Unintended Consequences: The Inflation Reduction Act (IRA) and the Impact of the Small Manufacturer Discount Phase-in on Patient Access Over the Next Three Years (2025–2028)

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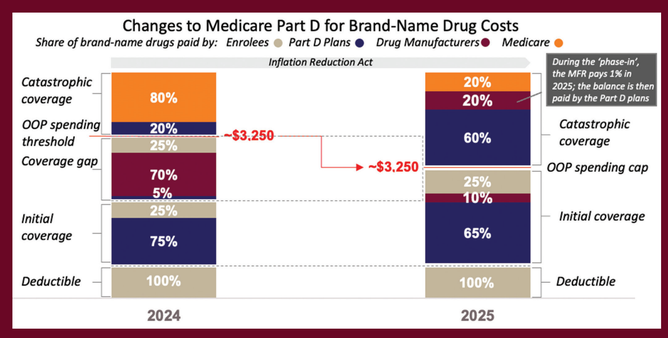
A) Objectives

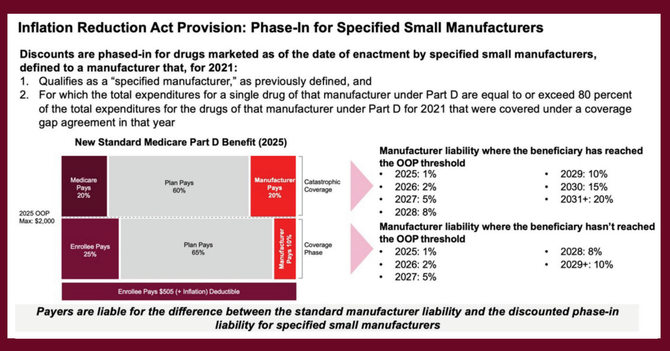
The aim of this research was to evaluate the potential impact of the Inflation Reduction Act (IRA) on drug access for small, single-drug manufacturers. We examined the implications of the Medicare Part D Manufacturer Discount Program (Discount Program), and how managed care companies might respond to approximately 185 small, single-drug manufacturers receiving a phased-in discount liability until 2031. Our objectives were to assess:

- Managed care experts' familiarity with and understanding of the Medicare discount program and the phase-in for small, single-drug manufacturers
- The cost and complexity of implementing the discount phase-in program
- The potential impact on patient access to medications due to pressures on managed care budgets, benefit design, formulary selections, and rebate contracting over the next three years

B) Introduction

The IRA have made significant changes to Medicare Part D, resulting in the discontinuation of the Coverage Gap Discount Program (CGDP) as of December 31, 2024, and its replacement with the Discount Program. This program requires drug manufacturers to provide discounts on brand-name and biologics in the initial and catastrophic phases of 10% and 20%, respectively,[i] which are also covered under Medicare Part D.





The specified small manufacturer phase-in applies to applicable drugs of specified small single drug manufacturers that are marketed as of August 16, 2022, and are dispensed to applicable beneficiaries.[ii]

As noted by Centers for Medicare & Medicaid Services (CMS), the 'phase-in' aims to provide a gradual adjustment period for small manufacturers, ensuring they can comply with the new discount requirements without immediate financial strain.

C) Methodology

Survey Design

The primary method used to assess payers' understanding and thoughts on the Discount Program was a quantitative survey. The survey was designed to capture comprehensive insights from various payer types, including National Managed Care Organizations (MCOs), Regional MCOs, Pharmacy Benefit Managers (PBMs), and Integrated Delivery Networks (IDNs). The survey consisted of 23 closed-ended quantitative questions.

Participant Recruitment

Participants were selected from a diverse pool of professionals within the payor community, ensuring a representative sample across various organization types and experience levels. The recruitment process involved a targeted email campaign utilizing Petauri's proprietary managed care decision-maker panel. To be included, participants needed to be decision-makers with experience in Medicare.

Survey Administration

The survey was administered online using a secure survey platform to ensure data integrity and confidentiality. Participants were provided with a unique link to access the survey, which included detailed instructions and an estimated completion time of 10–15 minutes. The survey was open for responses over a 3-week period so as to maximize participation.

