

# Pharmaceuticals & Public Health Crises: State Strategies to Improve Access While Ensuring Fiscal Sustainability

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**NATIONAL GOVERNORS ASSOCIATION**

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# NGA Project – Overview

**Launched:** November 2017

**States:** Delaware, Louisiana, Massachusetts, New Mexico, New York, Ohio, Oregon, Rhode Island, Virginia and Washington

**Goal:** Identify potential strategies for states to address public health crises by increasing access to pharmaceuticals while ensuring fiscal sustainability of public programs

**Structure:**

- Intensive work with states to collect data and identify potential strategies
- Series of roundtable discussions with states and key stakeholders to vet strategies

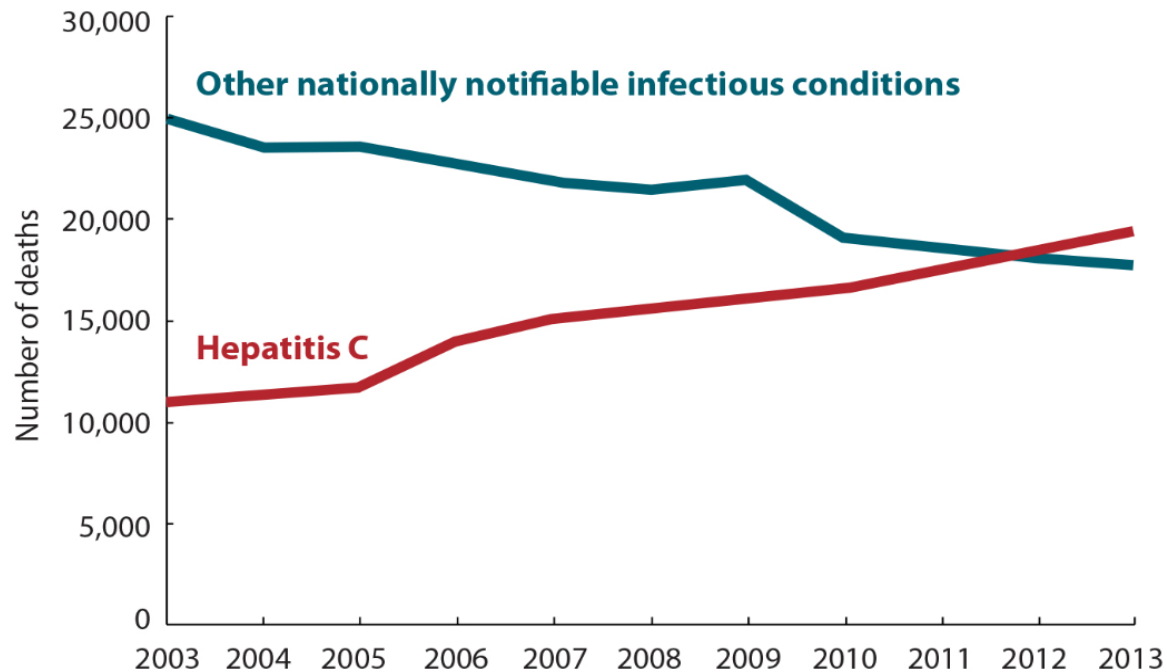
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## Defining “Public Health Crisis”

“Public health crises include morbidity and mortality arising from hazards and vulnerabilities whose scale, rapid onset, or unpredictability stresses or overwhelms the routine capabilities of government, the private sector, and individuals. Addressing such crises requires proactive efforts by all sectors designed to prevent, detect, and mitigate threats by deploying and adapting plans and resources to meet the emerging needs of the situation.”

