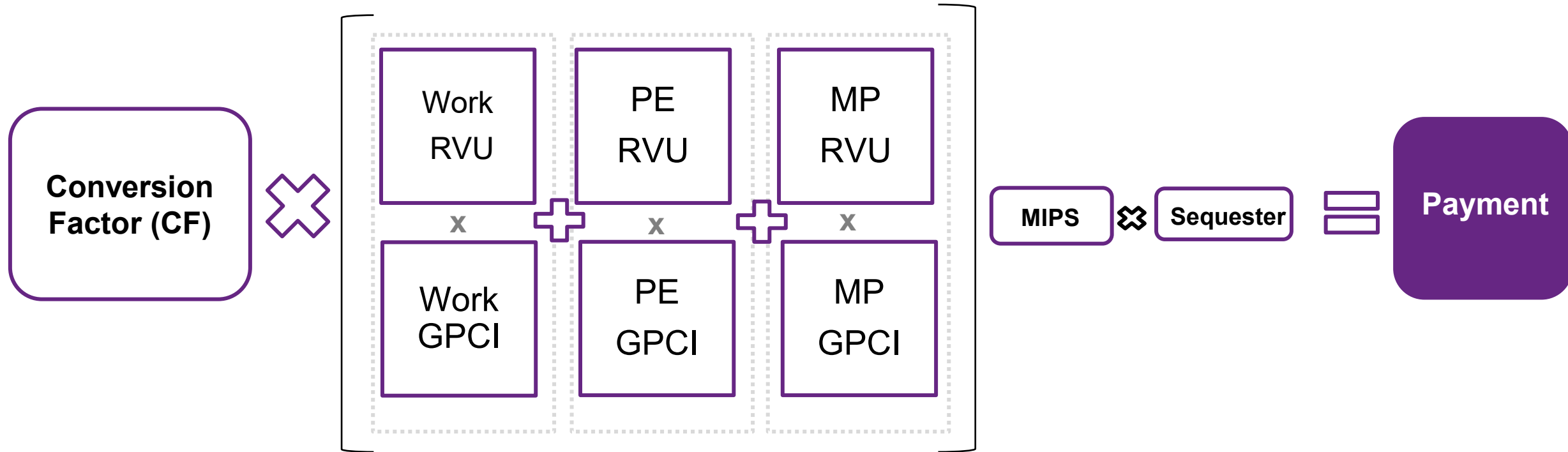
CY 2022 Conversion Factor		34.6062
Conversion Factor without CY 2022 Protecting Medicare and American Farmers from Sequester Cuts Act		33.5983
Statutory Update Factor	0.00 percent (1.0000)	
CY 2023 RVU Budget Neutrality Adjustment	-1.60 percent (0.9840)	
CY 2023 Conversion Factor		33.0607

- 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 Act² (-4%)

RVU Changes: Specialty Impact by Setting¹

Specialty	Total Non-Facility/Facility	Allowed Charges (millions)	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%

Medicare Service Payment Calculation¹



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

“Other” Evaluation and Management (E/M) Services¹

Medical decision-making (MDM) & time-based coding

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

Centers for Medicare & Medicaid Services (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 Definitions¹

CMS finalized its decision to maintain the 2022 definition of the “substantive portion” of an E/M service performed by both a physician and 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 PHE¹

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 Services¹

- 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 Screening¹

- 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.

Manufacturer Refunds For Discarded Drugs¹

CMS finalized provisions from the Infrastructure Investment and Jobs Act requiring drug manufacturers to provide a refund to CMS for certain discarded amounts from a **refundable single-dose container or single-use package drug paid under Medicare Part B.**

Finalized the requirement to use modifier **JW** to identify discarded billing units of a billing and payment code to calculate the refund amount effective January 1, 2023.

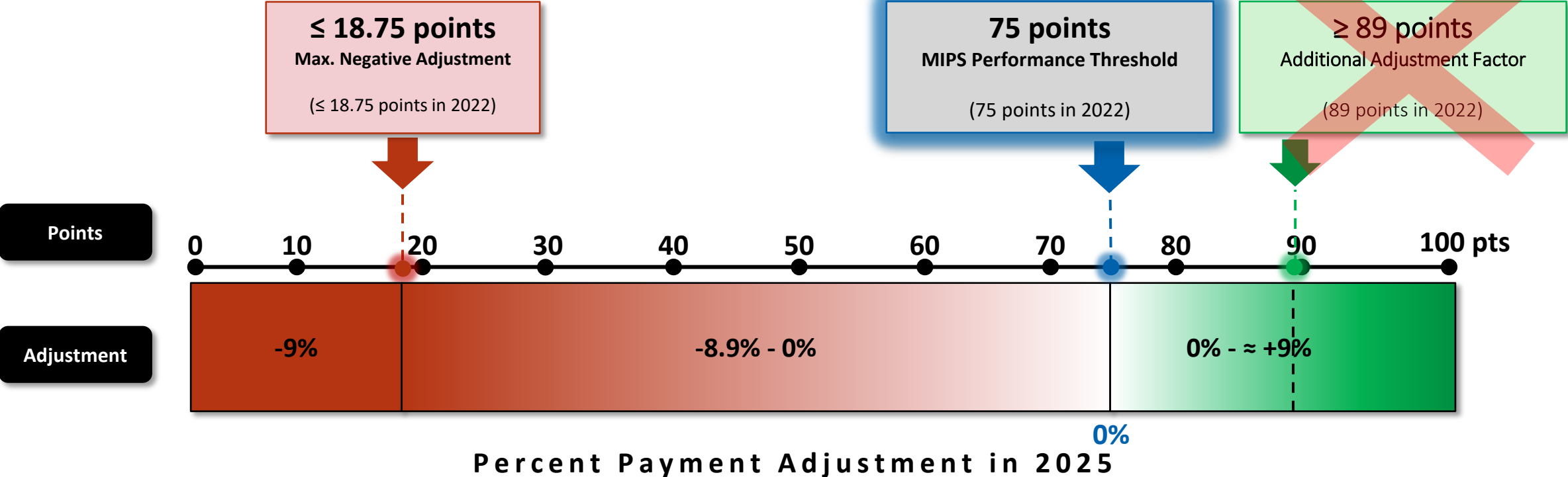
Finalized the requirement to use a new modifier **JZ** for attesting there was no discarded amount from the single-dose vial or single-use package paid under Part B by July 1, 2023.

CMS will issue a preliminary report on estimated discarded drug amounts based on claims from the first two calendar quarters of 2023 no later than December 31, 2023.

Quality Payment Program Updates¹

Final Merit-Based Incentive Payment System (MIPS) Thresholds¹

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

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

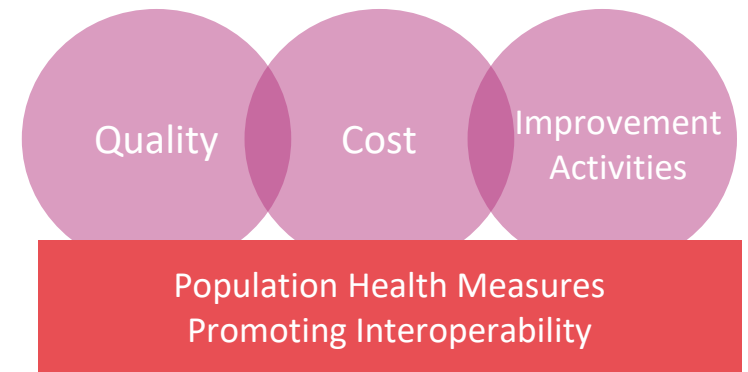
MVP Reporting Requirements:

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 Timeline¹

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 Payments¹

- Originally authorized under the Medicare Access and CHIP Reauthorization Act (MACRA), these 5% advanced APM incentive payments support providers who are 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 Rule⁶

Change to 340B Drug Reimbursement as a Result of Supreme Court Decision⁶

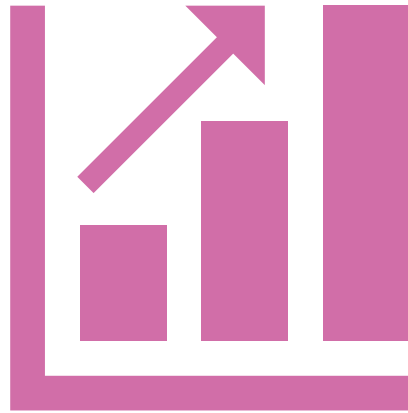
CY 2018-2022

- 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 to 2022 in future rulemaking prior to the CY 2024 HOPPS/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%)

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

Congressional Updates

The Inflation Reduction Act of 2022⁷

- 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 Provisions⁷

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 co-payments 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 Provisions⁷

2023

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

2024

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% of the Federal Poverty Level

2025

Caps Part D out-of-pocket spending at \$2,000 annually and implements other Part D benefit changes

2026

HHS is authorized to negotiate the price of 10 high-cost Part D drugs

2027

Expand HHS authority to negotiate prices for an additional 15 Part D drugs

Delays implementation of Trump Administration's Rebate Rule to 2032

2028

Price negotiation for 15 more Part D *and* Part B drugs

2029

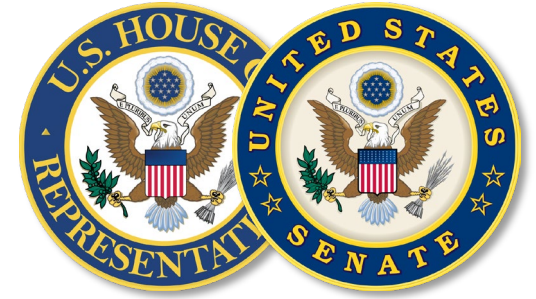
Price negotiation expands to 20 additional Part B *and* Part D drugs (Cumulatively up to 60 Part D drugs and 35 Part B drugs)

Medicare prescription drug price negotiation

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

What can we expect from Congress for the rest of this year?

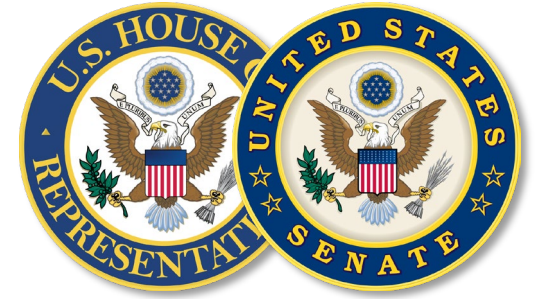
Medicare MPFS CF & Budget Neutrality⁹



Supporting Medicare Providers Act of 2022 (HR 8800)

- On Sept. 13, 2022, Reps. Ami Bera, MD, (D-CA) and Larry Bucshon, MD, (R-IN) introduced bipartisan legislation to mitigate CMS' proposed MPFS conversion factor (CF) 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.

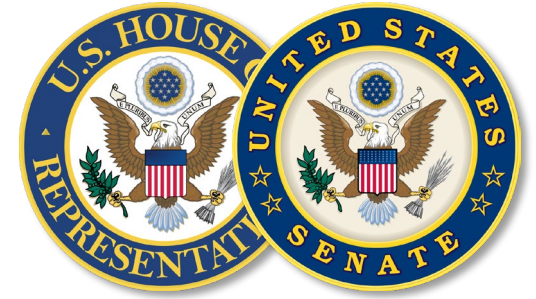
Continuation of Telehealth Flexibilities⁴



Advancing Telehealth Beyond COVID-19 Act of 2021 (HR 4040)

- Would extend many Medicare telehealth flexibilities and waivers through December 31, 2024, regardless of when the COVID-19 public health emergency ends, including:
 - The ability for beneficiaries to continue to receive telehealth services from any site, including their home
 - 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 Advantage⁸



Improving Seniors' Timely Access to Care Act of 2021 (HR 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
 - Meet other standards relating to the quality and timeliness of prior authorization determinations.
- House passed by unanimous voice vote on Sept. 14

Predictions for the 118th Congress



OPEN FOR QUESTIONS



Thank you!
Please reach out and stay in touch:

mdevino@accc-cancer.org

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



References

1. Centers for Medicare & Medicaid Services, Department of Health and Human Services. Medicare and Medicaid Programs; CY 2023 payment policies under the physician fee schedule and other changes to part B payment and coverage policies; Medicare shared savings program requirements; implementing requirements for manufacturers of certain single-dose container or single-use package drugs to provide refunds with respect to discarded amounts; and COVID-19 interim final rules. Published 2022. Accessed November 9, 2022. <https://public-inspection.federalregister.gov/2022-23873.pdf>
2. Congress.gov. H.R. 1319 – American Rescue Plan Act of 2021. Accessed November 5, 2022. <https://www.congress.gov/bill/117th-congress/house-bill/1319/text>
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8. Congress.gov. H.R. 8487 – Improving Seniors’ Timely Access to Care Act of 2022. Published 2022. Accessed November 9, 2022. <https://www.congress.gov/bill/117th-congress/house-bill/8487>
9. Congress.gov. H.R. 8800 – Supporting Medicare Providers Act of 2022. Published 2022. Accessed November 9, 2022. <https://www.congress.gov/bill/117th-congress/house-bill/8800>



Mark Your Calendar:

ACCC
National Oncology
Conference (NOC)

Austin, TX

October 4-6, 2023

Follow ACCC on
LinkedIn & Twitter
& *ACCC Connect* emails
for updates



Coffee Break

10:30-11:00 A.M.



Brief Remarks



Matt Devino, MPH

*Director of Cancer Care Delivery
& Health Policy*

Association of Community Cancer Centers

@ACCCBuzz

#ACCCORM

Financial Navigation in Radiation Oncology



Francinna Scott-Jones, CPAR, ROCC
Northside Hospital Cancer Institute

@ACCCBuzz | #ACCCORM

Why Financial Advocacy Is Important for Patients with Cancer

The Statistics

- Patients with cancer demonstrate more anxiety over the cost of their treatment than dying from their disease¹
- **42%** of insured patients with cancer express significant financial burden²
- Medicare patients have on average **\$4,727 in out-of-pocket expenses** for their oncology care³

Patients Want to Know their Costs of Care⁴

- At a foundational level, patients need to understand the basics of health insurance and their own specific benefits.
- **Over two-thirds of patients** with cancer say they **want to know their out-of-pocket costs before treatment**—visibility is likely to decrease their anxiety and increase the chance that they will pay for at least a portion of their care.

