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Staying ahead of the curve: Navigating policy changes and ensuring patient access in the era of IRA and EU HTA

Educational symposium

May 6, 2024

Meet the speakers

Pr. Michael Drummond

Professor of Health Economics,
University of York

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Kimberly Westrich

Chief Strategy Officer,
National Pharmaceutical Council

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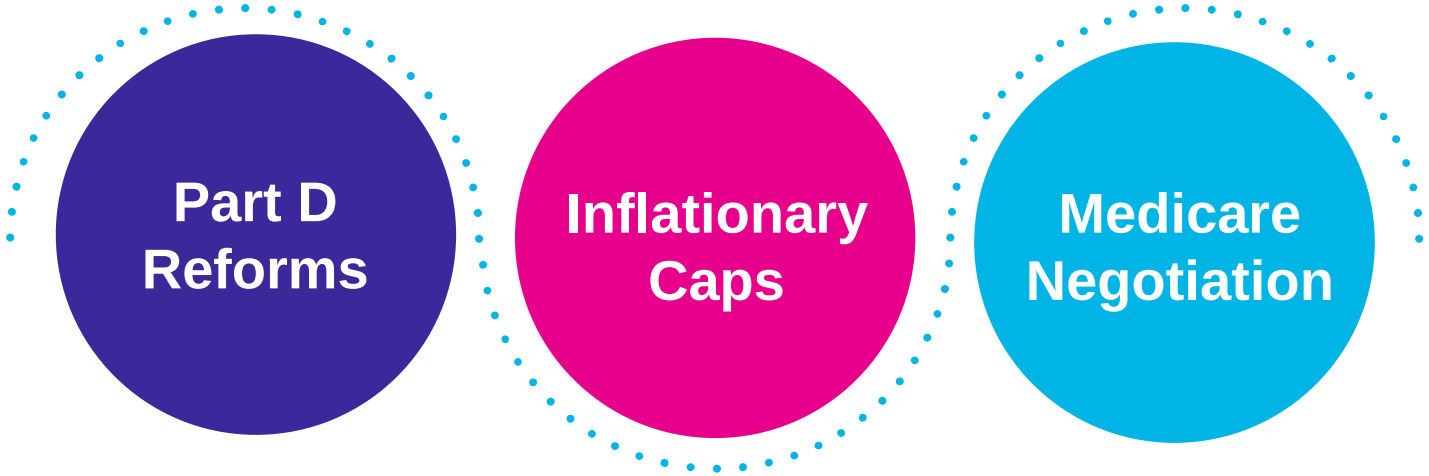
Considerations for stakeholders in the wake of IRA implementation

Kimberly Westrich, Chief Strategy Officer, NPC

Core healthcare components of the IRA



OOP cap in 2024
Larger redesign to begin 2025
Expands LIS eligibility
$0 OOP for Part D vaccines

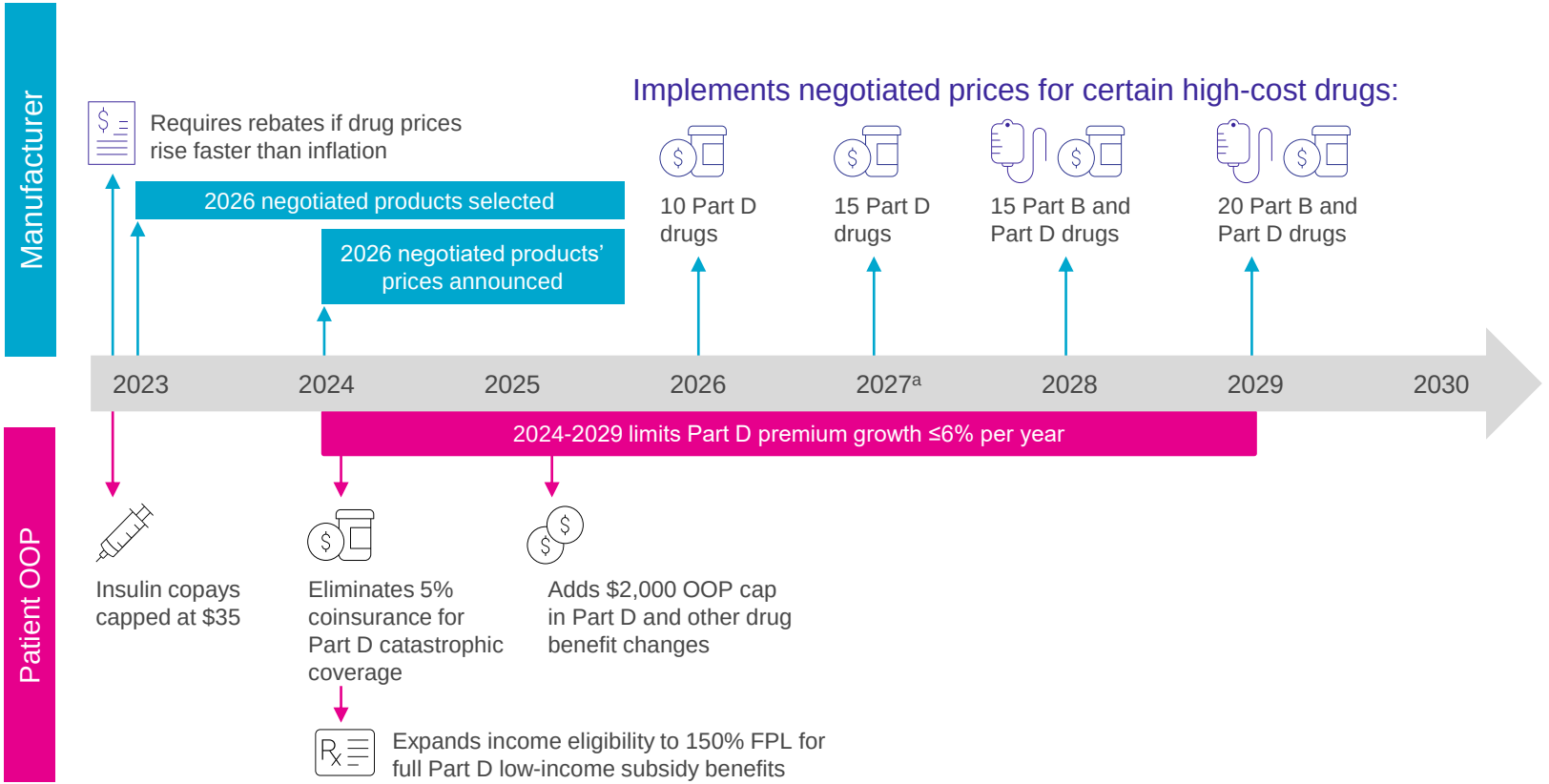
Medicare Part B and Part D price increases that outpace inflation owe rebates

