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EVERY PATIENT POSSIBLE

2025 Healthcare Industry Outlook

Opportunity Through Uncertainty

Avalere
part of Avalere Health

Avalere | Part of Avalere Health
1201 New York Avenue NW, Suite 1000
Washington, DC 20005

202.207.1300
avalere.com

Finding Opportunity Through Uncertainty

New market and policy dynamics in 2025 create a challenging healthcare environment, but also present stakeholders with new possibilities.

As cost pressures and reimbursement changes related to the Inflation Reduction Act and other policies continue to evolve, so too will the behaviors and incentives of manufacturers, payers, providers, and patients.

Alongside a new fiscal landscape, scientific progress and a new balance of power in Washington create both uncertainty and opportunities to expand business in novel areas such as artificial intelligence, mixed-indication vaccine products, and healthcare treatments like GLP-1s.

These changes add up to an increasingly complex healthcare environment that requires an equally sophisticated business strategy. Once-siloed functions must now coordinate with one another in an approach that integrates points of view from policy, regulatory, evidence, and patient access.

Despite the uncertainty in the healthcare environment we expect in 2025, we hope you will join us as we navigate the ever-changing healthcare ecosystem with an eye toward opportunity and growth.

Sarah Alwardt, PhD
President
salwardt@avalere.com

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We are part of **Avalere Health**, a global strategic partner formed to solve the biggest challenges in health—at pace and at scale. Learn how we unite to imagine new possibilities for a healthier world.

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AI: Artificial Intelligence; **HEOR:** Health Economics and Outcomes Research; **MFP:** Maximum Fair Price; **OOP:** Out of Pocket; **UPL:** Upper Payment Limit

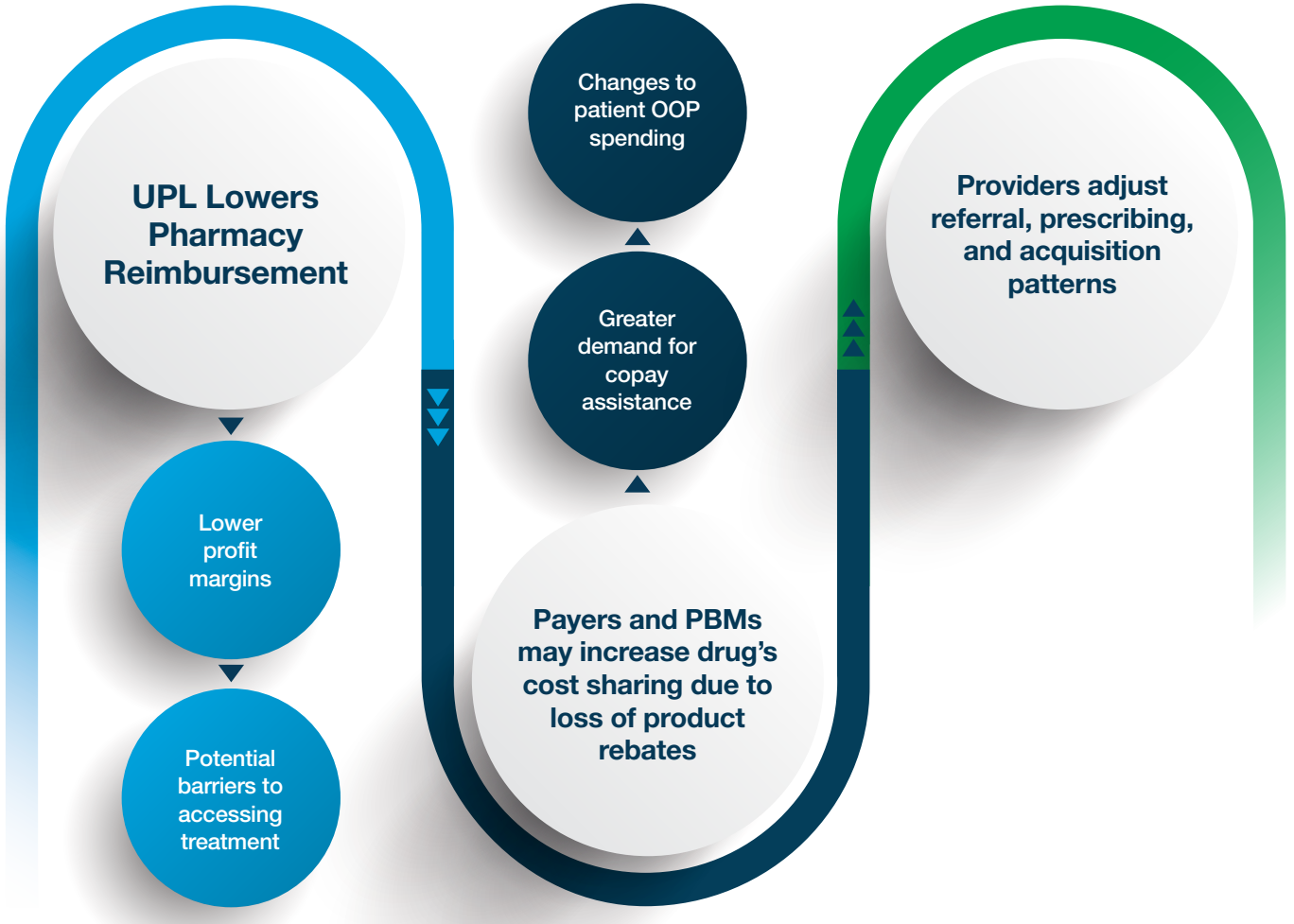
Succeeding Amid Financial Pressure: Recognizing New Stakeholder Behaviors

1. **Understanding Ripple Effects of State Upper Payment Limits on Drugs:** Several states are poised to ramp up their efforts to cap prescription drug costs in 2025, with implications for reimbursement, cost sharing, and provider behavior.
2. **Navigating Financial Pressures on Providers:** Facing system-wide cost pressures, providers are prioritizing value-based care, partnering with management service organizations, and shifting care to lower cost settings, among other strategies.
3. **Forecasting the Impact of Part B Negotiation:** When Part B drug price negotiation goes into effect in 2028, provider reimbursement is expected to fall across therapeutic areas.
4. **Priming Part D Enrollees for Out-of-Pocket Spending Changes:** In 2025, Part D plans will shift more of their formulary tiers from copayment to coinsurance-based cost sharing, which could lead to unanticipated out-of-pocket spending increases.

Understanding Ripple Effects of State UPLs on Drugs

Following years of little movement, state PDABs are expected to ramp up their efforts to cap prescription drug costs. At least three states (CO, MD, OR) could set UPLs this year, with effects beyond the state-regulated markets and products they target. UPL proposals could have unintended effects on drug supply chains, provider reimbursement, and patient access to treatment. Educating policymakers about potential consequences could support providers' ability to offer care and avert access and affordability issues.