Improve Patient Collections⁴

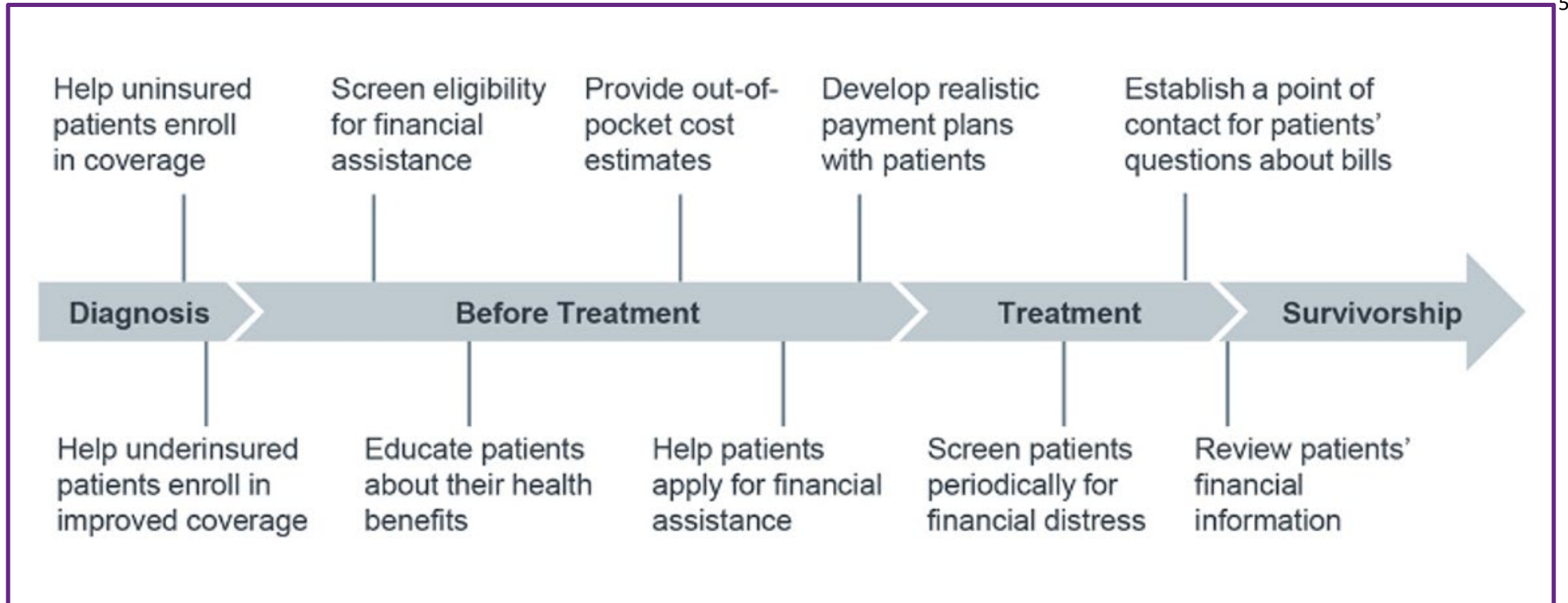
- As providers' revenue increasingly depends on patients' payments, cancer programs and practices need to improve their ability to collect on patients' financial responsibilities.
- Point-of-service collections represent the biggest opportunity to decrease bad debt, yet **only 35%** of hospital leaders say their organization consistently collects from patients with cancer at point of service.

The Ideal Financial Advocacy Program

The most successful financial advocacy programs have multiple access points through the care continuum:

- Consult scheduling
- Time of consult
- Distress screening
 - During the first week of treatment
 - Last week of treatment
- Provide a resource to answer questions once the patient's course of treatment is complete

The Ideal Financial Advocacy Program



At Minimum, Your Financial Advocacy Program Should Include:

Financial Counseling Meeting



Financial counselor schedules in-person meeting with every patient during first week of treatment

Benefits Review



Financial counselor reviews each patient's insurance benefits prior to meeting

Benefits Explanation



- Financial counselor uses template to guide discussion during meeting
- Explains basic insurance terms and individual coverage details

Who Needs Financial Advocacy?



6

Uninsured Patients⁷

- Most uninsured people are non-elderly adults, in working families, and/or in families with low incomes.
- In 2018, over 7 in 10 of uninsured people (**72%**) had at least one full-time worker in their family
 - An additional **11%** had a part-time worker in their family.

Uninsured Patients⁷

- Individuals with incomes **below 200% of the federal poverty level** are at the highest risk of being uninsured.
- In total, **more than 8 out of 10** uninsured individuals were in families with incomes **below 400% of the federal poverty level** in 2018.

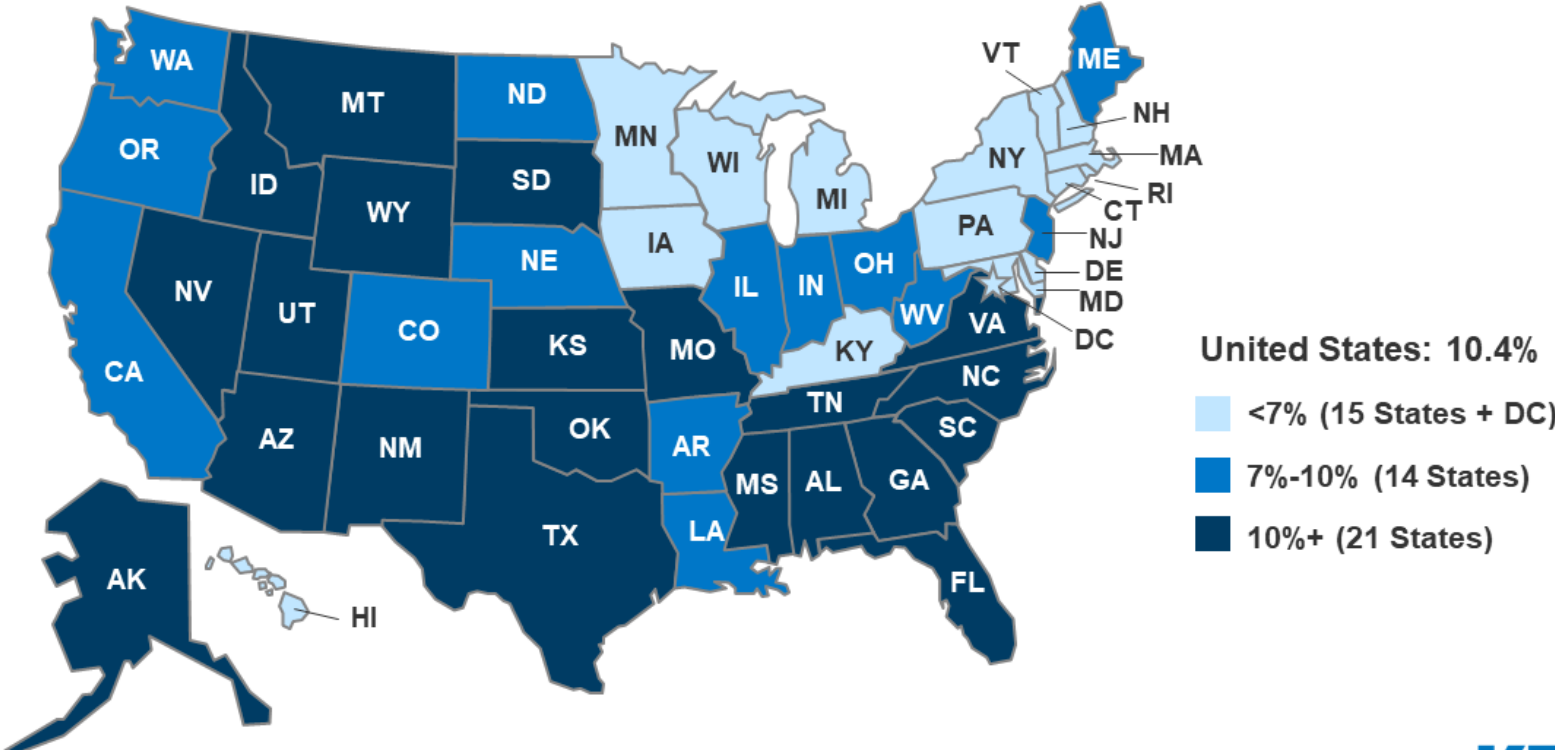
Uninsured Patients⁷

- Costs still pose a major barrier to coverage for uninsured people.
- In 2018, **45%** of uninsured, non-elderly adults report they were uninsured because the cost of insurance was **too high**, making it the most common reason cited for being uninsured.

Uninsured Patients⁷

Figure 5

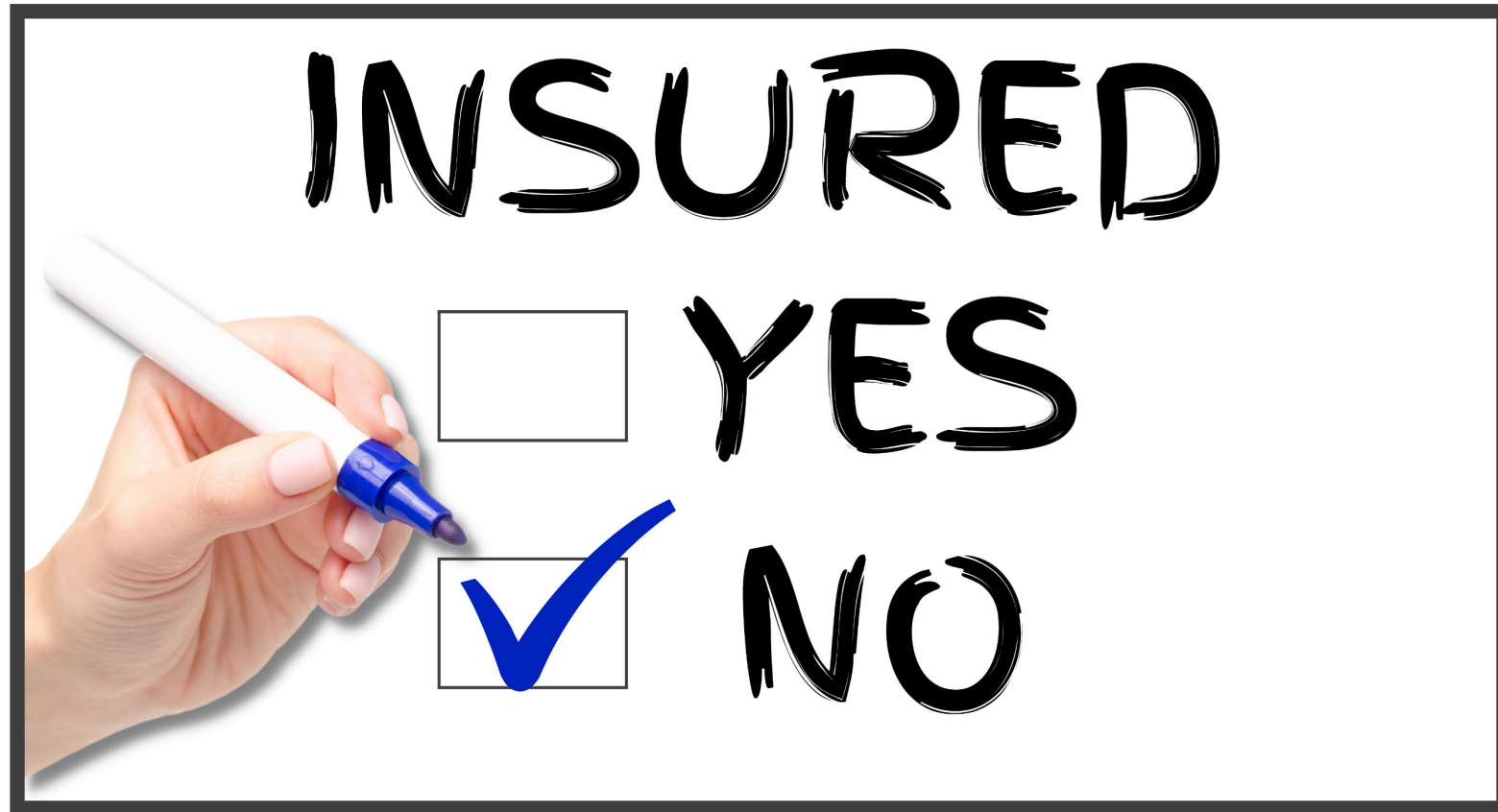
Uninsured Rates among the Nonelderly by State, 2018



NOTE: Includes nonelderly individuals ages 0 to 64.
SOURCE: KFF analysis of 2018 American Community Survey, 1-Year Estimates.



It's Not Just Uninsured Individuals



Underinsured Patients⁸

- **About a quarter** of non-elderly Americans with private insurance **do not have sufficient liquid assets** to pay a mid-range deductible (\$1,200 for single coverage and \$2,400 for family coverage)
- **More than a third** don't have the resources to pay higher deductibles (\$2,500 for single coverage and \$5,000 for family coverage)
- In 2014, an estimated **7 million people** were underinsured because of their deductible alone

Underinsured Patients⁸

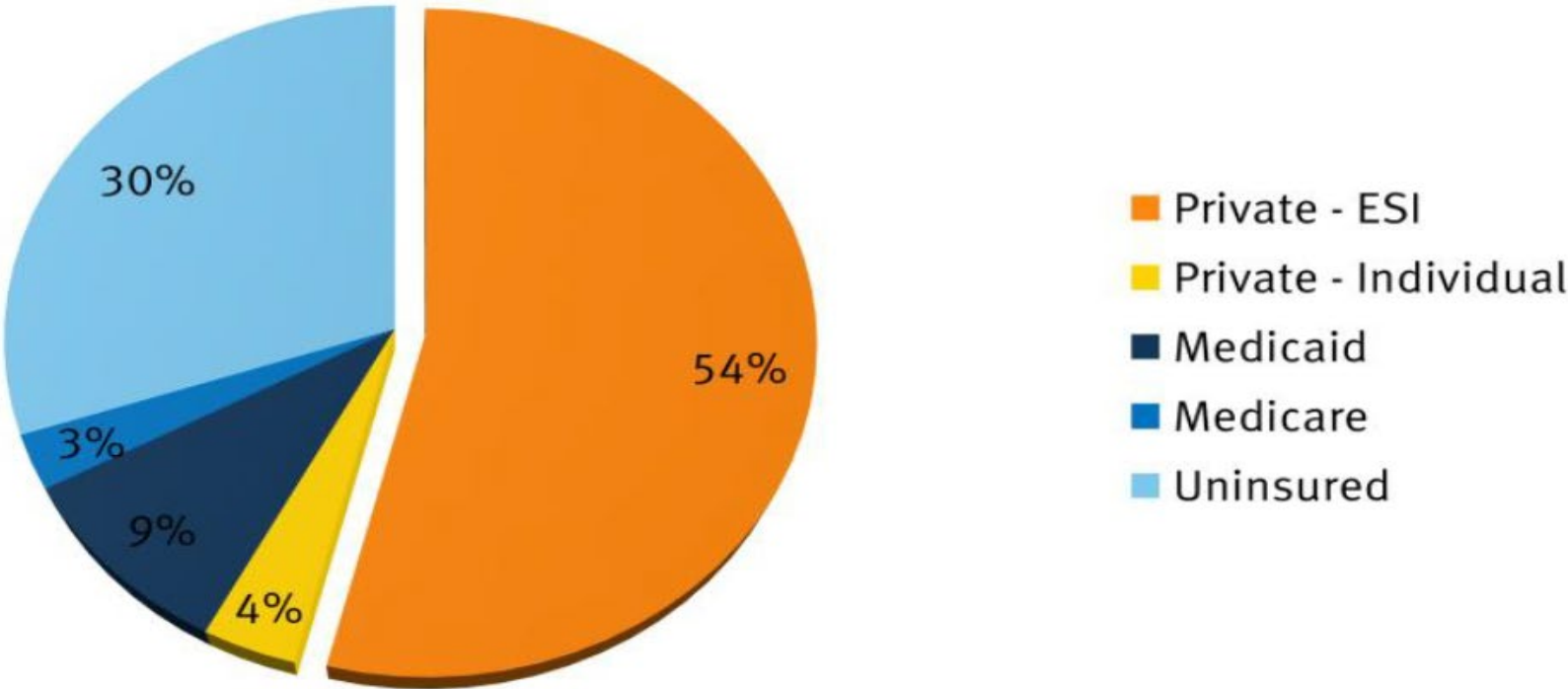
- When families are underinsured, they are at high risk of forgoing needed care and struggling to pay their medical bills when they cannot postpone care
- **51%** of underinsured adults report problems with medical bills or debt
- **44%** of underinsured adults do not get needed care because of costs
- **50%** of underinsured adults with high deductibles have debt of \$4,000 or more

American Families Have Difficulty Paying Their Medical Bills⁹

- Difficulty paying medical bills can have significant consequences for American families.
- About one-fourth of United States adults (**26 percent**) say they or a household member have had problems paying their medical bills in the past year.
 - About half of this group (**12 percent of all Americans**) say their medical bills had a major impact on their family.

