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Financial Survival: It's not Easy Being Green!!

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Learning Objectives

1. Discuss proposed 2025 changes to Medicare Outpatient Prospective Payment System (OPPS/ASC) and Physician Fee Schedule (PFS) reimbursement, along with necessary operational adjustments for successful implementation.
2. Apply insights from the Inflation Reduction Act (IRA), the 340B Remedy Final Rule, the Drug Price Negotiation Program, Medicare Part B and Part D inflation rebates, and the Medicare Part D redesign to enhance health-system billing procedures.
3. Articulate the transitions in business models from fee-for-service to capitated bundled payments, episode-of-care payments, and site-of-care changes as well as the impact of the continuing growth of Medicare Advantage (MA) Part C.
4. Identify key components of the Drug Price Negotiation Program that will impact drug costs, billing requirements, and overall revenue.
5. Discuss methods for maximizing reimbursement through effective third-party management, contracting, and strategic purchasing options.

Insights into Pharmacy Financial Survival: It's everyone's responsibility!

The P&T Committee

The MD writing orders

IT

The patient taking responsibility

Pharmacy

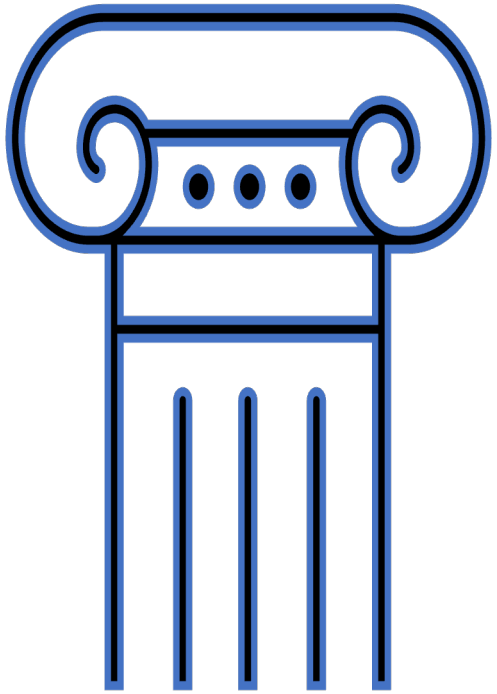
Social Services

Rev Cycle Team

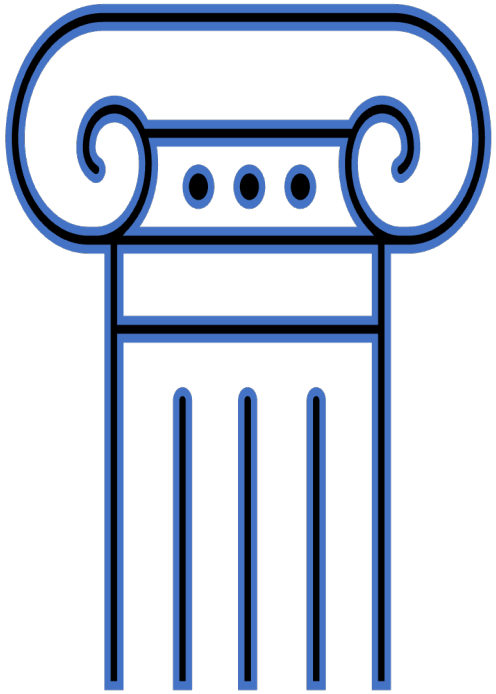
Nursing

The 3 pillars of payment

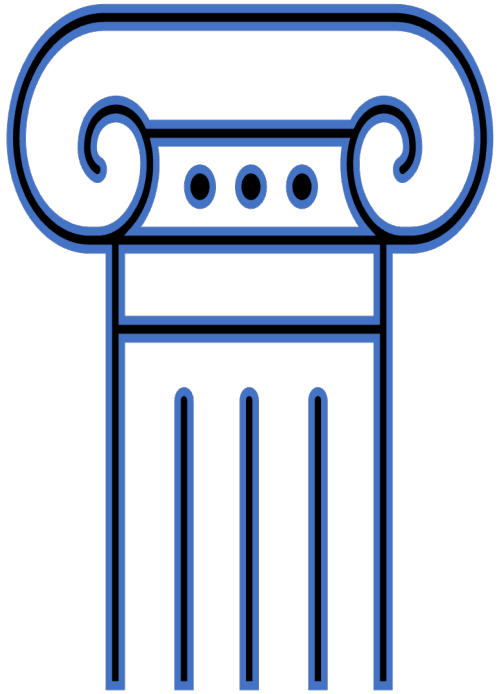
Payor requirements, Rule & Regulations



Health system Adherence



Infrastructure



Medicare

The single largest payor, others follow their lead

>50% have moved to MA (Part C)

Part A (IPPS) Hospitalization
Not eligible for 340B pricing

Part B Outpatient (OPPS) & MD Office (PFS)
Drugs covered as incident to in both OPPS & PFS
Eligible for 340B pricing

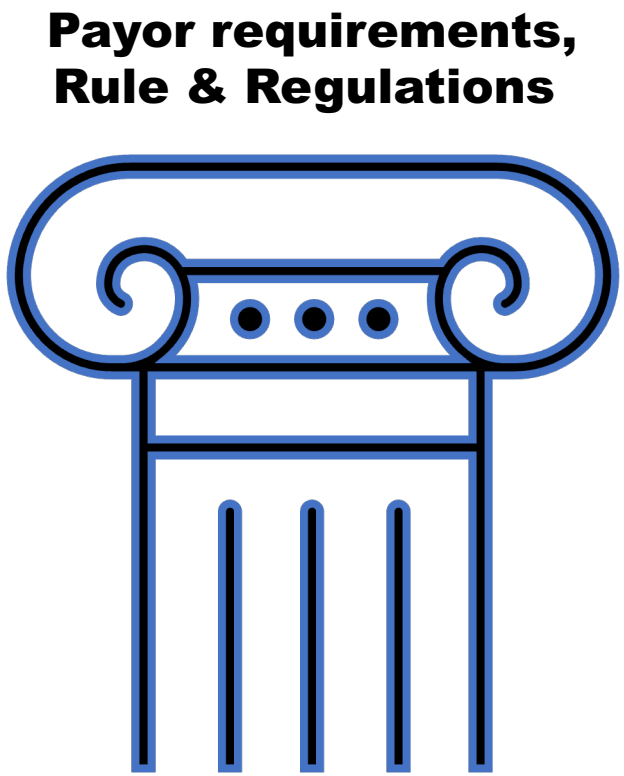
Covering this today

Private insurance option

Part C
Medicare Advantage, may include drugs controlled by PBMs

Part D
Rx Drug Coverage for Home/ Ambulatory use, MTM applies
Eligible for 340B pricing