The survey comprised several sections, each focusing on different aspects of the small single drug manufacture phase-in program:

1. **Demographic Information:** Basic demographic information was collected, including the respondent's title, organization type, and total years of experience in the commercial and Medicare Part D sectors
2. **Familiarity with the Small Single Drug Manufacturer Phase-in:** The respondents' familiarity with the 2025 small manufacturer exception/ phase-in within the CMS Medicare Part D Discount Program was assessed, as well as their organization's readiness for its implementation
3. **Impact on Utilization Management:** The anticipated impact of the exception on utilization management approaches was explored, including specific changes to step therapy protocols, prior authorization requirements, formulary placement, and clinical guidelines
4. **Impact on Budget:** Questions were focused on the expected budgetary impact of the exception over the next 1–3 years, and the strategies planned to mitigate potential budget increases
5. **Impact on Benefit Design:** Examined the extent to which respondents anticipated modifying their benefit design in response to the exception, including changes to cost-sharing, formulary tiers, and access restrictions
6. **Impact on Contracting Strategy:** The influence on contracting strategies with small manufacturers was investigated, including demands for discounts, performance-based contracts, and leverage in negotiations
7. **Impact on Commercial Channel Management:** Potential effect on management approaches within the commercial book of business was assessed, as well as the specific changes expected
8. **General Perception:** Overall perceptions of the impact of the 2025 small manufacturer exception/phase-in on the organization's ability to manage drug costs were gathered

Data Analysis

Secondary research was conducted to delineate the requirements of the Medicare Small Manufacturer phase-in programs. Quantitative data from the survey were analyzed using descriptive statistics in MS Excel®, allowing for a comprehensive summary of responses and the identification of key trends.

Ethical Considerations

The study adhered to ethical guidelines for research involving human participants. Informed consent was obtained from all respondents, and participation was voluntary. Data confidentiality was maintained throughout the study, and results were reported in aggregate to protect individual identities.

D) Results

A total of 15 managed care decision-makers (payers) were recruited with representative distribution across PBMs (5), IDNs (1), and MCOs at a national (4) and regional (5) level . While nearly half (46%) of the payers reported being very familiar with the specifics of the phase-in program, none indicated having developed a comprehensive strategy. Additionally, 66% noted that they have initiated discussions but are still in the early stages.

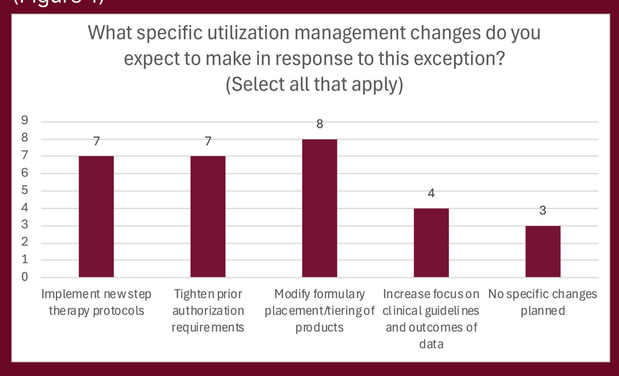
When asked, "Will the small manufacturer exception make managing drug utilization from these manufacturers more challenging?" 66% of respondents indicated that they anticipate management to be "slightly more challenging with some added complexity." As a result, payers noted that they would increase their utilization management (UM), as demonstrated in Figure 1. A possible reason for the increased UM is that the majority (66%) anticipated a modest Medicare Part D budget impact, averaging 6.8% over the next 1–3 years. In addition to increasing UM, payers noted that they would look to negotiate additional discounts/ rebates (73%) and/or shifting utilization to lower cost alternatives who do not have an exception (66%). When asked if the small manufacturer exception could reduce formulary options available to members, 86% of respondents felt it would either have a minor impact or no impact at all. Notably, none of the respondents believed it would have a significant impact on formulary options.

When asked about the impact of the small manufacturer exception on payers' contracting strategies, responses ranged from aggressive to neutral, offering limited clarity on payers' potential reactions (Figure 2). When further questioned about the leverage that payers might have during contracting, 67% believed that they would experience a slight increase in leverage (Figure 3). Lastly, payers expressed a range of concerns with regard to the phase-in for small manufacturers (Figure 4).