Characteristics of People with Difficulty Paying their Medical Bills¹⁰

In 2012, the majority of people with difficulty paying medical bills had employer-sponsored private insurance (ESI)



Three Categories of Patients

Patients without insurance or those who are underinsured fall into 1 of 3 categories:

1. Patients who **can pay** their medical bills **but refuse to pay**.
2. Patients who **can pay** their medical bills **and are willing to pay**.
3. Patients who **do not have the resources to pay** their medical bills.

By counseling all patients, you are better equipped to understand which of the 3 categories each patient falls within.

“I Can’t Afford to Pay”



11

FINANCIAL TOXICITY

THE COSTS OF CANCER



While being diagnosed with cancer alone can put a person under tremendous amounts of mental and emotional stress, the additional burden of the outrageously expensive medical care only adds to the strain. The dramatic rise in the cost of cancer treatments has now given rise to what is being called Financial Toxicity.

Three Domains of Financial Toxicity

Financial hardship encompasses three domains:

1. Material Conditions

Example concepts within this domain:

- Out-of-pocket expenses
- Missed work
- Reduced/lost income
- Medical debt/bankruptcy

2. Psychological Response

Example concepts within this domain:

- Feeling of distress due to costs of cancer care
- Concern about wages/income meeting expenses related to costs of cancer care

3. Coping Behaviors

Example concepts within this domain:

- Took less or skipped medication
- Delayed or missed physician visit



What Are the Effects of Financial Toxicity on Those in Active Anti-Cancer Treatment?¹⁴

- **130% increase** in financial difficulties for those younger than 65 years old
- **67% increase** in financial difficulties for those without insurance
- **42% increase** in financial difficulties for underserved populations

What Are the Effects of Financial Toxicity on Those in Active Anti-Cancer Treatment?¹⁴

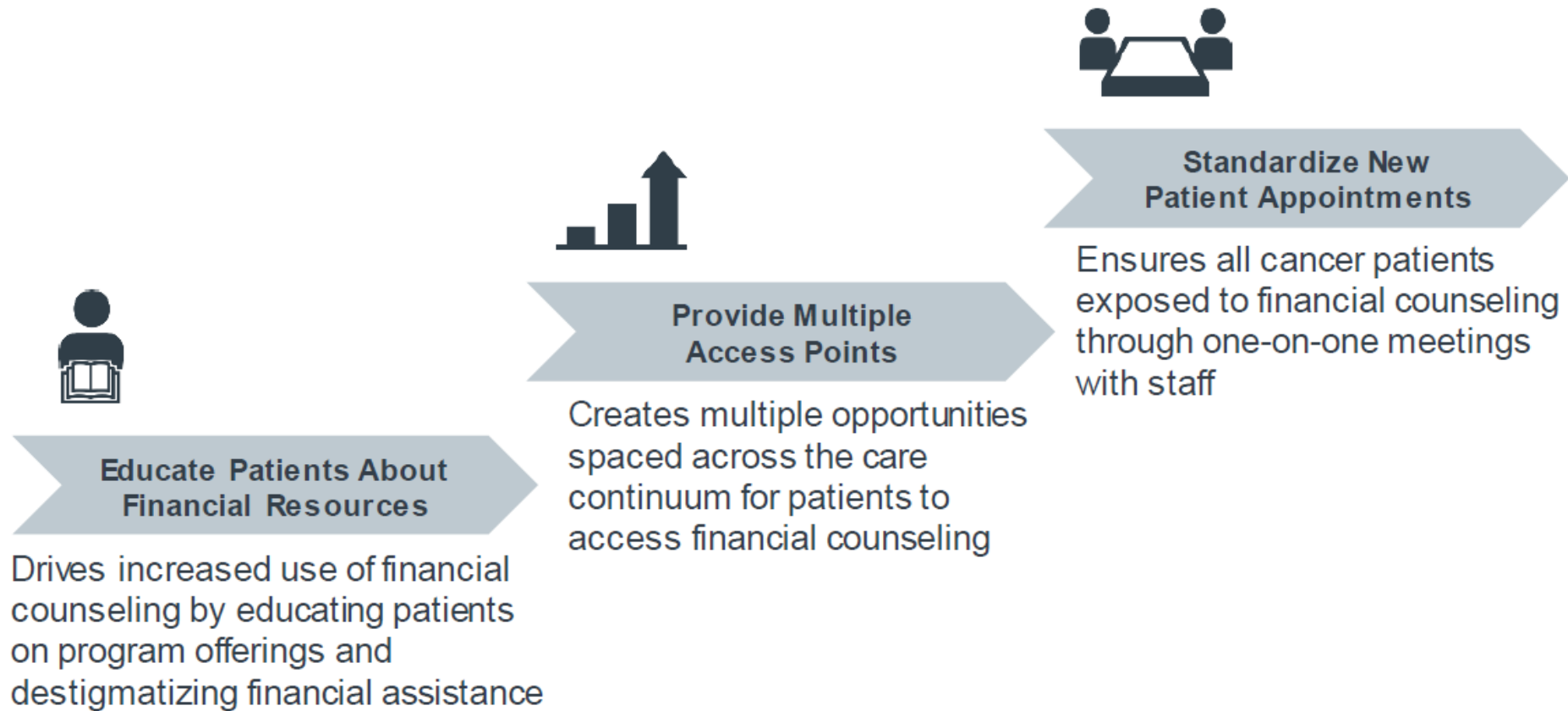
- **37%** of individuals make at least one work/career modification due to a cancer diagnosis
- **27%** of individuals report at least one financial hardship, including bankruptcy, debt, etc.

Managing Financial Toxicity

- **Identify** uninsured/underinsured patients early
- **Inform** patients of their financial obligations to identify possible challenges
- **Educate** patients (financial resources, billing processes)
- **Reassure** patients that you are there to help them

Identifying Patients with Hardships

Three Approaches to Identify Patients with Need



Educate Patients About Assistance Programs

When patients express that they will face difficulty meeting the financial obligations presented to them at the time of financial advocacy, we should educate them on possible assistance:

- Financial assistance programs
- Independent charity programs
- Medicaid programs
- Self-pay discounts

Educate Patients About Assistance Programs

Your financial advocates should be aware of what the basic requirements are to qualify for these various programs, so they can provide direction to patients as needed.

Challenges in Radiation Oncology Financial Advocacy

- Most financial assistance programs are supported by drug manufacturer companies—not a lot of resources for patients in radiation oncology
- In some cases, financial assistance may be provided to patients undergoing radiation treatment from the treating hospital/organization’s internal financial assistance/charity program
- Other assistance can be accessed through grants from independent foundations like the American Cancer Society (ACS).
 - The issue: these grants are generally focused on supporting “other” costs like transportation, gas, and housing, not direct treatment costs.

Advocacy in Radiation Oncology

A Glance At Our Program

- Insurance verification prior to consult
- Benefit summary given to patient at the time of consult
- Financial clearance
- Initial interview
- Available for questions throughout the course of treatment
- Exit interviews

Benefit Summary Sheet



DEPARTMENT OF RADIATION ONCOLOGY

Patient: John E. Appleseed

D.O.B: 01/02/1954

Insurance: United Anthem PPO

Based on Insurance verification conducted on **October 20, 2022** your current benefit are as follows:

Patient Benefits	
Deductible \$500.00	Amount Met \$500.00
Out Of Pocket Max \$2500.00	Amount Met \$1825
Does OOP Include Deductible	Yes
Benefits are paid at what %	80% until OOP Met
Secondary coverage	N/A

Financial Clearance

- Collecting a percentage of OSB (outstanding balance)
- Collecting a percentage of estimated liability for the treatment course
- Assisting patients with applying for financial assistance if they don't have the ability to pay
- Ensuring prior authorization for treatments are approved before the patient starts treatment

Initial Interview

- ✓ Review benefits information specific to radiation oncology
- ✓ Have patient sign any documents (estimates/financial arrangements)
- ✓ Review explanation of charges
- ✓ Provide contact information of the oncology financial resource specialist who will be assisting the patient through out their treatment journey
- ✓ Initial interview *should* occur within the first week of treatment

Explanation Of Charges



DEPARTMENT OF RADIATION ONCOLOGY

EXPLANATION OF BILLING CHARGES

Your physician, physicists, and therapists determine which categories of services best reflect your treatment. Below is an explanation of items you may see on your bill. You may receive bills from two separate entities for our services: one bill from Northside Hospital (facility charges) and the other from a separate billing entity (physicians' professional service). The billing company for the physicians' service may vary based on your physician. Some of these services are done behind the scenes at times when you are not physically in our office. We will bill your insurance accordingly.

CONSULTATION: 99241-99245 or 99261-99265 (Medicare)

The course of treatment is usually initiated by referral to one of our radiation oncologists. This consult consists of an evaluation to determine if you will benefit from receiving radiation therapy. This analysis will include: a comprehensive review of your medical history, diagnostic findings, and a physical exam. A consultation report will be sent to your referring physician.

CT SIMULATION: 77280-77290

This is a CT scan done in our department for the purpose of acquiring images used to design the best and most precise treatment plan for you. Depending on the treatment site, there may be some instructions on how to prepare for this scan.

TREATMENT PLANNING: 77261-77263

A comprehensive treatment plan is developed by your radiation oncologist for your individual case after carefully reviewing all the above mentioned data. Specific radiation fields are developed appropriate for your case and the proper energy of radiation is selected.

TREATMENT DEVICES: 77332-77334 & 77348 (MLC for IMRT)

There are two types of devices commonly used. An immobilization device will assist in establishing and maintaining a reproducible treatment position for the patient during treatment. The other is a beam-modifying device made of special materials that protect normal healthy tissue from unnecessary radiation exposure.

PORT FILMS: 77417

Special x-rays that are taken to ensure that the radiation targets the specific area that is receiving radiation therapy while minimizing exposure to healthy tissue.

DAILY AND WEEKLY TREATMENT CHARGES: 77401, 77402, 77407, 77412, 77385, 77386

Some providers tally treatment charges on a daily; others on a weekly basis. Likewise, some carriers split the professional charge for the physician and a technical charge for facility usage. While other carriers may prefer a "global" bill to include both of those charges. (Simple, Intermediate, Complex, and Conformal, IMRT)

IGRT CHARGES: 77387, 77014, G6002, G6017

Image-guided radiation therapy (IGRT) is the process of frequent two and three-dimensional imaging, during a course of radiation treatment, used to direct radiation therapy utilizing the imaging coordinates of the actual radiation treatment plan. This process normally occurs on a daily or weekly basis, depending on the physicians orders.

BRACHYTHERAPY: 77778 (LDR) 77770 - 77772 (HDR)

Brachytherapy, also known as internal radiation, is the administration of radiation by the use of special radioactive sources that are placed inside the body by the radiation oncologist. These sources include Cesium, Iridium, Iodine, and Palladium. Patients can be treated with brachytherapy alone or in combination with external beam radiation therapy (EBRT).

SPECIAL TREATMENT PROCEDURES: (77470)

This code refers to treatment procedures that are complex, time consuming or used in combination with other treatment modalities such as surgery, chemotherapy or brachytherapy.

PHYSICS CHARGES:

Radiation physicists and dosimetrists help the physician with verification of treatment doses, machine calibrations and treatment planning. Physics personnel assure the quality and quantity of radiation given for a single treatment and total treatment. Customary items include:

- **BASIC DOSIMETRY CALCULATION (77300):** Includes appropriate calculations necessary to your treatment.
- **CONTINUING MEDICAL RADIATION PHYSICS (77336):** Physicists monitor accurate delivery of your treatments.
- **ISODOSE PLAN 77306-77307, 77316-77318:** Extensive care is given by your physicians and physicists to accurately determine the exact distribution of radiation doses using sophisticated medical computers. These plans are generated by the physicists and dosimetrists then reviewed by the physician.
- **TLD/SPECIAL DOSIMETRY (77331):** Special dosimetry includes measurements of electron doses, off Axis calculation for some very large fields and other special situations.
- **SPECIAL PHYSICS CONSULT: (77379)**
A special physics consultation is appropriate when the treating physician requires the input of a qualified medical physicist for a specific medical concern while planning a course of therapy for a particular patient.

Exit Interview

- ✓ Review pending claims that have pending payments from an insurance company
- ✓ Discuss any balances that are the patient's responsibility
- ✓ Provide the patient with the business office(s)' phone numbers for any additional follow-up that may be needed once they finish treatment
- ✓ Exit interviews *should* occur within the final week of treatment

In Conclusion:

Identify patients who need assistance as soon as possible

Have multiple access points throughout patients' treatment journey

Educate patients on their insurance benefits, resources, and billing protocols

Provide patients with the information needed to follow-up on bills after they have completed treatment

Questions?

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Brief Remarks

Matt Devino

*Director of Cancer Care Delivery & Health Policy
Association of Community Cancer Centers*

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Monitoring Your Revenue Cycle with a Fiscal Watchdog



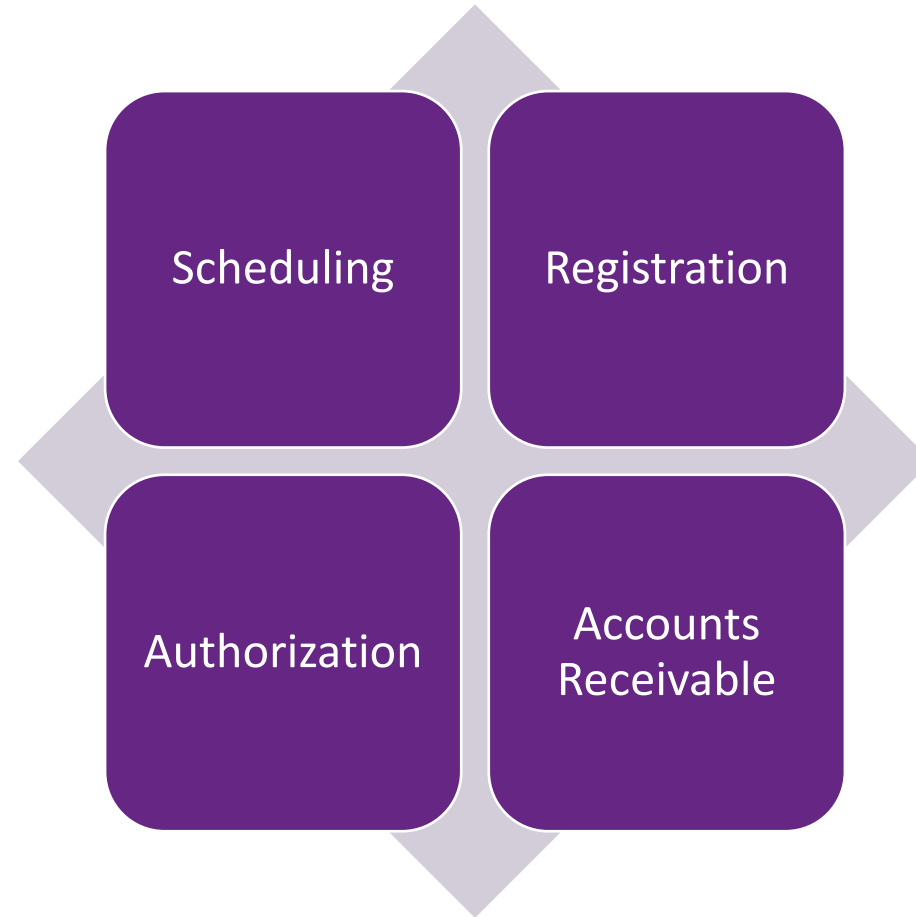
Angie Santiago, CRCs-I
*Sidney Kimmel Cancer Center at the
Thomas Jefferson University
Health System*

