U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Transforming Health Care

Brian E. Shiozawa M.D.
Regional Director, Region 8 (CO, MT, ND, SD, UT, WY)
US Department of Health and Human Services

HHS.GOV/OPIOIDS

FDA
Food and Drug Administration

2017 Budget Outlay:
$2,698M
FTEs: 17,134

2017 Budget Outlay:
$3,672M
FTEs: 615

SAMHSA

HRSA
Health Resources & Services Administration

2017 Budget Outlay:
$10,372M
FTEs: 2,211

2017 Budget Outlay: $300M
FTEs: 325

AHRQ

INDIAN HEALTH SERVICE · PHS · 1955

2017 Budget Outlay:
$5,191M
FTEs: 15,096

2017 Budget Outlay:
$1,006,929M
FTEs: 6,495

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

2017 Budget Outlay:
$7,920M
FTEs 11,948

2017 Budget Outlay:
$54,479M
FTEs: 1,352

ADMINISTRATION FOR CHILDREN & FAMILIES

NIH
National Institutes of Health

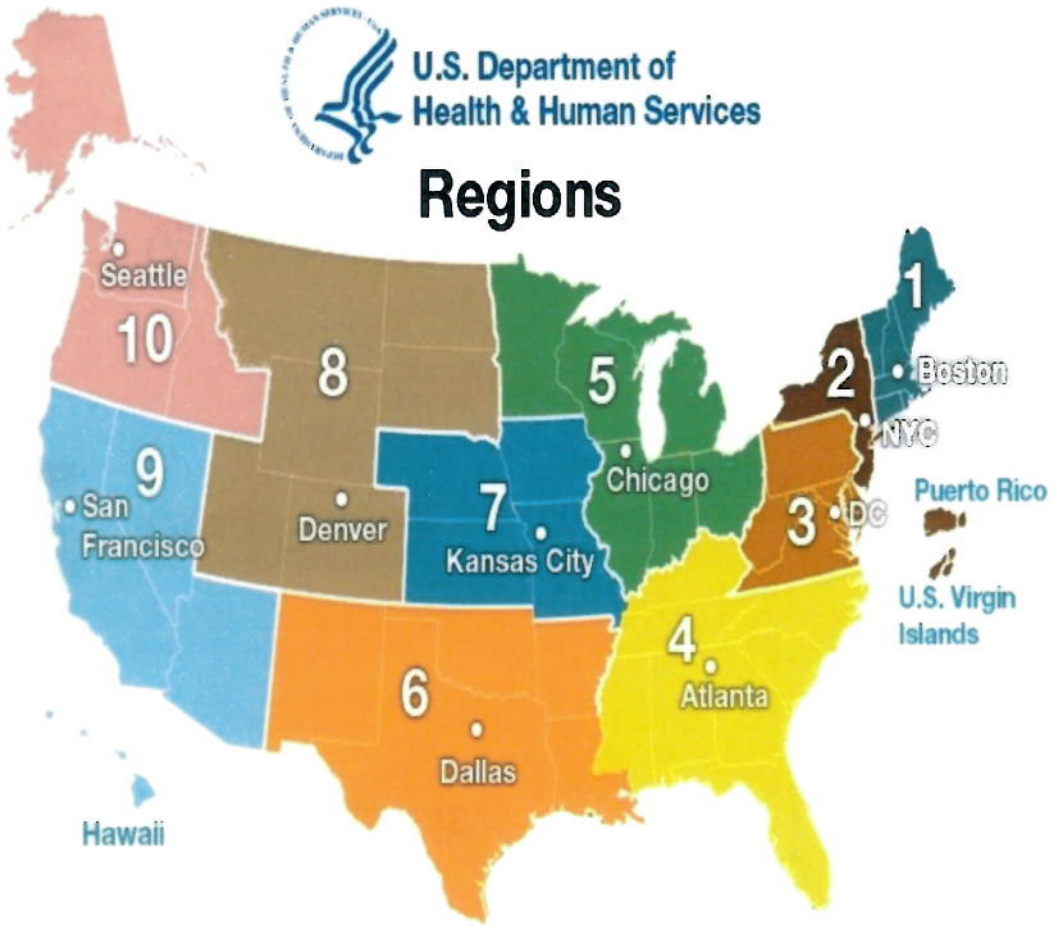
2017 Budget Outlay:
$32,117M
FTEs: 18,105

2017 Budget Outlay:
$1,956M
FTEs: 199

ACL
Administration for Community Living

HHS Office of the Regional Director

- The Office of Intergovernmental and External Affairs hosts 10 HHS Regional Offices led by a President-appointed Regional Director.
- The Secretary's Regional Directors ensure the Department maintains close contact with state, local, and tribal partners and addresses the needs of communities and individuals served through HHS programs and policies.



Secretary Azar's Priorities

HHS.GOV/OPIOIDS

1 Opioids Crisis

2 Drug Pricing

3 Value Based Care

4 Affordable Health Insurance

The opioid epidemic by the numbers

4.4%

of the population, or 11.5 million – have Opioid Misuse Disorder.

170

people die from drug overdoses a day – 116 are opioid-related.

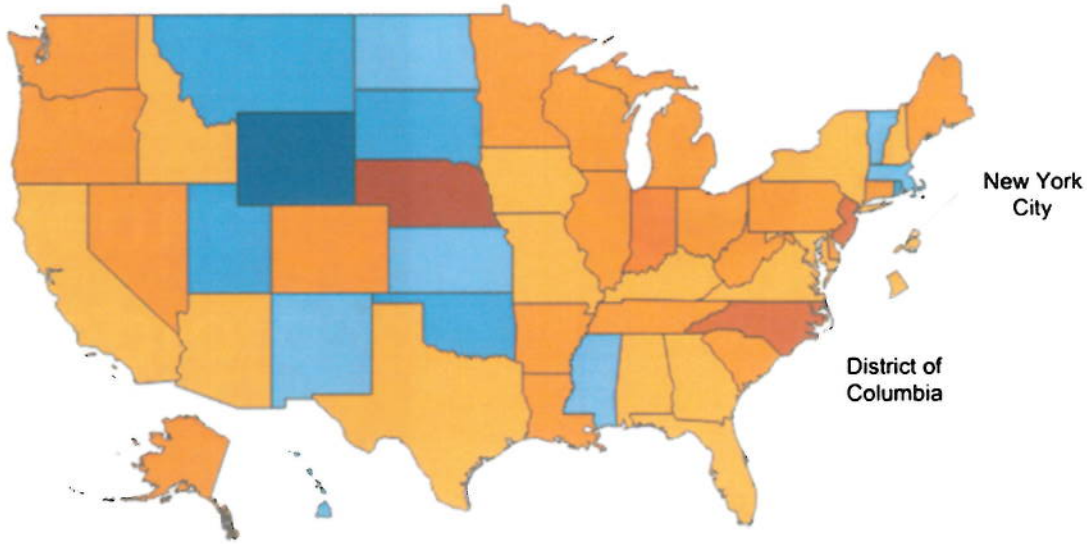
13%

Increase in overdose deaths 2016-2017

HHS.GOV/OPIOIDS

STATE COMPARISONS (CDC, August 2018)

Figure 1b. Percent Change in Predicted 12 Month-ending Count of Drug Overdose Deaths, by Jurisdiction: January 2017 to January 2018