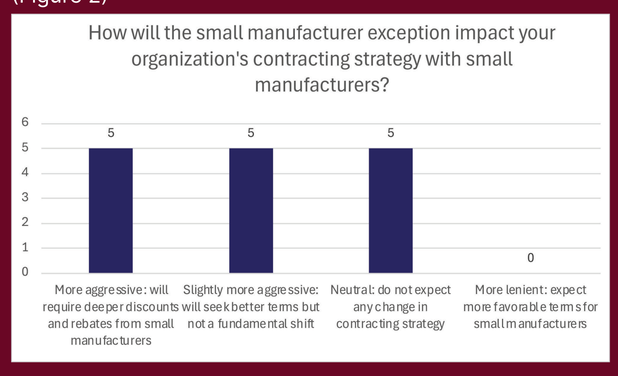
Limitations

The study acknowledges potential limitations, including response bias and the representativeness of the sample. Efforts were made to mitigate these limitations through careful survey design and participant recruitment strategies. We limited our survey time horizon to three years due to concerns about respondents' ability to accurately predict further into the future, given that the phase-in program will begin in 2025.

(Figure 1)



(Figure 2)



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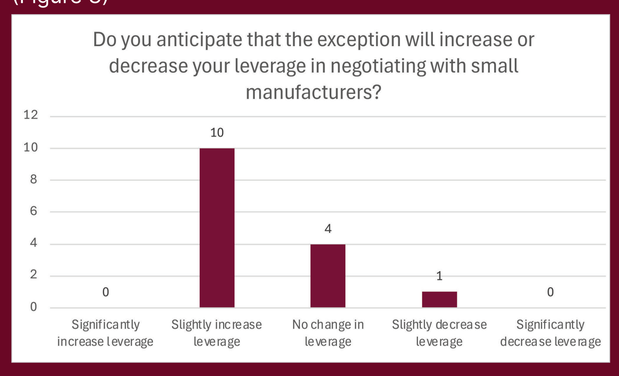

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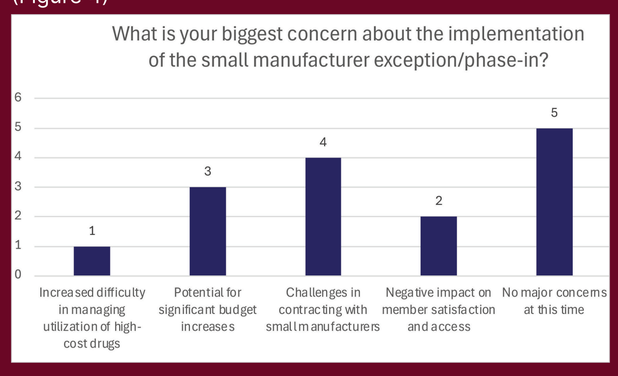

Conclusion

While the IRA aims to provide a gradual adjustment period for small manufacturers by phasing in discounts during the coverage and catastrophic phases, it may inadvertently increase costs for US payers. Our survey indicates that payers anticipate these cost increases. If these costs are not mitigated, it could lead to reduced patient access to medications due to increased utilization management and reduced formulary coverage. Payers note that they will pursue rebate contracting with applicable small pharmaceutical manufacturers to offset their increased costs.

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References

[i] KFF Diagram: Explaining the Prescription Drug Provisions in the Inflation Reduction Act | KFF

[ii] https://www.cms.gov/files/document/manufacturer-discount-program-specified-and-specified-small-manufacturer-methodology.pdf

Abbreviations

- CGDP = Coverage Gap Discount Program
- CMS = Centers for Medicare & Medicaid Services
- IDN = Integrated Delivery Network; also known as 'payer'
- IRA = Inflation Reduction Act
- MCO = Managed Care Organization; also known as 'payer'
- MFR = Pharmaceutical Manufacturer
- OOP = Out of Pocket
- PBM = Pharmacy Benefit Manager; also known as 'payer'
- UM = Utilization management