# Public Health Crisis: Hepatitis C

**Annual number of hepatitis C-related deaths vs. other nationally notifiable infectious conditions in the US, 2003-2013**



Source: Centers for Disease Control and Prevention

# Roll Up of State Data: Hepatitis C

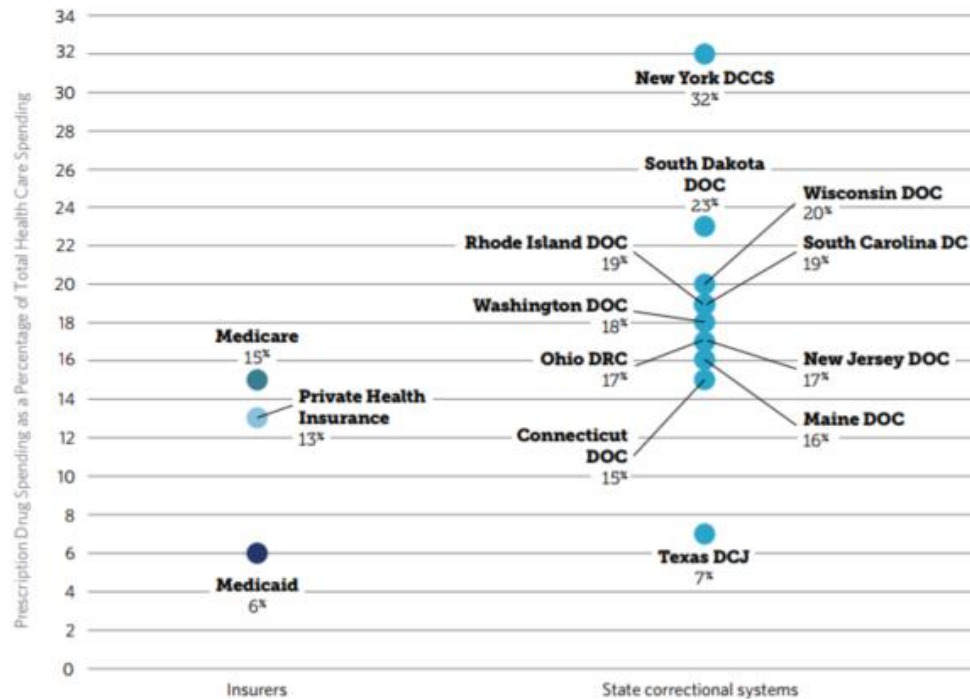
## Ranges and Averages Across States

- **Prevalence:** 1% - 4.85%; Average: 2.15%
- **Medicaid average cost per treatment:** ~ \$25,000
  - Percentage of Medicaid budget necessary to treat all enrollees with Hepatitis C in select states: 3.2%, 5.8%, 8.8%
- **Corrections average cost to treat:** \$58,000
  - Percentage of corrections services budget necessary to treat all incarcerated with Hepatitis C in select states: 4.3%, 8.0%

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# Pharmacy Spending in Corrections

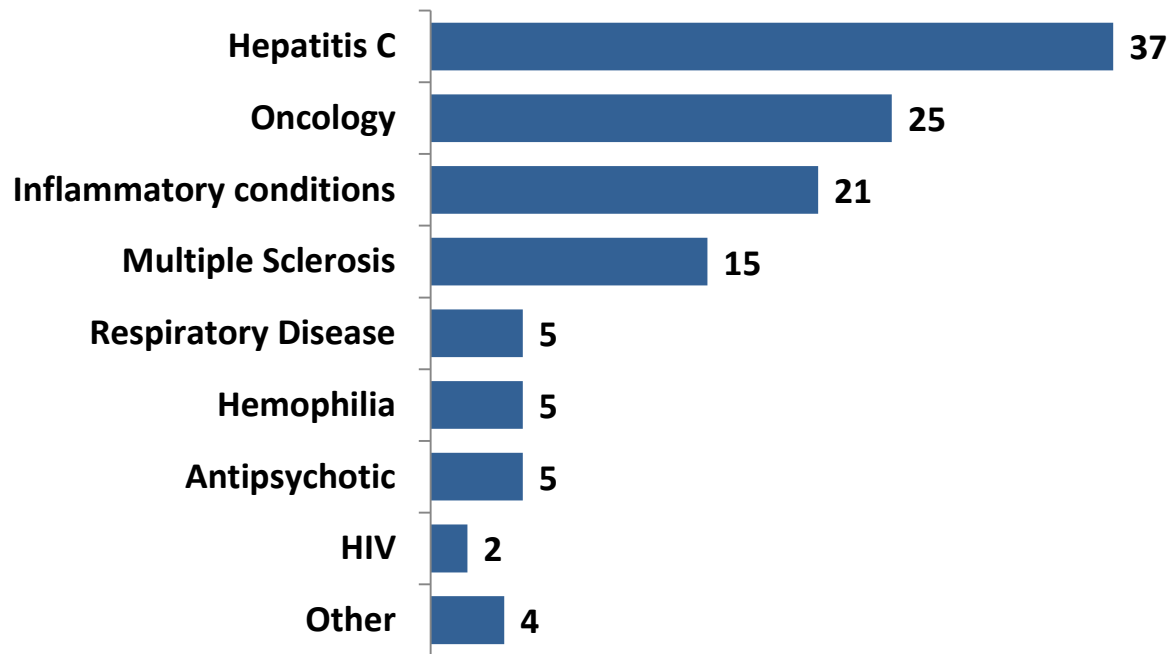
Drug Spending as a Share of Total Health Care Spending in Departments of Corrections, 2015