Negotiation starts earlier (2023), implementation in 2026

LIS – Low-Income Subsidy; OOP – out of pocket

Prepared by Cencora. IRA Boot Camp: Navigating the Implementation of the Inflation Reduction Act. July 10, 2023.

IRA implementation timeline for prescription drug provisions



[a] Repeals Trump administration's drug rebate rule until 2031.

Prepared by Cencora. IRA Boot Camp: Navigating the Implementation of the Inflation Reduction Act. July 10, 2023.

IRA's drug pricing provisions may have unintended consequences for health care stakeholders

Future innovation

- May result in **fewer indications** for small molecules
- May **reduce post-approval outcomes research** that informs clinical guidelines

Patient access to needed medications

- May cause vulnerable patient populations to **wait longer for innovative treatments**
- May create new incentives for payers to **increase utilization management**

Patient experience

- May **not follow best practices** to incorporate or account for the **patient perspective**

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Understanding the EU Joint Clinical Assessment (JCA)

Pr. Michael Drummond, Professor of Health Economics, University of York

Casper Paardekooper, Partner, Vintura, part of Cencora

What is the Joint Clinical Assessment (JCA)? When & who does it impact?

<9mths to go

New EU-wide HTA process; a single clinical assessment occurring in parallel with the European Medicines Agency (EMA) marketing authorization process.

Aims:

- ✓ Harmonize processes and evidence requirements
- ✓ Avoid duplication of dossier development for manufacturers
- ✓ Accelerate patient access across its member states (“solidarity”)

Comparative effectiveness

Price/ value/ economics

January 12, 2022

Formal enactment of EU HTA Regulation by the European Parliament and the Council of the EU

2022–2024

Pilot phase, formation of a Coordination Group (one member per EU country; main tasks: establishment of formal and methodological guidance), formation of a stakeholder network

January 12, 2025

JCA mandatory for new oncology drugs, ATMPs

January 13, 2028

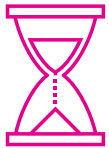
JCA **mandatory for orphan drugs**

January 13, 2030

JCA **mandatory for all drugs** registered centrally by the EMA

JCA will also be necessary for any follow-on indications for these products (slightly abbreviated process)

Key challenges of the new JCA process



CHALLENGING TIMELINES

- Process aims to publish report just 30 days after EC regulatory decision
- Manufacturers have just 100 days* to prepare their submission after scope publication
- Expected PICO multiplicity likely to drive early preparation of necessary statistical analysis

MINIMAL ENGAGEMENT

- Minimal involvement of manufacturers in scoping process (just an “explanation” meeting)
- No sharing of individual member state PICO requirements
- Unclear how patient and clinical organisations will participate

HIGH TRANSPARENCY

- High demand for sharing of manufacturer materials via process
- Only 7 days to fact check report and mark commercial in confidence
- Unclear process for challenging publishing of confidential material

*Based on an assumed average clock stop

*Note: Points on this slide are accurate at the time of writing (1st May 2024)

Thank you

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Connect with the Cencora team at booth #607


Thank you धन्यवाद Děkujeme Mange
takk Vă mulțumesc Gracias Vielen D
شكراً لك Teşekkürler Dėkojame jum
спасибо Merci 谢谢 Obrigado ありが
ございました cảm ơn bạn Paldies 감사합
Hartelijk dank Thank you धन्यवाद Dě
Mange takk Vă mulțumesc Gracias
Vielen Dank شكراً لك Teşekkürler D