Upper Payment Limits May Introduce New Cost and Reimbursement Pressures that Impact Patient Access /



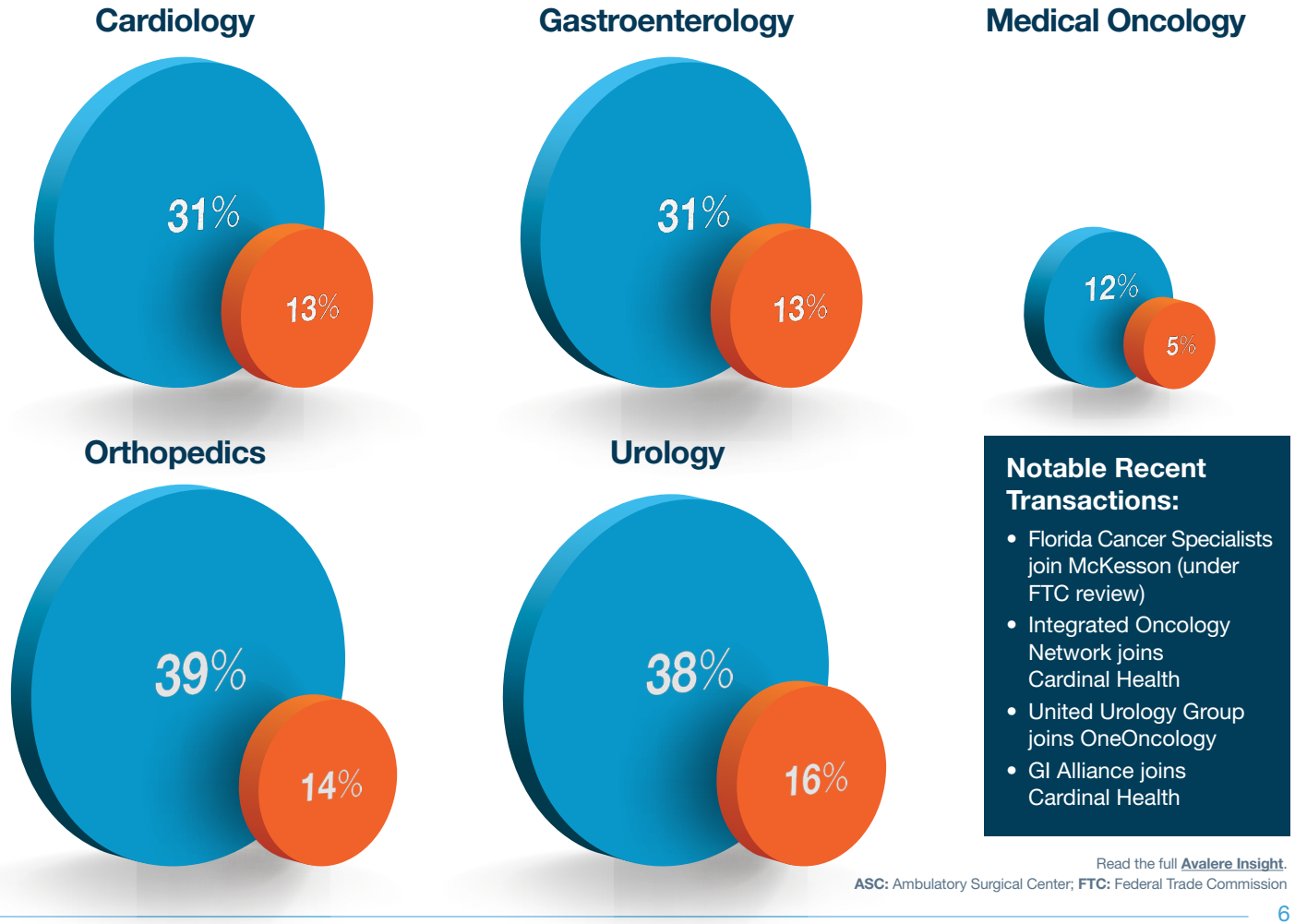
OOP: Out-Of-Pocket; **PBM:** Pharmacy Benefit Manager; **PDAB:** Prescription Drug Affordability Board; **UPL:** Upper Payment Limit

Navigating Financial Pressures on Providers

Pharmacies, physician practices, and other providers are contending with system-wide cost pressures driven by environmental changes. Consequently, providers are expanding their strategies for remaining financially viable. These strategies include incentivizing business practices that demonstrate high-quality care, partnering with management service organizations, and shifting care to different settings such as outpatient offices, ASCs, and home infusion providers. Chain and independent pharmacies are implementing wide-scale store closures.

Share of Medicare Physicians in Unaffiliated Private Practice by Specialty, 2019 and 2022 /

Physicians are increasingly joining hospital, corporate, and private equity-backed entities



Notable Recent Transactions:

- Florida Cancer Specialists join McKesson (under FTC review)
- Integrated Oncology Network joins Cardinal Health
- United Urology Group joins OneOncology
- GI Alliance joins Cardinal Health

Read the full **Avalere Insight**.

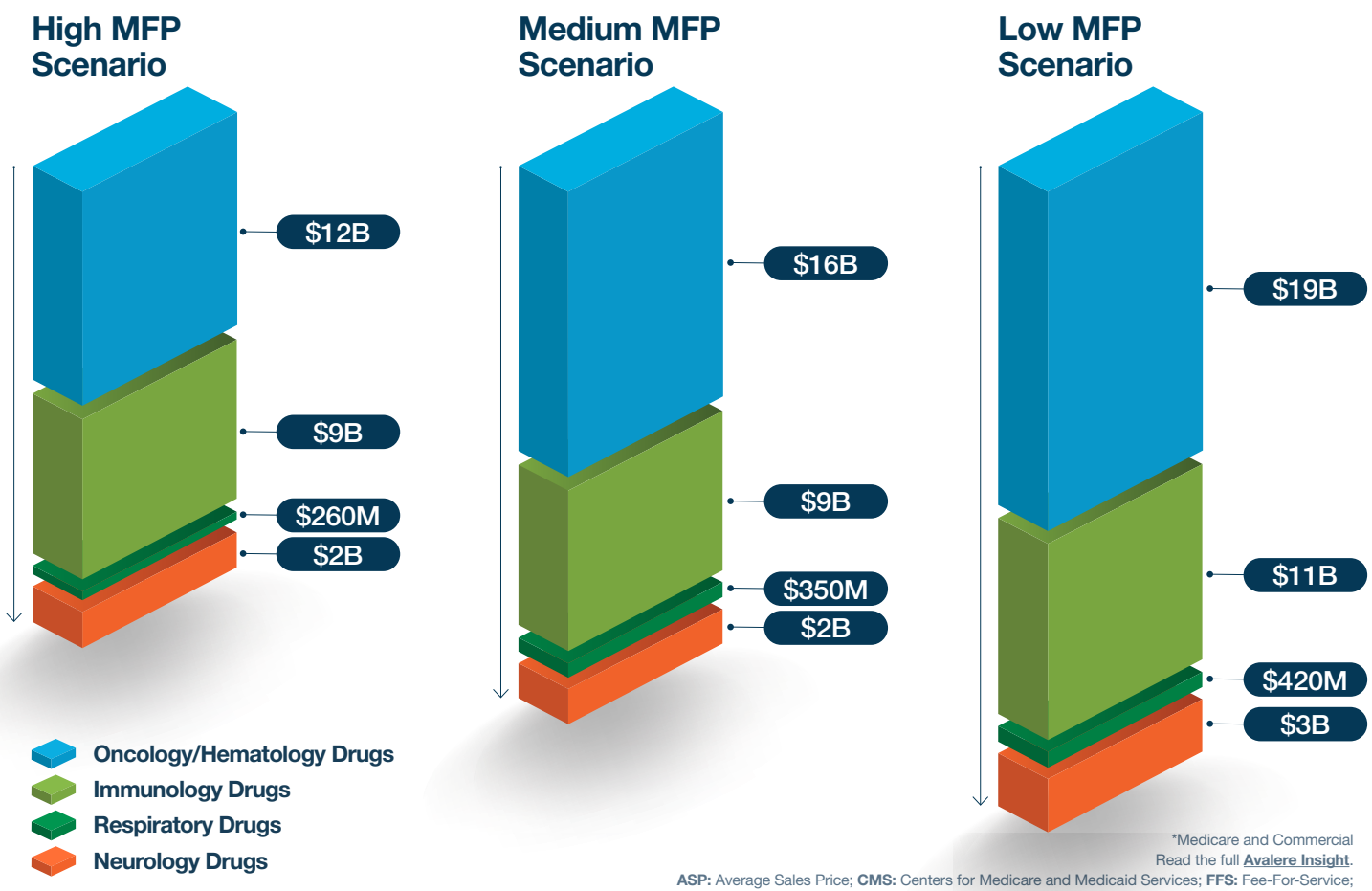
ASC: Ambulatory Surgical Center; **FTC:** Federal Trade Commission