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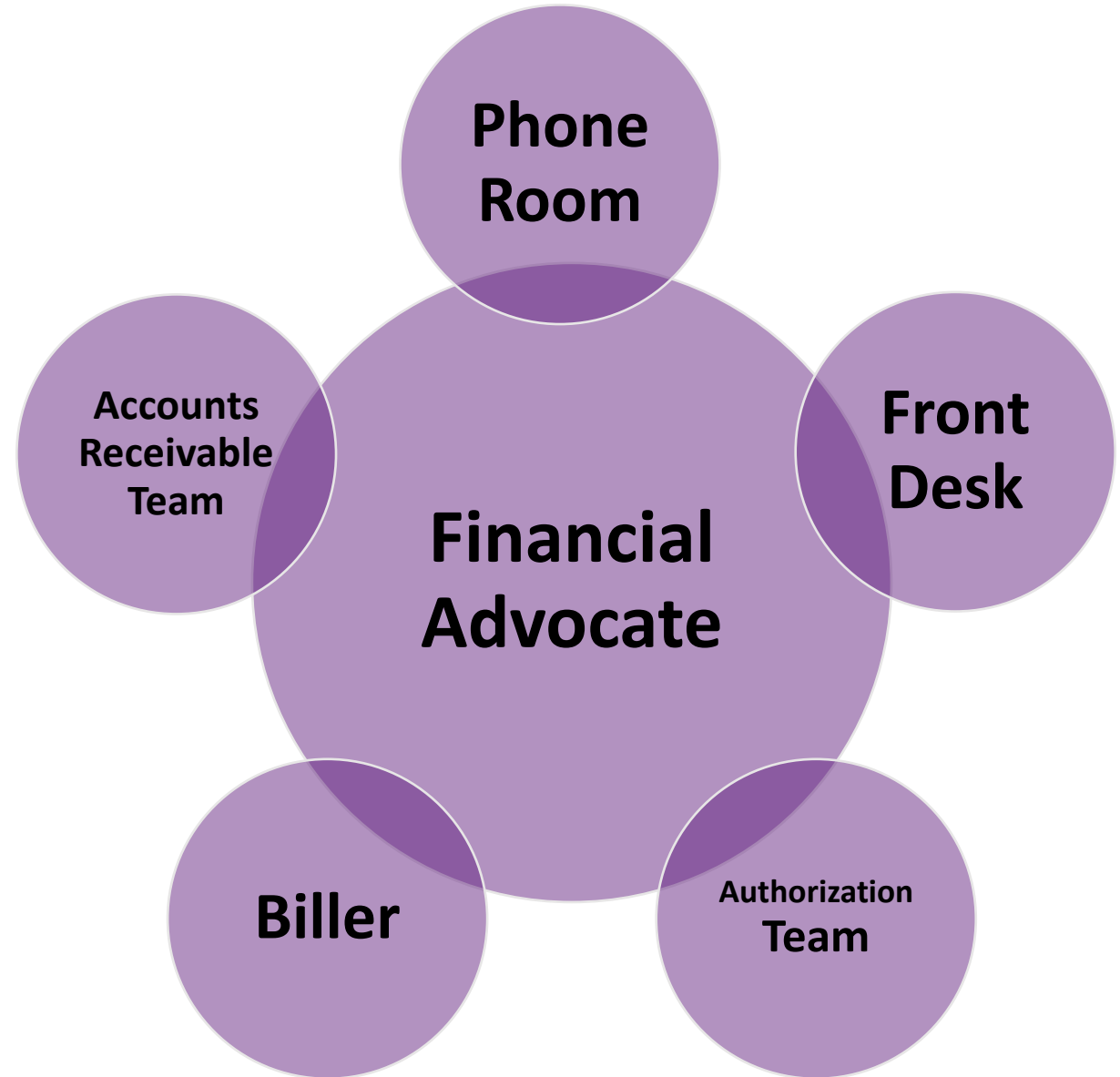
Agenda

- Benefits of having a “fiscal watchdog”
- Best practices learned to ensure a positive impact to the revenue lifecycle

What Is a Fiscal Watchdog Watching? (My Definition)



Revenue Lifecycle



Before Payments Rendered

- Communication
 - Phone room
 - Front desk
 - Authorization team

Phone Room

- Insurance participating guide
- Scripts for non-participating coverage options
- Email/notification of new appointments

Phone Room Communication Includes

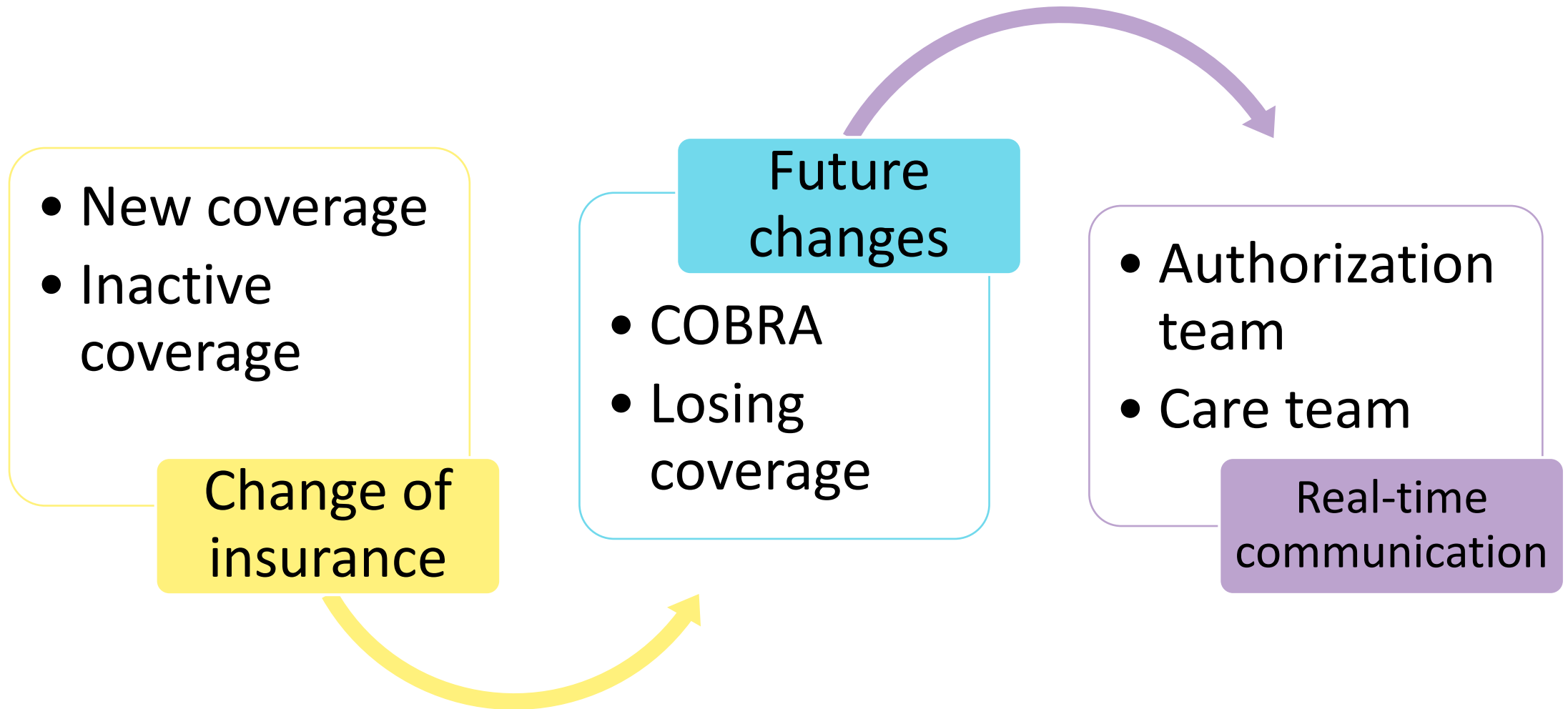
Phone Room

- Referrals to financial advocacy team

Financial Advocacy Team

- Reviews options:
 - Identify participating facilities
 - Identify change of coverage options

Front Desk



Front Desk Communication

Front Desk

- Coverage verification prior
 - If inactive, proactively reach out
- Patient check-in
 - Ensure copy of insurance card
- Update registration for new coverage or term coverage
- Notify changes in real time

Authorization Team Communication Coverage Change Example

**Authorization Team:
New Coverage**

- Subject matter experts
 - Review new coverage
 - Preferred drug
- Immediate authorization request

Financial Advocate Communication

Lost Coverage Example

**Financial
Advocacy Team:
Inactive Coverage**

- Promptly assess coverage options
 - COBRA
 - Medical assistance
 - Affordable Care Act (ACA) plan

Care Team

- Notified of potential treatment hold

Treatment Process

INFUSION AUTHORIZATION PRECERTIFICATION PROCESS

Provider Places Order

EPIC referral generated in Workqueue 1227
(Internal Episode Based Medications Referrals)

Infusion Authorization Team Reviews/Approves

Infusion Schedulers Notified

Patient Scheduled
(Exception Hydration orders are allowed to be scheduled before approval)

Authorization Team Capable of Identifying

**Medicaid
Changes**

Fee-for-
service to
managed
care

Treatment

- Preferred drug
- Specialty
- Site of service

Coding

Documentation

Treatment

Preferred drug

Specialty drug

Site-of-service drug

Preferred Drug > Chemotherapy Authorization Manual

Aetna Commercial & Medicare	Step One- Payer/Benefits Check	Step Two- Review Drug	Step Three- Documentation NPR	Step Four- Authorization Required	Step Five- Approval	
	Check Thru Availability	Document All Drugs/HCPCS	For NPR Chemo Drugs, review payer policy when applicable	Enter Authorization Information in Service Level Auth Field	Send in basket to advise approved	
	Quote Coins/Copay/Ded/OOP	Add Diagnosis if applicable	Must attach Aetna print out that showed NPR	Attach copy of approval to EPIC Referral		
	For POS/HMO Plans check if referral is needed Obtain Referral from PCP for treatment rendering location	Check for Auth Requirements thru Aetna's website for prior auths (Link Below)	Must attach either Payer Policy or NCCN guidelines when ON Pathway is not available			
	Enter Referral in Service Level Auth Field	If Auth required start request thru Novologix via Availability				
Preferred Drug	PreMeds/Iron/ Etc	Pegfilgrastim	Filgrastim	Trastuzumab	Rituximab	Bevacizumab
		Neulasta	Neupogen	Herceptin	Rituxan	Avastin
		Nyvepria	Releuko	Kanjinti	Truxima	Zirabev
		Ziextenzo	Nivestym	Trazimera	Ruxience	Mvasi
		Udenyca	Zarxio	Herzuma	Riabni	
	Fulphila	Granix				
LINKS	https://www.aetna.com/health-care-professionals/precertification/precertification-lists.html					

Specialty Drug, Also Known as Mandated Process

Authorization

- Identifies unable to buy/bill
- Blast email

Infusion Schedulers

- 7 business days

Infusion Pharmacist

- Enters orders to hospital specialty pharmacy
- Checks off patient supplied

Hospital Specialty Pharmacy

- Able to fill script
- Unable to fill script

Financial Advocacy

- Works with specialty pharmacy
- Ensures no charge

Site of Service



Most Cost-Effective Setting Program, Also Known as Site of Service

Authorization

- Identifies
- Documents

Infusion Schedulers

- Schedule injection/treatment under office

Infusion Pharmacist

- Drug ordering for office side

Authorization Team Manual

INFUSION PRIOR AUTHORIZATION PROCESS

- Always** start with Insurance
 - Check Eligibility
 - PCP Referral Needed
 - If needed, check to see if referral on file
 - If not, then request from PCP
- Review Therapy/Treatment Order**
 - Review for other active treatment plans to ensure that all drugs are approved together
 - Document all Drugs/CPT codes
 - Update Visit Count on general
 - Review each drug if payer requires an authorization
 - If required, start process
 - Before starting authorization process ensure labs/notes/testing complete
 - If NPR, documentation is **required**
 - Online PDF, Fax
 - Phone#, Insurance Representative, Date/Time, Ref# if given

Documentation Summary

Notes - General

Insurance benefits

(Coinsurance, co-pay, deductible, out of pocket for chemotherapy)

Referral required or not

All drugs being approved with Current Procedural Terminology (CPT®) codes and if precertification is required

Attachments required

If no precertification required, provide documentation whether fax, payer website, reference number

If no precertification required, then either payer policy and/or on pathway or National Comprehensive Cancer Network (NCCN) Guidelines®

If authorization is obtained, copy of authorization required

What Does Accounts Receivable See?

The screenshot displays a software interface for account review. At the top, a navigation bar includes tabs for 'Acct Summary', 'Guar Summary', 'Hosp Tx Inquiry', 'Doc Review' (selected), 'Prof Tx Inquiry', 'Liability Buckets', 'Coverages', and 'History'. Below this, the page title is 'Doc Review - 1 of 1 Account'. A secondary navigation bar contains icons for 'List', 'Account Activities', 'Collect Payment', 'Patient Refund', 'Go To', 'Finish', and 'OnBase Viewer'. On the left, a sidebar menu lists various medical categories, with 'Patient Visit' selected. The main content area is divided into sections: 'Referred To' (Location and Department), 'Visits' (Requested: 12, Authorized: 12, Completed: 4, Scheduled: 1), 'Diagnoses', 'Referral Notes' (General by Angie M Santiago at 10/2/2022 1729), and 'Attachment' (Referral Attachment - Scan on 10/2/2022 5:29 PM). A 'Status History' table shows a change from 'Pending Review to Authorized' by 'Angie M Santiago' on '10/02/2022 2129'. A 'Questionnaire' section is partially visible at the bottom.

