Drug Pricing in a World Without Rebates

GOVERNMENT PRICING IMPLICATIONS OF THE PROPOSED REBATE ELIMINATION RULE

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Agenda

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5. Conversion: In to Out; Out to In
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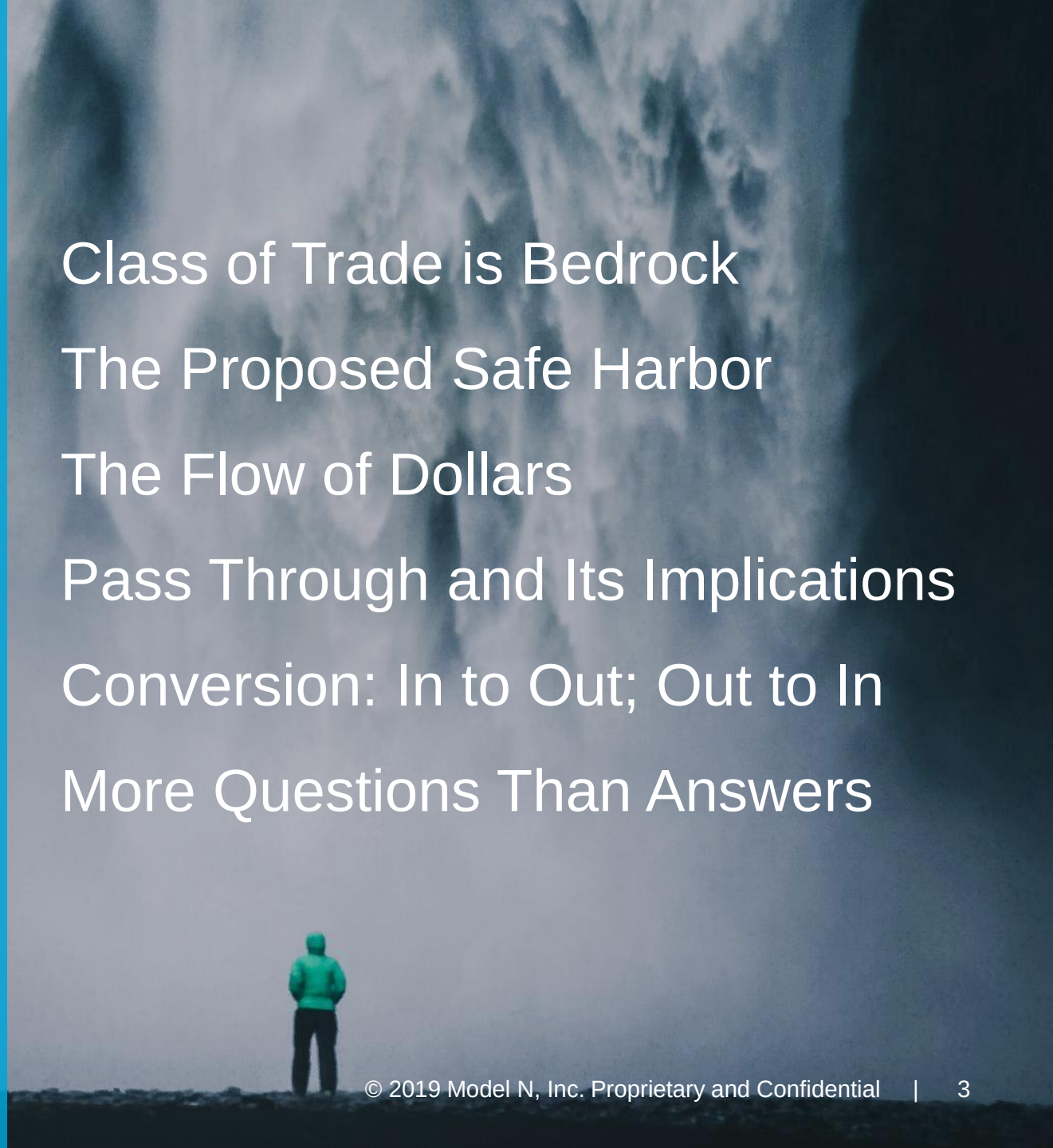

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Class of Trade is Bedrock

AND THEY'RE MONKEYING WITH IT

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Class of Trade is Bedrock

Foundational Concept in GP

- The ground upon which everything else is built
- **Classifying** our customers and **filtering** transactions by class of trade is fundamental to accurate government pricing
- Its importance can be overlooked in the context of the complexity of the rest of government pricing
- For example, it took more than 20 years for the MDRP to seriously define ‘retail pharmacy class of trade’