Select predicted or reported number of deaths

- (●) Predicted
- ( ) Reported

Percent Change for United States

6.6

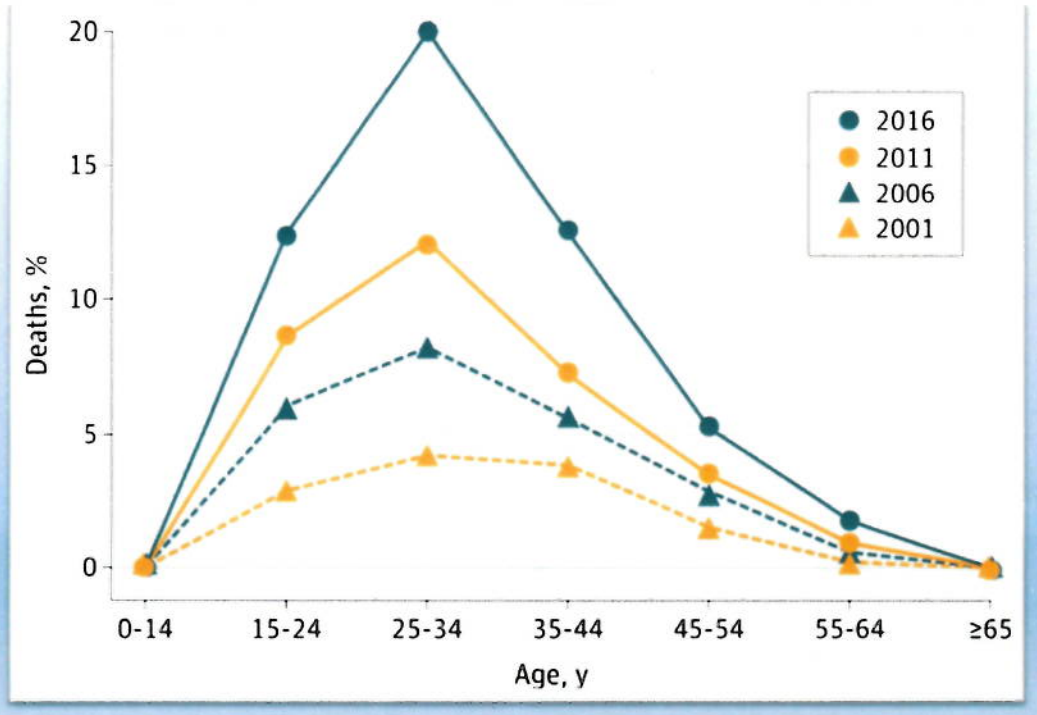
Legend for Percent Change in Drug Overdose Deaths Between 12-Month Ending Periods

-33.3  33.3

HHS.GOV/OPIOIDS

PROPORTION OF DEATHS RELATED TO OPIOIDS BY AGE GROUP

2001, 2006, 2011, and 2016



"The Burden of Opioid-Related Mortality in the United States"