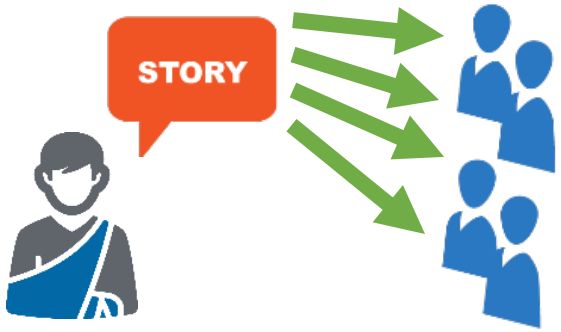
Payment Erosion



- Patient mix shift (traditional Medicare to MA)
- Increased payor denials
- Increased DRG downgrades
- Expansion of risk arrangements
  - Value based care
  - Stuck with antiquated contracts?

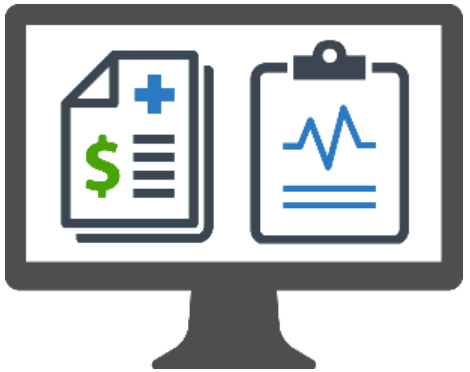
It's no longer just about $ but about assuring data accuracy and integrity!

Telling the patient's story accurately and completely

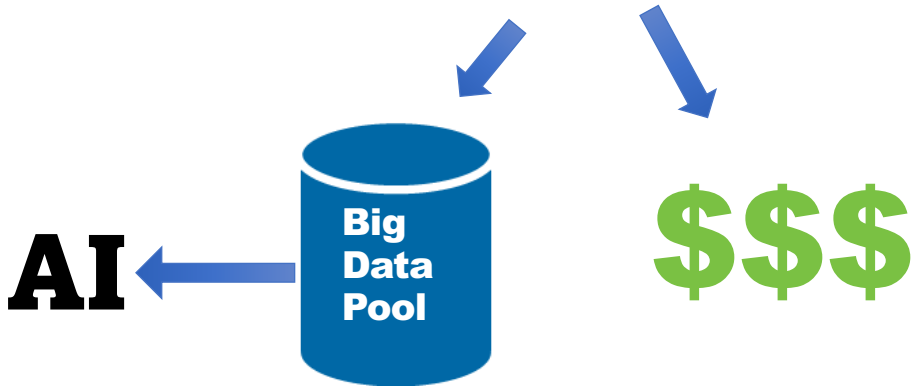


Diabetes with complications
Congestive heart failure
Compromised renal function
Consults
Scans & x-rays
Multiple lab tests
Several procedures
Prescription drugs
Specialty drugs

=



ICD10 codes
CPT codes
HCPCS codes
Modifiers to codes



Pharmacy Revenue Streams

Drugs and Biologicals

- **NTAPs (inpatient)**
- **Outpatient (340B, Drug waste)**
- **Ambulatory (retail pharmacy, 340B)**
- **Vaccine administration**
- **Home healthcare**

Clinical services/ Digital Therapeutics

Telehealth

Working with Rev Cycle and IT…. Scenarios and Rule changes impacting my day!

A newly FDA approved entity

A plethora of new HCPCS codes

Waste billing

Details in the APPENDIX!

Proposed CY2025 Hospital Outpatient Prospective Payment System (OPPS/ASC)

- **Payment for Remote Services**
  - **align OPPS payment for services furnished remotely to patients in their homes with payment under PFS**
  - **includes payment for diabetes self-management training, remote nutrition therapy, and mental health services**
- **Access to Non-Opioid Treatments for Pain Relief**
  - **provide temporary additional payments for access to non-opioid pain relief treatments (from 2025-2027)**
  - **7 drugs and 1 device eligible for additional payment**
  - **pay separately in hospital outpatient departments and ASCs**
- **Other issues**
  - **electronic prescribing for controlled substances**
  - **single-dose and single-use product discarded amount manufacturer refunds**
  - **radiopharmaceutical payment**
  - **quality metrics**

2025 Proposed Rule OPPS/ASC Addenda Table of Contents

Addendum A Proposed OPPS APCs for CY 2025
Addendum B Proposed OPPS Payment by HCPCS Codes for CY 2025
Addendum C Proposed HCPCS Codes Payable Under the 2025 OPPS by APC
Addendum D1 Proposed OPPS Payment Status Indicators for CY 2025
Addendum D2 Proposed OPPS Comment Indicators for CY 2025
Addendum E Proposed HCPCS Codes that Would Be Paid Only as Inpatient Procedure for CY 2025
Addendum J Comprehensive APCs
Addendum L Out-Migration Adjustment for CY 2025
Addendum M Proposed HCPCS Codes for Assignment to OPPS Composite APCs for CY2025
Addendum N Proposed ByPass List for CY 2025
Addendum O New and Revised CY 2025 CPT Codes
Addendum P Proposed Device-Intensive Procedures for CY 2025
Data Addendum B Data Status Indicators, Data APC Assignments, and Data Comment Indicators Used in the Development of the Geometric Mean Costs for HCPCS codes and APCs for CY 2025
Addendum Q Estimated CY 2025 Payment Rates for Drugs Qualifying for Add-on Payment to IHS and Tribal Hospitals Based on CY 2024 AIR

OPPS Addenda available at: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices

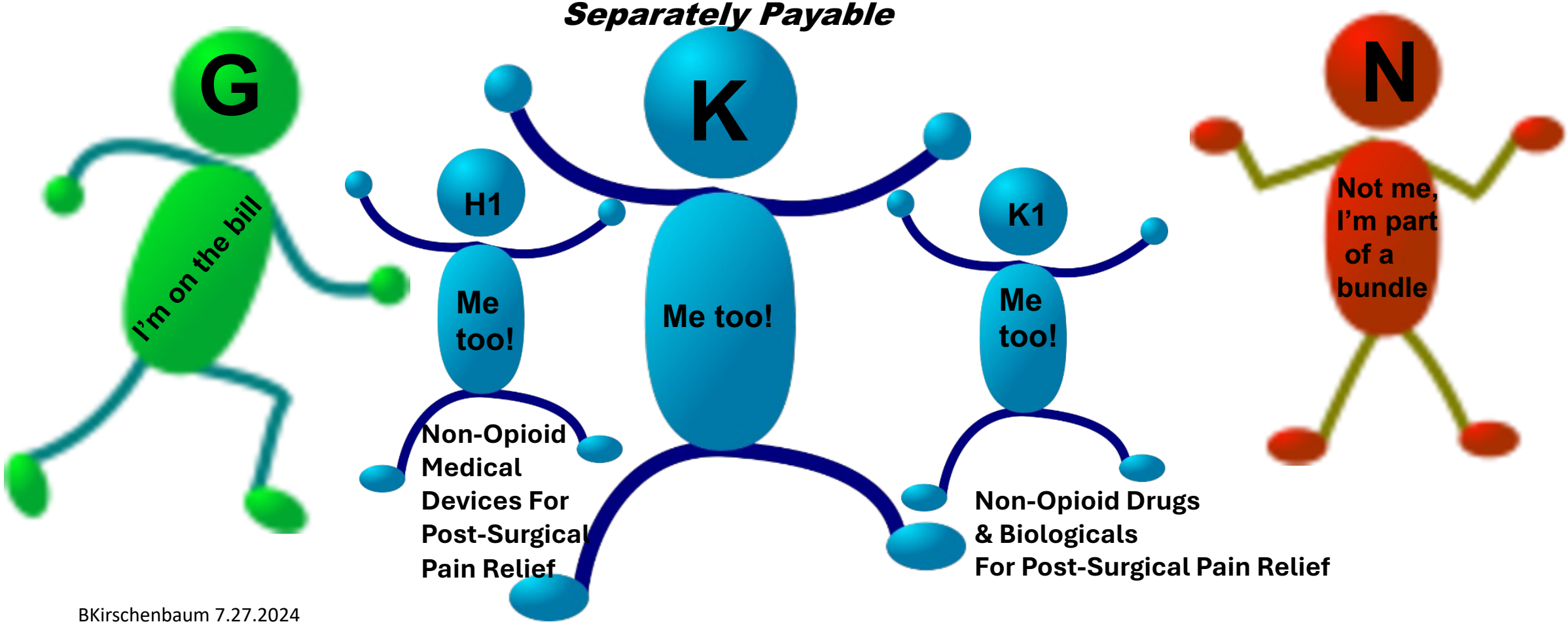
ASC Addenda available at: https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices

Payment for Drugs 2025 OPPS Rules
We're the *new* SI Team, here to help you!

Pass Through Drugs
Separately Payable

Nonpass-through drugs + nonimplantable biologicals + radiopharmaceuticals
Separately Payable

Packaged or bundled products:
Not separately payable



Packaging Thresholds and Rates

OPPS

- drug packaging threshold is proposed to be $140 for CY 2025 for all drugs, biologicals, and therapeutic radiopharmaceuticals
- propose separate payment for diagnostic radiopharmaceuticals when their per day cost exceeds the proposed threshold of $630

OPPS Rates: ASP + 6% (mark-up variable, determined each year)

PFS Rates: ASP+6% by statute

New drugs no HCPCS codes yet	Pass-through drugs SI G	Nonpass-through drugs + nonimplantable biologicals + radiopharmaceuticals >$140/day SI K, K1, H1	Policy packaged by lower-cost threshold ≤$140/day SI N	Policy pkg By statute SI N. Paid as part of service/procedure ***Regardless of Cost!!***
WAC+3% if no ASP available	✓ ASP+ 6%, WAC+3% if no ASP available ✓ All biosimilars** eligible for pass-through, not just the 1st one for each reference product ✓ 57 products keep/gain pass-through status ✓ Pass-through status expires for 25 drugs in CY2024 and 28 drugs in CY2025 ✓ *See Appendix for complete listing*	✓ Paid at ASP + 6% ✓ Payment based on WAC+3% until enough ASP data gathered ✓ AWP-priced drugs: 69.46% of AWP ✓ JG, TB modifier requirements remain ✓ biosimilar biologics temporary payment ASP + 8% of the reference biological's ASP for 5 years	✓ NO separate reimbursement; drug costs are bundled into the procedure ✓ Threshold: No change ✓ Paid as part of service or procedure	NO separate payment: *Diagnostic* radiopharmaceuticals* -Contrast agents -Anesthesia drugs -Implantable biologicals -Drugs, biologicals, radiopharmaceuticals used as supplies in diagnostic tests procedures -Drugs, biologicals used as supplies or implantable devices in surgical procedures

*possible pay separately for diagnostic radiopharmaceuticals with per-day costs above a proposed threshold

Proposed CY2025 Physician Fee Schedule (PFS)
Theme: Drive Whole-Person Care and Improve Health Quality for All Individuals with Medicare

- ***Proposed policies would increase value-based care, strengthen primary care, and expand access to behavioral and oral health care***

E/M Codes

G2211:an office/Outpatient (O/O) add-on code to Evaluation and Management (E/M) services that can be used on the same day as an annual wellness visit, vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting

Virtual Supervision: make permanent virtual supervision for the lowest level E/M visit (99211) but would discontinue virtual supervision for other codes, absent congressional action

Telehealth: an "interactive telecommunications system may include 2-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary" if the beneficiary requires it. Allows practitioners to continue to use their practice location rather than their home address when providing telehealth services from their home through 2025.

Proposed CY2025 Physician Fee Schedule (PFS) cont'd

Opioid Treatment Programs (OTPs): new flexibilities for OTPs, including permanently allowing audio-only periodic assessments and allowing the OTP intake add-on code to be furnished via 2-way audio-video communications technology when billed for the initiation of treatment with methadone when clinically appropriate

- an increase in payment for OTPs, as well as add-on codes for new FDA-approved opioid agonist and antagonist medications

Part B Preventive Services Payment:

- ***Hepatitis B Vaccination***: expanding coverage of hepatitis B vaccinations to beneficiaries who have not been previously vaccinated or whose vaccination status is unknown. CMS will no longer require a physician's order for hepatitis B vaccination to facilitate roster billing.

- ***PrEP and other Drugs Covered As Additional Preventive Services (DCAPS)***: a new payment methodology for supplying and administering DCAPS such as pre-exposure prophylaxis (PrEP) for HIV consistent with ASP methodology (i.e., ASP + 6%). Use this PrEP payment methodology as it finalizes its NCD moving PrEP coverage from Part D to Part B.

Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

- **PFS and CY 2025 Proposed Rule for HOPDs and ASCs requirement**
- **Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, 11.15. 2021) ("the Infrastructure Act") amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h)**
  - **requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug**
- **December of 2023: CMS provided preliminary information on estimated discarded amounts of refundable drugs for each labeler code based on available claims data from 1st 2 quarters CY 2023 for any refundable drug for which discarded units were billed using the JW modifier**
- **Discarded drugs, discarded drug refund and JW and JZ modifier policy found at**

https://www.cms.gov/medicare/payment/part-b-drugs/discarded-drugs

Inflation Reduction Act

- **On August 16, 2022, President Biden signed the *Inflation Reduction Act of 2022* into law**

- **The law contains 3 primary components related to prescription drugs:**
  - **Drug Price Negotiation Program**
  - **Medicare Part B and Part D Inflation Rebates**
  - **Medicare Part D Redesign**

Inflation Reduction Act Rebate Program Implementation proposals

- **codify policies related to rebates drug manufacturers must pay when the price of their product increases more rapidly than inflation**
- **remove 340B Drug Pricing Program claims using NPIs and/or Medicare Provider #s from all claims used to determine rebate amounts**
- **establish a process for reconciling rebate amounts for Parts B and D drugs**
- **clarify rebate amounts in specific circumstances such as when drugs are subject to wastage refunds**

Biosimilars**: Melding IRA and OPPS CY2025

OPPS: Continue previous policies for biosimilars

IRA: New biosimilars furnished before ASP data available must have a payment limit set not exceeding 103% WAC or 106% lessor of WAC or ASP

OPPS: Threshold Packaging policy:

Biosimilars excepted when their reference biologicals are separately paid (**goal: promote use as a lower cost alternative**)
If reference product cost/day falls below threshold, all biosimilars related to it would be similarly packaged regardless of whether their costs/day are above it

IRA: Qualifying Biosimilar = product with ASP < reference product ASP for a calendar quarter during an applicable 5 yr period

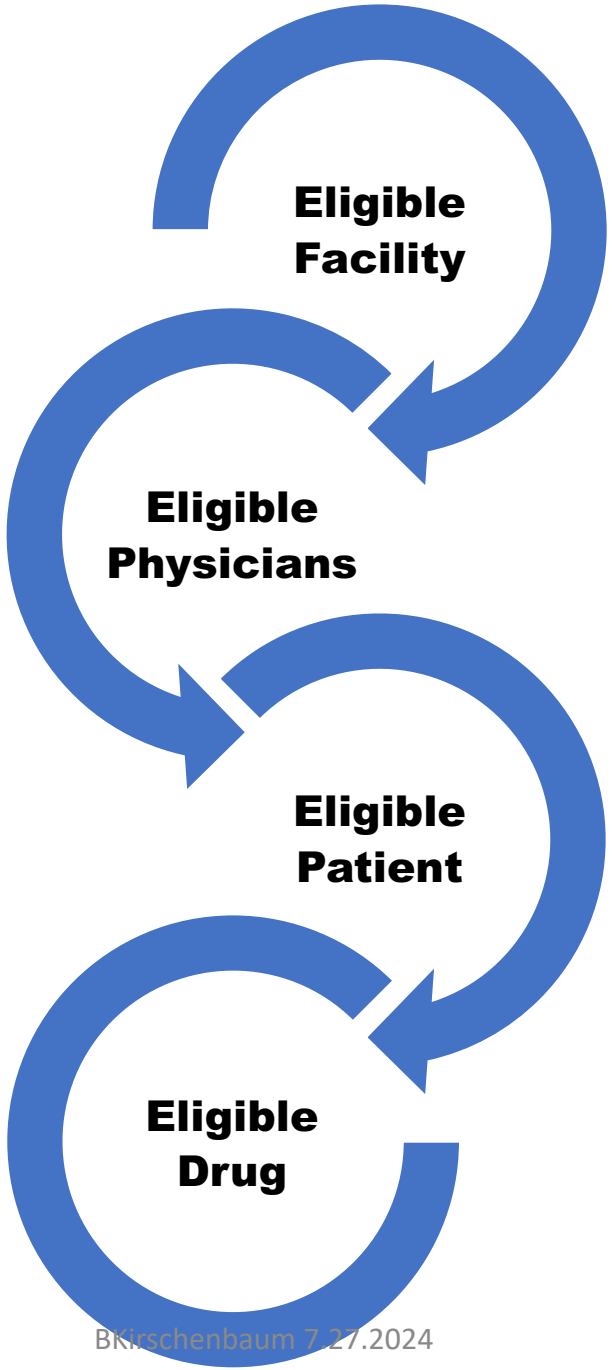
IRA: Payment **ASP + 8%** of the **reference product ASP**

IRA Part B Reimbursement Changes for Biosimilars

- ***Establishes a payment rate for biosimilars under Part B during the initial period:***
  - **For biosimilars furnished on or after 7/1/24, the initial period payment rate is the lesser of the biosimilar's wholesale acquisition cost (WAC) + 3% or 106% of the reference product's ASP**

- ***Increased the Part B add-on payment for qualifying biosimilars from 6% to 8% of the reference product's ASP for a 5-year period*.**
  - **During this period, the payment for such biosimilars would be the biosimilar's ASP + 8% of the ASP of the reference biological**