Class of Trade is Bedrock

Foundational Concept in GP

- With limited exceptions, when a price concession is paid to an entity, that concession ‘sticks’ and no further GP analysis is necessary
- Increasing obligation to see beyond class of trade, however:
  - Stacking
  - Pass through
  - Discounts negotiated by A but paid to B

Class of Trade is Bedrock

An Emerging Class of Trade

- We’ve gotten very good at identifying, assigning, and treating most classes of trade
- But we’re just beginning to discover one that is teeming with importance and complexity, one that is at the white-hot center of our national political dialogue, one that is central to the reputational crisis our industry finds itself in:
- Patients

Class of Trade is Bedrock

Patients are Both Critical and Enigmatic

- The true end user is ultimately the only purchaser that matters
- Rise of patients with high cost exposure
- Yet the costs to patients are so shrouded by their idiosyncratic coverage situations that their ‘prices’ are hard to discern and have been deemed not relevant to AMP, BP and ASP

Class of Trade is Bedrock

Patients are Treated Ham-Handedly in **Best Price**

- Patients are not part of the set of Best Price-eligible purchasers in the statute; but the regulations draw them in
- “Direct” sales to patients are excluded (implication for “indirect” patient sales?)
- Free drugs to patients are out *unless* there is a ‘purchase requirement’ associated with the free product
- Under certain conditions, assistance programs for patients are ignored; but what’s to be done when one of those conditions is violated?
- What spillover to ASP?

Class of Trade is Bedrock

The Proposed Rule Challenges Us to Think Again about CoT

- All of this matters because HHS would upend the status quo by eliminating many rebates
- Government pricing needs to adapt, react, accommodate, and do what it can remain compliant

The Proposed Safe Harbor

A STRANGE BEAST

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Proposed Rebate Rule

Leveraging the Anti-Kickback Statute

- Would exclude Part D PDP and Medicaid Managed Care rebates from AKS discount safe harbor protection
- Whether negotiated directly or through a PBM
- Potentially applicable to most/all commercial payor/PBM rebates
- Creates a safe harbor for certain fees
- Target effective date of January 1, 2020 (hmmm)

Proposed Rebate Rule

Creates a New Safe Harbor for Point of Purchase Discounts

- Price concession set in advance with PDP/MMCO/PBM
- No “rebates” are permitted, but “chargebacks” may be used to provide price concessions to the dispensing pharmacy….
- …as long as the price concession is completely applied to the price of the drug charged to the patient at the point of sale

Proposed Rebate Rule

Price Concession Terminology

- “Rebate” Washington’s new bogeyman
- “Chargeback” means a payment made **directly or indirectly** by the manufacturer to a dispensing pharmacy so that the total **payment to the pharmacy** is at least **equal to the amount agreed upon** with the PDP/MMCO/PBM

Proposed Rebate Rule

Claims to Not Affect Medicaid Price Reporting

- The proposed rule, according to its authors, does not "alter the regulations and guidance to implement Section 1927 provisions"
- We'll see about that

The Flow of Dollars

WHO WOULD GET WHAT IN THE NEW REGIME

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The Flow of Dollars

Follow the Money Under the New Safe Harbor

- Manufacturers would negotiate concessions with PBMs/payors and pay them to *someone* for eventual pass on to pharmacies
- PBMs/payors would negotiate concessions with manufacturers, pay pharmacy reimbursement, and benefit from at least some of the negotiated concession
- Pharmacies would be made whole, collectively, by manufacturer payments + patient payments + PBM/payor reimbursement
- Patients would pay $0, or less than they otherwise would, depending on their insurance regime and the negotiated discount

The Flow of Dollars

Follow the Money Under the New Safe Harbor (continued)

- But what is the mechanism by which manufacturer price concessions get to the pharmacies? Direct payments? Wholesalers? A PBM? Some other kind of third party discount manager?
- Not a traditional chargeback because it must take place after the dispense

The Flow of Dollars

Follow the Money Under the New Safe Harbor (continued)

- The relevant price concession is a rebate
  - negotiated by the PBM/payor,
  - paid to the pharmacy,
  - via some intermediary,
  - for the benefit of
    - the patient and
    - the payor

The Flow of Dollars

Follow the Money Under the New Safe Harbor (continued)

- The **pharmacy** is made whole
- The **patient** gets the benefit of the negotiated price concession to the extent that concession is equal to or less than the patient's co-pay/deductible obligation
- The **payor/PBM** gets the benefit of the negotiated price concession to the extent it is greater than the patient's obligation

The Flow of Dollars

Follow the Money Under the New Safe Harbor (continued)

- Visibility/transparency to manufacturer at the patient level is close to nil
- Constant variability of ‘price to patient’ given unique position of each vis-à-vis his/her insurance provider, moment in coverage, other medicines taken, carrier-specific negotiated discount
- Gamesmanship by the PBM/payor to distinguish discount to patient from discount to PBM/payor?
- All of this assumes a relatively static WAC

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Pass Through and its Implications

WHERE DOES THE PRICE CONCESSION LAND?