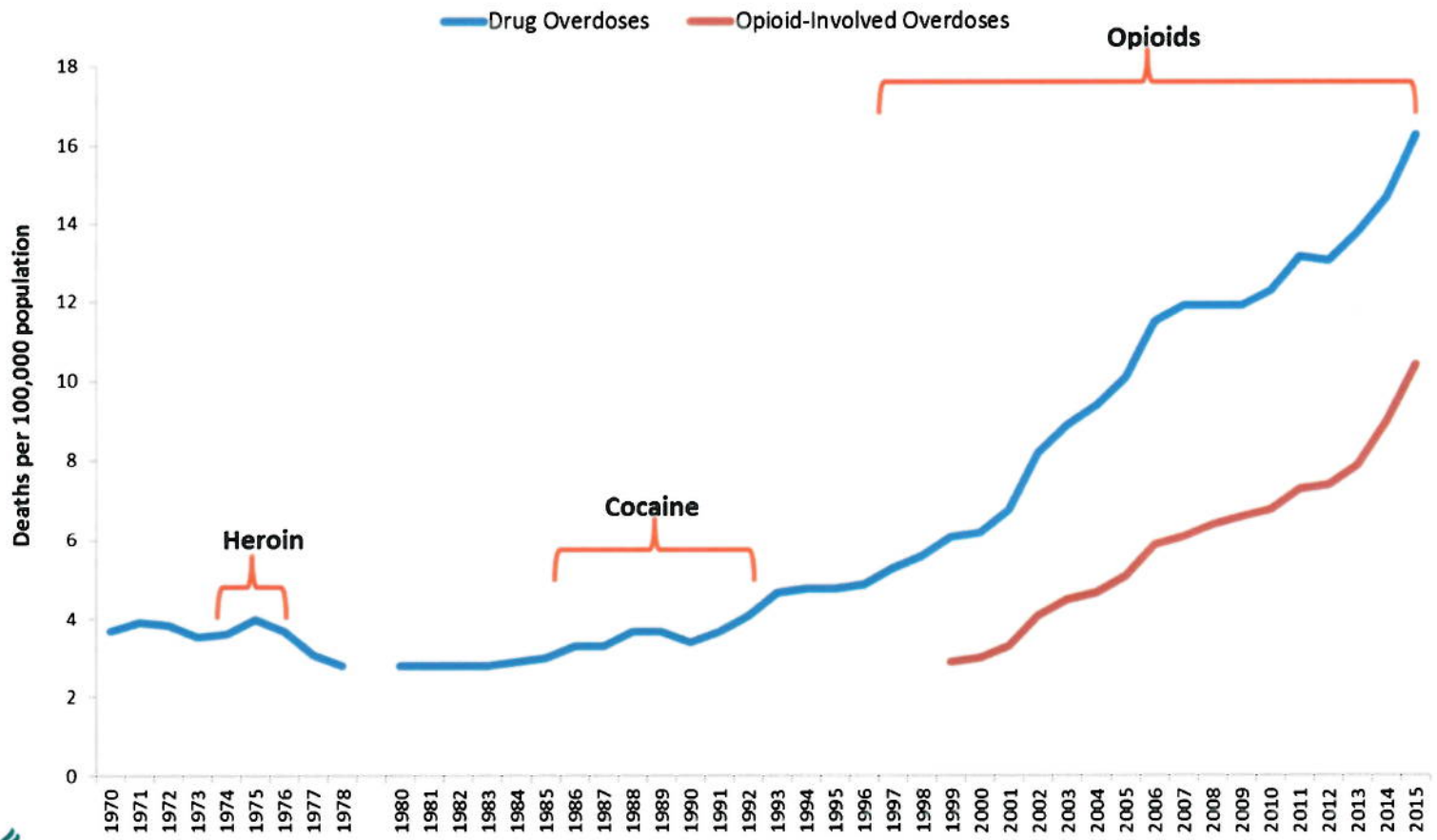
JAMA Network™

June 2018

HHS.GOV/OPIOIDS

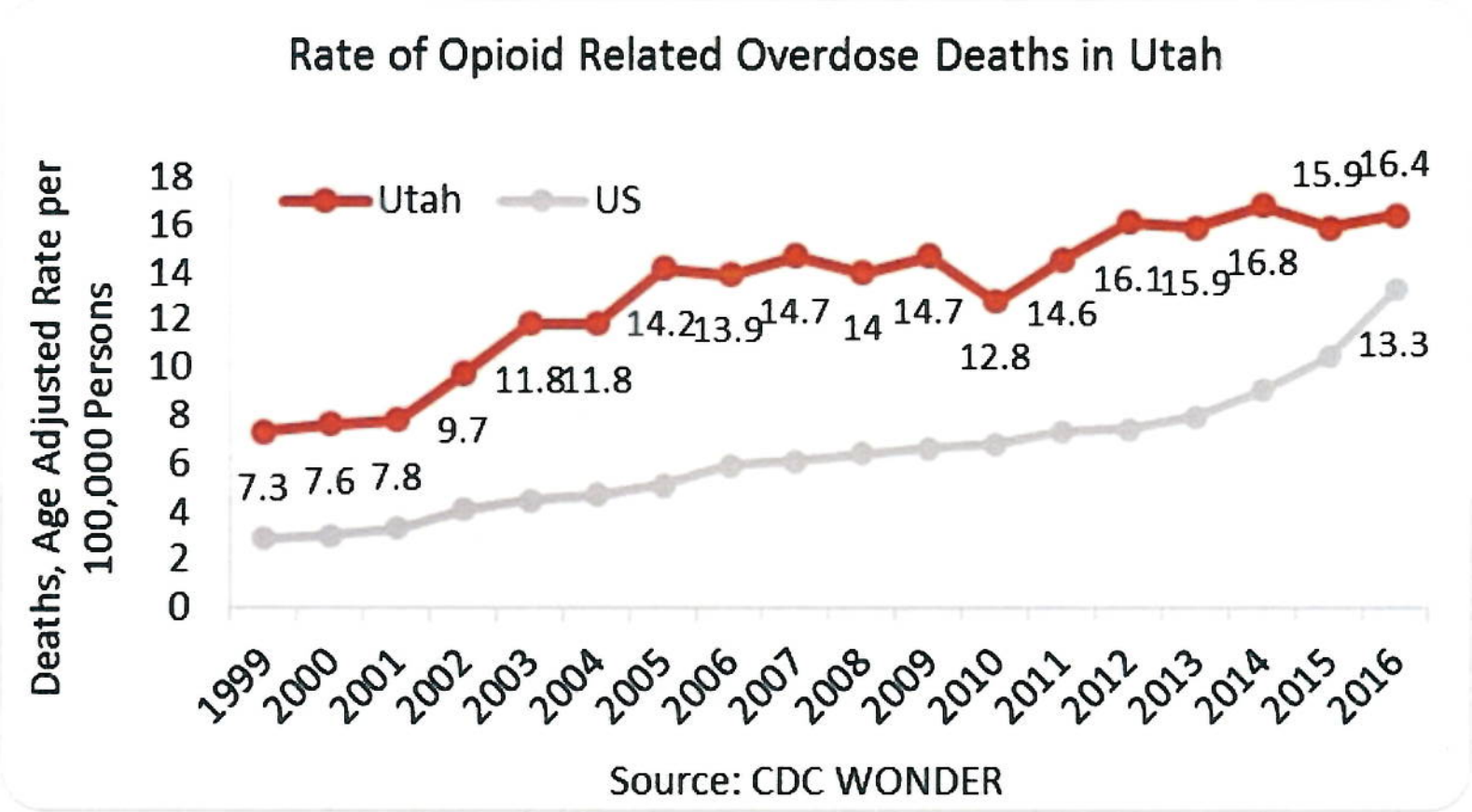
The crisis in context

Drug overdose deaths from 1970–2015

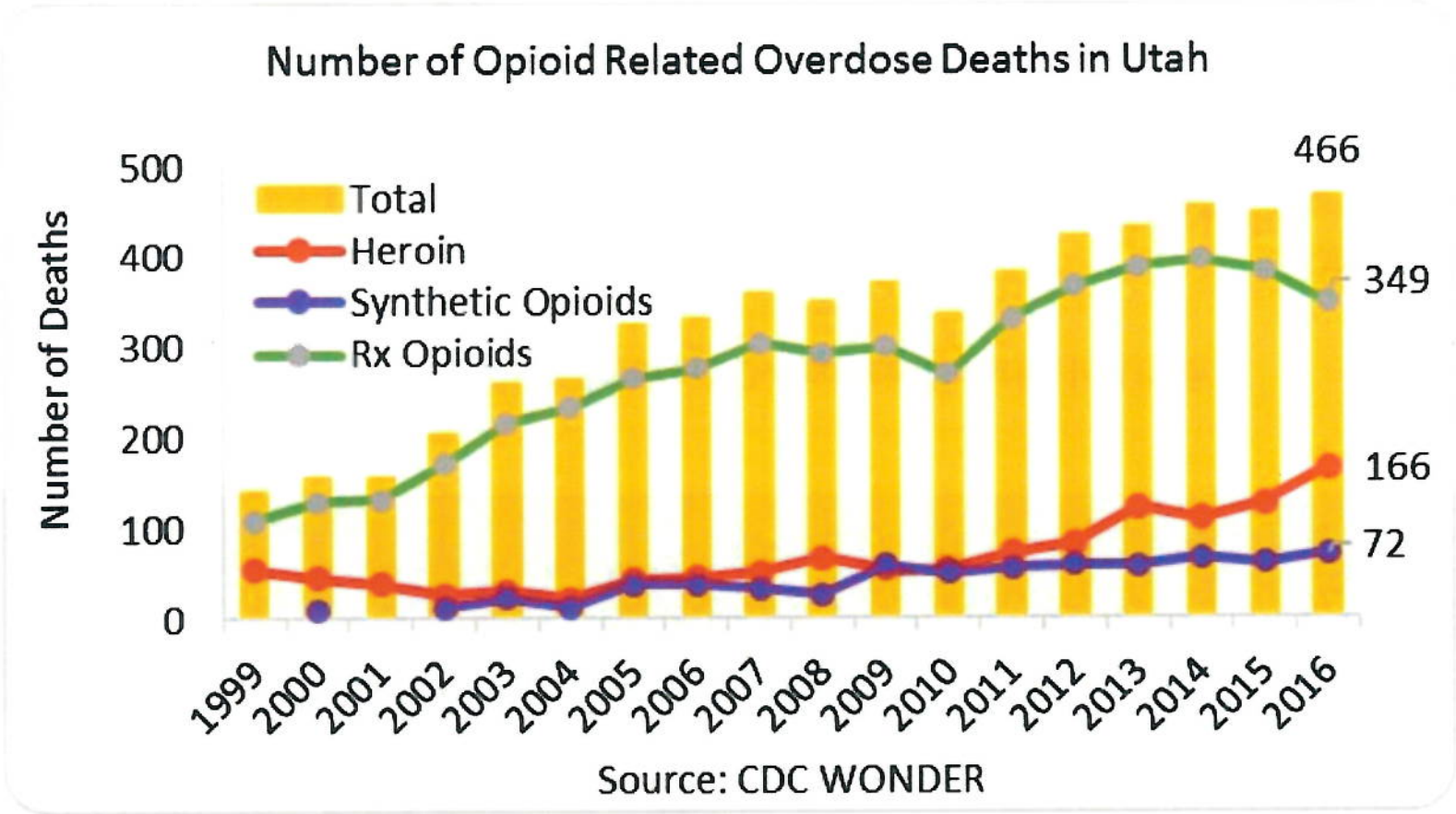


HHS.GOV/OPIOIDS

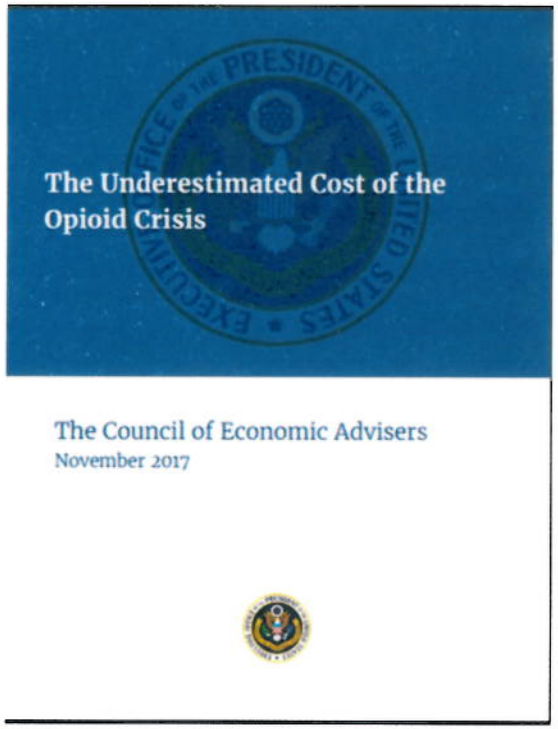
The crisis in context



The crisis in context



CEA Report:



- Diverges from the previous literature by quantifying the costs of opioid-related overdose deaths based on economic valuations of fatality risk reduction, the 'value of a statistical life'(VSL)"
- Considers the costs of non-fatalities: estimated costs per person for those who do not die within the year
- **Estimated opioid crisis cost: Over $500 billion in 2015**

