



EVERSANATM

Operational Concerns for Key Enacted and Proposed Changes Under Medicare and Medicaid

“A Tornado of Healthcare Legislation....Continues”

Still Making Our Way Through The Storm

Presentation Agenda

1. Proactively Addressing Change
2. URA Cap
3. Medicare Part B Wastage Rebate
4. Medicaid Accumulator BP Rule
 - What could have been
5. Q&A

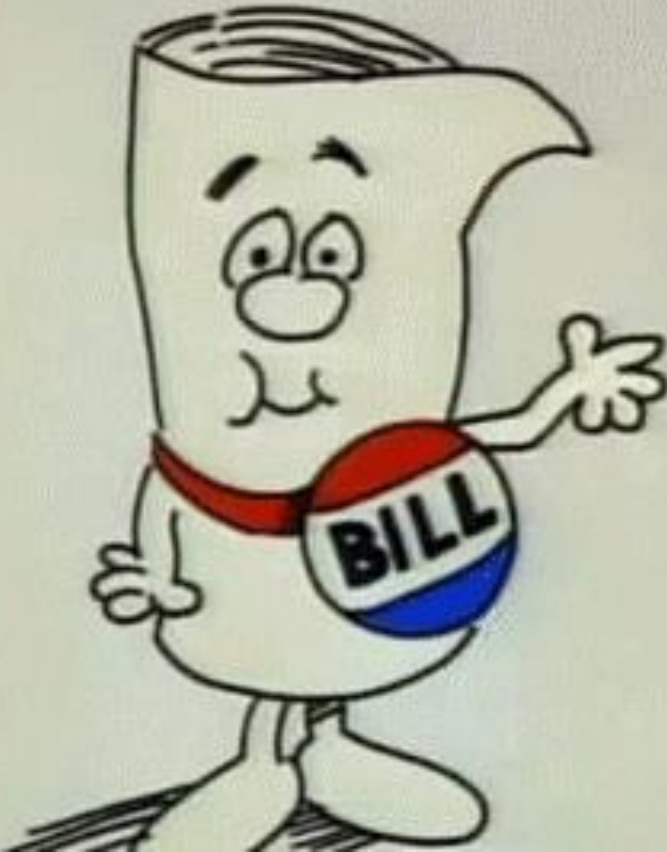


EVERSANA™



I'm just a bill.....or a regulation

This little guy has been busy, and he brought friends



RECENT ACTIVITY

Legislation

- 2021 Infrastructure Bill – Part B Wastage
- The American Rescue Plan Act of 2021 – URA Cap Removed
- Build Back Better (not enacted) – Medicare inflation caps (Price Protection)

Regulations / Litigation

- CMS Final Rule
 - Accumulator Best Price Impact

Manufacturer Release 116

- Technical Guidance - Value-Based Purchasing (VBP)