340B Requires

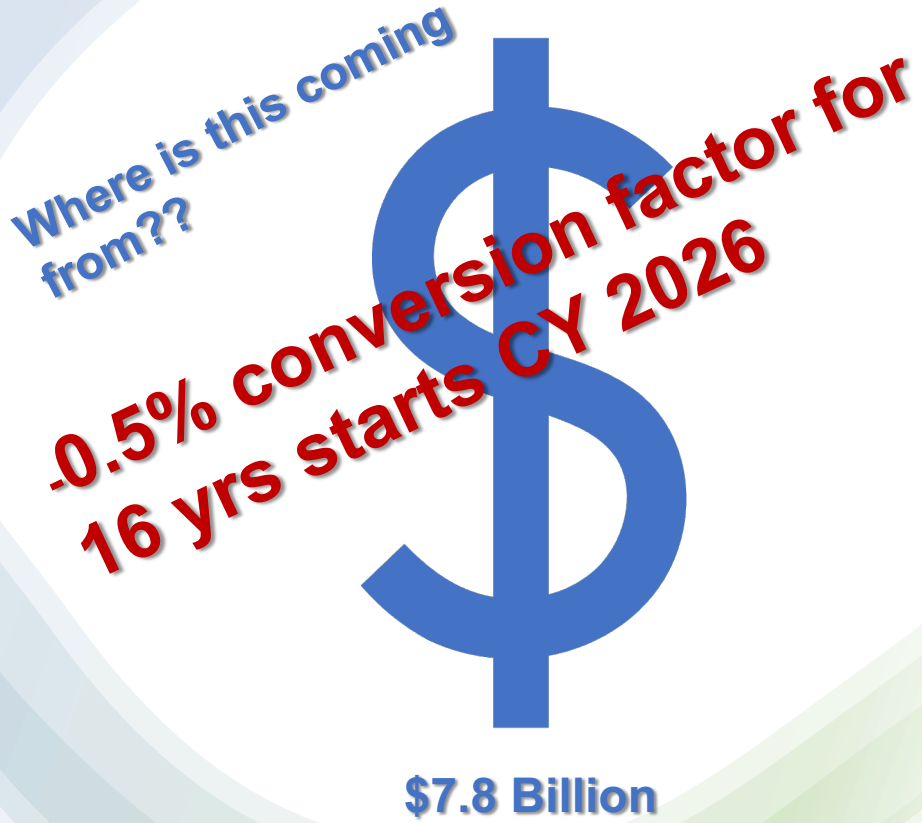


Got all 4?

There's no such thing as presumptive eligibility !

340B Remedy Final Rule

- 2024: CMS will make a one-time, lump sum payment to 340B hospitals to account for unlawful payment reductions on 340B drugs from CY 2018 to September 27 of CY 2022
- CY 2026: CMS will apply a prospective offset for the higher payment for non-drug items or services that was applied from CY 2018 to September 27 of CY 2022



In a digital age, does **site of care** change meaningfully address these issues?

Accessibility

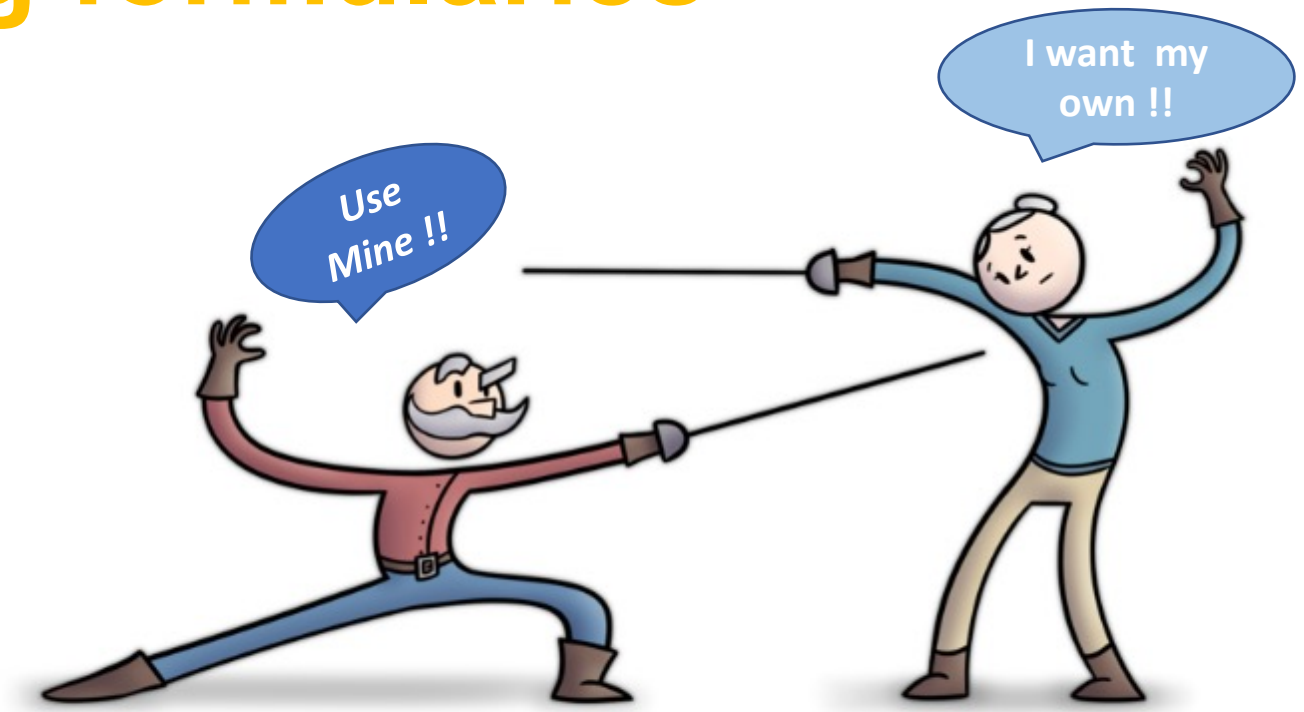
Affordability

Patient experience

If so, should your Healthcare system be fighting it or embracing it?

Dueling formularies

- MA plan formularies
- PBM NPF's
- Part D plans



What good is it to try to save $ on purchasing something you're not going to get paid for but refusing to use a drug that you will get paid for or get as a white bag at no cost?

Try negotiating a prep/handling fee with the payor.

Site of Care Strategy
Pharmacy's Role in Healthcare Environments
It could be you in your system, or not!

Environments

- Acute/Inpatient
- Outpatient's Many Settings
  - Clinics
  - Infusion Center
  - Diagnostic Areas
  - ED
  - Observation Patient
- Home Infusion
- Hospital at home
- Ambulatory
  - ASC
  - Physician Office
  - Retail in person
  - Mail – order
  - Specialty Pharmacy

Each has its own

- Payor relationships, requirements
  - Federal Manuals & Resources - CMS, FDA, Medicaid, MACs
  - Payor reimbursement shifts
- Revenue Cycle Stages
- Reimbursement Requirements
- Type of contracts
  - Government and/or commercial
  - Fee for service, Managed Care or Value based
- Peculiarities in how you structure/manage
  - Compliance and date integrity
  - Clinical documentation
  - P&T committee(s)
  - electronic health record build,
  - charge master build &maintenance
  - coding, billing, claims clearinghouse
  - denials avoidance teams
  - revenue integrity & underpayment teams
  - Finance relationships

What does a PDM do?

- Manage Rx drug benefits for payors (insurers, Part D plans, large employers, Medicaid, etc)
- Maintain formularies for the payors
- Negotiate pharma manufacturer rebates and discounts
- Contract directly with pharmacies for drug reimbursement
- Could offer disease management programs
- Could offer mail order pharmacies

What do these terms mean??