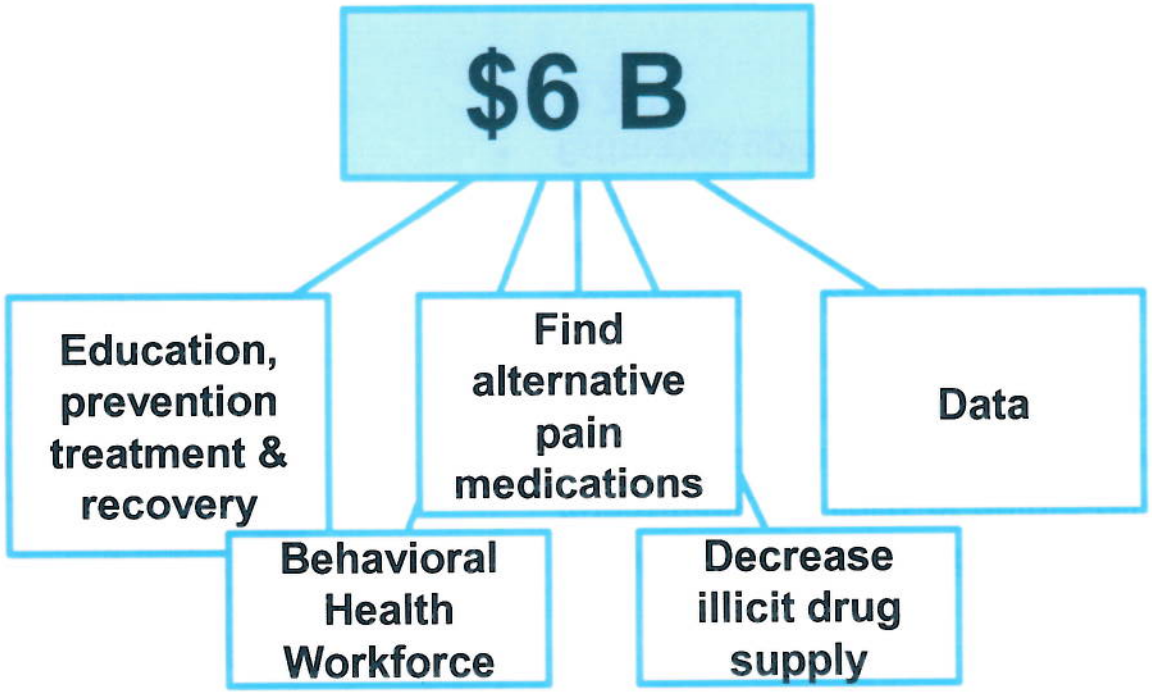
Table 2: Estimated Cost of the Opioid Crisis in 2015 (2015 $)

VSL Assumption	Fatality Costs	Non-fatality Costs	Total Costs
Age-dependent	$431.7 billion	$72.3 billion	$504.0 billion
Low	$221.6 billion	$72.3 billion	$293.9 billion
Middle	$393.9 billion	$72.3 billion	$466.2 billion
High	$549.8 billion	$72.3 billion	$622.1 billion

https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf

FY2019

Additional New Funding



HHS.GOV/OPIOIDS

Drug Pricing

Secretary Azar: "The time to act is now: Not only are costs spiraling out of control, but the scientific landscape is changing as well. Securing the next generation of cures for the next generation of American patients will require radical reforms to how our system works."

HHS has identified four challenges in the American drug market:

1. High list prices for drugs
2. Seniors and government programs overpaying for drugs due to lack of the latest negotiation tools
3. High and rising out-of-pocket costs for consumers
4. Foreign governments free-riding of American investment in innovation

Under President Trump, HHS has proposed a comprehensive blueprint for addressing these challenges, identifying four key strategies for reform:

1. Improved competition
2. Better negotiation
3. Incentives for lower list prices
4. Lowering out-of-pocket costs

HHS's blueprint encompasses two phases:

1. Actions the President may direct HHS to take immediately
2. Actions HHS is actively considering, on which feedback is being solicited

Drug Pricing

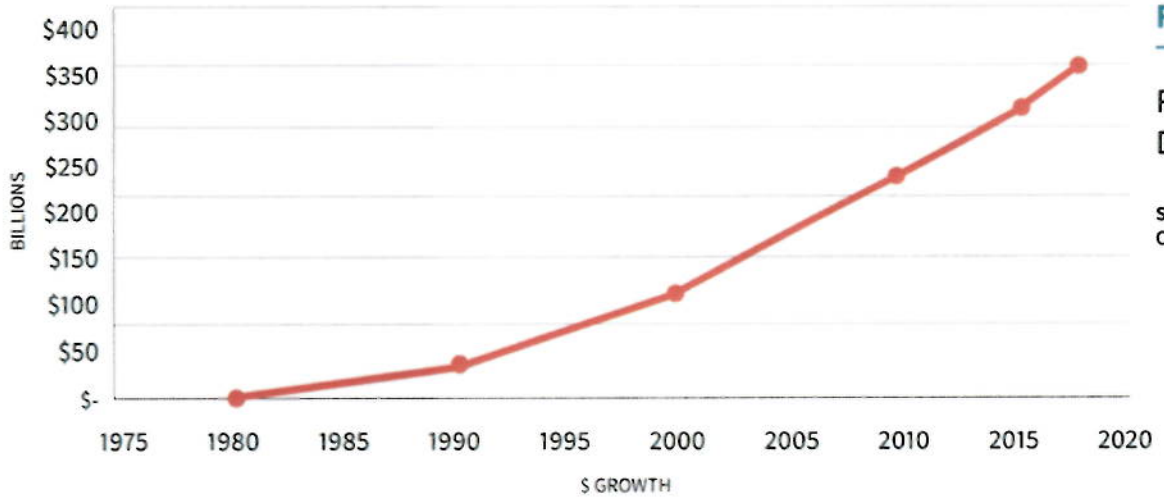


FIGURE 2

Retail Prescription Drug Spend

SOURCE
CMS Office of the Actuary

https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

Drug Pricing

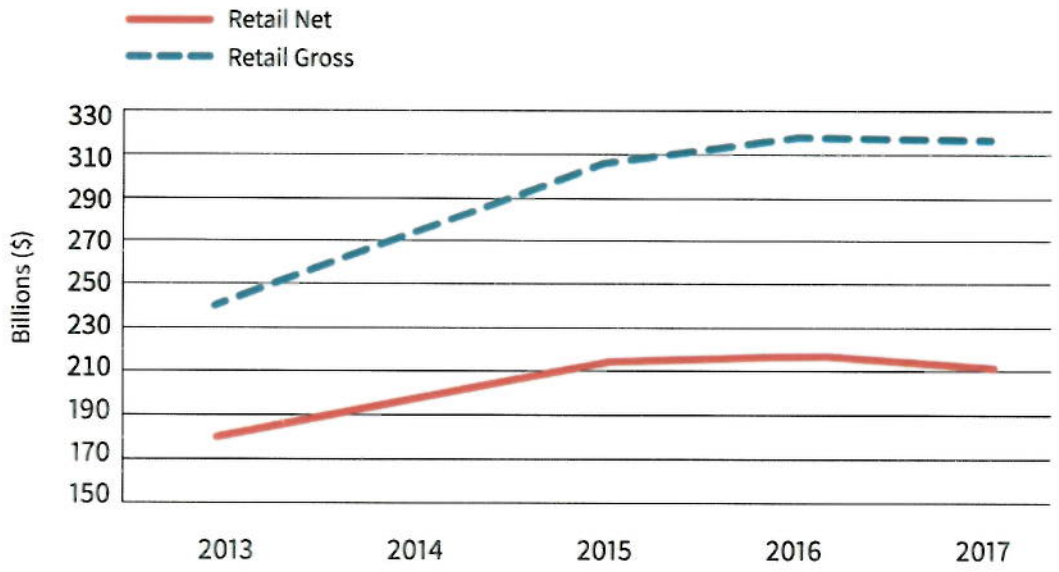


FIGURE 3

List Price vs.
Net Price

SOURCE
Medicine Use and Spending in the U.S.; A Review of 2017 and Outlook to 2022. April 19, 2018