Source: 49-state surveys of DOCs developed and administered by The Pew Charitable Trusts.

# Pharmacy Spending in Corrections

Most expensive drugs by unit price in DOCs, 2015



Source: 49-state surveys of DOCs developed and administered by The Pew Charitable Trusts.

# Trend: Specialty Medicines

## Specialty Medicines

- In the past five years, proportion of overall pharmacy spend rose from 24.7 percent in 2008 to 46.5 percent in 2017.
- In 2017, accounted for \$9.8 billion of \$12 billion net growth in brand-name drug spending
- Account for 0.9 percent of claims and 32 percent of Medicaid drug spending
- Spending will reach \$400 billion by 2020, or about 9.1 percent of all health care spending (just shy of current spending on all drugs)



# Trend: Price Increases

## Price Increases

- Price increases on existing drugs is common practice – occurring for hundreds of products every year
- Example: Naloxone
  - One product rose from \$690 to \$4,500 in two years
  - One product was priced at less than \$1 as recently as 10 years ago
- Medicaid is uniquely protected from significant price increases, but other state programs are not

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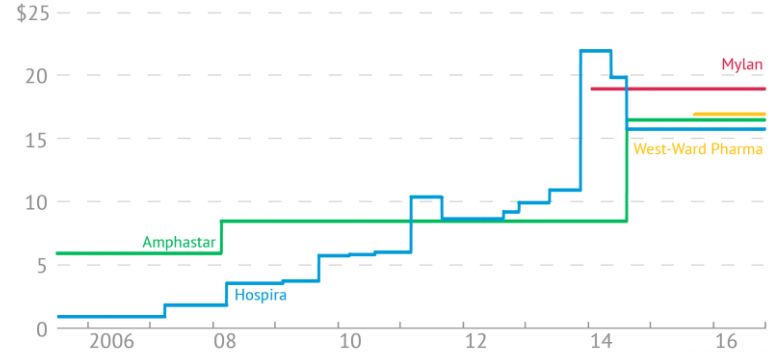
# Naloxone Pricing

Recent and Current Prices for Naloxone.\*

Naloxone Product	Manufacturer	Previous Available Price (yr)	Current Price (2016)
Injectable or intranasal, 1 mg-per-milliliter vial (2 ml) (mucosal atomizer device separate)	Amphastar	\$20.34 (2009)	\$39.60
Injectable			
0.4 mg-per-milliliter vial (10 ml)	Hospira	\$62.29 (2012)	\$142.49
0.4 mg-per-milliliter vial (1 ml)	Mylan	\$23.72 (2014)	\$23.72
0.4 mg-per-milliliter vial (1 ml)	West-Ward	\$20.40 (2015)	\$20.40
Auto-injector, two-pack of single-use prefilled auto-injectors (Evzio)	Kaleo (approved 2014)	\$690.00 (2014)	\$4,500.00
Nasal spray, two-pack of single-use intranasal devices (Narcan)	Adapt (approved 2015)	\$150.00 (2015)	\$150.00