Referred To
Location: _____ Department: _____

Visits
Requested: 12 Authorized: 12 Completed: 4 Scheduled: 1

Diagnoses

Referral Notes
General by Angie M Santiago at 10/2/2022 1729
Keystone 65 Select HMO
COINS-20%, COPAY/DED-NA, OOP-\$4900
OP NSCLC CARBOplatin/ PACLitaxel w/RT (WEEKLY)
PREMEDS NPR/ATTACHED
DECADRON-J1100, ALOXI-J2469, BENADRYL-J1200, PEPCID-J3490
CHEMO-NPR/ATTACHED
TAXOL-J9267, CARBO-J9045
NCCN ATTACHED

Attachment
> Referral Attachment - Scan on 10/2/2022 5:29 PM

Status History

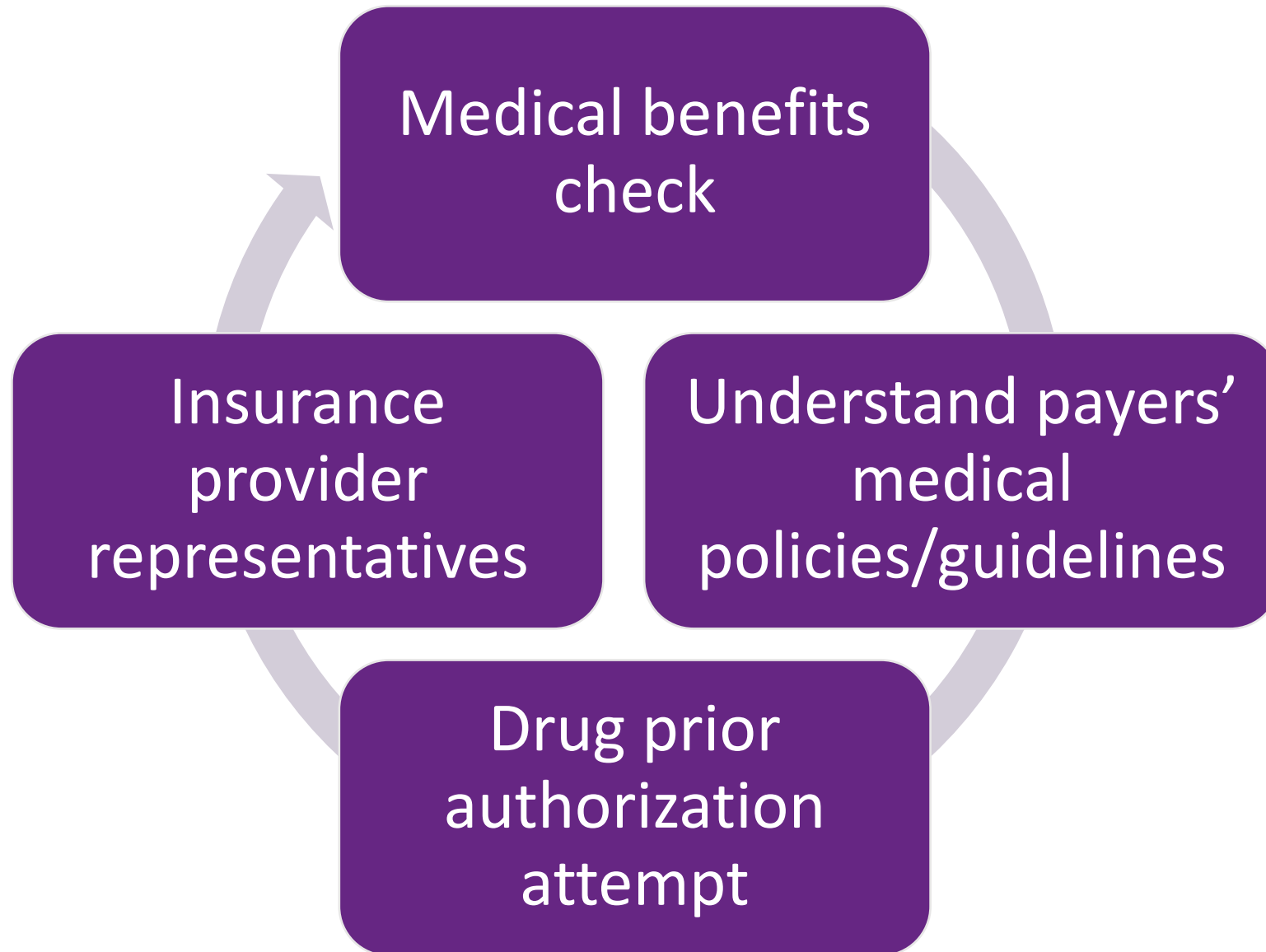
Change	User	Date/Time
From Pending Review to Authorized	Angie M Santiago	10/02/2022 2129

Questionnaire

Question	Answer
Is documentation complete?	Yes



Tips for the Authorization Team



Accounts Receivable Team

System
adjustments

Bundled
payments

Denials

Review of
authorized
documentation

System Adjustments/Bundled Payments

Contractual write-offs are those wherein the excess of the billed amount over the carrier's allowed amount is written off.

- System adjustments:
 - Request accounts receivable team to provide adjustments
- Bundled payments:
 - Ensure revenue integrity has correct build

Denials/Review of Authorized Documentation

- Group effort
 - Work queue accounts reviewed within 7 days
 - Resolved within 30 days
- Monthly reviews:
 - Identify trends
- Timely communication

Questions?

Angie Santiago, CRCS

Manager, Oncology Financial Advocacy

Phone: 215.503.5213

Angie.Santiago@Jefferson.edu

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Brief Remarks

Matt Devino

*Director of Cancer Care Delivery & Health Policy
Association of Community Cancer Centers*

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ASSOCIATION OF
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CANCER CENTERS

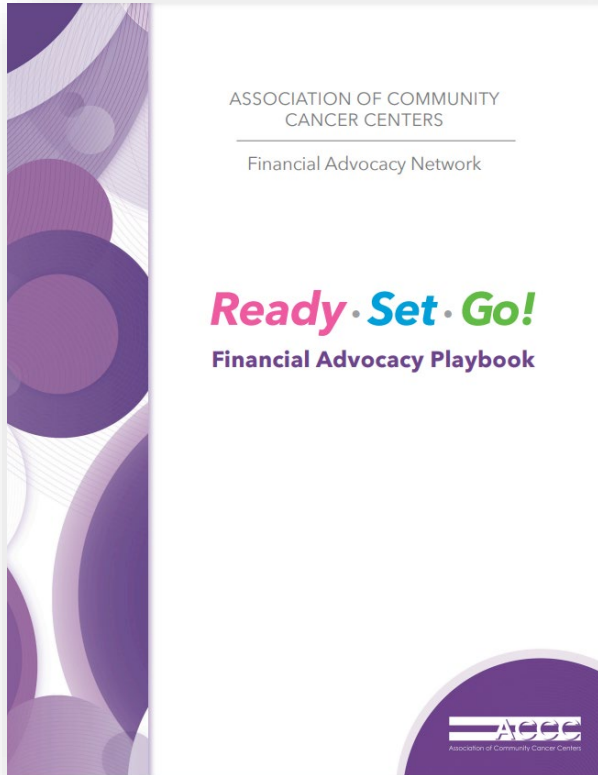
FINANCIAL
ADVOCACY
NETWORK

Financial Advocacy Resources

ACCC-CANCER.ORG/FAN

ACCC Financial Advocacy Network Resources and Tools

Financial Advocacy Playbook



16


Tool Kit

- The Financial Advocacy Toolkit includes a multitude of resources, including:

<input type="checkbox"/> BENEFITS VERIFICATION	<input type="checkbox"/> FILING CLAIMS	<input type="checkbox"/> MEDICARE & MEDICAID
<input type="checkbox"/> COMMUNICATION	<input type="checkbox"/> FINANCIAL ASSISTANCE	<input type="checkbox"/> PRIOR AUTHORIZATION
<input type="checkbox"/> DENIALS & APPEALS	<input type="checkbox"/> FINANCIAL TOXICITY & SCREENING	<input type="checkbox"/> PROGRAM DEVELOPMENT
<input type="checkbox"/> EMPLOYMENT & DISABILITY	<input type="checkbox"/> INSURANCE EDUCATION & OPTIMIZATION	<input type="checkbox"/> TRACKING & REPORTING

Boot Camp





Lunch Break in Resource
Center
12:30 – 1:30 PM

Brief Remarks

Matt Devino

*Director of Cancer Care Delivery & Health Policy
Association of Community Cancer Centers*

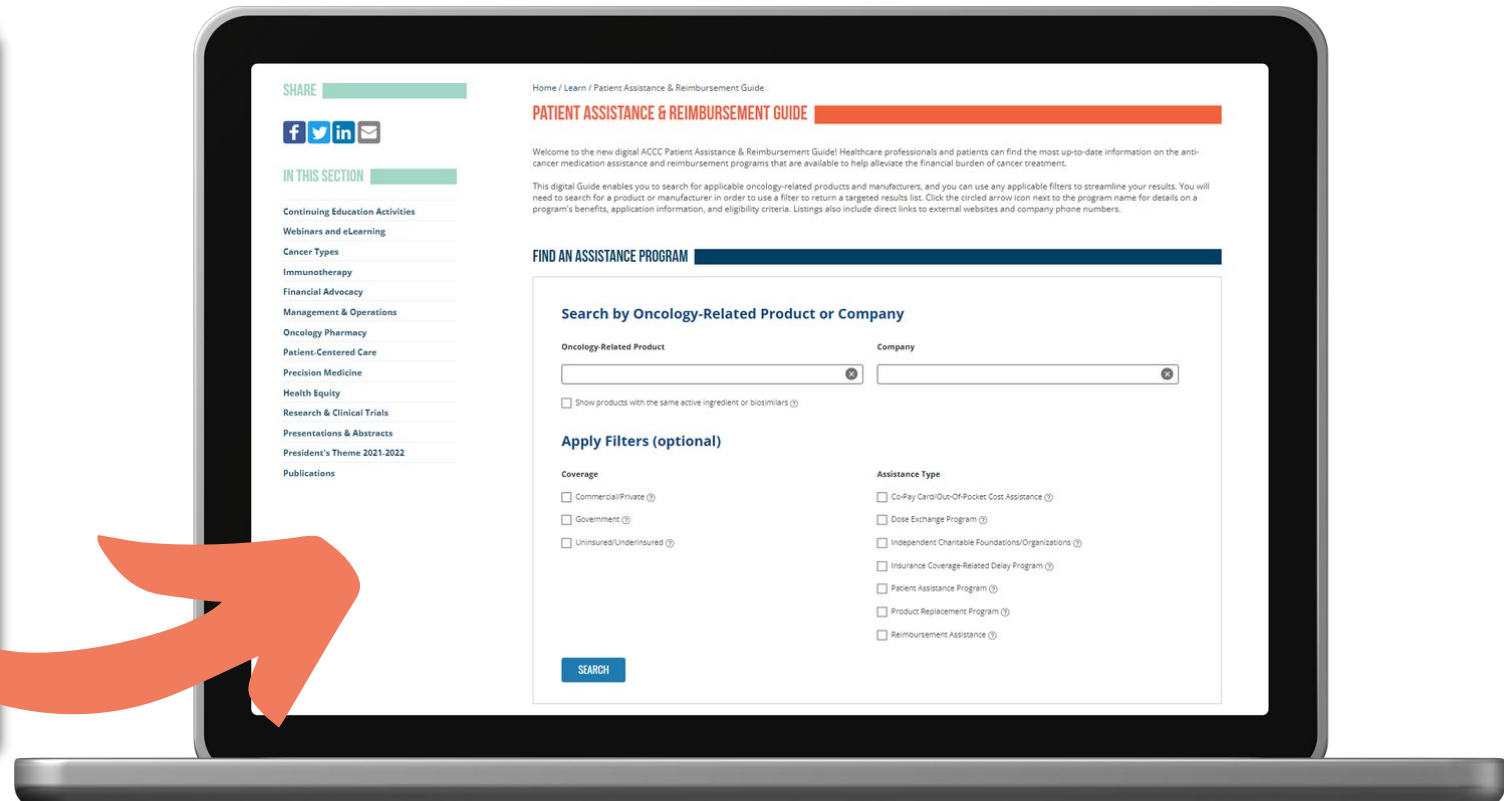
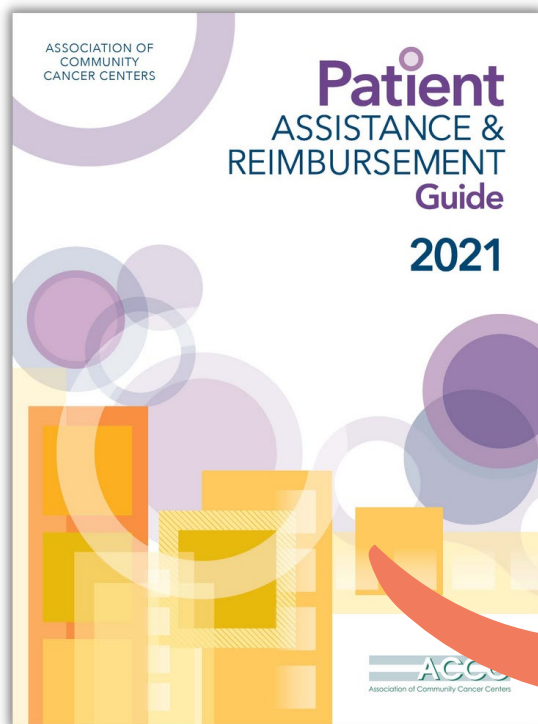
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The DIGITAL Patient Assistance & Reimbursement Guide

Find the most up-to-date oncology assistance & reimbursement programs by searching for a prescribed product or company name, then streamline your search by applying coverage and assistance-type filters.

Access ICD-10 codes and the Library of NCCN Compendia for current indications.

[ACC-CANCER.ORG/PAG](https://acc-cancer.org/pag)



Pharmacy Benefits Managers and Enhancing Oncology Model



Matt Devino, MPH

*Director of Cancer Care Delivery
& Health Policy*

Association of Community Cancer Centers

@ACCCBuzz






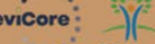


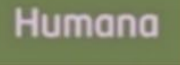














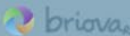



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Policy Potpourri: Pharmacy Benefit Managers & The Enhancing Oncology Model

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

Pharmacy Benefit Manager (PBM) Reform Efforts

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

Plan Sponsors	   	  			
PBMs					
Rebate Aggregators					
PBM-Owned Specialty Pharmacies			  		

→ 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^{1,2}

- 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)³

- 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 co-pay assistance programs, waivers, and third-party payments for prescriptions as part of patients' 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-based assistance programs from counting toward patients' deductible and/or annual out-of-pocket maximum.
- By using CAAPs, PBMs reduce the value of manufacturer-based 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)⁴ 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* ruling⁵ 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 Tool⁶

The screenshot displays the COPA Legislative Tracking Tool interface. At the top, the COPA logo (Community Oncology Pharmacy Association) is visible on the left, and navigation links for ABOUT, RESOURCES, MEMBERSHIP, EVENTS, and STUDIES & PUBLICATIONS are on the right. The main content area features a map of the United States with states color-coded: red for states with active legislation, blue for states with pending legislation, and grey for states with no active or pending legislation. A list of legislative issues is shown on the right, with 'PBM Regulation' highlighted in red, indicating it is the current focus.