https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

Complex U.S. Pharmaceutical Market

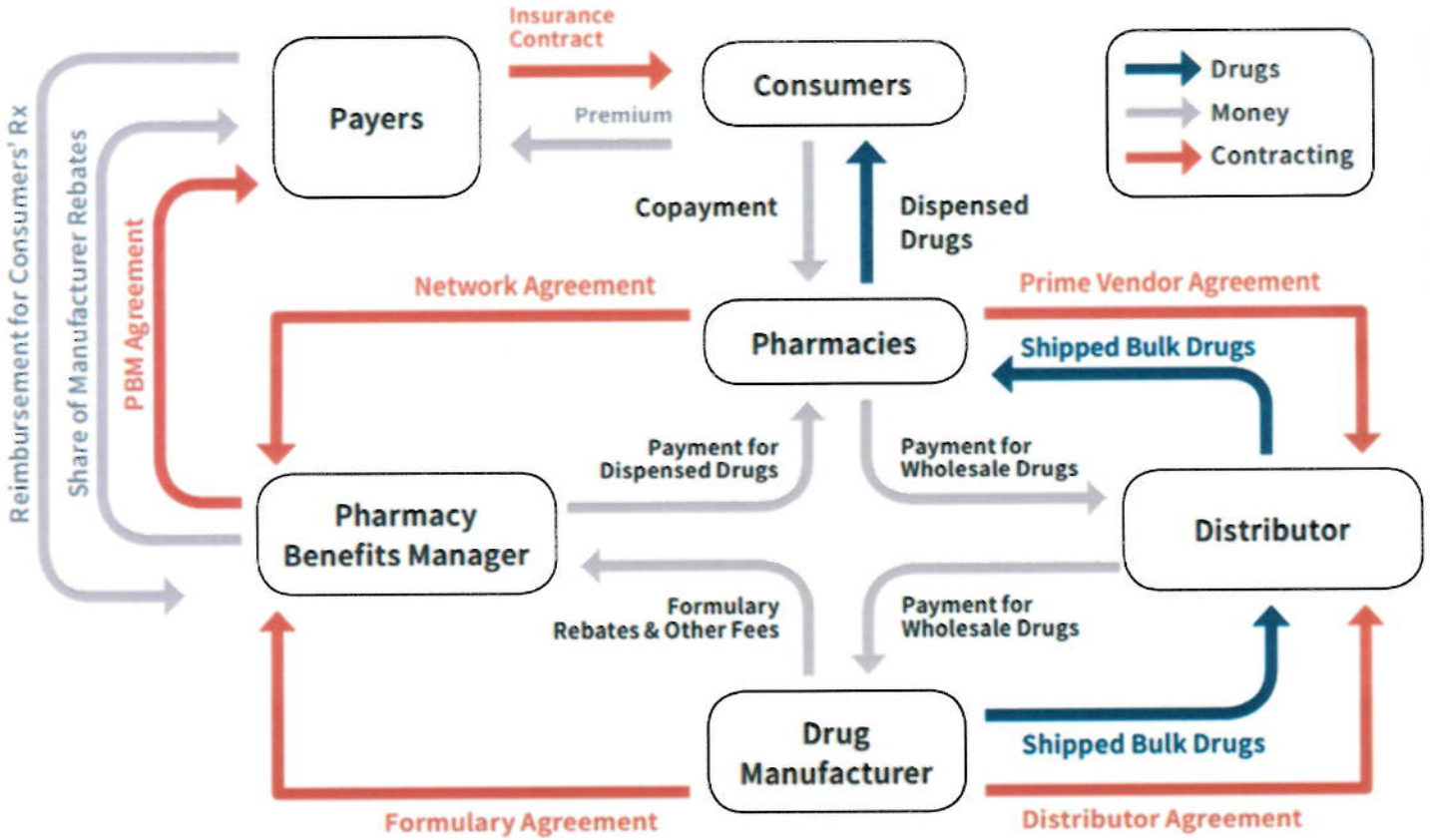


FIGURE 1

ADAPTED FROM: Fein, Adam. J., The 2016 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2016.

https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

Drug Pricing

Lowering Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients

HHS Secretary Alex Azar and Inspector General Daniel Levinson have proposed a regulation that would create incentives to lower list prices and reduce out-of-pocket spending on prescription drugs.

WHAT'S WRONG WITH TODAY'S SYSTEM

1. Rebates reward ever-increasing list prices.
2. Drug companies pay rebates and other payments to PBMs, but these payments are not reflected in patient out-of-pocket drug costs.
3. The current rebate system discourages the use of safe, effective lower-priced generics and biosimilars.

WHAT THIS MEANS FOR PEOPLE WITH MEDICARE

Replacing safe harbor protections for opaque rebates with transparent discounts is expected to lead to lower Part D spending for Medicare beneficiaries as a whole, because the projected reductions in out-of-pocket costs are larger than potential increases in premiums.

WHAT THIS MEANS FOR PRIVATE PLANS

This rule exercises HHS' regulatory authority to address the rebate system as it relates to federal healthcare programs. Congress has more power to prohibit rebates in commercial insurance.

HOW THE PROPOSAL WOULD WORK

This proposal would update the discount safe harbor to explicitly exclude reductions in price offered by drug manufacturers to PBMs, Part D, and Medicaid managed care plans from the safe harbor's definition of a "discount." It would also create a new safe harbor designed specifically for price reductions on pharmaceutical products, but only those that are reflected in the price charged to the patient at the pharmacy counter.

Drug Pricing

Part of the Presidents Blueprint

Replacing the rebate system with upfront discounts for patients was one of the ideas put forth in President Trump's "American Patients First" blueprint for lowering prescription drug prices and out-of-pocket costs. Today's proposal will also enhance other key ideas from the blueprint that have already been implemented or are in the process of implementation, including:

- Providing new tools for Medicare Part D plans to negotiate deeper discounts for patients, which under today's proposal will be directly reflected in patients' cost-sharing.

- Requiring television advertisements for prescription drugs to disclose the drug's list price, which is currently used to calculate many patients' cost sharing and is expected to more closely resemble many drugs' total net cost after the implementation of today's proposal.

- Cutting down on practices that impede the approval and marketing of generic drugs and biosimilars, which are expected to be made more competitive by the replacement of rebates with upfront discounts.

Value Based Care

Four areas of emphasis for building a system that delivers value:

1. Maximizing health IT such as Medicare's Blue Button and continued work on interoperability.

2. Improving transparency in price and quality, including a CMS proposal disclosure of drug prices in TV ads and posting hospital charges in machine readable, accessible format.

3. Pioneering bold new models in Medicare and Medicaid that emphasize patient centered medical care and empower states to develop their own innovative solutions, including 1115 Medicaid waivers and 1332 state flexibility waiver, as well as Direct Private Contracting in Medicare.

4. Presidential Executive Order: Removing government burdens starting with a comprehensive review of regulations.

Affordable Health Insurance: A Continued Focus at HHS

ACA Highlights

- Signed into law on March 23, 2010
- Created the Health insurance Marketplace: ACA health exchanges were fully certified and operational by January 1, 2014, under federal law.
- Preexisting Conditions:
    - Individual and group health plans must guarantee issue policies to all applicants, regardless of health status or other factors.
- Remove lifetime caps on how much care is paid if consumer is sick.
- Children up to age 26 may stay on parents health plan.
- Tax credits for plans purchased on the Health Insurance Marketplace: Household income between 100% to 400% FPL. (FPL based individually up to a family of 4)
- 80/20 rule: insurance companies must spend at least 80 cents of your premium dollar on your health care or improvements to care.
- Plans on the Marketplace must cover 10 Essential health benefits including: Ambulatory patient services, Emergency services, Hospitalization, Maternity and newborn care, Mental health and substance use disorder services, including behavioral health treatment, Preventive and wellness services and chronic disease management etc.
- CMS Innovation Center established by section 1115A of the Social Security Act (as added by section 3021 of the Affordable Care Act).
    - Congress created the Innovation Center for the purpose of testing "innovative payment and service delivery models to reduce program expenditures ...while preserving or enhancing the quality of care" for those individuals who receive Medicare, Medicaid, or Children's Health Insurance Program (CHIP) benefits.