- **Vertical Integration**
  - **A single company owns the health plan, the PBM & the pharmacy**
- **Spread Pricing**
  - **PBM keeps the $ difference (spread) between $ paid by the plan and $ they reimburse the pharmacy**
- **Rebate Pass through**
  - **PBM negotiates manufacture rebates in exchange for preferred formulary status**
  - **PBM keeps some (retained rebate) and passes on a portion to health plan**
- **Transparency**
  - **Require PBM to disclose detailed info to the plan**
- **Delinking**
  - **Prohibit PBM $ from being calculated using Rx Drug's list price or rebates off of list price**

Wearing the payor's hat… My #1 Job? Spend less on health care services

- How can I appropriately plan and manage benefit coverage with so many expensive specialty drugs coming down the pipeline?
- What tools do I have?
  - Prior authorization
  - Bundled payments
  - Medical to pharmacy benefit
  - Treatment pathways
  - Closed formularies
- Does site of care matter?
- *Payviders:* risk sharing collaborations between payers and providers

Do you have any idea what payor contract terms your facility agreed to?

How do YOU incorporate these?

Congress considering mandating real time PA decisions. Can you process a PA request in < 1hr? Building that capacity?

Payment's possible only when the payor has agreed to pay & the patient wants the service

- Commercial payors: which ones? Target this group
- 1st hurdle: automatically get payor info on every outpatient
- Prepare your "ask" document, not longer than 1 page
  - Include a brief background of why you're asking, what it covers and how much you're asking for
  - Work with Finance/Rev Cycle to determine how and when this will be billed, include this
  - It's not an "auto add on charge", it's a patient specific add on charge for a specific payor when a specific service is provided. No 'Robo-billing" here
- Determine who in your facility/system negotiates agreements with commercial payors and work with that person/group to hone your "ask sheet".
  - They'll be presenting the "ask" to the payor, not you.
  - You're the only one who knows what the "ask" is for, you need to be able to convey that in clear terms and ensure a complete understanding
  - Avoid being turned down/led astray/ derailed because payors don't understand what you want

The prior authorization stepladder… *with the primary payor and the secondary one too!*

- **Who's responsible for these to be completed BEFORE the appointment is made and the drug prepared?**
- **Who coordinates this with pharmacy?**
- **Just how many could there be? More than you may think!**
  - **Authorization of provider**
  - **Authorization of site of care**
  - **Authorization of treatment**
  - **Authorization of procedure, service, drug**

Prior Approval vs NCDs and LCDs

	Prior Approval (Payor)	NCDs and LCDs
Applies to:	3rd party carriers (possibly Medicaid)	Medicare (possibly Medicaid)
Need Patient's payor status?	yes	yes
Drug tagged in CPOE/PDM?	yes	yes
Link to actual rule needed?	yes	yes
Rule Requirements:	Ask permission first before drug administration	Understand & follow requirements, document completely and thoroughly. Code correctly and as required.
Payment:	Only if permission is given first	Determined after the fact and may be denied if not all rules followed

LCDs, NCDs & Prior Authorizations

- **Essential that all concerned**
  - **understand which drugs have these requirements**
  - **have set a procedure for how to handle them**
  - **ensure required EHR documentation BEFORE drug order is written and ESSENTIAL before drug is actually prepared & administered. No remedy later. this step not taken or documentation missing, no payment made**
- **Get LCDs & NCDs from your MAC's website + PA list from your payors. Pay attention to the ICD-10 codes that apply**
- **Work out a plan: who's doing what, who's documenting what, how's this info going to be transmitted to pharmacy**
- **Equally important is ensuring that it remains a permanent part of the record in real time sequence for auditing purposes**
- **Officially Accepted Compendia can be used to support an off-label decision. Be aware of what they are!**

It’s all about Revenue Integrity

Are you contributing to Low Quality Data?

PREVENTION vs. CORRECTION
Which is better?

- **Preventing Denials**
- **Just Correcting them**

Impact of Billing Errors on Pooled Average Reimbursement Across All Facilities

Prior auth/LCD in place
HCPCS code correct
Billing unit calculation correct
Appropriate waste billed

Prior auth/LCD in place
HCPCS code correct
Billing unit calculation wrong
No waste billed

New reimbursement
everyone's paid

Find & fix your issues quickly, they're impacting everyone!!

Impact of Billing Unit Errors: a Clinical Standpoint

Dose sent to Claim

Prior auth/LCD in place
HCPCS code correct
Billing unit calculation correct
Appropriate waste billed

Dose sent to Claim

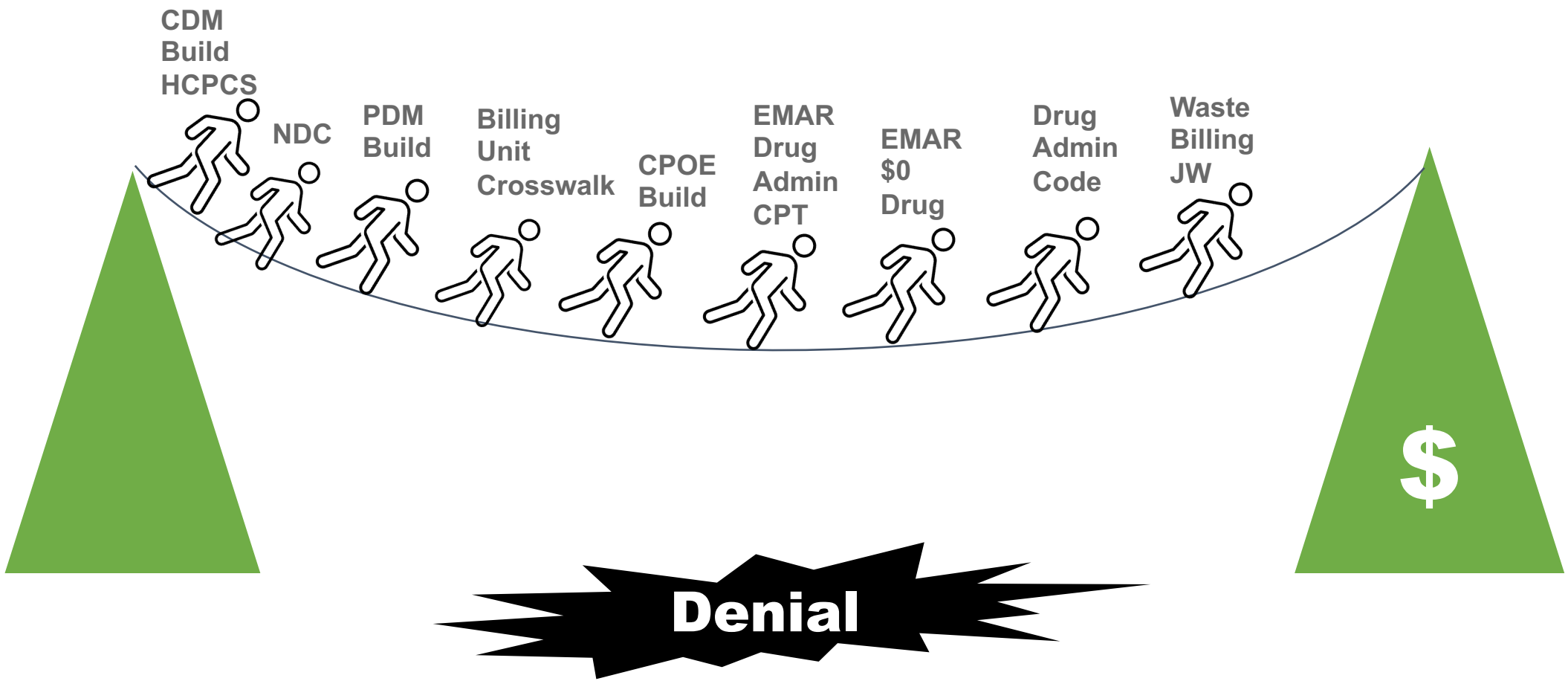
Prior auth/LCD in place
HCPCS code correct
Billing unit calculation wrong
No waste billed