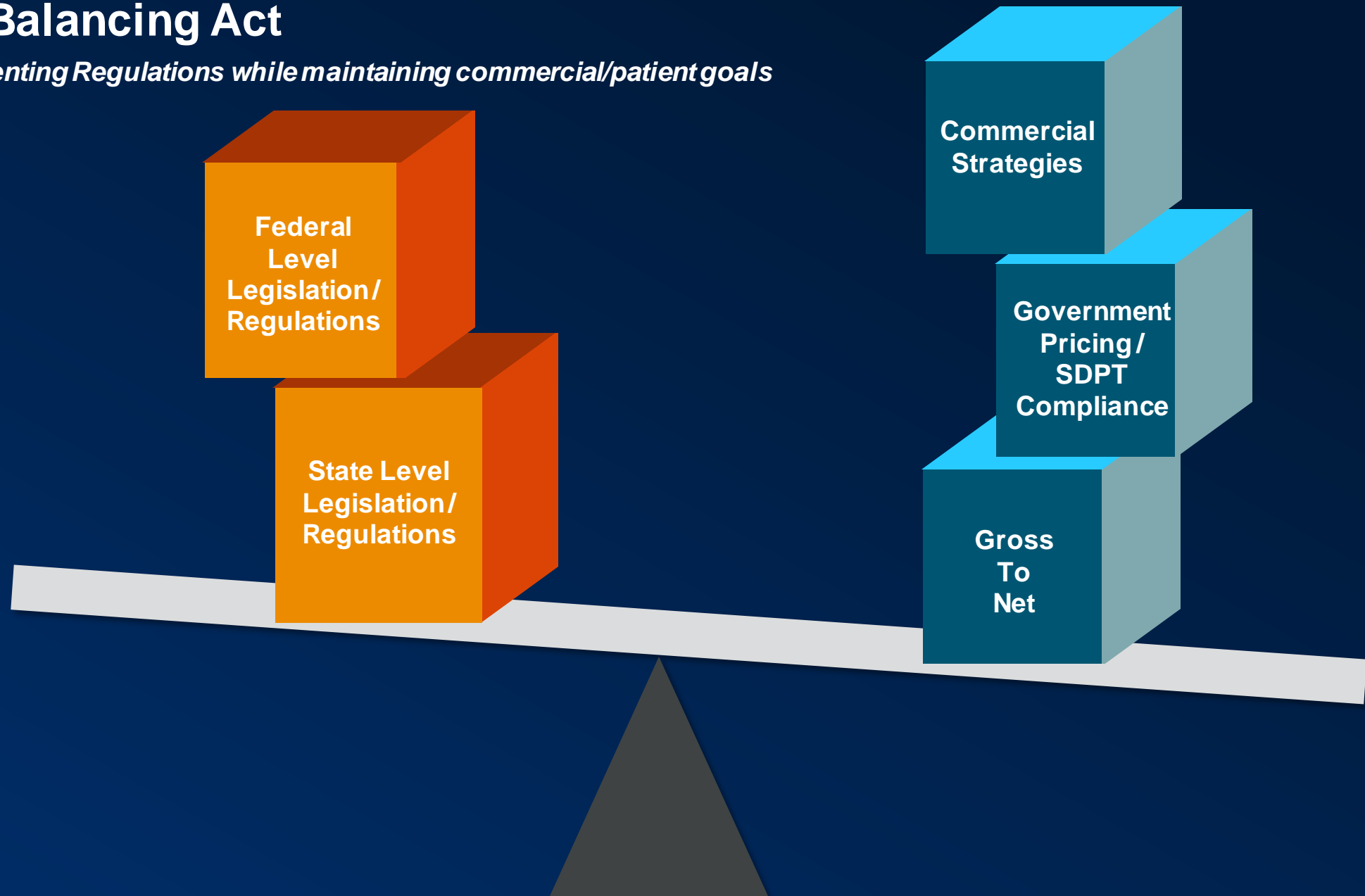
The Big Picture

Treat GP Like Commercial



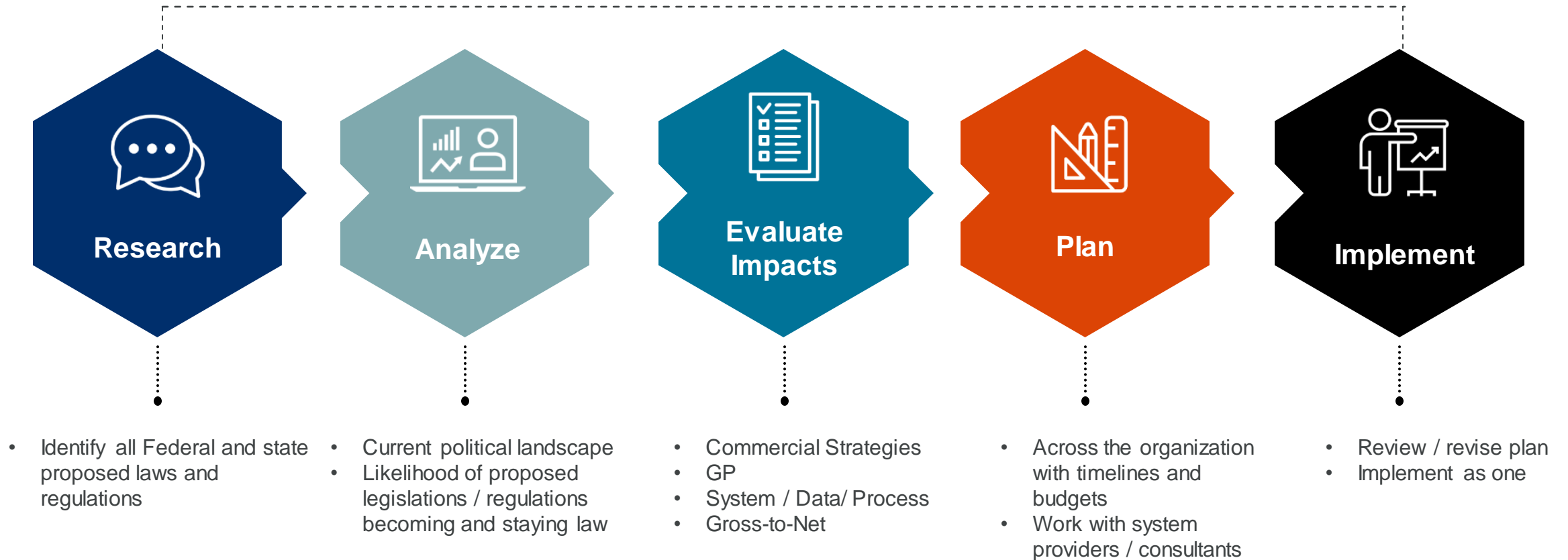
The Balancing Act