Affordable Health Insurance: A Continued Focus at HHS

Affordable Health Insurance

- The Tax Cuts and Jobs Act **repealed** the individual **penalty** for not having health insurance, but that provision takes effect 2019.
- **Executive Order**: The Secretaries of the Treasury, Labor, and Health and Human Services published a proposed rule to consider allowing short-term, limited-duration insurance to cover longer periods and be renewed by the consumer on February 21, 2018 in response to both stakeholder input in the Request for Information "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients," as well as Executive Order 13813 entitled "Promoting Healthcare Choice and Competition Across the United States."

Resulted in Short Term Limited Duration Insurance: Provides consumers with more affordable options for health coverage. They will now have the ability to purchase short-term, limited-duration insurance policies that:

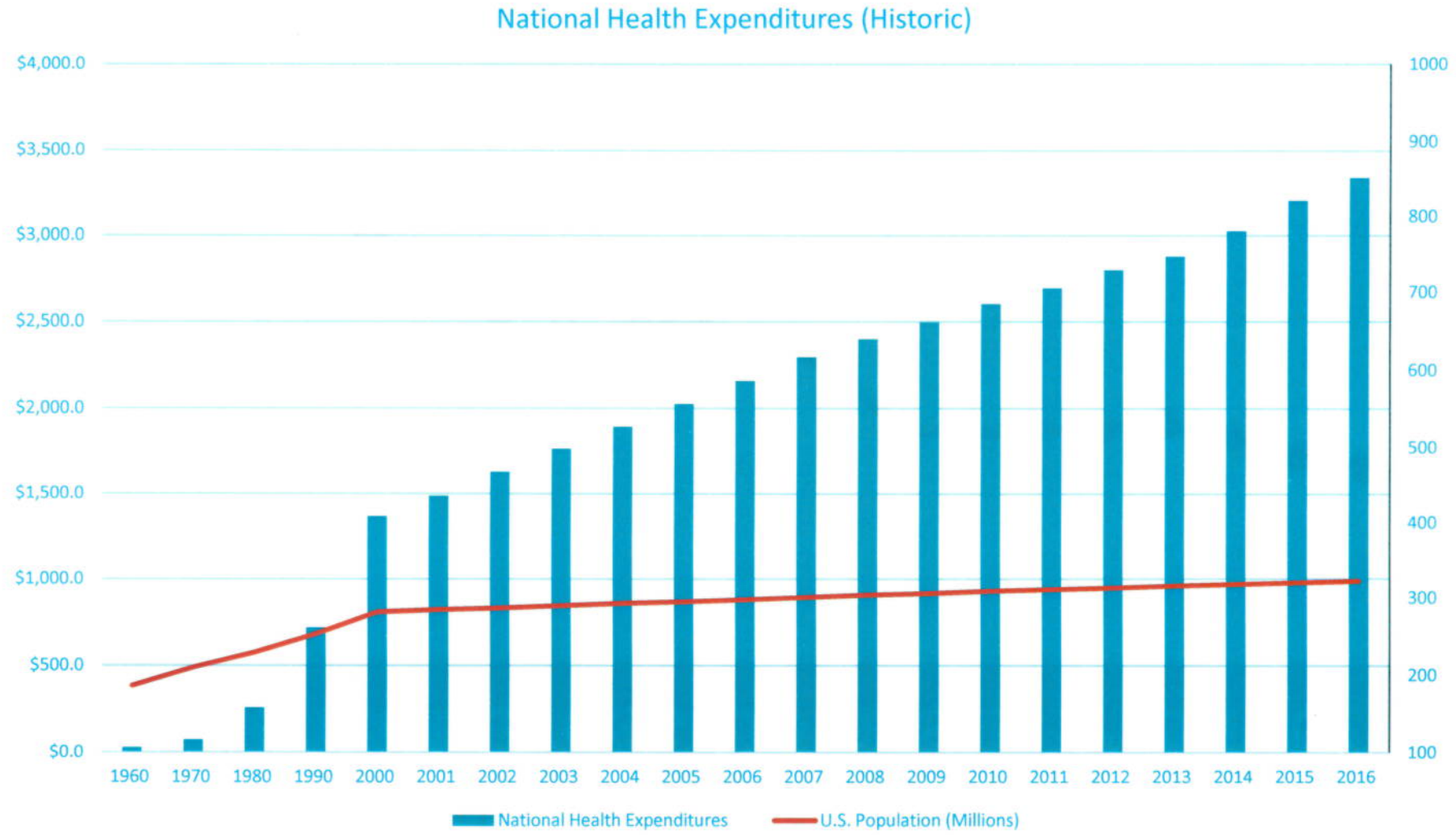
- Are less than 12 months;
- Contain important language to help them understand the coverage they are getting; and
- May be renewed for up to 36 months.

Enrollment in Private Health Insurance, Medicaid, and Medicare, and the Uninsured (Levels in Millions)

	2013	2014	2015	2016
Private Health Insurance	**187.6**	**192.8**	**196.3**	**196.4**
Employer Sponsored	169.2	169.8	172.2	173.1
Individual	20.0	24.5	25.6	24.8
Marketplace		*5.4*	*9.0*	*10.0*
Medicaid	**58.9**	**65.9**	**69.1**	**71.2**
Medicaid Newly Eligible		6.6	9.6	11.4
Medicare	**51.3**	**52.8**	**54.3**	**55.8**
Uninsured	**44.2**	**35.5**	**29.5**	**28.6**
Insured Share of Population	**86.0%**	**88.8%**	**90.8%**	**91.1%**