A new average dose given? No! Just bad data from *wrong entries!*

How aggregated BIG Data portrays the acceptable dose

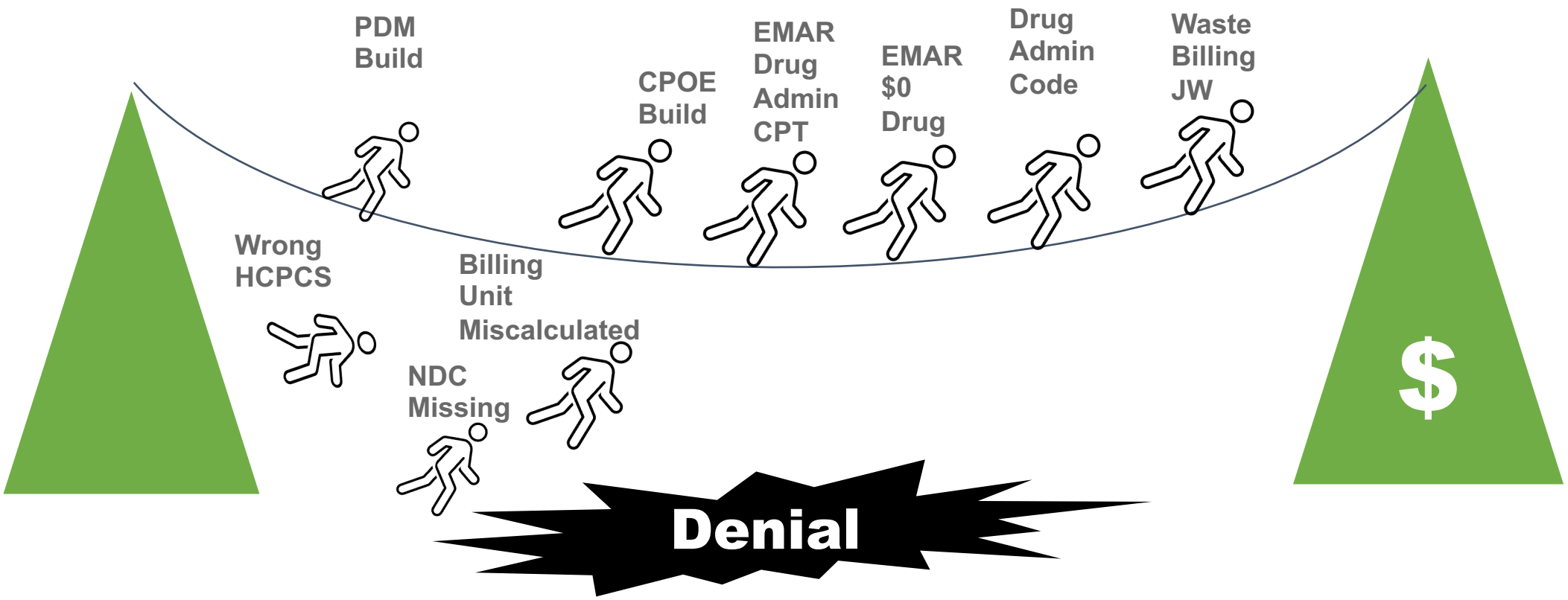
Find & fix your issues quickly, they're impacting everyone!!

Pharmacy Controls These! How's your performance?