Implementing Regulations while maintaining commercial/patient goals



At a High Level

ASSESSMENT



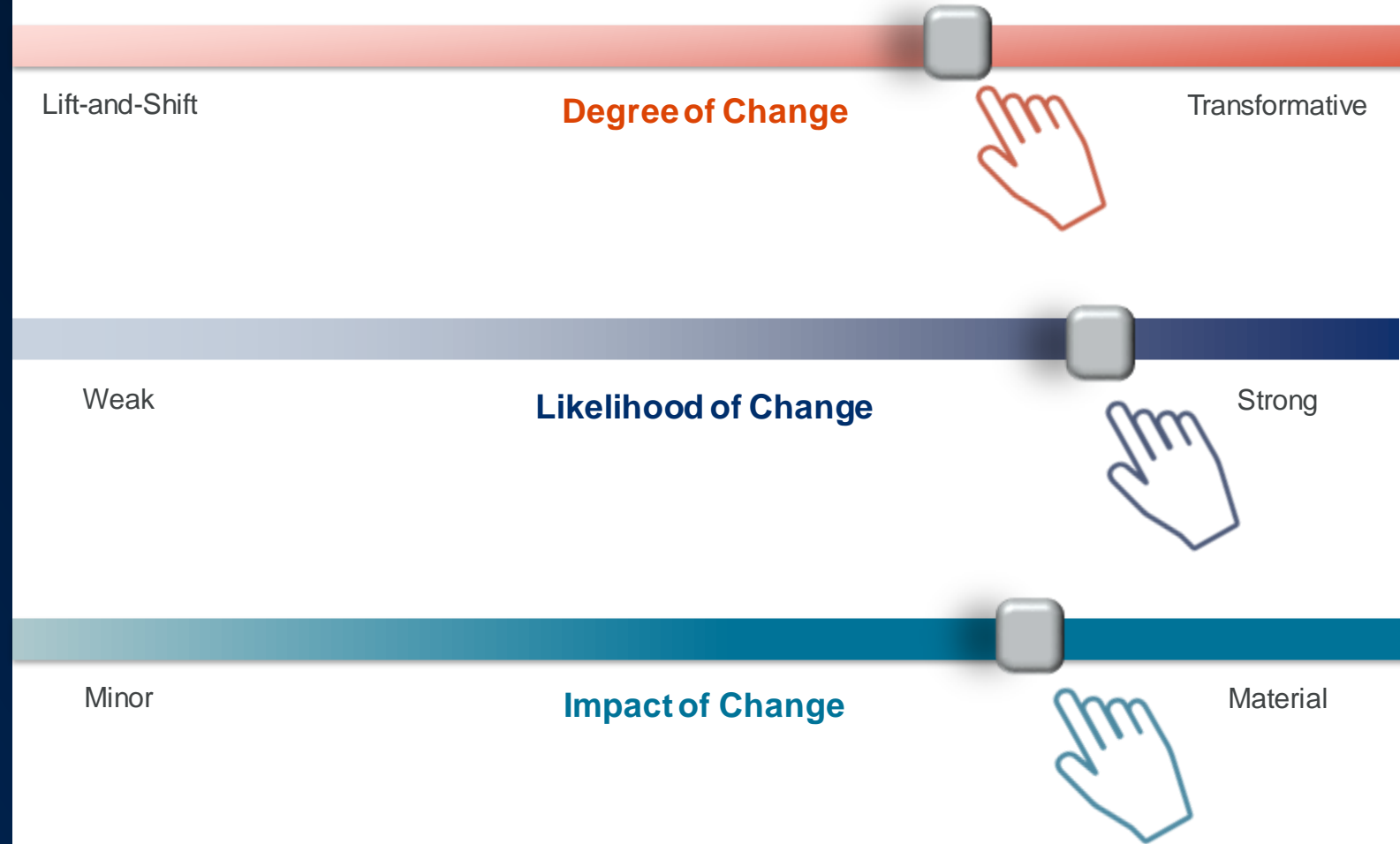
With limited available resources for planning:

Focusing on what is likely to occur is key

- This includes post approval barriers

Then balance the degree and impact of the change

- What is the GTN and financial impact?
- Does the change impact policy, strategies, pricing, or systems?
- What is the effort and cost to implement?



Tracking Legislation

Key Fields

- Name of regulation / law
- Description
- Link
- Level (Fed / State)
- Type (Regulation, Law, etc.)
- Status (Proposed, In Committed, Passed, Failed, etc.)
- Next action and date
- Likelihood of enactment
- Date to be enacted
- Impacts
 - Policy / Strategy / Systems / Financial Impact including cost to implement



Organizational Alignment

(One lead point to manage the process)



When Faced With Significant GP Impacts

Significant GP policy and financial impacts can be the result of changes in regulatory or business strategies or a change in product portfolio



Financial Impact

Work with appropriate teams to build impact analysis

Accrual updates?

GTN Impact



Strategy Impact

Ensure Commercial teams are aware of impacts

Strategy updates to mitigate exposure



Policy Updates

Approvals and outside counsel reviews take time



System Updates

Determine system / data impacts to identify required resources and budget



What Can You Do....

Strategies to ensure compliance and mitigate risk

BUILD RELATIONSHIPS

- Both professional and personal
- Work to understand; not just to be understood

BE AN ENABLER

- Perform GP impact analysis to balance not impede commercial strategies
- Don't just say "NO". Offer suggestions (enable)
- Commercial understanding of GP impacts/needs

TRULY BE A PART OF THE COMMERCIAL TEAM

- Attend commercial status meetings on a regular basis
- Become a non-voting Pricing Committee member
- Be a part of product strategy meetings (Government Agencies are customers)



What Can You Do....

Strategies to ensure compliance and mitigate risk

UNDERSTAND YOUR PRODUCTS

- Potential / Current patient base
 - Projected GP utilization / Net Price
- Clinical outcomes vs. competitors and surgery

UNDERSTAND COMMERCIAL OPERATIONS

- Understand your commercial system(s) capabilities and gaps and related processes
- If possible, become a commercial contract reviewer in the approval process



Medicaid URA Cap Removal

Let's Start Simple



URA AMP Cap Removal

A simple update but don't forget to close the loop



Estimate Impact

Work with Commercial and Finance teams to understand current impact

Apply findings to prior periods as a baseline

Accrual and GTN forecasting



Review Options

Work with Commercial teams

Pricing or strategy adjustments required?