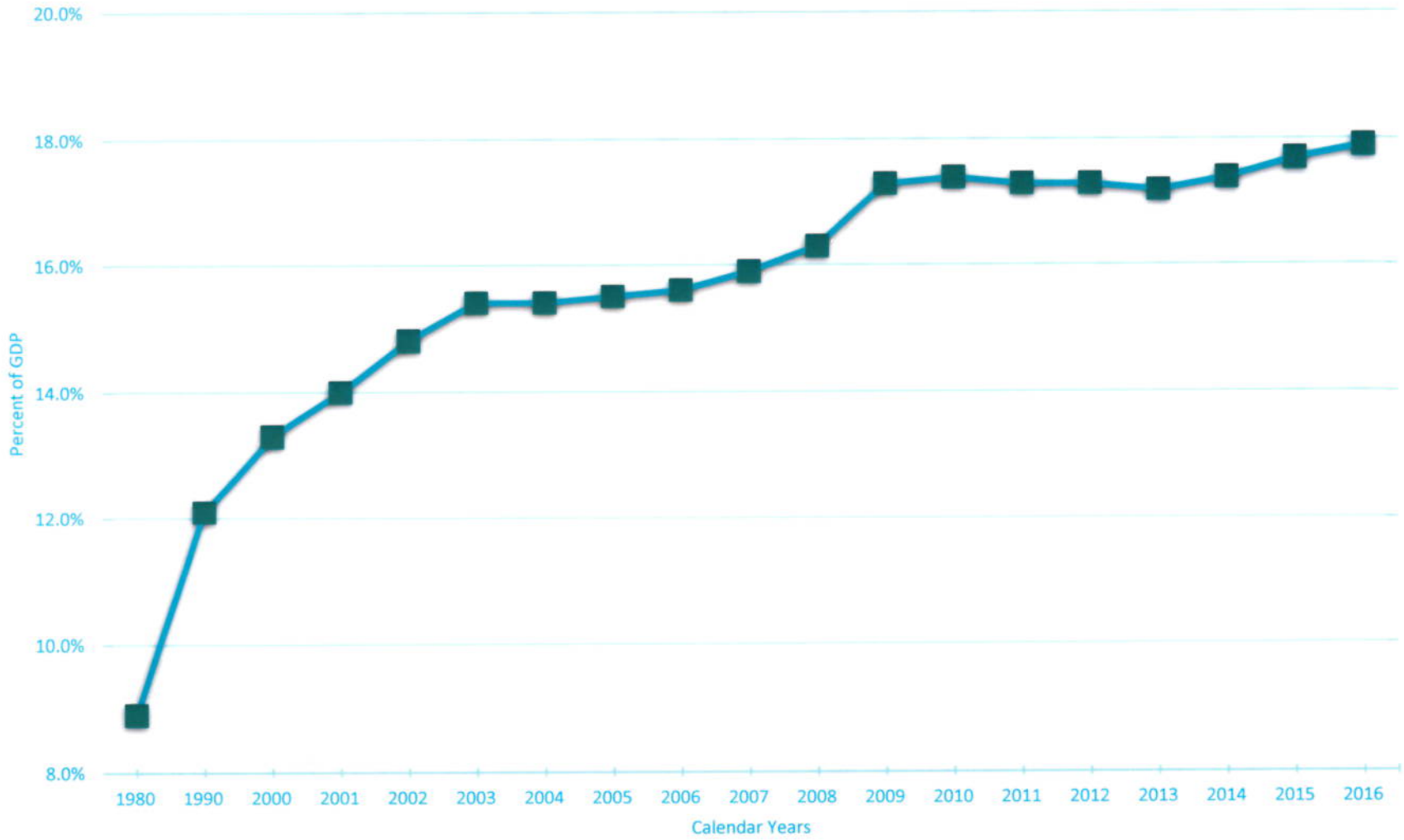
SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

National Health Expenditures/ U.S. Population(Historic)



https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html

National Health Expenditures as a Percent of Gross Domestic Product

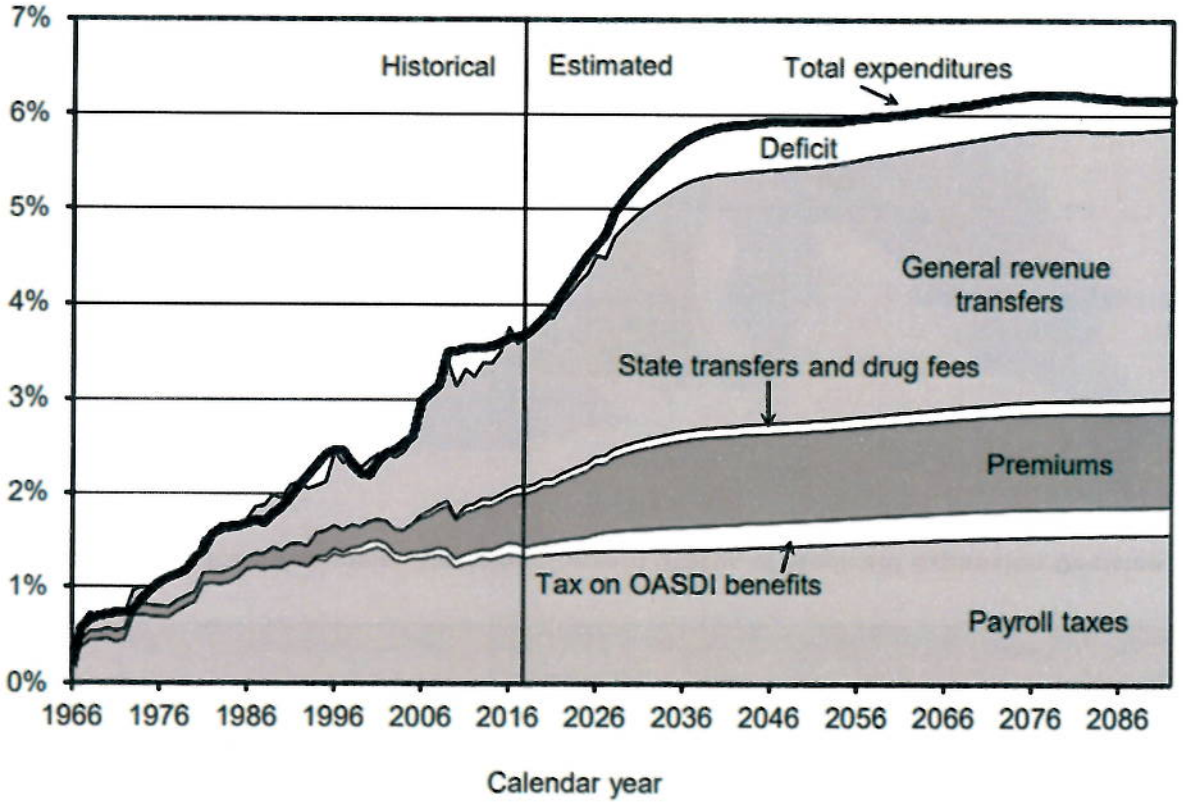


https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html

Medicare Expenditures as a Percentage of the GDP

Overview

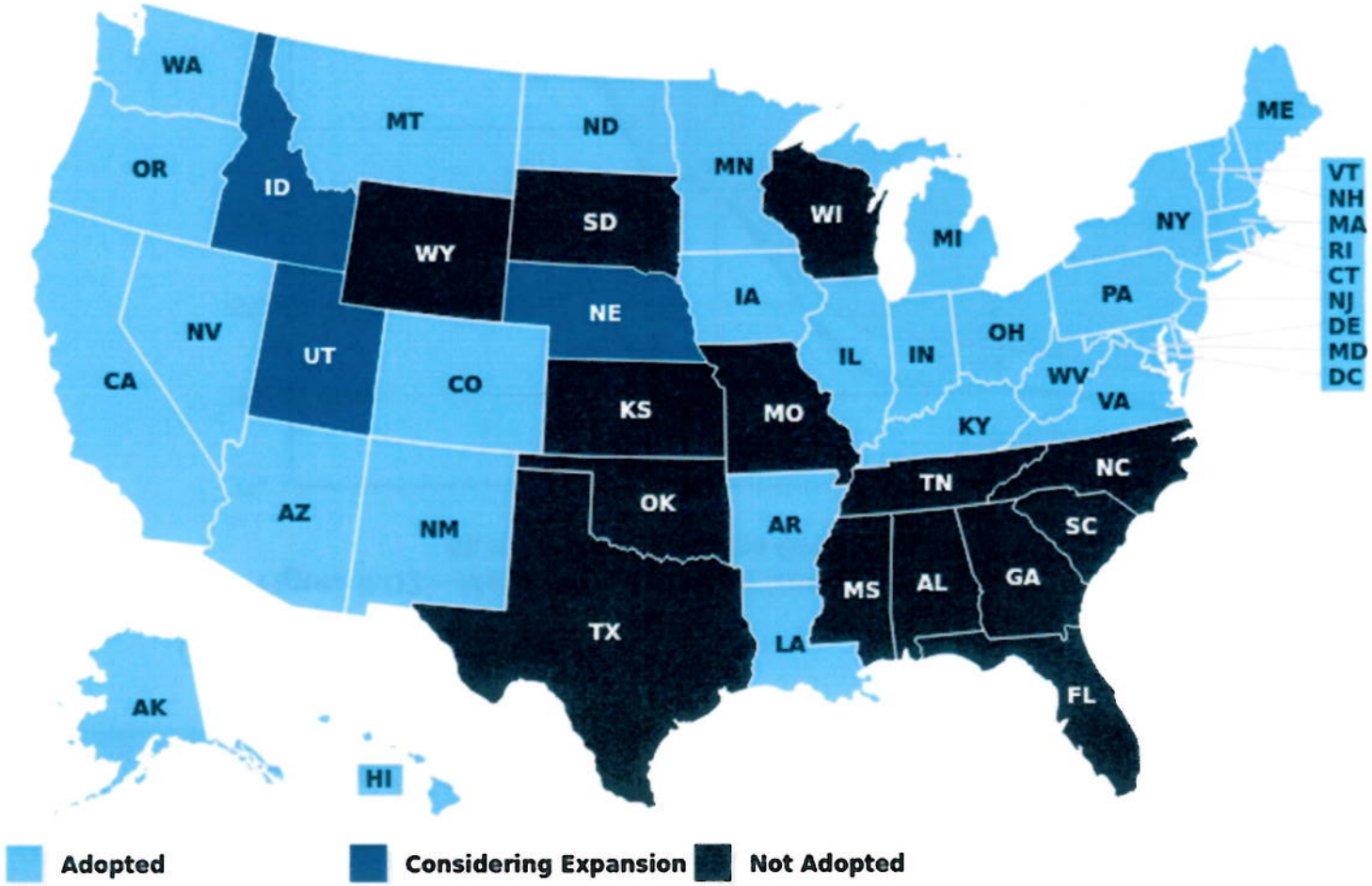
Figure II.D2.—Medicare Sources of Non-Interest Income and Expenditures as a Percentage of the Gross Domestic Product