Forecasting the Impact of Part B Negotiation

In Part B, CMS now primarily uses a drug's ASP +6% add-on payment to reimburse providers. Starting in 2028, Part B drugs will also be included in the MDNP, and physician payment for negotiated drugs will be based on the MFP, which is expected to be much lower than the ASP. The MFP will cause ASP erosion over time, impacting FFS, MA, and commercial reimbursement, which may compound the IRA's financial impact on providers. Stakeholders should prepare for these upcoming changes and consider policies that could preserve the IRA's intent to lower prices and limit the impact on providers.

Projected Changes to Provider Reimbursements for Physician-Administered Drugs Likely to Be Negotiated /

Reductions in Add-On Payments* Due to Shift from ASP to MFP, 2028-2032



*Medicare and Commercial

Read the full **Avalere Insight**.

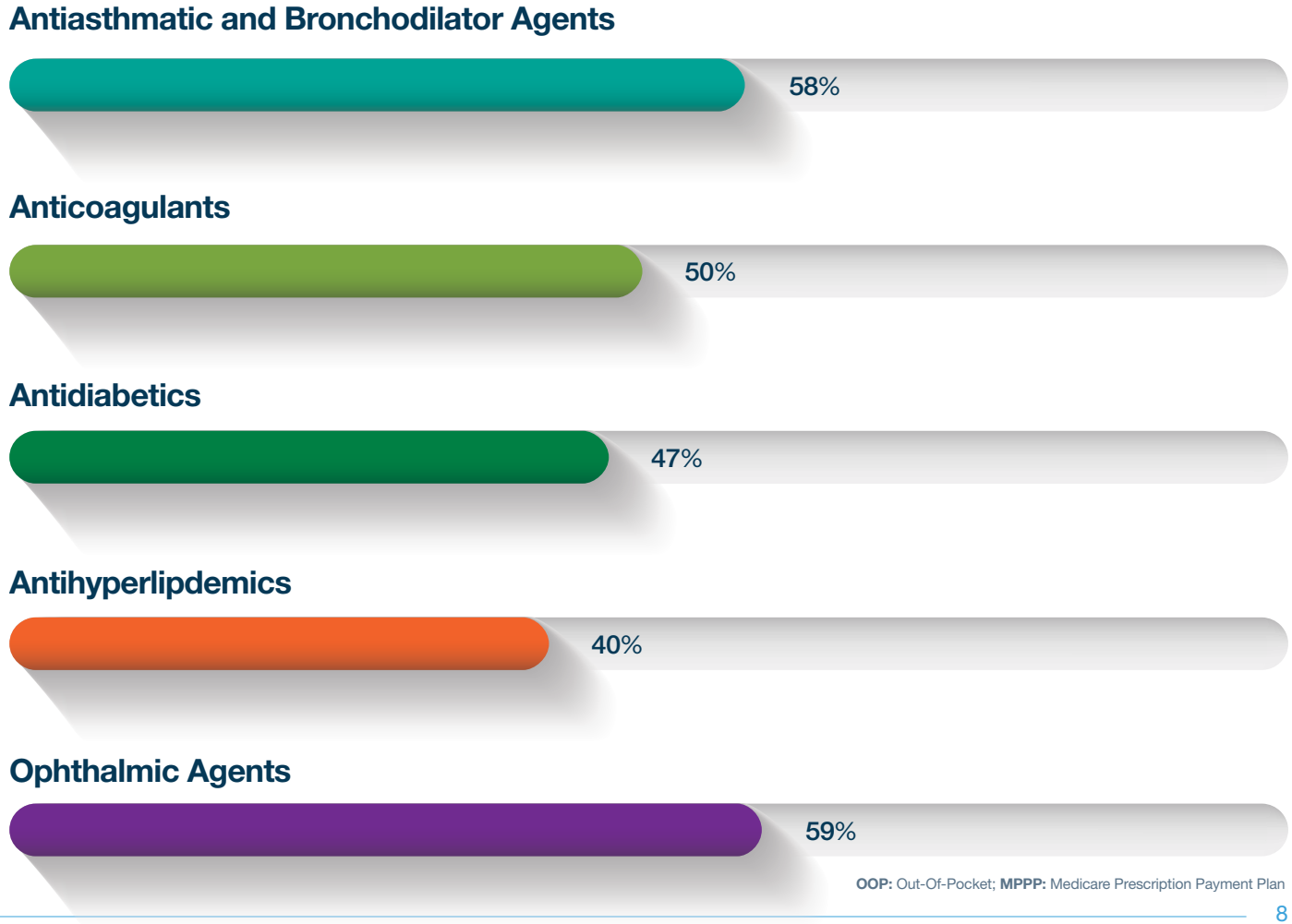
ASP: Average Sales Price; **CMS:** Centers for Medicare and Medicaid Services; **FFS:** Fee-For-Service; **IRA:** Inflation Reduction Act; **MA:** Medicare Advantage; **MDNP:** Medicare Drug Negotiation Program; **MFP:** Maximum Fair Price

Priming Part D Enrollees for OOP Spending Changes

In response to financial pressure and market uncertainty, in 2025 Part D plans shifted more of their cost-sharing tiers from copayments to coinsurance. While the 2025 OOP cap may limit substantial increases in OOP costs, a shift to coinsurance could lead to surprise increases in per script OOP spending, qualifying more beneficiaries for the MPPP than previously expected. However, their OOP costs may fall below the threshold for notification about the program from their plan or pharmacy. Educating patients about the MPPP may help them better manage changes to their cost sharing.

Share of Covered Drugs with Coinsurance, 2023 and 2025 /

View Comparison | View 2023 | View 2025



OOP: Out-Of-Pocket; **MPPP:** Medicare Prescription Payment Plan

Meet the Experts

How are cost pressures and reimbursement changes impacting stakeholder behavior and incentives?

Margaret Scott

Read Bio

Margaret applies her background in Medicaid drug policy and pharmacy benefit management to advise clients' policy advocacy and market strategy.

Margaret's Take

"PBM reform proposals include de-linking fees from drug costs and prohibiting vertical integration with health plans and pharmacies. The new Congress will likely continue to debate PBM policy."