Adjudication

GP / Medicaid system updates

Policy updates



Medicare Part B Drug Waste

Prepping For a New Rebate



Medicare Part B Wastage: An Overview

BACKGROUND

- Per a MedicareAdvantage.com study, 2017 - 2019 Medicare Part B drug wastage accounted for \$2.1 Billion
- Bipartisan (2019) - Senators Dick Durbin (D) / Rob Portman (R)
- Signed into Law 11/15/2021: H.R.3684 - Infrastructure Investment and Jobs Act, Sec. 90004

THE BILL

- To begin Q1 2023
- For each single-dose container or single-use package, CMS is to supply to the manufacturer:
- Per drug, total number of units discarded of the billing and payment code per the JW modifier (or successor modifier per the Secretary),
- The refund amount that the manufacturer is liable for based on ASP (WAC if ASP is unavailable) and discarded units less applicable percentage (10% unless otherwise stated by the Secretary)
- Manufacturer Audits – penalty of 25% of owed amount
- Prescriber Audits – JW
- Within 3 years, CMS & FDA to report impact to Congress



“(i) a drug or biological that is either a radiopharmaceutical or an imaging agent;

(ii) a drug or biological approved by the Food and Drug Administration for which dosage and administration instructions included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process; or

(iii) <> a drug or biological approved by the Food and Drug Administration on or after the date of enactment of this subsection and with respect to which payment has been made under this part for fewer than 18 months.”

Also drugs not separately payable under Part B

Medicare Part B Wastage: Exceptions



JW Modifier

- Effective January 1, 2017
- JW modifier is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used on a Medicare Part B drug claim to report the amount of drug or biological (hereafter referred to as drug) that is discarded and eligible for payment under the discarded drug policy.
- The modifier shall only be used for drugs in single dose or single use packaging.
- Claims for drugs furnished on or after January 1, 2017 containing billing for discarded drugs that do not use the JW modifier correctly may be subject to review.



Actions to Consider

Proactive planning to mitigate and implement the law



Estimate Impact

Work with Brand, Finance, and Reimbursement teams to understand current wastage volumes

Apply findings to prior periods as a baseline

Accrual and GTN forecasting

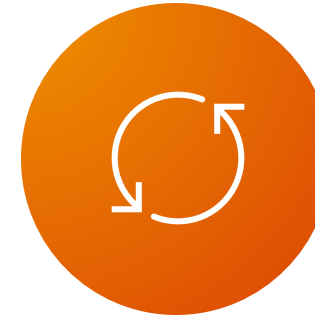


Review Options

Work with Brand and Regulatory teams

Package size adjustments, terminations or launches may help reduce impacts

Understand complications such as weight based dosing and variable indications



Adjudication

Still awaiting CMS's regulations

Stay attentive

Prep Finance of what CMS is required to supply and potential limitations

Work cross functionally to determine which team and system will be responsible



Medicaid Best Price Accumulator Rule

A Lesson Learned



Accumulator programs are utilized by insurers and PBMs to offset the impact of manufacturer contributions on a patient's deductible and annual maximum out-of-pocket (OOP) costs.

- Normally, a patient's copay is applied against their deductible and OOP Max. With an accumulator, the portion of the copay made by the manufacturer no longer counts toward the patient's deductible.
- Most drug manufacturers place annual savings limitations on coupon programs.
- The patient will be responsible for the full cash price of the drug until they reach their deductible and out-of-pocket annual maximum.

Accumulators: A Brief Description



Best Price Implications

Final rule released 12/31/2020

From the Proposed Rule:

- CMS' position is that “**manufacturers have the ability to establish coverage criteria** around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient.”

Responses from the Final Rule:

We understand the concerns from the commenters that **manufacturers may not currently have the ability to track their manufacturer assistance** to ensure it is provided in full to the patient. However, we believe that the **electronic prescription claims processing infrastructure** that is currently in place can serve as a possible foundation for manufacturers...

