



Avalere's Perspective: Value and Evidence Determination Post-IRA

Avalere Health | A Member of Fishawack Health
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Medicare Negotiation as Outlined in the IRA Formalizes Value Assessment During Later Product Lifecycle Stages

Medicare Negotiations Evidence Requirements

- R&D costs and the extent that they have been recouped
- Current unit costs of production and distribution
- Prior federal funds for discovery and development
- Market data and revenue and sales volume data for the drug
- Extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.
- Food & Drug Administration (FDA) prescribing information
- Comparative effectiveness data, with a focus on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations
- Extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy

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Maximum Fair Price (MFP)

Ceiling: % of n-FAMP as laid out in statute



Determined through negotiation

Floor: Production + Distribution Costs + Fee

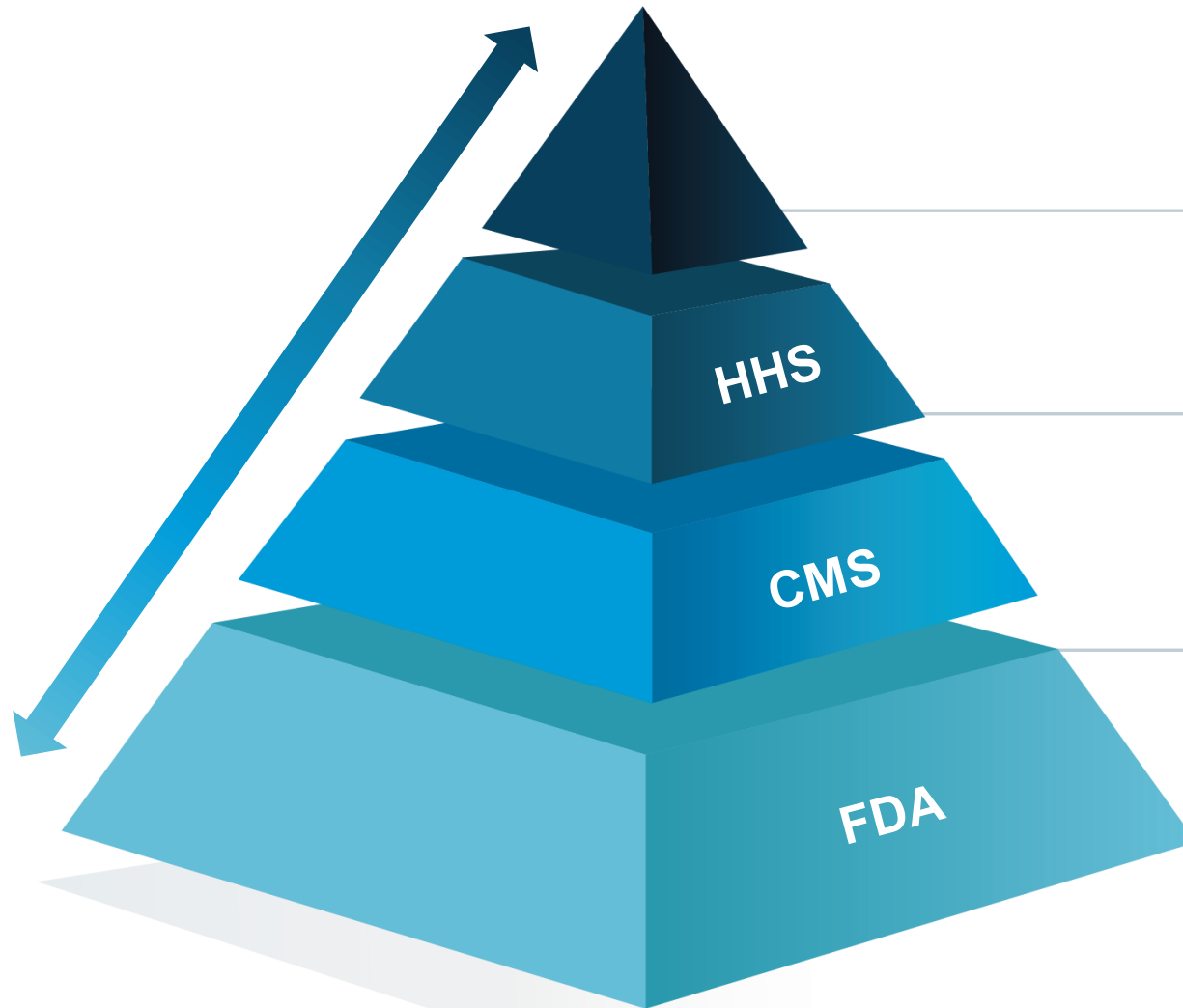
IRA: Inflation Reduction Act; R&D: Research & Development; n-FMAP: non-Federal Average Manufacturer Price



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The Inflation Reduction Act Will Require Interactive And Dependent Layers of Evidence

Evidence generation was previously considered distinct and sequential.