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Pass Through and its Implications

How the MDRP Handles Pass Through

- Not particularly well, as it turns out
- A combination of analytical rigidity (*e.g.*, classes of trade and policy-oriented inclusion/exclusion rules), market complexity, and drug distribution opacity hampers our ability to address pass through
- We don’t know how to consistently interpret and incorporate concessions that are, for example, negotiated by one party, paid to a second, enjoyed by a third

Pass Through and its Implications

Pass Through Questions

- Is the appropriate class of trade the entity to which the price concession is directly paid/made available by the manufacturer?
- Or the one to which it is passed?
- What level of awareness by the manufacturer is necessary to make us responsible for incorporating a pass?
- What if the GP inclusion/exclusion treatment changes between payee and pasee?

Pass Through and its Implications

Examples of Pass Through Complexity

- PBM rebates and Best Price
- Service fees (including sell side discounts)
- Accumulator programs, patient assistance, payors and Best Price

Conversion: In to Out, Out to In

WHAT MIGHT IT ALL MEAN, IN THE END

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Conversion

Inclusion-Exclusion Shifting Under the New Regime

- Combining the requirements of the new safe harbor with the concepts of class of trade and pass through has the potential of creating odd government pricing implications
- Must the standard inclusion/exclusion rules be modified to suit a new reality, forced on us by potential elimination of traditional rebates?

Conversion

Inclusion-Exclusion Shifting Under the New Regime

- Standard AMP
  - Currently unaffected by rebates to PBMs/payors
  - Could be reduced if the new concession were understood to land with the pharmacy or the wholesaler
  - Unaffected if it were deemed to land instead with the patient or the PBM/payor

Conversion

Inclusion-Exclusion Shifting Under the New Regime (continued)

- 5i AMP
  - Currently reduced by rebates to non-excluded payors (PDP rebates out)
  - Unaffected if the new concession were understood to land with the pharmacy, the wholesaler, or the eligible payor
  - Increased if the new concession were understood to land with the patient (because it would be affirmatively excluded)

Conversion

Inclusion-Exclusion Shifting Under the New Regime (continued)

- Best Price (assuming no stacking)
  - Currently (generally) reduced by rebates to non-excluded payors (PDP rebates out)
  - Unaffected if the new concession were understood to land with the pharmacy, the wholesaler, or the eligible payor
  - Potentially increased if understood to land with an excluded intermediary

Conversion

Inclusion-Exclusion Shifting Under the New Regime (continued)

- Best Price (assuming no stacking) **lands with *patient***
  - Likely unaffected if for every full or partial patient discount there is also a full corresponding payor discount
  - Potentially increases if patient is excluded and payor/patient 'prices' bundled
  - Query whether this arrangement is 'patient assistance'?
  - Query if this could be converted to a direct sale?
  - Potentially decreases if PBM rebates currently excluded, but non-exempt patient discount were to be included
  - Irrelevant if price "negotiated by" Part D PDP?

Conversion

Inclusion-Exclusion Shifting Under the New Regime (continued)

- ASP
  - Presumably follows Best Price (but we don't know for certain)
  - Potentially significantly more complicated because we can't short cut to lowest price and must include all eligible sales
- Non-FAMP
  - Currently unaffected by PBM/payor rebates
  - Decreased if concession is (a) understood to land with, or (b) is effectuated through a wholesaler

More Questions Than Answers

SO THERE'S STILL A LOT TO BE WORKED OUT

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More Questions than Answers

Truly an Age of Uncertainty

- What will emerge as the preferred mechanism for point of sale discounts?
- What kind of entity will effectuate them?
- Will it be an established GP class of trade or something new?
- Will our treatment of pass through need to be more rigorous and consistent?
- How will this affect patient assistance programs?
- How long will we be required to cobble together reasonable assumptions before CMS updates the regulations in response?

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Thank you

Happy to take questions under this rock

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