ISSUE
Drug Pricing and Cost Containment
Fair Pharmacy Audit
Home Infusion
Maximum Allowable Cost
PBM Regulation
Prior Authorization or Step Therapy
Prompt Pay Laws
Rebate Pass Through (RPT)
Repository Programs
Spread Pricing

State Policy: COPA's Legislative Tracking Tool⁶



Virginia

Oncology Pharmacy Laws, Regulations, and Pending Legislation

[File a Board of Pharmacy Complaint](#)

Virginia Enacted / Passed

ISSUE	SUMMARY	PRACTICAL NOTE	BILL OR STATUTE	
Prompt Pay Laws	Every provider contract entered into by a carrier shall contain specif...	PBMs fall under the br...	§ 38.2-3407.15. Ethics a...	View More
Any Willing Provider	Insurers, HMOs and PPOs shall establish terms and conditions in or...	While these sections ...	Va. Code Ann. § 38.2-3...	View More
DIR Fees and Clawbacks	No provider contract between a health carrier or its PBM and a phar...	While this law does no...	VA ST § 38.2-3407.15:4...	View More
White or Brown Bagging	A pharmacy may deliver a dispensed prescription drug order to a pr...	While the Board of Ph...	18VAC110-20-275	View More



COApharmacy.com

The Enhancing Oncology Model

The Enhancing Oncology Model (EOM)⁷

- The EOM is a new oncology-specific alternative payment model announced by the Centers for Medicare & Medicaid Services (CMS) in June 2022.
- Builds upon the Oncology Care Model (OCM) with a new focus on health equity.
- The EOM will be a five-year, voluntary, multi-payer model beginning July 1, 2023.
- Like the OCM, EOM participants will be responsible for the total cost of care during a 6-month episode for patients undergoing chemotherapy.
- Drug reimbursement is same as fee-for-service (FFS) Medicare: payment typically ASP+6%; total cost of care responsibility includes Part B drug payment and certain Part D expenditures.
- **Applications were open through October 10 and were non-binding. Accepted applicants will need to sign an EOM participation agreement in early 2023 to confirm participation.**

Key Design Differences: EOM vs. OCM⁸

Model Design	OCM	EOM
Beneficiary Population	Beneficiaries with a cancer diagnosis receiving chemotherapy (including hormonal therapies)	Beneficiaries with a cancer diagnosis for one of 7 included cancer types (breast, lung, lymphoma, multiple myeloma, small intestine/colorectal, prostate, and chronic leukemia) receiving systemic chemotherapy (not including exclusively hormonal therapies)
Price Prediction Models and Risk Adjustment	All cancer types included in one price prediction model , novel therapy adjustment and trend factors calculated in aggregate	Included cancer type-specific price prediction models , novel therapy adjustments and trend factors calculated separately for each included cancer type
Required Participant Redesign Activities (PRAs)	Six cross-cutting requirements that provide for broad improvements in cancer care including documenting a care plan, 24/7 access to a clinician, and patient navigation services.	Same as OCM with the addition of two new PRAs: the gradual implementation of electronically submitted patient reported outcomes and screening EOM beneficiary social needs using a health-related social needs screening tool. Also, participants must establish a health equity plan as part of the continuous quality improvement (CQI) requirement.
Data Collection	Participants not required to collect any sociodemographic data	Required submission of sociodemographic data, if available

Required Participant Redesign Activities^{8,9}

1. Patients must have 24/7 access to a clinician with real-time electronic health record (EHR) access
2. EHR must be certified by the Office of the National Coordinator and meet meaningful use Stage 2
3. Patients must have access to navigation support services
4. Treatment plans must comply with evidence-based national guidelines
5. Practice must adopt the EOM oncology quality measures, report data on all EOM patients, and use data internally for quality improvement
6. Each patient must have a documented Institute of Medicine (IOM; now the National Academy of Medicine) Cancer Care Management Plan
7. **Identify health-related social needs using an appropriate patient screening tool**
8. **Use of electronic patient-reported outcomes (ePROs)**

Health Equity Plan⁸



Practices will share patient sociodemographic data with CMS



CMS will provide data and report back to practices based on this data to help identify disparities



Practices develop, maintain, and implement a health equity plan to address disparities based on their local population with annual reporting



Health Equity Plan⁸

Practices will screen patients for health-related social needs to inform health equity plans

- Allowable screening tools yet to be determined

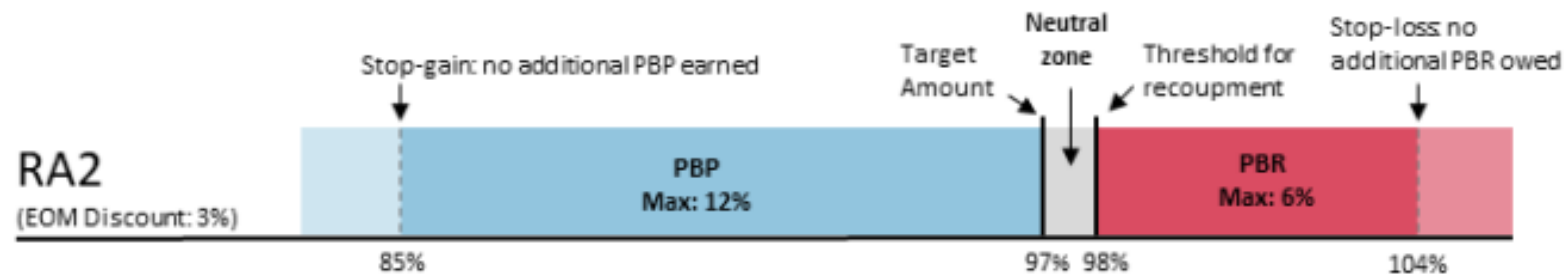
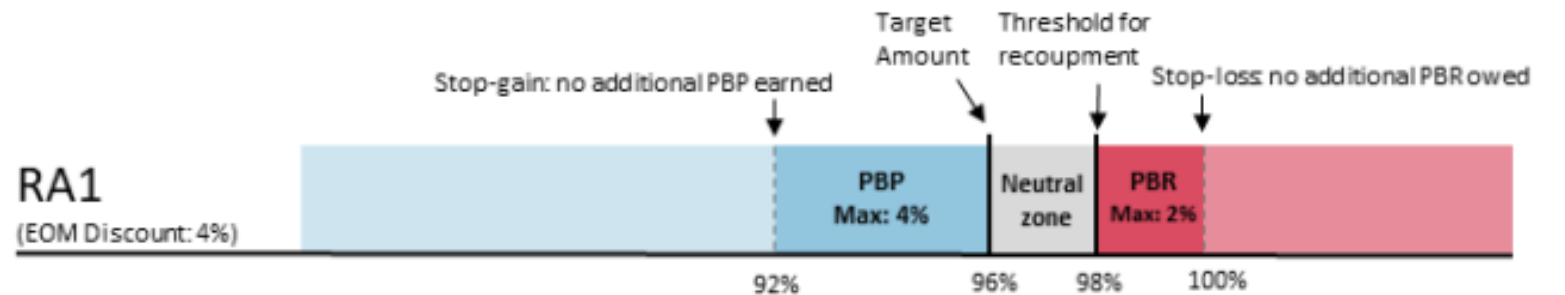
Higher per member, per month (PMPM) payment (+43%) for dual eligible patients reflecting higher patient complexity

Key Financial Differences: EOM vs. OCM⁸

Model Design	OCM	EOM
Monthly Enhanced Oncology Services (MEOS) Payment	MEOS payment amount = \$160 PMPM for each OCM beneficiary; the entire \$160 is included as episode expenditures	MEOS payment amount = \$70 PMPM (beneficiary not dually eligible for Medicaid and Medicare); or \$100 PMPM (beneficiary dually eligible for Medicaid and Medicare) of which \$70 will be included as episode expenditures in reconciliation calculation
Risk Arrangements	<p>One-sided risk in performance period (PP) 1, followed by the option for one- or two-sided risk in PP2-PP7.</p> <p>Participants earning a performance-based payment by the initial reconciliation of PP4 had the option to stay in one-sided risk in PP8—PP11; other participants had to either accept two-sided risk in PP8—PP11 or be terminated from the model.</p>	<p>Two-sided risk required from the start of the model. Participants to choose one of two options with downside risk:</p> <ol style="list-style-type: none"> 1) Less aggressive two-sided risk arrangement option (RA1): Discount=4% of benchmark Upside=4% of benchmark; Downside=2% of benchmark 2) More aggressive two-sided risk arrangement option (RA2): Discount=3% of benchmark Upside=12% of benchmark; Downside=6% of benchmark <p>For both risk arrangements, if the EOM participant's performance period episode expenditures are greater than 98% of the benchmark, they will owe a performance-based recoupment (PBR).</p>

EOM Payment Model⁸

- Compare actual vs. predicted total cost of care for 6-month chemotherapy episodes:
 - If your claims are lower than 96% of predicted (RA1) or 97% of predicted (RA2), CMS shares savings in the form of a performance-based payment (PBP)
 - If your claims are higher than 98% of predicted, you pay a penalty in the form of a performance-based recoupment (PBR)



**So what can we predict about the EOM in
2023?**

OPEN FOR QUESTIONS



Thank you!
Please reach out and stay in touch:

mdevino@accc-cancer.org

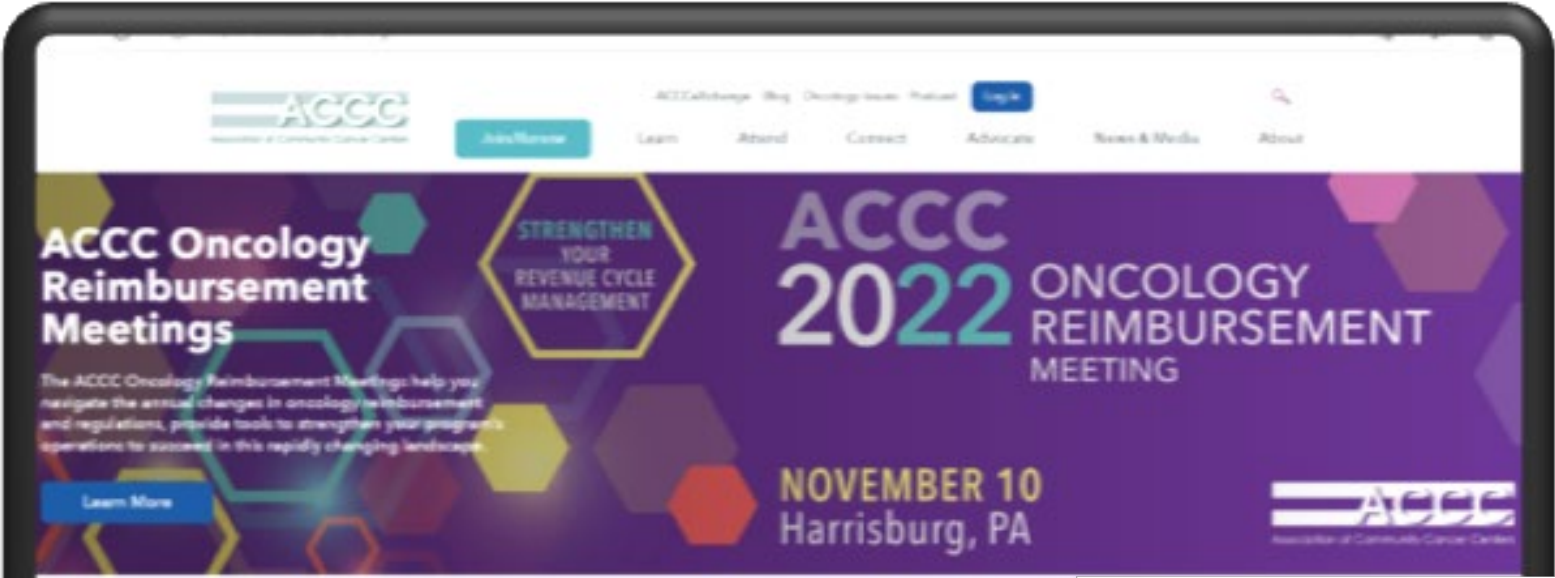
Matt Devino, MPH
Director of Cancer Care Delivery & Health Policy
Association of Community Cancer Centers



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- Clinical Updates

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*Blog Post:
How Does the EOM
Compare to the OCM?*

Improving Your Formulary and Denials Management



Andre D. Harvin, PharmD, MS
*Executive Director of Pharmacy,
Oncology
Cone Health Cancer Center*

@ACCCBuzz | **#ACCCORM**

Learning Objectives

- Assess the fundamentals of formulary design and denials management as it relates to oncology care
- Explain how to approach present and emerging challenges in formulary and denials management
- Justify the need to merge pharmacy and revenue cycle expertise to supercharge your revenue integrity

What Is a Formulary?

- *Conceptually:* An integrated patient-care process that enables physicians, pharmacists, and other healthcare professionals to work together to promote clinically sound, cost-effective medication therapy and positive therapeutic outcomes¹
- *Definition:* A continually updated list of medications and related-products supported by current evidence-based medicine and the judgment of physicians, pharmacists, and other experts in the diagnosis and treatment of disease and preservation of health²

Development and Management

- Formulary development:
 - Oversight by a Pharmacy & Therapeutics (P&T) Committee
 - Comprised of physicians, pharmacists, and healthcare professionals with relevant expertise
 - Evaluate medical and clinical trials as well as treatment guidelines to determine inclusion/exclusion from facility formulary

Development and Management

- Formulary management:
 - Driven by the Department of Pharmacy
 - Evaluation of formulary decision after a decision has been made
 - Leverage medication-use evaluations (MUE)
 - Interlay economic data, evolving guidelines, payer mandates, etc.
 - Recommendations still approved by P&T Committee

Location Matters

- *Open formulary*: Generally, all U.S. Food and Drug Administration (FDA)-approved drugs are available for utilization
- *Closed formulary*: Not all FDA-approved drugs are available for utilization. Restrictions at the drug, dose, or indication level
- *Value-based formulary* emphasizes the clinical effectiveness over costs

Location Matters

- Inpatient:
 - Closed formulary
- Outpatient/Retail:
 - Open formulary
 - Transitions into value-based ongoing
- Oncology:
 - Open formulary
 - Transitions into value-based ongoing

Inpatient Reimbursement³

- Medicare Severity Diagnosis Related Group (MS-DRG): A data set that represents more than 7 million discharges across more than 3,000 United States hospitals
 - It classifies Centers for Medicare & Medicaid Services (CMS) patients' hospital stay into various groups in order to facilitate payment services

Inpatient Reimbursement³

- These payments cover the entirety of patients' stay in the hospital, including procedures, drugs, etc.
- The goal for inpatient formularies is to reduce drug costs so that your total spent is **less than** your anticipated MS-DRG payment

Outpatient/Oncology Reimbursement⁴

- Hospital Outpatient Prospective Payment System (HOPPS): Sets payments for individual services using a set of relative weights, a conversion factor, and adjustments for geographic differences in input prices
 - Allots for additional payments through outlier adjustments for high-cost services and pass-through payments for new technologies

Outpatient/Oncology Reimbursement⁵

- Physician Administered Drug Program: An outpatient drug other than a vaccine that is typically administered by a healthcare provider in a physician's office or other outpatient clinical setting

Different Approach, Similar Results

- Inpatient:
 - Closed formulary
 - MS-DRG/bundled payment structure
 - Goal: reduce drug expenditure while maximizing patient outcomes
- Outpatient, Oncology:
 - Open or value-based formulary
 - HOPPS and Separately Payable Drug Program
 - Goal: maximize patient outcomes and strengthen reimbursement

Living in Denial

- *Denial*: The refusal of an insurance company or carrier to honor a request by an individual (or their provider) to pay for healthcare services obtained from a healthcare professional⁶
- The average claim denial rate across the healthcare industry is between 5% to 10%⁷
 - Representing almost \$300 billion annually⁸

Living in Denial

- Other than **patient eligibility** the other most common reasons for denials include:⁹
 - Duplicate or late submissions
 - Missing or incorrect data
 - Lack of documentation or prior authorization

Challenges in Denials Management

- **Lack of training and skill alignment:**
 - Increased administrative burden stresses staff
 - Increasing complexity and challenges require timely clinical/operational support
- **Manual processes in a digital world:**
 - Disparate systems and processes require the use of multiple systems, not often linked digitally
 - Results in a large number of denials being unaddressed due to systems failures
- **Lack of financial and full-time equivalent (FTE) resources**

Ongoing Oncology Accelerated Approvals

- The last few years have seen a record number of FDA approvals for cancer-related therapies
- Accelerated approvals for malignant hematology and oncology have brought **64** drugs to market prior to their original projected completion date¹⁰

Ongoing Oncology Accelerated Approvals

- Cancer care is still projected to have the largest pipeline of new treatment options due to unmet needs¹¹
- The proliferation of “ultra-high cost” or “ultra-expensive” drugs is set to make formulary and denials management more difficult

Present and Emerging Challenges

- Biosimilar integration
- Site of care restrictions
- White and brown bagging
- Adoption of value-based care arrangements
- Genetics
- Step therapy

Biosimilars^{12,13}

- FDA definition: A biosimilar product is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product
- *Highly similar*: Analysis of the structure and function of both the reference product and the proposed biosimilar. Leverages technology to compare purity, chemical identity, and bioactivity
- *Clinically meaningful*: The proposed biosimilar product has no clinically meaningful differences from the reference product in terms of safety, purity, and potency (safety and efficacy)