Jessica Cortez

Read Bio

Jess draws on her experience as a former healthcare revenue cycle manager and her expertise as a skilled reimbursement strategist to deliver value to clients.

Jessica's Take

"The next frontier of reimbursement will be defined by how stakeholders integrate innovative payment frameworks with technology to balance cost efficiency and equitable patient access."

Shareef Ghanem

Read Bio

Shareef provides due diligence and advisory support to financial sponsors investing in the healthcare sector and to their portfolio companies.

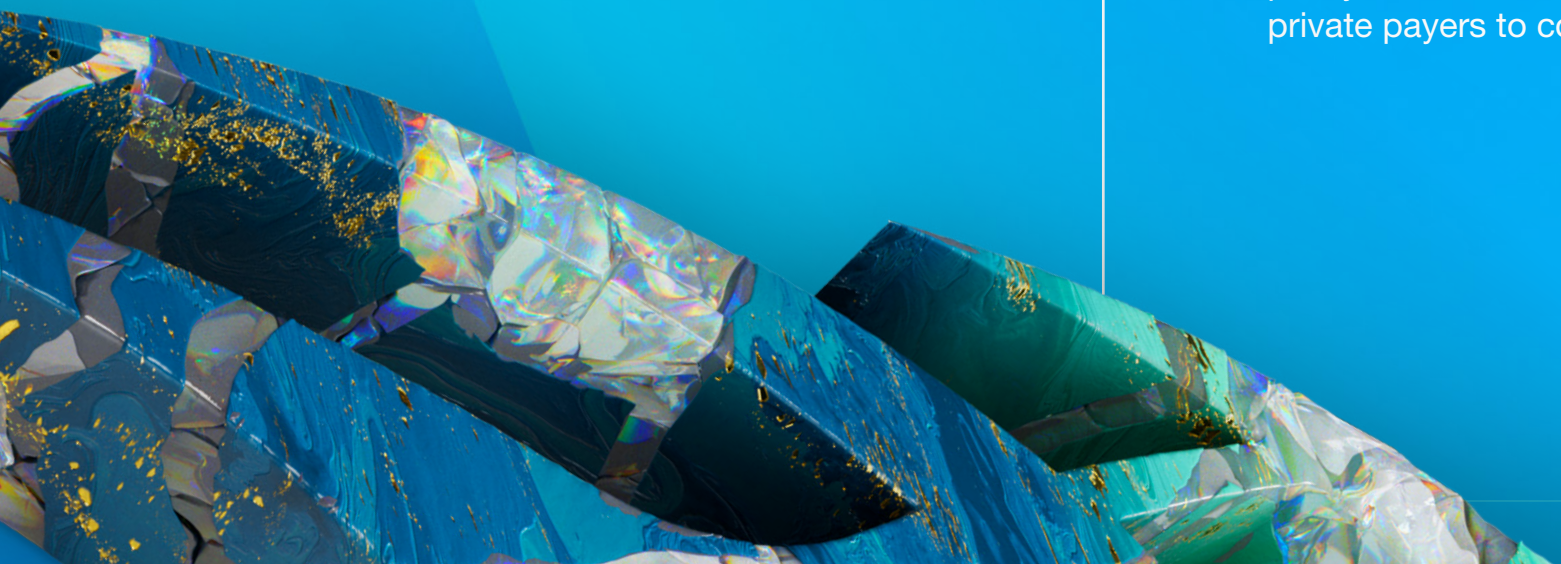
Shareef's Take

"Investors remain bullish on VBC. Some models have underperformed, but we've seen consistent performance by organizations supporting complex and underserved populations."

PBM: Pharmacy Benefit Manager; **VBC:** Value-Based Care

Finding Advantage in Ambiguity: Navigating Tech Advances and Policy Change

1. **Demonstrating AI Benefits Amid Apprehension:** Demonstrating AI's advantages will be important for gaining public acceptance of uses that could save costs and optimize care.
2. **Considering Maximum Fair Price Impacts Across the Supply Chain:** Assessing MFP effectuation requires considering both near- and long-term impacts for manufacturers, providers, plans, and pharmacies.
3. **Anticipating Federal Vaccine Policy Changes:** As key cabinet nominees express interest in reforms, stakeholders should understand which policy changes are possible and remain nimble for engagement with policymakers.
4. **Determining Coverage Strategies for GLP-1s:** With growing patient and policymaker interest in AOMs, there is increasing pressure on public and private payers to cover products such as GLP-1s.



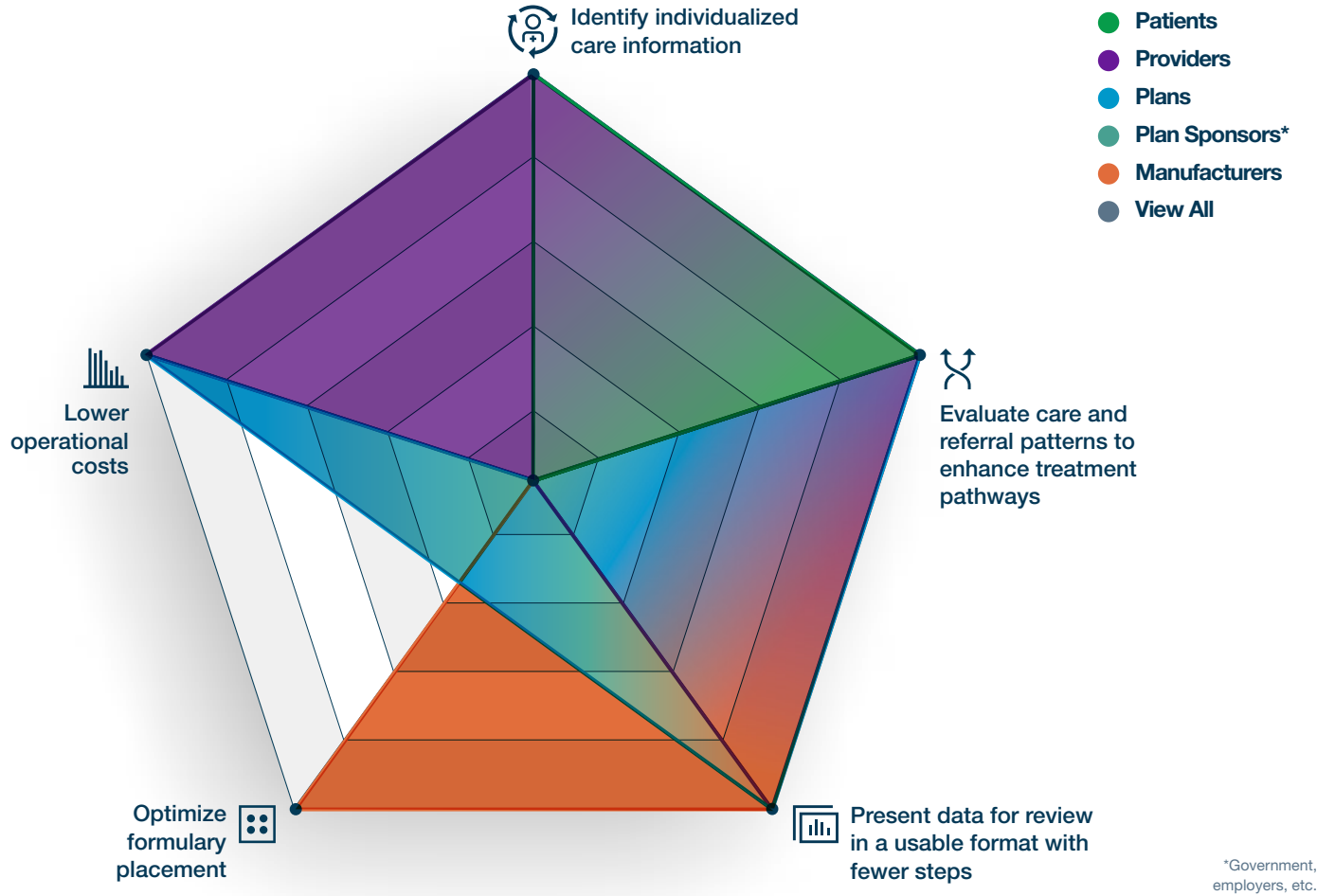
AI: Artificial Intelligence; **AOM:** Anti-Obesity Medication; **MFP:** Maximum Fair Price