Manufacturers also have relationships with PBMs, given that they pay rebates and other price concessions for formulary placement on the PBMs' formularies. **Thus, the electronic and contractual infrastructure is in place** for manufacturers to better understand how the PBMs are using the manufacturer assistance. **We believe and have the expectation that PBMs will work with manufacturers** to provide this information to the manufacturers to help them ensure that their assistance is passed through.

“Alternatively, manufacturers may consider **redesigning assistance programs to require patients pay for the drug first** and then have the patient collect the rebate directly from the manufacturer.”



A Quick Study on the Complexities of Implementing Major Change

June 2020

Proposed Rule

CMS issues proposed rule on accumulator impacts on Best Price and Average Manufacturer Price

May 2021

PhRMA Files Complaint

D.C. District Court

May 4, 2022

In-person Arguments

June 2020

Jan' 2021

June 2021

Jan' 2022

June 2022

December 2020

Final Rule

CMS issues final rule on accumulator impacts on Best Price and Average Manufacturer Price

March 2022

All Motions Submitted

Consent motions filed as well in support of and in defense of

May 17, 2022

Ruling in favor of PhRMA



A Comparison of Proposed Rule Comments vs. the Court's Ruling

Judge Carl J. Nichols agrees with commenters

FINAL RULE PREAMBLE COMMENTS

- "...requiring manufacturers to include the value of manufacturer assistance ...subsequently taken away from patients by plans in the...best price is contrary to the statutory definition of best price **because patient assistance is not a price, or a price concession that is available from a manufacturer to plans.**"
- "...**CMS lacks statutory authority** for the proposals in this section, that they are based on erroneous interpretation of ... Medicaid drug rebate statute..."
- ...**it is unfair, infeasible**, and contrary to statutory intent to hold manufacturers responsible for ensuring that the discount goes exclusively to the consumer ... when manufacturers are not involved in the application of tools that change how assistance is applied to the patient's insurance benefit.

MEMORANDUM OPINION

- "A manufacturer's financial assistance to a patient does not qualify as a price made available from a manufacturer to a best-price-eligible purchaser...As a result, **HHS lacks the statutory authority to adopt the accumulator adjustment rule.**"
- The government's position is...that the best price calculation must take account of a price made available from the manufacturer to the commercial health plan through an insured patient. **But the statute does not sanction the last leg of this journey (i.e., through an insured patient)**
- "manufacturers would need to conduct transaction-by-transaction investigations...even though manufacturers have no control over (and sometimes no information concerning) those programs. Such a requirement makes it **infeasible** for manufacturers to report the best price to the agency in a timely fashion as the statute requires.
- "That new obligation will impose on the manufacturers numerous compliance **requirements that will affect pocketbooks**"



But Did We?

Actions that could have been performed along the way



Estimate Impact

Work with Commercial, Patient Assistance, and Finance teams to understand current impact

Apply findings to prior periods as a baseline

Accrual and GTN forecasting



Review Options

Work with Commercial teams to understand contracting options

Work with Patient Assistance teams to explore options

Seek guidance from consultants and BPO providers



Comment

Provided comments on the proposed rule either directly or via a trade group

Work with Government Affairs to understand the pulse of legislation – Roughly 15 states have laws prohibiting or limiting accumulators

Stay abreast and communicate legal status



Potential Medicare Price Controls

A Potential for More Rebates



Current Biden Plans

These have been discussed in the past and are highly dependent on the current political landscape

MEDICARE INFLATION REBATES

Per Build Back Better

- Quarterly rebates / 30-day payment terms
- Includes biosimilars / excludes vaccines
- Rebate is similar to URA additional rebate
 - Benchmark ASP = 1Q 2016
 - Benchmark CPI-U = 3Q 2015
 - Rebate Period CPI-U = Current Qtr. – 2 Qtrs.
 - Rolling Benchmarks for newly launched drugs
- Watch for movement. If it appears to gain momentum, work with Commercial and Finance to estimate impacts and mitigation strategies

OTHER OPTIONS

- Capping Insulin Costs
- Federal Government Medicare Price Negotiations
- Again, keep a mindful watch



QUESTIONS?



THANK YOU