Note: Percentages are affected by economic cycles.

Medicaid Expansion States

Status of State Action on the Medicaid Expansion Decision: Current Status of Medicaid Expansion Decision, as of September



SOURCE: Kaiser Family Foundation's State Health Facts.

Waivers: 1115 vs 1332

1115 Waivers:

Section 1115 of the Social Security Act gives the Secretary of Health and Human Services authority to approve experimental, pilot, or demonstration projects that are found by the Secretary to be likely to assist in promoting the objectives of the Medicaid program. The purpose of these demonstrations, which give states additional flexibility to design and improve their programs, is to demonstrate and evaluate state-specific policy approaches to better serving Medicaid populations.

Here is a link on basic information on 1115 waivers on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html

Section 1332 Waivers - State Relief and Empowerment waivers

Under Section 1332 of the Affordable Care Act (ACA), a state can apply for a State Innovation Waiver, allowing states to implement innovative ways to provide access to quality health care that is at least as comprehensive and affordable as would be provided absent the waiver, provides coverage to a comparable number of residents of the state as would be provided coverage absent a waiver, and does not increase the federal deficit. If approved, these waivers can begin on or after January 1, 2017.

Here is a link to some FAQs which talk about 1332 waivers: https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-.html#Frequently%20Asked%20Questions%20about%201332%20State%20Innovation%20Waivers

Expansion Report

October 17, 2018

UTAH DEPARTMENT OF HEALTH MEDICAID

Targeted Adult Medicaid (TAM) Enrollment by Subgroup

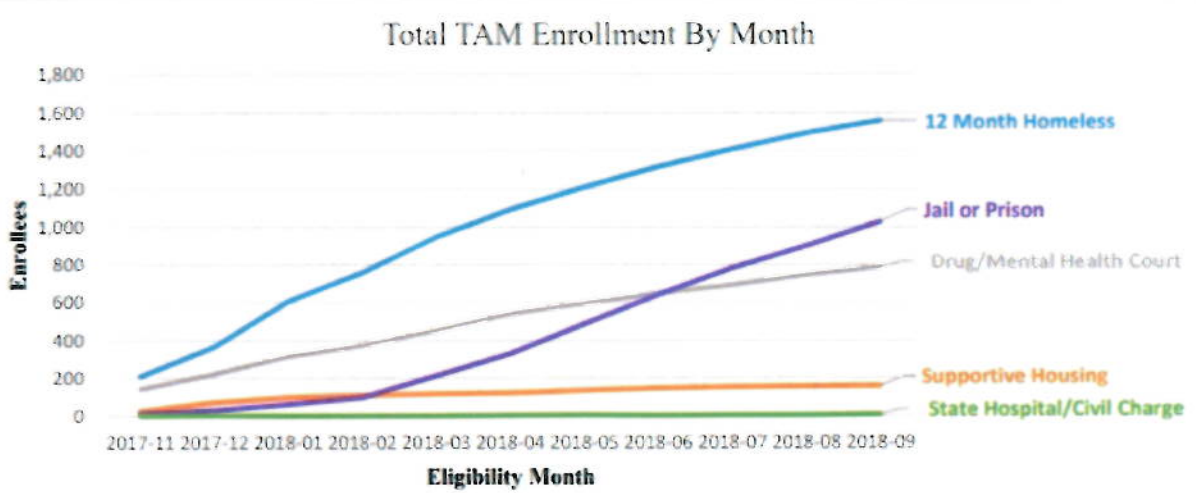


Figure 1

TAM Enrollment by Month

	FY18								FY19		
TAM Category	**2017-11**	**2017-12**	**2018-01**	**2018-02**	**2018-03**	**2018-04**	**2018-05**	**2018-06**	**2018-07**	**2018-08**	**2018-09**
12 Month Homeless	208	367	604	758	950	1,095	1,208	1,315	1,408	1,492	1,559
Supportive Housing	25	70	96	109	115	120	133	145	151	154	156
Drug/Mental Health Court	140	220	317	374	455	540	595	646	691	746	787
Jail or Prison	11	30	62	96	212	331	486	639	782	901	1,031
State Hospital/Civil Charge	1	3	1	1	1	3	5	2	3	3	7
Total	**385**	**690**	**1,080**	**1,338**	**1,733**	**2,089**	**2,427**	**2,747**	**3,035**	**3,296**	**3,540**

Table 1

Notes:
Enrollment as of October 17, 2018. Enrollment includes retroactive applications processed up to the run date. Enrollment numbers reported here are subject to change with future applications that may include retroactive coverage.

Looking Ahead

- **Opioid Epidemic**
  - Innovative Treatment:
    - NAS (Neonatal Abstinence Syndrome)
    - M.O.M (Maternal Opioid Misuse)
  - Increase Access:
    - More integrated Primary Care and Behavioral Health
    - Telehealth
    - Increase workforce
  - Funding
    - Tribal Opioid Groups
    - Community Grants
    - State Targeted Response (STR) Grants

University of Utah Prevention Technology Transfer Center (PTTC)
SAMHSA's Substance Abuse Prevention Center of Excellence in Region VIII:
Jason Burrow-Sánchez, PhD
Professor | Director of Clinical Training
Counseling Psychology Program
Dept. of Educational Psychology – University of Utah
Jason.Burrow-Sanchez@utah.edu
801-581-6212

- **Affordable Health Insurance**
  - 1115 Waivers
  - 1332 Waivers (State Relief and Empowerment Waiver)
    - HRA – Health Reimbursement Arrangements
    - Reinsurances/High Risk Groups
    - More flexible state plans
  - Executive Orders
    - *"Promoting Healthcare Choice and Competition"*
      - Association Health Plans
      - Short Term Limited Duration Plans

Looking Ahead cont.

- **Value Based Healthcare**
  - Patients over paperwork
    - Decrease excess regulations, i.e. quality measurement reporting
    - E/M codes consolidation
  - Interoperability
  - Transparency in Hospital Prices
    - Effective Jan 2019

- **Drug Pricing**
  - Remove Pharmacy Gag Clauses
  - Drug Prices listed on TV Ads
  - Drug Price Negotiation in Medicare Part D
  - Innovative Drug Supply: Civica RX
  - International drug price comparison to ensure US parity

Thank you

Brian E. Shiozawa, MD

Regional Director, Region VIII

Phone: 303-844-3372

Email: Brian.Shiozawa@hhs.gov