Demonstrating AI Benefits Amid Apprehension

AI is a valuable tool for health plans and healthcare providers that complements—but does not replace—human expertise in patient care and operational efficiency. For example, care managers can use AI-generated clinical summaries to accelerate decision making, and plans' analytics teams can run AI on back-end processes so that they can prioritize higher-level analysis. In an environment of regulatory wariness of AI, however, demonstrating the benefits of the technology for patients and the broader healthcare system will be important for gaining its acceptance.

AI-Driven Opportunities for Cost Saving and Care Optimization /

For decades, health plans have amassed extensive healthcare data. Today, advancements in AI can help them transform these data into actionable information.

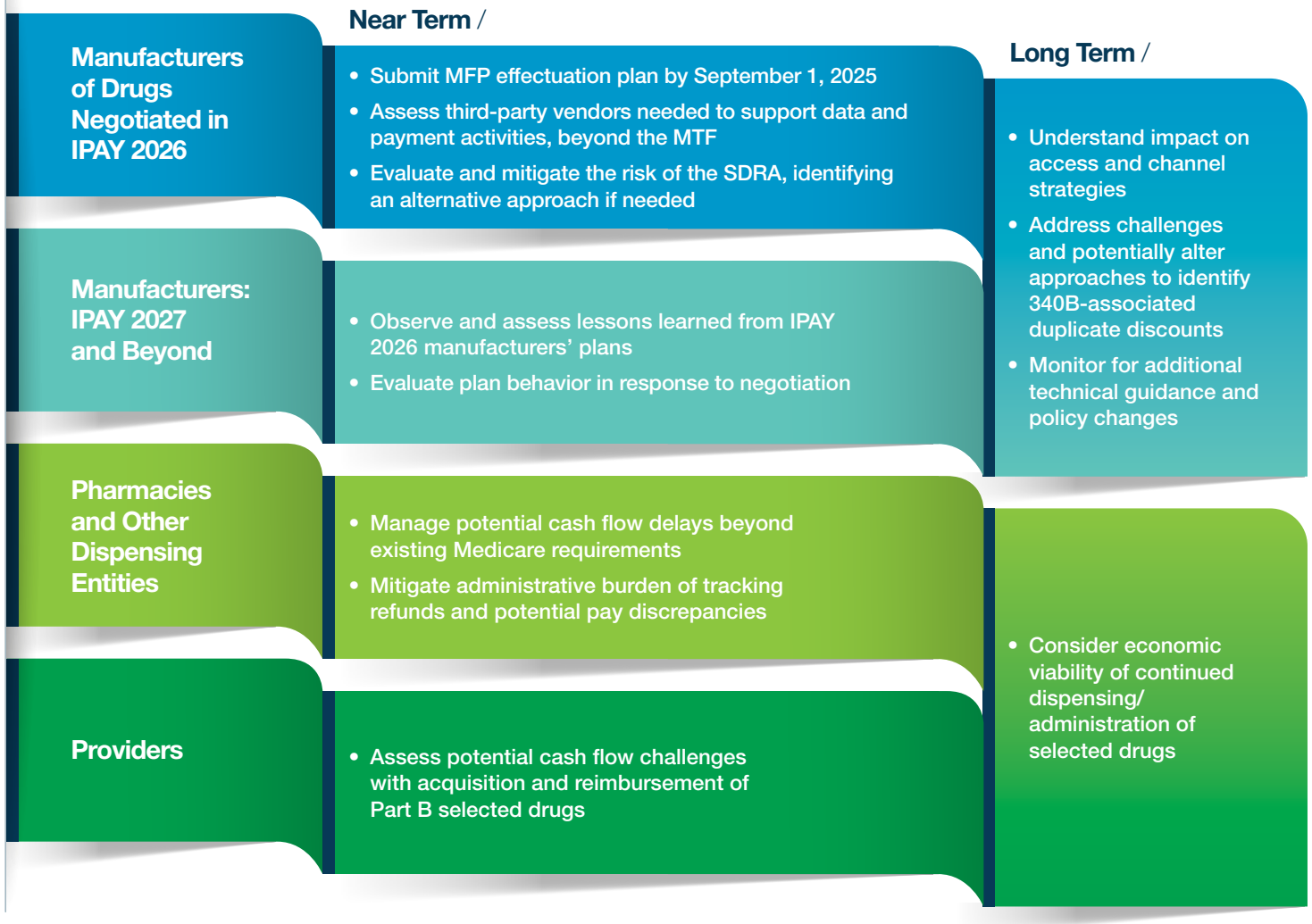


*Government, employers, etc.
AI: Artificial Intelligence

Considering MFP Impacts Across the Supply Chain

CMS guidance on maximum fair price effectuation leaves much discretion to primary manufacturers of selected drugs. Manufacturers of drugs selected for negotiation in initial price applicability year 2026 and beyond, as well as pharmacies, other dispensing entities, and providers, will need to consider both near-term and longer-term strategic planning as they assess the impact of effectuation over the next several years. Stakeholders should watch for regulatory and economic changes that could impact patient access and business strategies.

Stakeholder-Specific Operational Considerations Over Time /



CMS: Centers for Medicare & Medicaid Services; **IPAY:** Initial Price Applicability Year; **MFP:** Maximum Fair Price; **MTF:** Medicare Transaction Facilitator; **SDRA:** Standard Default Rebate Amount

Anticipating Federal Vaccine Policy Changes

Key cabinet nominees in the Trump administration have expressed a desire to reform various facets of current US healthcare policy, most notably those related to vaccines. While it is unclear how these positions could manifest in 2025, narrow Republican majorities in both chambers of Congress could limit the potential for certain vaccine policy reforms. Understanding the environment and remaining nimble in the face of potential vaccine policy changes can equip stakeholders for optimal policymaker engagement in the near and long term.

Trump Administration Nominees on Key Health Topics that Could Impact Vaccines in 2025 /

Robert F. Kennedy Jr. (HHS)

"I'm going to make sure… people can make individual assessments [about vaccines]."

Dr. Mehmet Oz (CMS)

"Vaccines work, but mandates don't."

Dr. David Weldon (CDC)

"Federal agencies…have failed to provide sufficient resources for vaccine safety research."