Patient Value

- Patient reported outcomes and patient views of quality

Social Science

- Social determinants of health
- Focus on unmet need and underserved populations
- Population level value

Reasonable and Necessary

- Heterogeneous patients and practice considered
- Observations study designs and considerable real-world data
- Outcomes of superiority are desired
- Best of the practice of medicine

Safe and Effective

- Requirements defined by the Food & Drug Administration (FDA)
- Generally homogenous groups studied
- Rigorous study design and quality controls
- Outcomes generally are powered for noninferiority
- Best of the science of medicine



Key IRA Negotiation Questions Will Shape Value and Evidence Strategy in Novel Ways

IRA Value and Evidence Implications

- 1 What do we know about how the negotiation process will play out, and what still needs to be refined?
- 2 What changes are needed to company evidence and value strategy (above brand) to support Medicare negotiation?
- 3 Where should I prioritize advocacy efforts in shaping Medicare negotiation?

IRA Negotiation Value and Evidence Strategy

- 4 What is the range of possible negotiation outcomes given my current evidence portfolio?
- 5 What additional evidence generation and 3rd party engagement can be done to improve my Medicare negotiation position?
- 6 What strategy and associated tactics are needed to prep for Medicare negotiation?

Implications of IRA for Follow-on Indications & Pipeline Strategy

- 7 How does Medicare negotiation impact the value of follow-on indications?
- 8 Should we consider adjusting development plans, indication sequencing, and related lifecycle management activities to optimize value potential?

Contact Us

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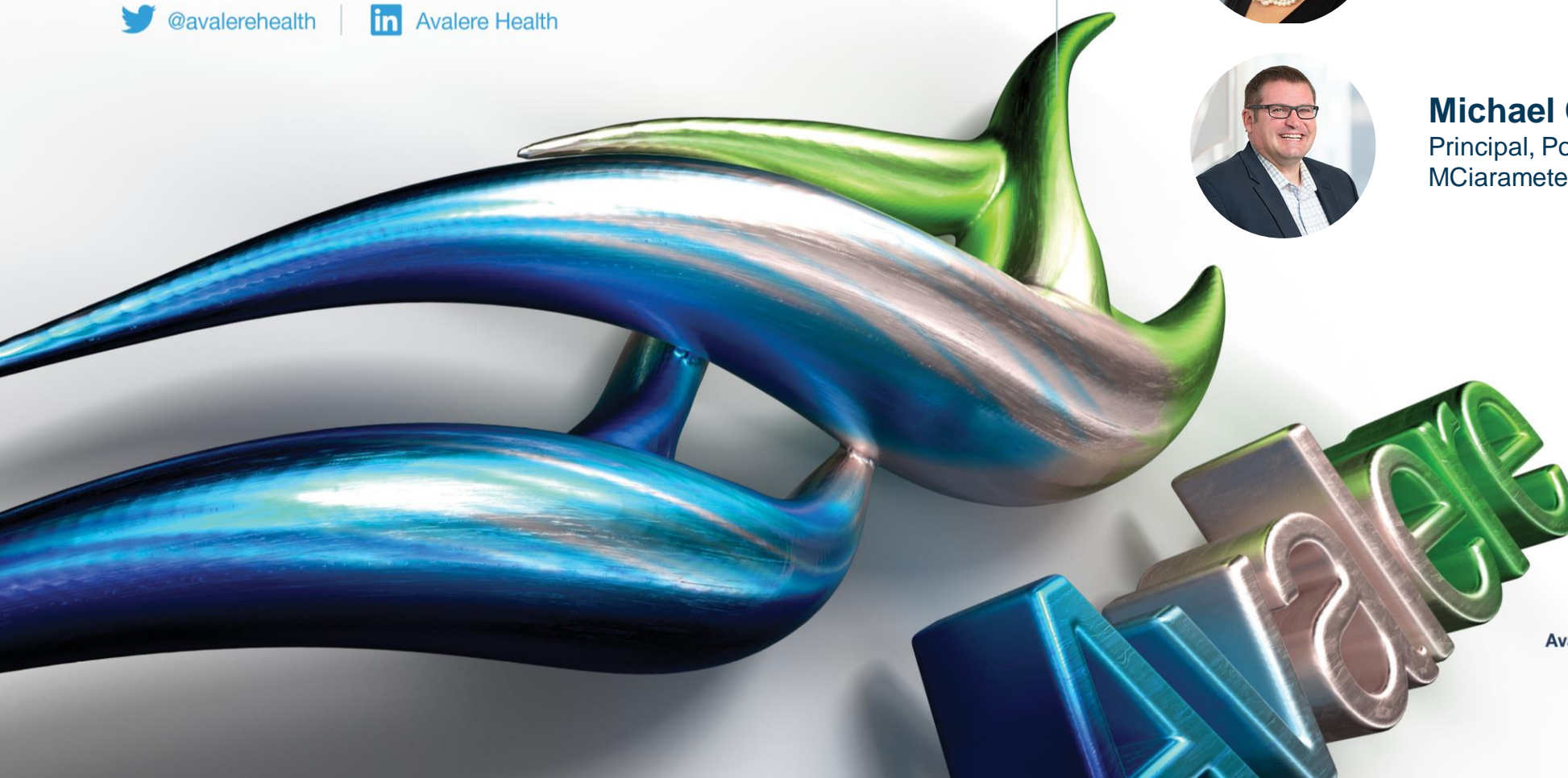
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