Medicaid Drug Rebate Program Proposed Rule

12866 Meeting with OIRA & DPC
April 17, 2024

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Agenda

1. **Introductions**
3. **J&J Recommendations and Examples**
4. **Conclusion**

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Urge Withdrawal of the Proposed MDRP Rule

CMS' Proposed MDRP Rule (May 2023) Is a Significant Destabilizer in the Medicaid Drug Rebate Program:

- Threatens patient access by creating **untenable uncertainty** for manufacturers participating in the program at a time when there is substantial opportunity to advance Program stability and access (churn, access to transformative therapies, etc.)
- Impacts small hospitals and other providers by **disincentivizing voluntary discounts**
- **Inconsistent with CMS regulations** aimed at advancing Value Based Purchasing arrangements
- CMS **lacks authority** to implement proposed changes, as they are not authorized by statute
- Best Price proposal introduces **patient privacy concerns**
- Poses significant workability and **operational challenges**, as manufacturers and other participants in the supply chain do not have the systems in place today to track and trace discounts
- It imposes **considerable burden** on manufacturers with a new requirement to collect and report extensive data for the proposed drug price "verification" survey that exceeds statutory authority

Maintain the Current Methodology for Calculating Best Price

- The “stacking” proposal conflicts with statute and historical interpretation affirmed by the courts
  - The 30-year interpretation of how best price is calculated is based on statute and CMS regulation, which defines it as: “the lowest **price available from** the manufacturer **to any** wholesaler, retailer, and provider…”
  - This was affirmed when the U.S. Court of Appeals for the Fourth Circuit ruled that this interpretation was “at the very least objectionably reasonable.” (USCA4 Appeal No. 20-2330),
  - CMS reinforced this interpretation in its 2016 final rule, 2016 presentation to industry and FAQs published in 2016, and indirectly through the OIG review of reasonable assumptions for calculation of Best Price.
- Despite framing as a technical clarification, this proposal is a wholesale change to the program that would introduce significant uncertainty and challenges
- It contemplates a calculation of a *fictional* best price that is not available in the market
- Could result in a negative best price and a base rebate that exceeds list price or average manufacturer price (*see example next slide*)
- Creates significant compliance challenges because manufacturers do not have the infrastructure to precisely track discounts for the same unit from downstream transactions across various channels

Example: Best Price Stacking Proposal Could Result in Negative Best Price and Base Rebate that Exceeds Average Manufacturer Price

Best Price Determination

	Best Price Eligible Entities			Current BP	Proposed BP
	Whlr	Provider	Payor*		
WAC	$100	$100	$100		$100
Max Disc.	$5	$40	$70		$115
Lowest Price	**$95**	**$60**	**$30**	Lowest Price to Single Entity	**($15)**

Current Rule: BP is **$30,** the lowest price available from the manufacturer and realized by single entity (incl. stacked discounts designed to adjust price to the same entity)

Proposed Rule: BP is **negative $15**, calculated as WAC $100 less $115 total stacked discounts realized by different entities

Medicaid Base Rebate Discount Impact

Non5i

	Medicaid Base Rebate (AMP-BP)				
Best Price	WAC	AMP	BP	Base Rebate	% WAC
Current Rule	100	95	$30	65	65%
Proposed Rule	100	95	($15)	110	110%

- The $115 total stacked discount realized by different entities is higher than WAC $100
- No one best price eligible entity received $115 in total discount
- Higher than WAC discount of $115 result in a calculated negative $15 BP
- The negative $15 BP is not a "drug price available from the manufacturer" to any entity

5i Drug

	Medicaid Base Rebate (AMP-BP)				
Best Price	WAC	AMP	BP	Base Rebate	% AMP
Current Rule	100	60	$30	30	50%
Proposed Rule	100	60	($15)	75	125%

- All commercial eligible discounts are already included in AMP calculation for 5i provider administered drugs.
- Including cumulative channel discounts in BP as a stacked discount could result in Medicaid Base Rebate that exceeds the average manufacture price (AMP)

*Payor Stacked Disc. Designed to Adjust Price to the Same Entity			
Disc (A+B+C)	Disc A	Disc B	Disc C
$70	$5	$10	$55

Example: "Track and Trace" Required to Accurately Stack Discounts for Best Price

	CHANNELS						
	Wholesaler		Provider		Payer		Cash Payer
	Whl 1	Whl 2	Small Pvdr	Large Pvdr	Payer 1	Payer 2	Cash Paying
Discounts	2%	5%	40%	10%	70%	30%	0%

Product Flow								BP Discount %
Unit 1	2%		40%			30%		72%
Unit 2		5%		10%	70%			85%
Unit 3	2%			10%				12%
Unit 4	2%			10%	70%			82%
Unit 5	2%			10%		30%		42%
Unit 6		5%		10%				15%
Unit 7 (potential)		5%	40%		70%			115%

- Based on their contracts, manufacturers calculate Best Price today as lowest price available to any single entity.
  - This could be the aggregate of two discounts calculated and intended to flow to a single entity
- Under the proposed rule, precise tracking of an individual unit and associated discounts for that unit across channels is required to accurately stack discounts for Best Price.
  - This example is simplified, as there are hundreds of potential product flows, and it is even more complex when accounting for units from various inventories with different prices.
  - Cannot confirm discounts for a unit without visibility to downstream transactions across channels.
  - Precise tracking of units across channels and associated discounts raises new patient privacy concerns, and it also assumes manufacturers can compel cooperation from other entities in the supply chain.
  - Disincentivizes voluntary discounts to small providers.

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Withdraw Proposed Manufacturer Price Verification Survey

- As proposed, the survey goes far beyond CMS' statutory authority to verify manufacturer reported prices.
- CMS’ proposal will impose significant operational burden
- CMS Burden Analysis is Inadequate.
  - CMS woefully underestimates the significant burden that the “Verification” survey would impose on manufacturers.
  - CMS estimates the survey would “take 5 hours… for an operations research analyst to complete.” This estimate is unrealistic and does not reflect the actual burden to manufacturers.
  - Manufacturers do not maintain some of the proposed data in the ordinary course of business.
- Threatens continued access to the most innovative therapies.

Maintain Current Definitions for Covered Outpatient Drug and Manufacturer

- Withdraw Proposed Change to “Covered Outpatient Drug” Definition:
  - The proposed change to include any drug separately listed by a provider on any claim form upends decades of settled Medicaid regulations
  - The proposed definition conflicts with Section 1927 of the Social Security Act which explicitly places a statutory exclusion on units that are bundled with inpatient or other associated services
  - Significant expansion and new rebate exposure for manufacturers with no benefit to patients in terms of increased access
- Withdraw Proposed “Manufacturer” Definition:
  - Including any “associated entity” in the definition for “Manufacturer” conflicts with statutes and significantly expands the entities subject to MDRP

Conclusion

- The proposed rule contains significant changes to MDRP which conflict with statute and would markedly alter program operations and longstanding definitions, significantly impacting manufacturers and reporting requirements under the Program.
- We urge the withdrawal of the proposed rule.
- J&J welcomes the opportunity to engage with the Administration, and others to advance our shared goal of bringing world-class life sciences innovation to those most vulnerable populations while preserving affordability to the beneficiary and efficient Medicaid program operations.