Dr. Marty Makary (FDA)

"Nothing speaks more to the intellectual dishonesty of public health leaders than their dismissal of natural immunity."

Dr. Jay Bhattacharya (NIH)

"I think the [COVID-19] lockdowns were the single biggest public health mistake."

CDC: Centers for Disease Control and Prevention; **CMS:** Centers for Medicare & Medicaid Services; **FDA:** Food and Drug Administration; **HHS:** Department of Health and Human Services; **NIH:** National Institutes of Health

Determining Coverage Strategies for GLP-1s

Patient and policymaker interest in GLP-1s indicated for obesity is growing. In the CY 2026 MA and Part D proposed rule, the Biden administration proposed allowing Part D† and Medicaid coverage of AOMs when used for obesity care, for the first time ever. Payers and AOM manufacturers should closely monitor whether and how the Trump administration enacts this policy, and plan accordingly. Manufacturers of other medications should consider how AOMs impact formularies.

Anti-Obesity Medicine (AOM) Coverage Landscape /

Commercial

Plans may cover AOMs at their discretion. Many employer-sponsored health plans have carve-outs for AOMs

Medicaid

States have discretion to determine AOM coverage; 12 states cover GLP-1s for the purpose of treating obesity*

Part D

Plans are currently prohibited from covering drugs prescribed solely for weight loss

Medicare Advantage

Coverage varies by plan, with some offering limited coverage through supplemental benefits

AOMs Shift Plan Costs

Obesity-related plan costs have traditionally been spread over several years. Coverage of GLP-1s as AOMs would significantly increase costs in the present, which may prompt plans to increase premiums, limit AOM coverage, and/or limit coverage of other drugs.

† Part D currently allows coverage of these drugs for cardiovascular indications; *as of July 2024

CY: Calendar Year; **GLP-1:** Glucagon-like Peptide-1

Meet the Experts

How can the industry manage the uncertainty in the environment, or leverage it to create business opportunities?

Miryam Frieder

Read Bio

Miryam leads Avalere's Policy practice, advising a wide range of clients on Medicare Part D and the drug pricing policy environment.

Miryam's Take

"The new administration will want to make its mark on major initiatives like Part D redesign, lowering drug costs, and MA payment and oversight, and will likely be active on FDA reform and vaccine policy."

Omar Hafez

Read Bio

Omar advises a range of clients on issues including supply chain, drug pricing, launch planning, and portfolio strategy.

Omar's Take

"The negotiation element of the IRA may require new entities to play a role in the supply chain as the Medicare Transaction Facilitator, and new data feeds and money flows will need to be established."

Jason Lucas

Read Bio

Jason's background in pharmacy and medical claims data management informs his guidance to clients on evidence generation, analysis, and strategy.

Jason's Take

"AI/ML is transforming how life sciences and plans extract actionable signals from complex disease states, driving more targeted interventions and predictive insights with less data."

AI/ML: Artificial Intelligence/Machine Learning; **FDA:** Food and Drug Administration; **IRA:** Inflation Reduction Act; **MA:** Market Access

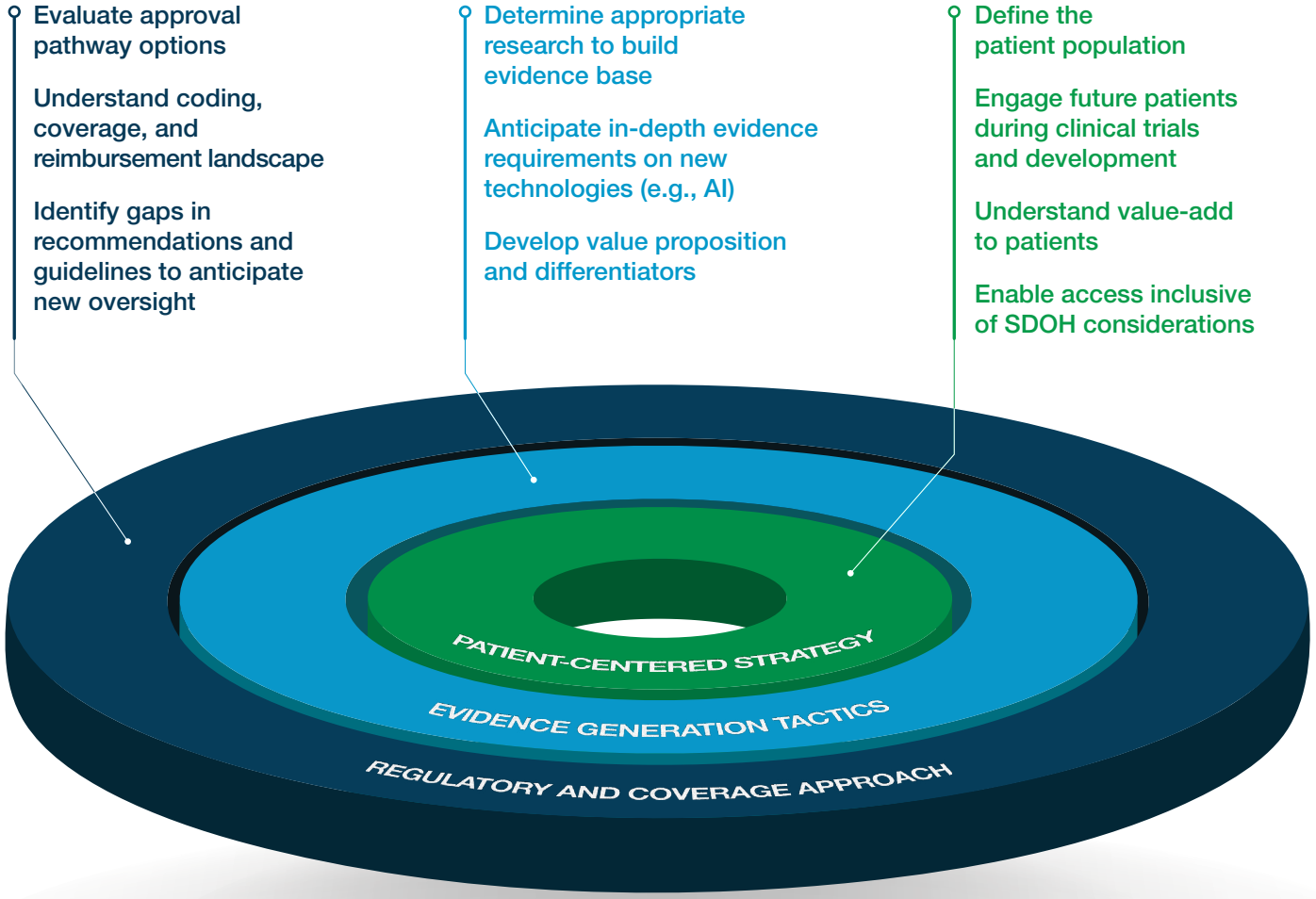
Thriving in Complexity: Building Integrated Business Strategies

1. **Strategizing for More Oversight of Diagnostics, Devices, and Technology:** Manufacturers' approach to regulatory and coverage strategy should incorporate evidence generation and a focus on the patient.
2. **Adapting to Greater Pressures on Plan Strategy & Operations:** Policy and regulatory scrutiny, rising costs, and use of technology are creating demands for increased efficiency and operational changes.
3. **Expanding Value via Reformulation:** Shortened product exclusivity periods increase the need for swift and efficient reformulation plans that consider how clinical, regulatory, pricing, and payer/market access strategies inform one another.
4. **Integrating Health Economics and Outcomes Research Strategy With Market Access:** Thoughtful evidence generation planning includes considering how effective value differentiation can inform provider and payer engagement to impact patient access and improve care.

