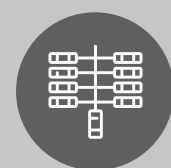


DRUG PRICING NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES: DRUG PRICING REFORM REPORT, PUBLISHED SEPTEMBER 9, 2021

ASCENIAN HTA AND
PAYER POLICY UPDATES |
SEPTEMBER 2021



DETAILS

The report proposes federal government intervention as follows:

1. Allow the Centers for Medicare and Medicaid Services (CMS) to negotiate Medicare Parts B and D drug prices with manufacturers
 - a. Report advocates "fair" prices but does not define how value or "fair" prices should be defined. **The report rules out cost per quality adjusted life year (QALY) as a way to quantify value.**
2. Stop "unreasonable" drug price increases
 - a. Report does not define "unreasonable"
3. Promote biosimilars and generics
 - a. More rigorously enforce laws against misleading statements on efficacy and safety of generics and biosimilars
 - b. Identify ways to reform patent system to prevent "ever-greening" - where manufacturers make tiny changes to a product to extend patent life - and "pay-to-delay" - where brand manufacturer pays generic / biosimilar manufacturer to delay launch
4. Increase transparency so patients and payers are aware of actual costs to them and other stakeholders of various drug options
5. Rejigger incentives to promote R&D on "valuable and accessible new treatments, not market gaming"
 - a. Report does not define "valuable," but does call out as low value "product hops" - where brand manufacturer makes a tiny (low-value) change to a drug and charges more for innovation
 - b. Create Advanced Research Projects Agency for Health

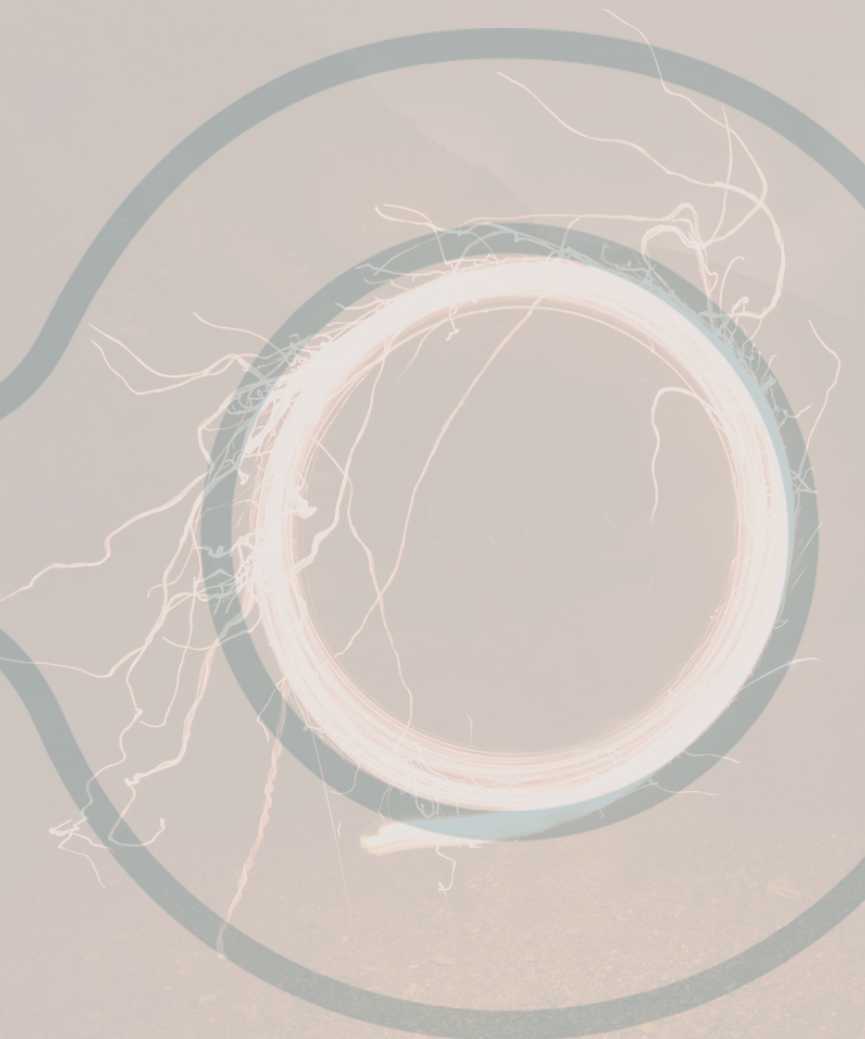


CONTEXT

President Biden issued Executive Order (EO) 14036, "Promoting Competition in the American Economy," on July 9, 2021. The EO identifies market failures that impede competition as targets for federal government intervention. The EO calls out drug pricing as an example. On September 9, 2021, the Department of Health and Human Services (HHS) issued a report in response to the EO. The HHS report outlines government intervention - including efforts already underway and proposed efforts - to reduce drug prices by increasing competition, innovation, and transparency.

CONCLUSIONS & POTENTIAL DIRECTION

With mid-term elections looming in 2022 and a highly polarized Congress, with a razor-thin split between the parties, little is likely to change significantly before 2023. If anything, politicians may cap financial responsibility in Part D, as this would help them get re-elected. **Until key stakeholders agree how to define a drug's value, how to quantify it, and how much US citizens are willing to pay for it, little will change.**



CONTACT:

MICHAEL.EPSTEIN@ASCENIAN-CONSULTING.COM