## The cost to reverse an overdose

Price of naloxone hydrochloride, per 1 ml



Source: Truven Health Analytics | Graphic by Nicholas Wells

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# NGA Project – Strategies

## **Establish a Medicaid Spending Cap for Pharmaceuticals**

Establish a target or capped Medicaid spending amount for pharmaceuticals, and develop policies that allow for negotiation or requirement of lower prices for certain products should spending exceed the established cap. This strategy can create a mechanism by which to address the unpredictability of prescription drug costs, including when new drugs without competition enter the market.

## **Pursue Alternative Payment Mechanisms (Subscription Model)**

Pursue alternative payment mechanisms such as a subscription model, which involves entering into an agreement with a pharmaceutical manufacturer in which the state pays a negotiated price for a certain volume of a drug over a specified period of time to increase access in a way that recognizes state budget constraints.

# NGA Project – Strategies

## **Consider Options for Excluding Select Drugs from Medicaid Coverage**

Consider options for excluding select drugs from Medicaid coverage to strengthen state negotiating power. Such flexibility would require federal approval, which under the current administration would likely require opting out of the federal Medicaid Drug Rebate Program (MDRP) altogether.

## **Engage in Bulk and Pooled Purchasing**

Leverage the purchasing power of one or more programs within or across states by purchasing products in bulk or in a pooled arrangement on behalf of those programs, with the goal of reducing costs through negotiated discounts for increased volume.

## **Determine and Pay Value-Based Prices**

Determine and pay value-based prices for drug treatments by incorporating value assessments, which could include a variety of methodologies and metrics, into policies and purchasing approaches within and across state health programs.

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# NGA Project – Strategies

## **Maximize Discounts for the Incarcerated Population through the 340B Drug Discount Program**

Increase discounts for prescription drugs for the incarcerated population by contracting for the provision of those health care services by covered entities under the 340B Drug Discount Program (340B Program), where applicable.

## **Explore Whether the Federal Government Would Invoke Section 1498 of Title 28 of the United States Code (U.S.C.)**

Explore whether the federal government would invoke 28 U.S.C. 1498 (section 1498), which allows them to use or acquire patents (such as those for pharmaceuticals) in exchange for “reasonable and entire” compensation to the patent holder for such use.

# NGA Project – Strategies

## **Pursue Legal and Regulatory Options to Foster Greater Transparency in the Pharmaceutical Market**

Foster greater transparency in the pharmaceutical market by pursuing state laws and regulations that require manufacturers and others in the pharmaceutical supply chain, such as wholesalers, health plans, pharmacy benefit managers and pharmacies, to publicly report details on prices, price changes, research and development, business relationships, marketing and advertising costs and other information needed to inform policy and the public.

## **Explore Whether the Federal Government Would Allow Nominal Pricing for Correctional Facilities**

Explore whether the secretary of the U.S. Department of Health and Human Services (HHS) would include state and local correctional facilities among the safety net providers exempt from the best price requirement of the MDRP, which would create the regulatory conditions necessary for state and local governments to negotiate nominal prices (less than 10 percent of the average manufacturer price) for corrections populations.

# Pipeline

- Continued focus on specialty medicine development, especially for rare/orphan diseases (e.g. hemophilia and cystic fibrosis) and cancer (CAR-T)
- Increasing focus on gene therapies that will have large price tags
- Primary therapy classes in the specialty drug pipeline: migraine, inflammatory conditions, MS, cancer, and HIV, autism
- Biosimilars offer opportunity for cost reduction, but have faced significant approval hurdles

# Questions?

- Are there strategies/approaches (in NGA's paper or otherwise) to help address cost and ensure access that seem most appealing or viable to you? Are there any that cause concern?
- How can Medicaid, Corrections, and Public Health effectively partner to establish and implement a Hep C elimination strategy (incorporating strategies to address cost, engagement, education, adherence, and other barriers)? Can any of you speak to how you are currently working on this in your state?