Strategizing for More Oversight of Diagnostics, Devices, & Tech

Last year the FDA overhauled regulation of LDTs, prompting a paradigm shift in the way that the diagnostic test industry approaches commercialization. As AI- and tech-driven offerings come to market and are increasingly widespread, manufacturers can expect greater regulatory oversight on coverage, reimbursement, and evidence requirements. There are several steps that manufacturers can take to prepare for the guidances, regulations, and rules shaping commercialization and evidence development in the years ahead.

Manufacturers Have Several Opportunities to Strengthen their Evidence Generation and Patient Engagement Strategies /



AI: Artificial Intelligence; **FDA:** Food and Drug Administration; **LDT:** Laboratory Developed Tests; **SDOH:** Social Determinants of Health

Adapting to Greater Pressures on Plan Strategy & Operations

Inflation, innovative treatments, pressure to improve quality, and other operational and regulatory dynamics will drive up the costs of healthcare administration and services for payers. Plans should evaluate product design, provider network performance, and care and utilization management programs to improve member outcomes and increase operational efficiencies. Additionally, emerging technologies such as AI may offer increased efficiency, but need to be thoughtfully evaluated and implemented.

Three Components Shaping Plan Strategy and Operations in 2025 /

Policy and Regulatory

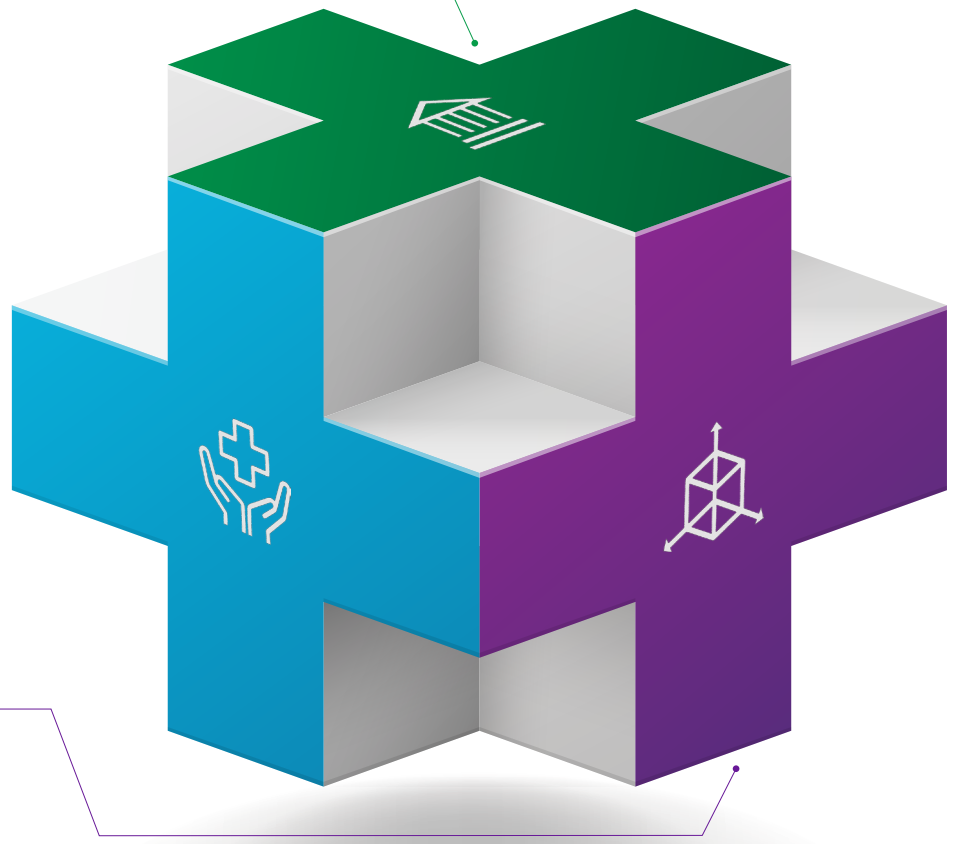
Federal and state governments will continue to address concerns about costs, access, and quality. Scrutiny regarding PBM vertical integration and appropriate use of clinical sources in risk adjustment will likely continue.

Healthcare Services

Healthcare service costs continue to rise, and the number of costly therapies plans must cover is increasing. Plan sponsors will need to balance costs with consumer demand for therapies such as GLP-1s.

Technology

Technologies such as AI are gaining attention, but their benefits, risks, and applications must be evaluated. As prior authorization practices continue to be in the spotlight, support technologies present both challenges and opportunities.