U.S. biosimilar market landscape

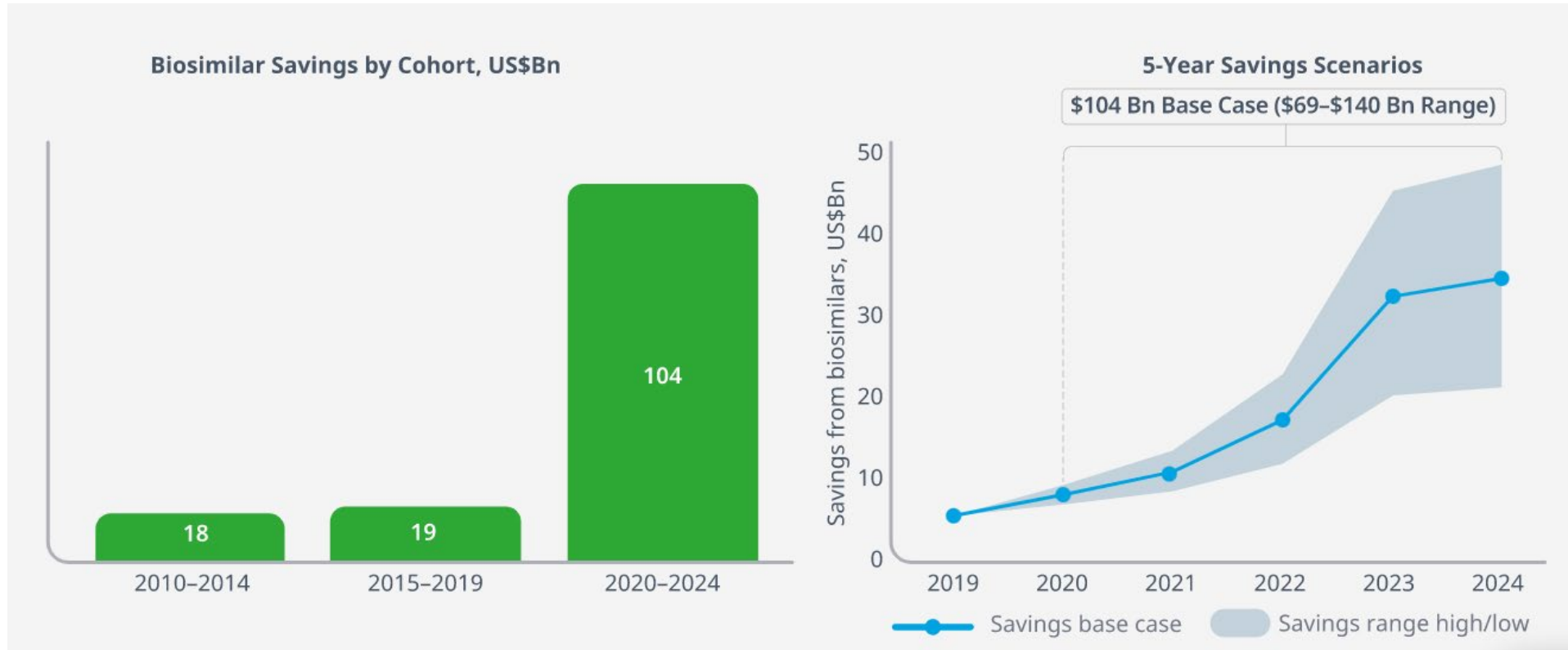
As of April 13, 2022

Class	Supportive care			Oncology		
Molecule	Filgrastim	Epoetin	Pegfilgrastim	Rituximab	Bevacizumab	Trastuzumab
Innovator	NEUPOGEN (Amgen)	EPOGEN / PROCRIT (Amgen / JnJ)	NEULASTA (Amgen)	RITUXAN (Genentech)	AVASTIN (Genentech)	HERCEPTIN (Genentech)
Launched Manufacturer launch date	ZARXIO Sandoz Sep 2015	RETACRIT Pfizer/Vifor Nov 2018	FULPHILA Mylan Jul 2018	TRUXIMA Teva Nov 2019	MVASI Amgen Jul 2019	KANJINTI Amgen Jul 2019
Approved Manufacturer FDA approval date	NIVESTYM Pfizer Oct 2018		UDENYCA Coherus Jan 2019	RUXIENCE Pfizer Jan 2020	ZIRABEV Pfizer Jan 2020	OGIVRI Mylan Nov 2019
			ZIEXTENZO Sandoz Nov 2019	RIABNI Amgen Jan 2021		TRAZIMERA Pfizer Feb 2020
			NYVEPRIA Pfizer Dec 2020			HERZUMA Teva March 2020
	RELEUKO Amneal Feb 2022					ONTRUZANT Organon Apr 2020
					ALYMSYS Amneal Apr 2022	

Benefits of Biosimilars^{15,16}

- By 2025:
 - Biosimilars are projected to reduce aggregate spending in the U.S. by \$133 billion
 - Out-of-pocket savings for patients are set to reach \$238 million
- Potential to increase patient access
- Success dependent on adoption in clinical practices

Benefits of Biosimilars



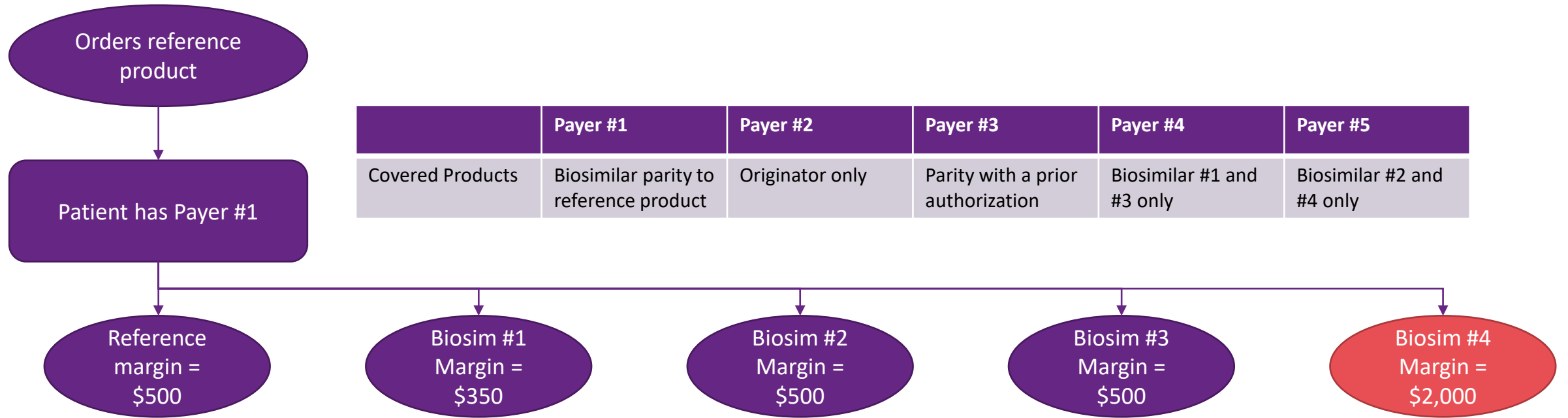
Barriers to Adoption

- Lack of interchangeable product(s):
 - Would allow for substitution without the intervention of the healthcare professional who prescribed the reference product
- Patient and provider education:
 - Changing products could cause anxiety for patients
 - Physicians receive little education on biosimilars

Barriers to Adoption

- Financial impact:
 - Lower cost drugs result in lower reimbursement in the outpatient environment
- Electronic health record:
 - Complex build, as these are unique products
- Health plan formulary:
 - As more biosimilars come to market, payers create manufacturer-specific formularies

Formulary Mismatch



Codes Galore

- Each biosimilar will have its own unique J-code or Healthcare Common Procedure Coding System (HCPCS) code
- Meaning that a single drug could have 5 to 6 possible codes, and increasing
- With each payer having their own preferred and non-preferred formularies

Biosimilar	J-Codes	Billing Codes
bevacizumab	J9035	10 mg
bevacizumab-awwb	Q5107	10 mg
bevacizumab-bvzr	Q5118	10 mg
epoetin alfa, non-end-stage renal disease (ESRD)	J0885	1000 units
epoetin alfa, ESRD on hemodialysis (HD)	J0886	1000 units
epoetin alfa-epbx, non-ESRD	Q5106	1000 units
epoetin alfa-epbx, ESRD on HD	Q5105	1000 units
filgrastim	J1442	1 mcg
tbo-filgrastim	J1446	5 mcg
tbo-filgrastim	J1447	1 mcg
filgrastim-sndz	Q5101	1 mcg
filgrastim-aafi	Q5110	1 mcg
pegfilgrastim	J2505	6 mg
pegfilgrastim	J2506	0.5 mg
pegfilgrastim-jmdb	Q5108	0.5 mg
pegfilgrastim-cbqv	Q5111	0.5 mg
pegfilgrastim-bmez	Q5120	0.5 mg
pegfilgrastim-apgf	Q5122	0.5 mg
rituximab	J9310	100 mg
rituximab	J9312	10 mg
rituximab-abbs	Q5115	10 mg
rituximab-pvvr	Q5119	10 mg
rituximab-arrx	Q5123	10 mg
trastuzumab	J9355	10 mg
trastuzumab-anns	Q5117	10 mg
trastuzumab-dkst	Q5114	10 mg
trastuzumab-qyyp	Q5116	10 mg
trastuzumab-pkrb	Q5113	10 mg
trastuzumab-dttb	Q5112	10 mg

Which Biosimilar Should I Choose?

- It depends...
- What are your formulary considerations?
 - Acquisition costs of the comparable reference and biosimilar agent(s)
 - Are there discounts or rebates associated with a group purchasing organization or portfolio contract?
 - Manufacturer assistance or free drug program(s)

Which Biosimilar Should I Choose?

- It depends...
- What are your formulary considerations?
 - Payer mix
 - Preferred biosimilar (could change over time)
 - Manufacturer reliability
 - Margin analysis
 - Pharmacy driven biosimilar interchange

Site of Care Restrictions

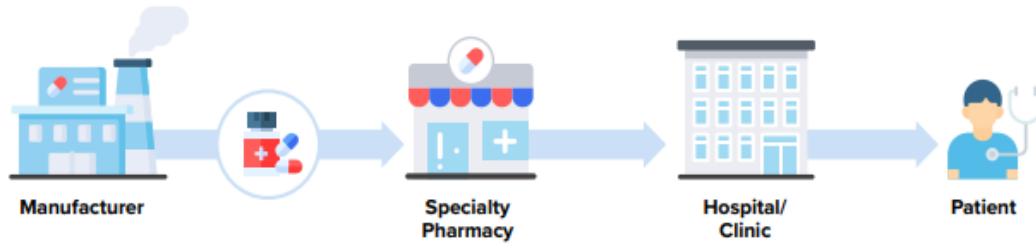
- A strategy for reducing the cost of specialty biologic medication administration; seeks to lower costs associated with certain infused or injected drugs by encouraging the use of clinically appropriate, lower cost care settings
- Previous shift from inpatient hospital administration to hospital-owned outpatient departments (HOPD)
- Recent shift from HOPD to alternative models, such as home infusion, hospital at home, and ambulatory infusion sites

Not so Fast

- Several cancer care-focused advocacy and professional groups have resisted this specific payer driven initiative
- Statements from ACCC, American Society of Clinical Oncology (ASCO), Oncology Nursing Society (ONS), American Society of Health System Pharmacists (ASHP), and others have highlighted the risks associated with the regular administration of anti-cancer therapies in the home or non-specialized environments¹⁸⁻²¹
- First 30-day tactics

White Bagging

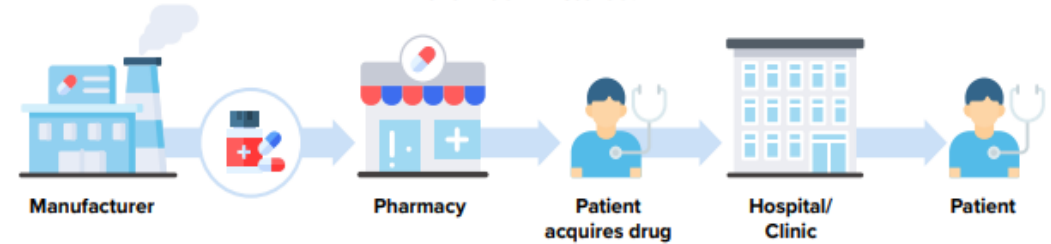
A specialty pharmacy ships a patient's prescription directly to the provider (Hospital or Clinic).



Transportation of drugs problematic. Drugs can be sent from anywhere, arrive late, etc. Issue is fragmentation of care and negative patient experience. Multiple steps in the process.

Brown Bagging

The practice of patients acquiring pharmaceuticals, through their pharmacy benefit and bringing the drugs to a physician's office or hospital to have them administered.



No longer legal in most places. Multiple failure points.

Clear Bagging

A health system's internal specialty pharmacy fulfills the patient's prescription, then transports the product to the location of drug administration. Effectively depicts transparency among stakeholders.



Functional solution but lacks holistic healthcare approach; widget movement only.

Gold Bagging

Incorporates transparent clear bagging approach AND emphasizes the gold standard of care. Correlates to Olympic gold medal performance through improved care process leading to better patient outcomes.



Holistic, best practice approach. SP dispenses drug from their inventory to their clinic for their patient. More controlled, fewer failure points, patients' physicians and EMR all available and updated. Promotes health equity. Gold Bagging acknowledges essential value in the pharmacy process steps, which are typically not reimbursable. Clinical pharmacist steps include: lab value monitoring and sterile infusion preparation.

