

Duke-Margolis 2023 Health Policy Conference

Reversing the Slide in America's Health

Duke
MARGOLIS CENTER
for Health Policy

SESSION: Pricing and Access Reforms for Higher-Value Pharmaceuticals

Amidst the broader shift from a fee-for-service (FFS) payment structure to a value-based U.S. health care marketplace, significant concerns have arisen over a medical product pipeline that is full of innovative—but also high-cost—therapies. These concerns have led to increased interest in developing new payment and alternative financing models that strive to ensure better outcomes for the dollars spent, and thus higher value. Additionally, after a flurry of legislative proposals at both the federal and state levels in recent years, Congress passed the Inflation Reduction Act (“IRA”) in August 2022. The IRA is the most substantial drug pricing, payment, and coverage legislation enacted since the Medicare Modernization Act of 2003, redesigning the Part D benefit, imposing penalties if drug prices rise above the rate of inflation, and allowing Medicare to directly negotiate prices of certain drugs—a significant agenda for the Centers for Medicare & Medicaid Services (CMS) to implement via a sustainable and predictable price determination framework. With this legislation, there are likely to be both intended and unintended implications in areas related to drug innovation, prices and costs, as well as post-market evidence development and alternative payment arrangements for drugs that are meant to improve outcomes and align with CMS’s care and payment reform goals.



Duke-Margolis Spotlights

Implementing Population-Level Coverage and Access Strategies

- [Advancing Hepatitis C Elimination](#): an effort to identify practical obstacles and feasible policy options to overcome them, and to leverage high policymaker interest and recent developments in drug purchasing, surveillance, testing and treatment to achieve a longstanding public health priority.
- [Outlining Coverage Options for Potential Alzheimer’s Treatments](#): an ongoing effort, building from a CMS National Coverage Determination, to establish feasible policies and infrastructure for coverage, access, and crucial evidence development.

Analyzing IRA Implementation

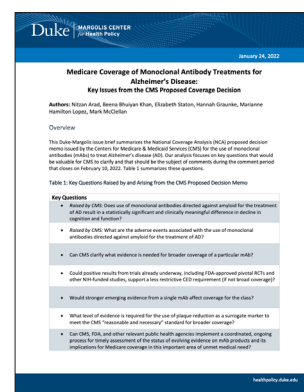
- [Drug Pricing Reform in the Inflation Reduction Act](#): explores likely consequences in areas related to prices, and includes an appendix with an example of how drug manufacturers might react to the provisions of the IRA to minimize revenue loss.

Strengthening Value-Based Payment Arrangements for Medical Products

- [Value for Medical Products Consortium](#): seeks to overcome current barriers to VBP arrangements by identifying and developing solutions to legal and regulatory issues; by addressing operational challenges such as fragmented and difficult-to-track patient outcome data; by identifying strategies to better align RWE development for multiple purposes; and by exploring the role of evidence in informing coverage policies.

Building Robust and Representative Evidence

- [Real-World Evidence Collaborative](#): a multistakeholder effort to drive progress in the development, regulatory acceptability, and use of real-world data and evidence
- [Coalition for Advancing Clinical Trials at the Point of Care \(ACT@POC\)](#): a collaboration to implement large-scale clinical trials in the routine care facilities where most of the U.S. population receives care



Cooperative Agreements with the US Food and Drug Administration (FDA): signature, years-long partnership with the agency on high-priority scientific and regulatory policy challenges. Recent convenings include:

[Emerging Best Practices and Future Directions in Data Privacy and Security](#)

[Workshop on Draft Guidance on Real-World Data: Electronic Health Records/Medical Claims Data and Data Standards](#)

[Understanding Priorities for the Use of Digital Health Technologies to Support Clinical Trials for Drug Development and Review](#)

[Measuring Clinical Benefit in Neonatal Randomized Clinical Trials: Challenges and Opportunities \(duke.edu\)](#)

[Exploring the Utility of Negative Controls for Causal Inference in the Sentinel Initiative \(duke.edu\)](#)

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