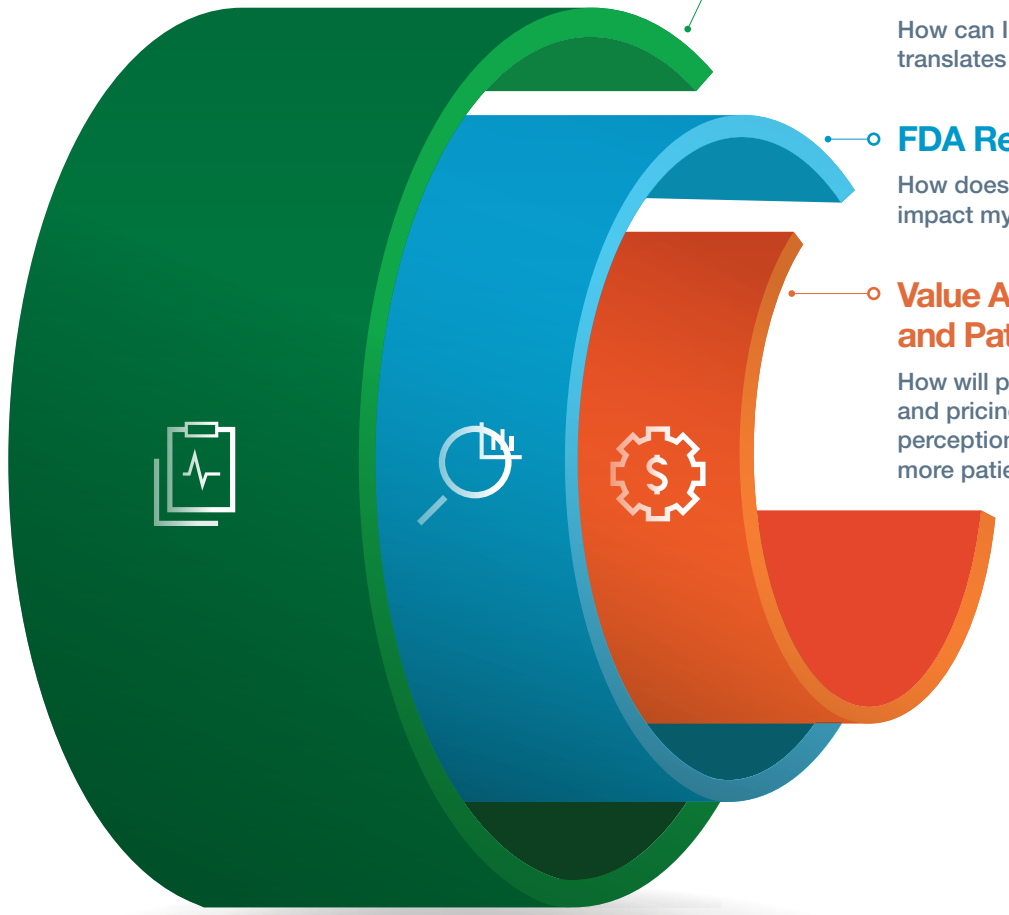


AI: Artificial Intelligence; **PBM:** Pharmacy Benefit Manager

Expanding Value via Reformulation

Sponsors launching new formulations of existing products should consider how their clinical, regulatory, pricing, and payer/market access strategies inform one another. This is especially important as shortened product exclusivity shrinks the timeframe for reformulation, placing greater competitive pressure on manufacturers and increasing the need for swift and efficient reformulation plans. In the past, reformulations took 2+ years to come to market. That timeline has since shrunk to 6-12 months, requiring more collaboration among clinical, regulatory, and market access teams.

Manufacturer Considerations to Maximize Access to a New Formulation /



Clinical Development

How can I demonstrate value that translates to the market?

FDA Regulation

How does my filing pathway and label impact my on-market strategy?

Value Assessment and Patient Access

How will product clinical differentiation and pricing influence stakeholder value perception? How will the reformulation allow more patients to access the therapy?

Types of Reformulation

- New dosage form
- New route of administration
- New dosing regimen
- New strength/volume

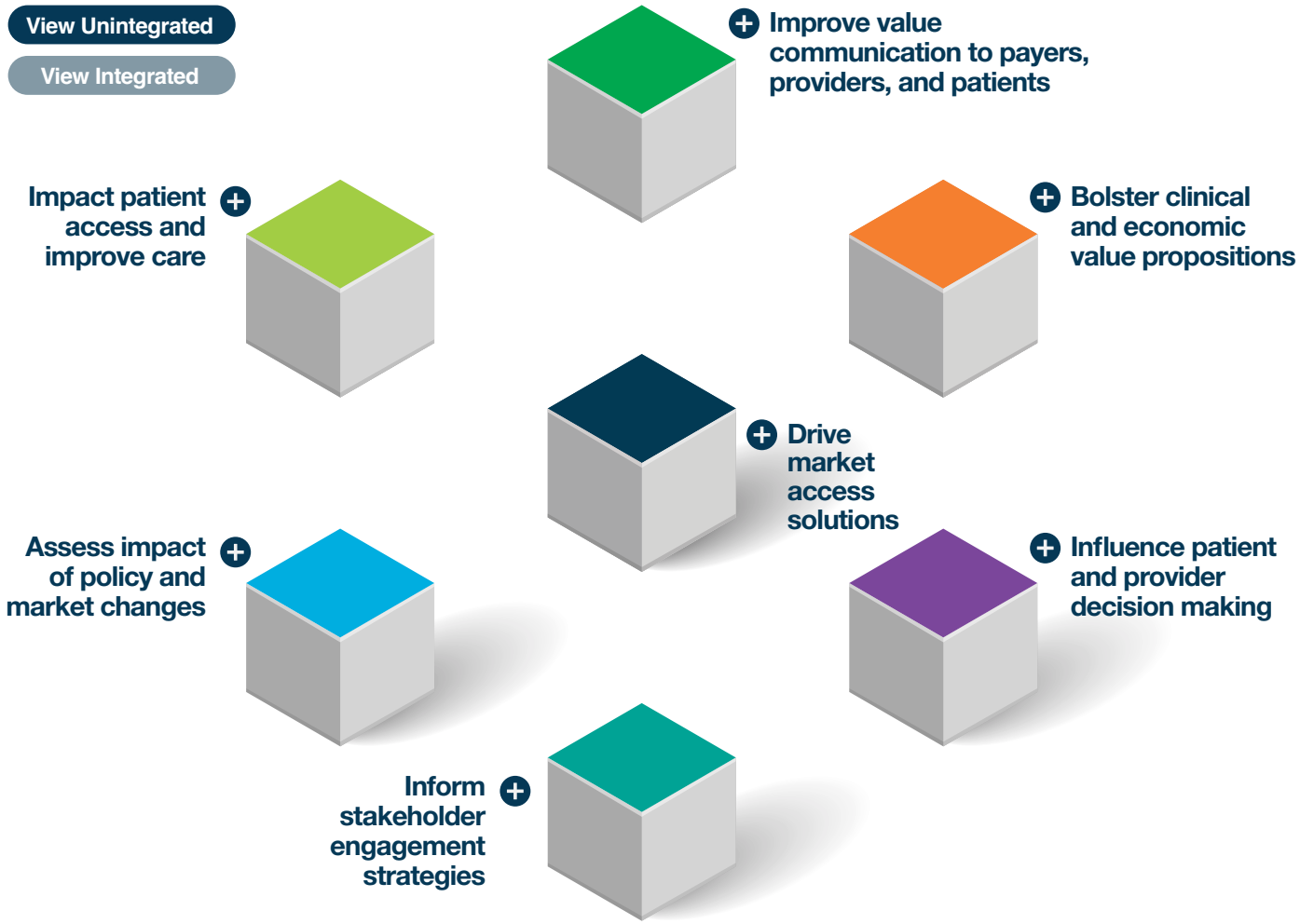
Read the full **Avalere Insight**.

FDA: Food and Drug Administration

Integrating HEOR Strategy with Market Access

IRA provisions have shortened product lifecycles and shifted risk tolerance across the healthcare industry, necessitating effective value differentiation, particularly in early asset evidence strategy and development phases. HEOR teams are increasingly navigating these demands with smaller budgets and teams, underscoring the importance of efficient yet thoughtful evidence generation planning. In response, HEOR teams can leverage evidence in their interactions with providers and payers, incorporate clinical and commercial perspectives, and design studies.

Opportunities Supported by a Cohesive HEOR and MA Strategy /



IRA: Inflation Reduction Act; **HEOR:** Health Economics and Outcomes Research; **MA:** Market Access

Meet the Experts

How do organizations benefit from including multiple points of view in their strategic planning?

Miron Dilmanian

Read Bio

Miron's scientific and healthcare commercialization background brings a comprehensive perspective across product lifecycle management.

Miron's Take

"Clinical value is the basis for successful product commercialization. New policies, like Medicare negotiation, do not change this, but may impact how and when market commercialization strategies are employed."

Shirley Bachman

Read Bio

Shirley spent 30+ years in the biopharmaceutical industry and now advises clients on rare disease launches, patient services, and go-to-market strategies.

Shirley's Take

"Manufacturers have an opportunity to lift up above brand to harmonize pricing strategies, contracting practices, and go-to-market approaches for consistent outputs and quality across the organization."

Roshan Rahnama

Read Bio

Roshan has 20 years of experience as a healthcare strategist and business leader focused on amplifying person-centric health and care.

Roshan's Take

"Market access can unlock new opportunity for value creation and brand differentiation by considering how determinants and equity status of health are essential to people's care experience and outcomes."

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1201 New York Avenue NW, Suite 1000
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