Secure the Bag

- Denials can occur if a payer mandates that a drug must be procured through an alternative bagging model (e.g., white, brown, clear)
- Communication between prior authorization team and pharmacy often breaks down with patient-specific requirements

Secure the Bag

- Prior authorization teams can push back on payers that require bagging
- Restrict at the organization level
- Advocate at the state and federal level to prevent the practice

Transition to Value-Based

- Payment models that favor care quality and outcomes over quantity of services provided
 - Initial model was the Center for Medicaid and Medicare Innovation's Oncology Care Model
 - Next-generation model (Oncology Care First) will put greater emphasis on enhanced collaboration, cost containment, and total cost of care
- Drug formularies and revenue cycle teams will need to rapidly adapt to new models and information to optimize therapy decisions

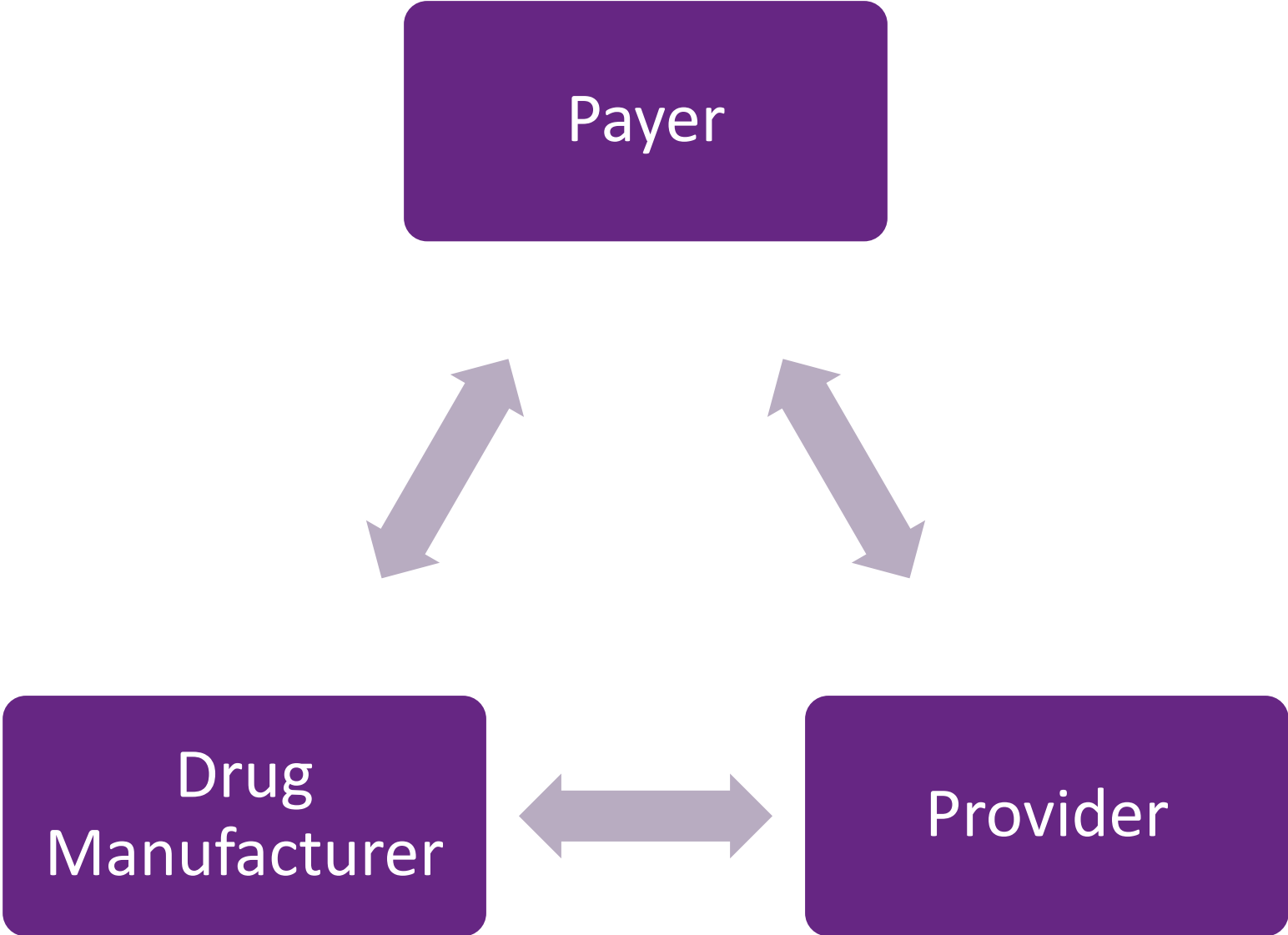
Example Strategy

- Novel product “X” gained FDA approval as a pre-chemotherapy supportive medication that could reduce the use of other expensive supportive therapy medications and reduce emergency department (ED) visits for specific patients
- Based on the above information would you add this to your inventory?
- Would your decision change if you learned that product “X” was priced at three times the cost of standard-of-care supportive drugs? Five times? More?

Example Strategy

- Product “X” was added to your formulary and utilized based on its FDA approval. After a year of utilizing product “X,” you find that ED visits for patients on product “X” shows no statistical difference from your previous standard of care. What do you do?
- It depends...
 - Evaluate practice and comparable patients
 - Reduce utilization of other healthcare resources

Shared Risk Payment Models



Cell and Gene Therapy^{23,24}

- *Gene therapy*: The use of genetic material in the treatment or prevention of disease. The genetic material changes how a single protein or group of proteins is produced by a cell
- *Cell therapy*: The transfer of intact, live cells into a patient to help lessen or cure a disease. The cells may originate from the patient (autologous cells) or a donor (allogeneic cells)
- The FDA predicts 10 to 20 genetic or cell therapy approvals per year by 2025

Costly Future

- Some of these therapies are expected to exceed \$1 million in total spending, per patient
- Requirements for some portions of the therapy to be completed inpatient with others in the outpatient
- Requirements for specific genetic testing prior to therapy initiation
- Potential to accelerate costs for pharmaceuticals while potentially eliminating certain diseases

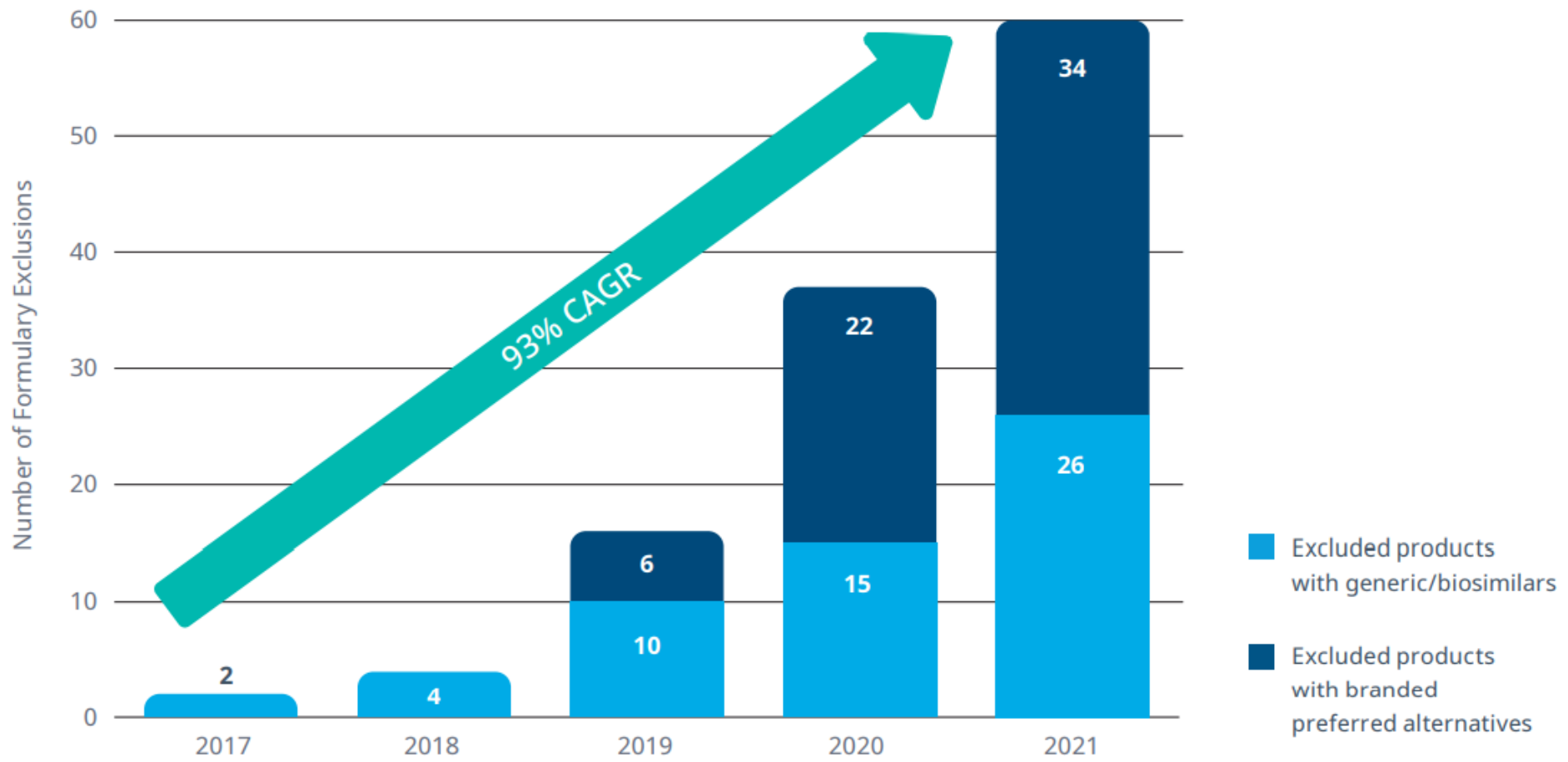
Step Therapy Challenges

- Known as a “fail first” or “try and fail” tactic, where a patient is required to try an alternative, typically cheaper, product (medicine, therapy, or service) before the one their physician prescribed²⁵
- Most often used for ancillary, supportive care medications used in the treatment of side effects like nausea, vomiting, and neutropenia

Step Therapy Challenges

- Response by insurers to slow drug costs
- Lack of real-world evidence in comparison to standard of care for new therapies will create a difficult environment in the immediate future

Number of National Formulary Exclusions (Top National Payers, Commercial Insurance, Oncology)²⁶



All About the Denials

- Get it right the first time!
- Timely resubmission of denials with required information
- Start from the beginning:
 - Require prior authorization before any procedure
 - Align practices with National Comprehensive Cancer Network or third-party clinical pathways

All About the Denials

- Get it right the first time!
- Timely resubmission of denials with required information
- Start from the beginning:
 - Review payer medical necessity guidelines even if payers do not require prior authorization
 - Ensure electronic health record is built correctly with billing codes
 - Evaluate your comprehensive charges to ensure you meet your allowable billing rates

Teamwork Wins the Day

- There is no one team that is accountable for formulary and denials management
- Siloed operations will lead to underperformance and the inability to meet future challenges
- Communication between pharmacy, prior authorization, and revenue cycle teams will be critical for future practice
- Denials often require additional clinical (trials, guidelines, testing, etc.) or operational (vial size, rounding, waste documentation, etc.) information that can be found with your pharmacy team

Next Steps?

- Evaluate your P&T Committee(s):
 - Do you have one specifically for oncology?
 - Does the committee have the expertise required?
 - Is it multidisciplinary?
- Understand how your upstream and downstream denials process works:
 - Do you have a prior authorization process?
 - Are pharmacy or medical oncologists integrated into the denials process?
- Do you have the right data available to be successful?

QUESTIONS?

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Brief Remarks

Matt Devino

*Director of Cancer Care Delivery & Health Policy
Association of Community Cancer Centers*

@ACCCBuzz | **#ACCCORM**

Preparing for Open Enrollment



Angie Santiago, CRCSC-I
*Sidney Kimmel Cancer Center at the
Thomas Jefferson University
Health System*

@ACCCBuzz | #ACCCORM

Medicare Open Enrollment

Dates

- Oct. 15 to Dec. 7 each year

Options

- Switch from original Medicare to a Medicare Advantage plan (or vice versa)
- Change Medicare Advantage plan
- Join/switch Medicare prescription drug plan

Tips

- Premium assistance
- State prescription assistance
- Medicare Extra Help
- Coverage network
- Compare plans

Medicare Open Enrollment

TIP: Encourage review of current plan changes, “Annual Notice of Change”

- Drug coverage changes
- Premium changes
- Overall benefit changes

Medicare Advantage Open Enrollment

Dates

- Jan. 1 to March 31 each year

Medicare Advantage Plan = Options

- Able to switch to a different Medicare Advantage plan
- Able to switch back to Original Medicare and pick up a separate Medicare drug plan

Original Medicare = No Options

- Unable to pick up a Medicare Advantage plan
- Unable to pick up a Medicare Drug plan
- Unable to switch Medicare Drug plans

Marketplace Open Enrollment

Dates

- Nov. 1 thru Jan. 15

Options

- Able to sign up for coverage
- Effective Jan. 1 if picked by Dec. 15 the previous year and the first premium is paid
- Effective Feb. 1 if picked by Jan. 15 that same year and the first premium is paid

Tips

- Coverage network
- Total out-of-pocket + premium
- Assess for foundation assistance
- Encourage review of plans
 - Specialist co-pay
 - Scan co-pay
 - Inpatient benefits
 - Infusion benefits
 - Calculate annual cost

Questions?

Angie Santiago, CRCS

Manager, Oncology Financial Advocacy

Phone: 215.503.5213

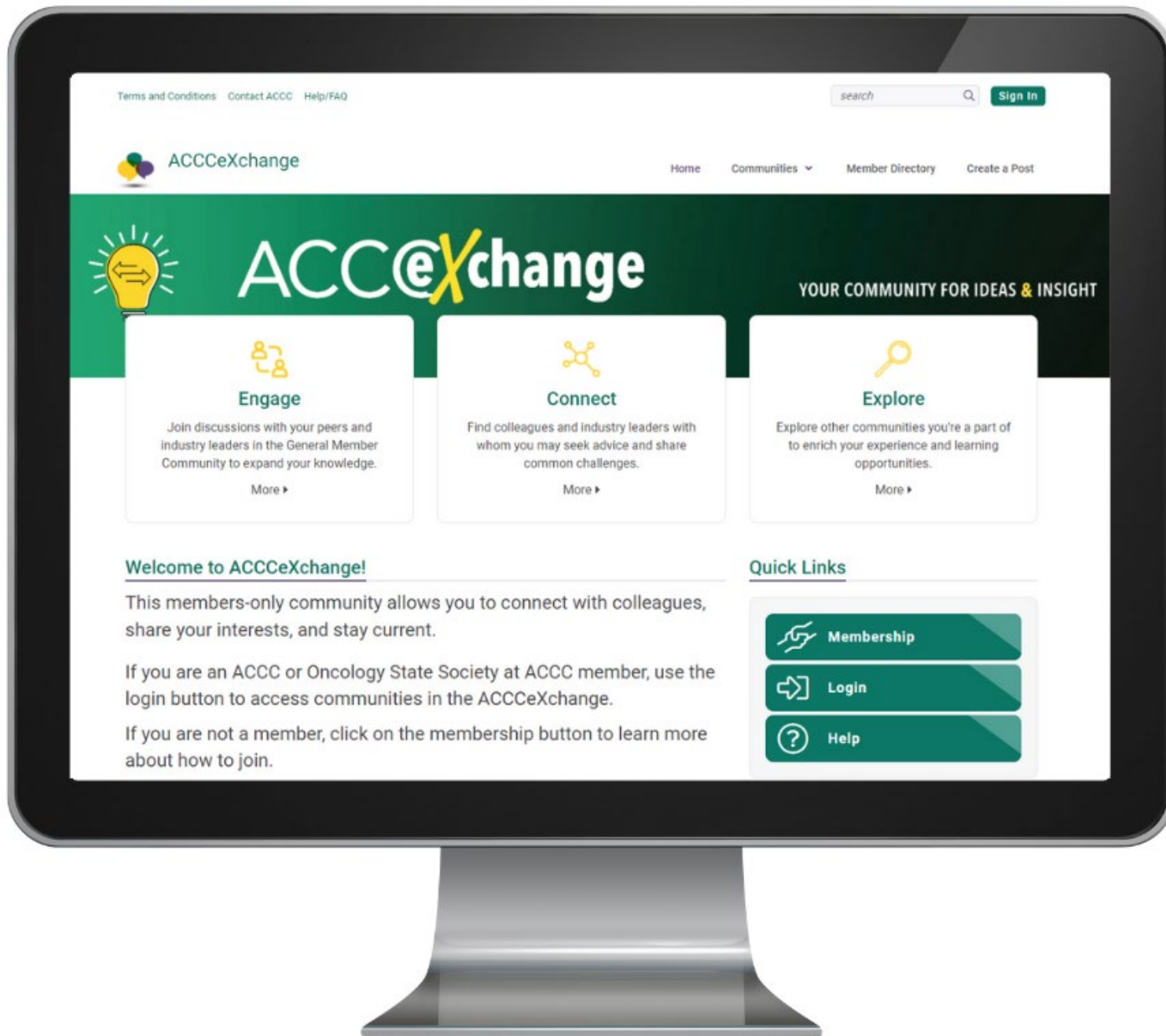
Angie.Santiago@Jefferson.edu

Closing Remarks!

Matt Devino

*Director of Cancer Care Delivery & Health Policy
Association of Community Cancer Centers*

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