

# High-Cost Drugs: Impacts on the Medicaid Program

Matt Salo

Executive Director

The National Association of Medicaid Directors

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# National Association of Medicaid Directors (NAMMD)

- NAMMD created in 2011 to support the 56 state and territorial Medicaid Directors.
- Core functions include:
  - Develop consensus on critical issues and leverage their influence with respect to national policy debates;
  - Facilitate dialogue and peer to peer learning amongst the members; and
  - Provide best practices and technical assistance tailored to individual members and the challenges they face.

# Medicaid & Rx Drugs: Background

- Outpatient prescription drugs are an optional Medicaid benefit, but all Medicaid programs cover them
  - Mandatory for Medicaid expansion population
- The Medicaid Drug Rebate program
  - Mandatory coverage of FDA-approved drugs in exchange for rebates from manufacturers
  - States are responsible for collecting rebates
  - Medicaid programs may impose clinical protocols and prior authorization on drugs
  - Medicaid programs **CANNOT** exclude coverage of drugs, unlike private insurers

# Hepatitis C in 2014: A Shock to the System

- Late 2013, Gilead brings Sovaldi to market
- Priced at \$1,000 a pill, no competition until late Q4 2014
- Combination of more effective treatment, large treatable population, and high pricing = significant upfront costs for payers
- Questionable value proposition in the long term for any one payer

# Hepatitis C: Medicaid Programs React

- Significant Medicaid spending in Q1, Q2 2014 on hepatitis C
  - Some programs saw spending in these quarters outpace previous 2 years **combined**
- Used clinical protocols, prior authorization tools to ensure appropriate utilization
  - Fibrosis scores
  - Abstinence from substance use
  - Prescribing provider requirements
- Attempted to negotiate supplemental rebates, limited success until competitors entered market

# A Sign of What's to Come?

- Will the hepatitis C breakthrough pricing model apply to other specialty drug products in development?
- If so, how can payers adapt to a model which prioritizes upfront costs in exchange for perceived long-term value?
- The Medicaid program as currently structured does not have the tools to support this pricing model
  - Increases in the drug budget require hard choices in other program areas
- A new conversation about value must take place

# 21<sup>st</sup> Century Cures: Innovation at What Cost?

- Curative treatments are a universal good, but access must be safeguarded
- Patient safety under accelerated approval pathways requires flexibility in Medicaid coverage of new therapies
  - Current program requires coverage regardless of approval pathway
  - Concerns about Medicaid population's unique characteristics under accelerated approvals
- Fiscal integrity of public programs, including Medicaid, must be considered

# 21<sup>st</sup> Century Cures: Innovation at What Cost?

- Extended exclusivity periods inhibit competitors' entrance into the market
- Lack of competition drives up costs for all payers, particularly Medicaid
  - Medicaid programs utilize supplemental rebates to expand access to new therapies
  - Negotiating rebates is contingent on competitors in the market
- These dynamics must be considered in any legislation aimed at overhauling the drug approval process