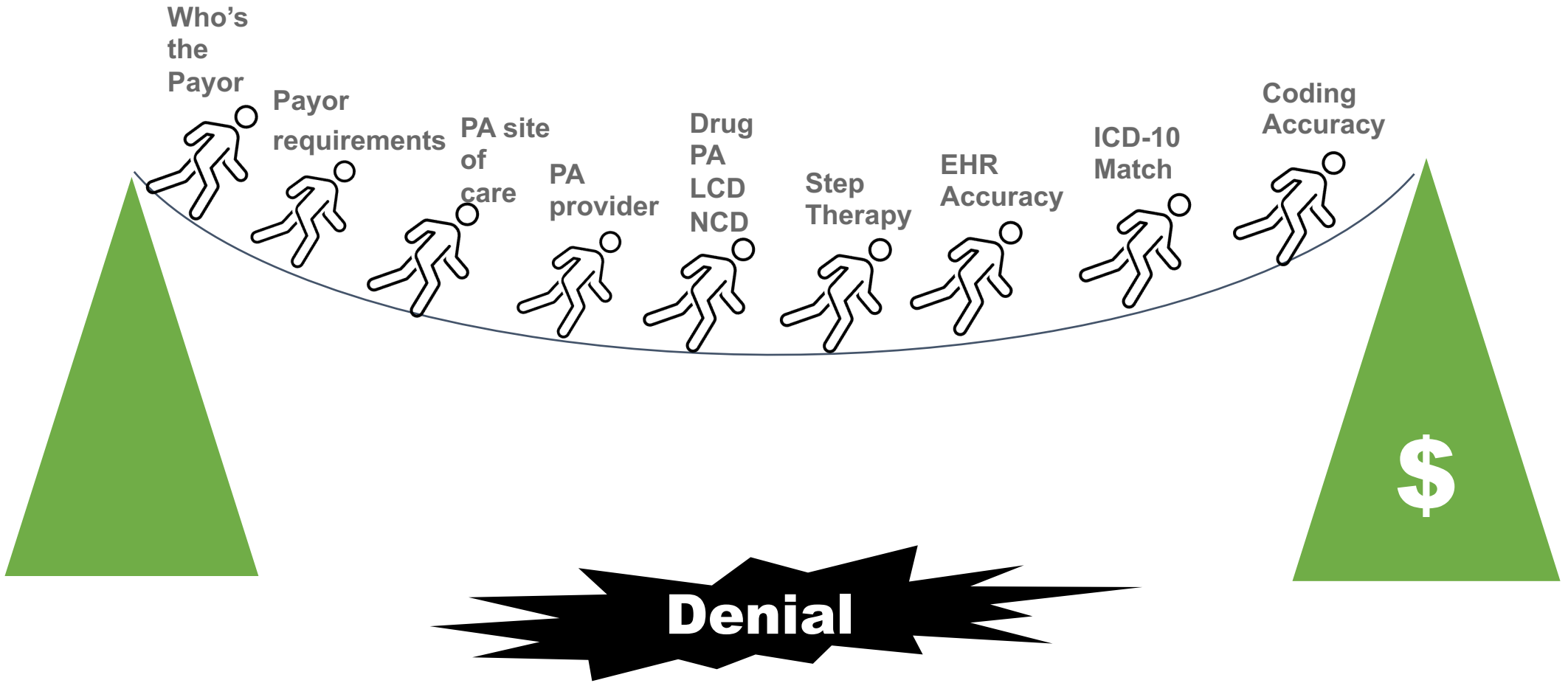


Pharmacy Controls These! How's your performance?

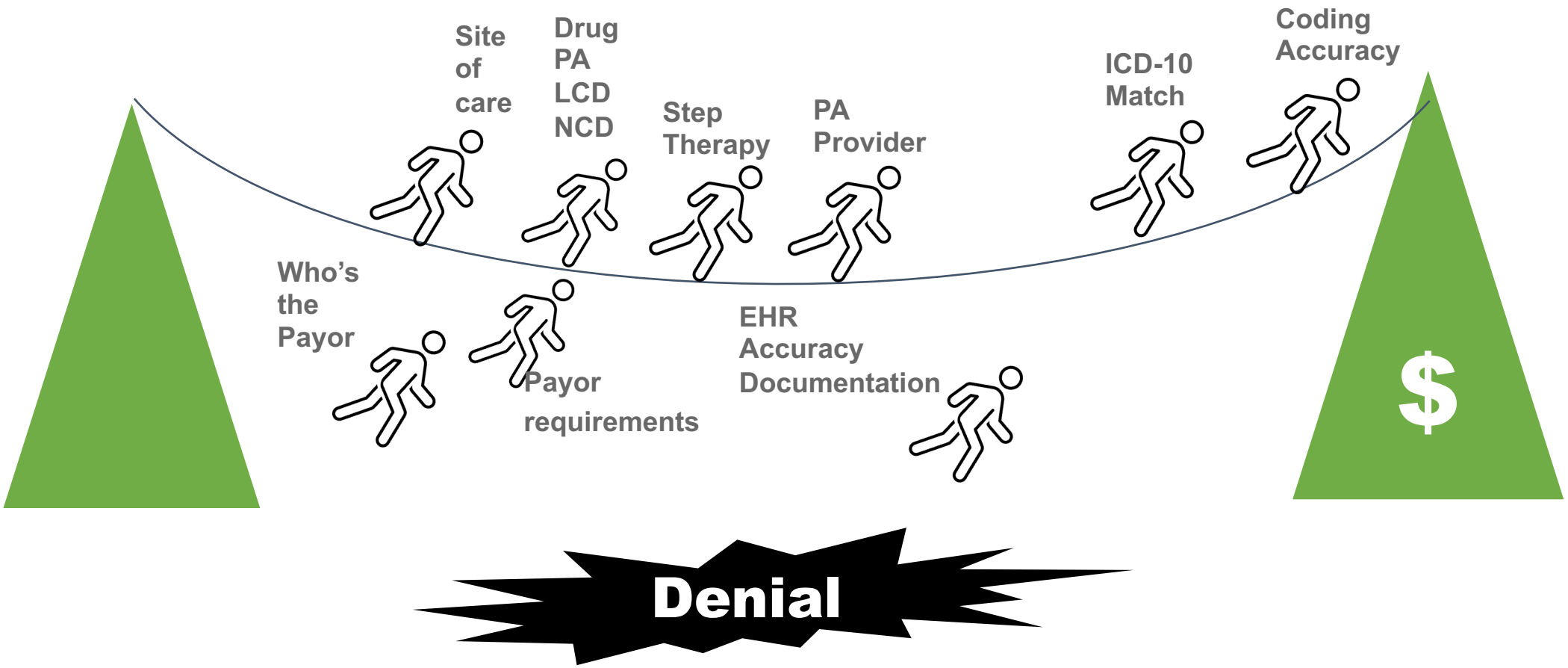
Failure of any one of these = Payment Denial



Pharmacy Working in Tandem: *How's your performance?*



Pharmacy Working in Tandem: *How's your performance?*



A Key Rev Cycle KPI: Clean Claim Rate!

https://www.hfma.org/data-and-insights/map-initiative/map-keys/

- Claim denials are a significant and costly problem
- clean claim rate: the proportion of claims that pass edits with no manual intervention
  - use the number of claims accepted into the claims processing tool for billing
  - HFMA says the amount includes primary, secondary, and tertiary claims or all applicable 837 types.
  - KPI excludes claims flagged with warnings because intervention is required, claims directly submitted to a 3rd-party payer, and claims "warned" in the tool for print and hardcopy submission.
- clean claim rate is essential to reducing the number of denied claims and identifying areas for claims management improvements
  - indicates issues with patient data collection, timely claim submission, and coding.
- aim for a clean claim rate of 90% or higher, with some sources citing a 95& rate as industry standard.

Key Takeaways

Telling the Patient's Story Accurately & Completely: Earning $ and Sharing Data

Know each patient's payor and the payment requirements for each drug. Is imprecise clinical documentation costing you $?

Ensure drug file builds support a clean, complete, error free claim and not just clinical components of the drug and CPOE file build. Is IT on it??

Be vigilant, accurate, don't take liberties/short cuts when interpreting rules

Repurpose clinicians from inpatient to outpatient/ambulatory care

Appendix

To receive the Appendix Information

Please email me at: BonnieKirschenbaum@gmail.com

- **Proposed CY2025 Payment Rules**
- **IRA**
- **Billing for Waste**
- **Working with Rev Cycle**
- **Drug Payment: The Fundamentals. How do all the pieces fit together?**
- **IV Drug Administration Payment**


Q&A