

Sep 22nd, 9:00 AM - 10:00 AM

Federal Policy Update

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Schmid, Carl, "Federal Policy Update" (2018). *7th Annual Rural HIV Research and Training Conference*. 10.
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Federal Policy Update

Carl Schmid

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The AIDS Institute

Disclosure Information

I **do not** have any conflicts of interest to disclose and I **do not** intend to discuss off label use of any drug or treatment during this discussion.

Presentation Objectives

- Learn how Congress and the Administration are:
 - addressing the opioid epidemic and the associated increases in HIV due to injection drug use
 - funding HIV programs as part of the annual budget and appropriations process
- Learn what is happening to implementation of the ACA & other access to care and treatment issues
- Learn how current Ryan White Program funding is distributed to states and efforts to improve equity

HIV and the Opioid Epidemic

Response by Congress and
the Administration



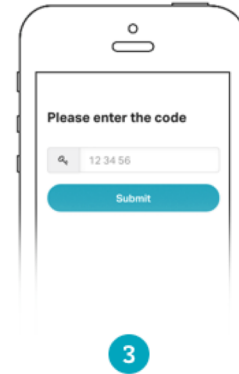
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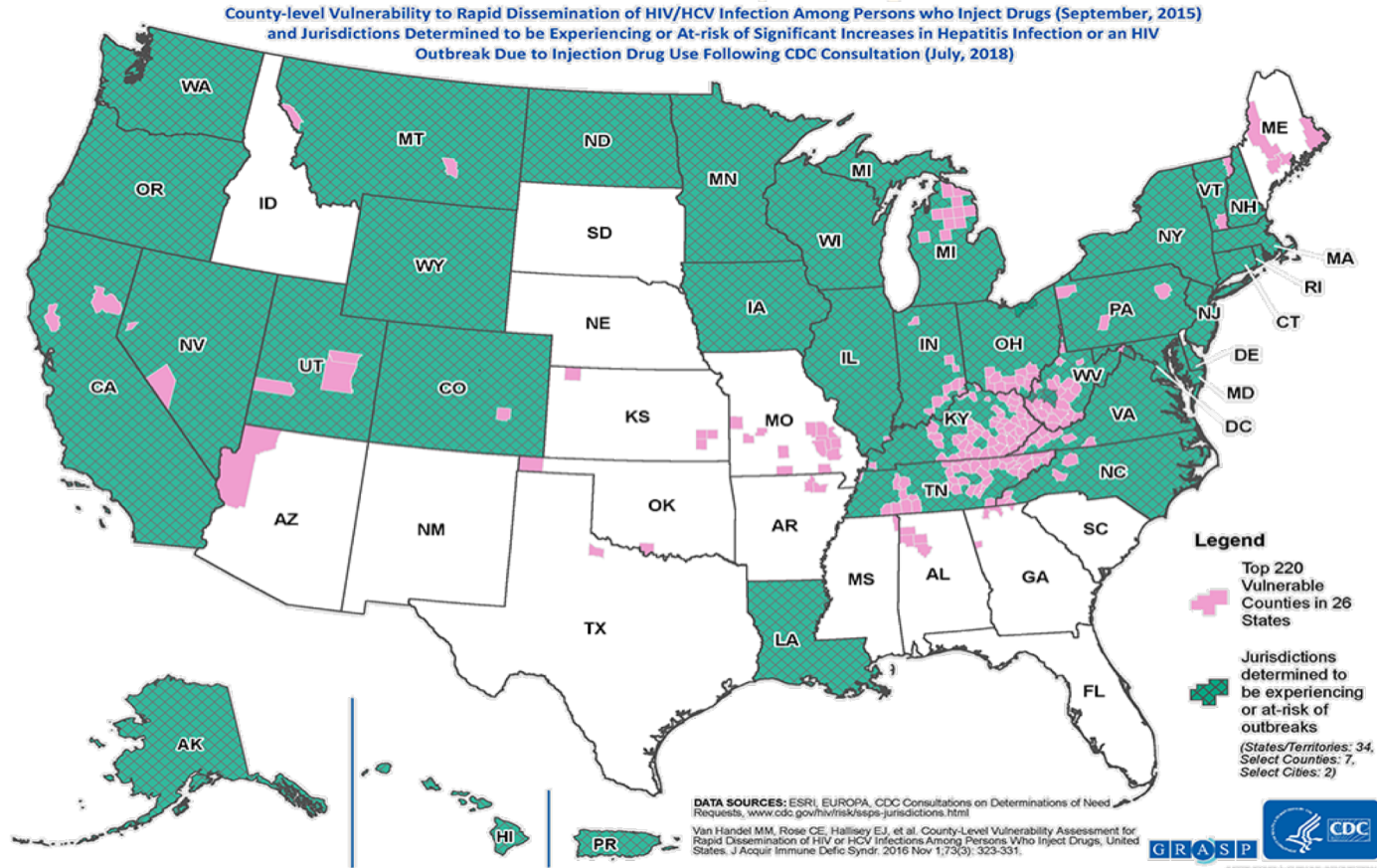
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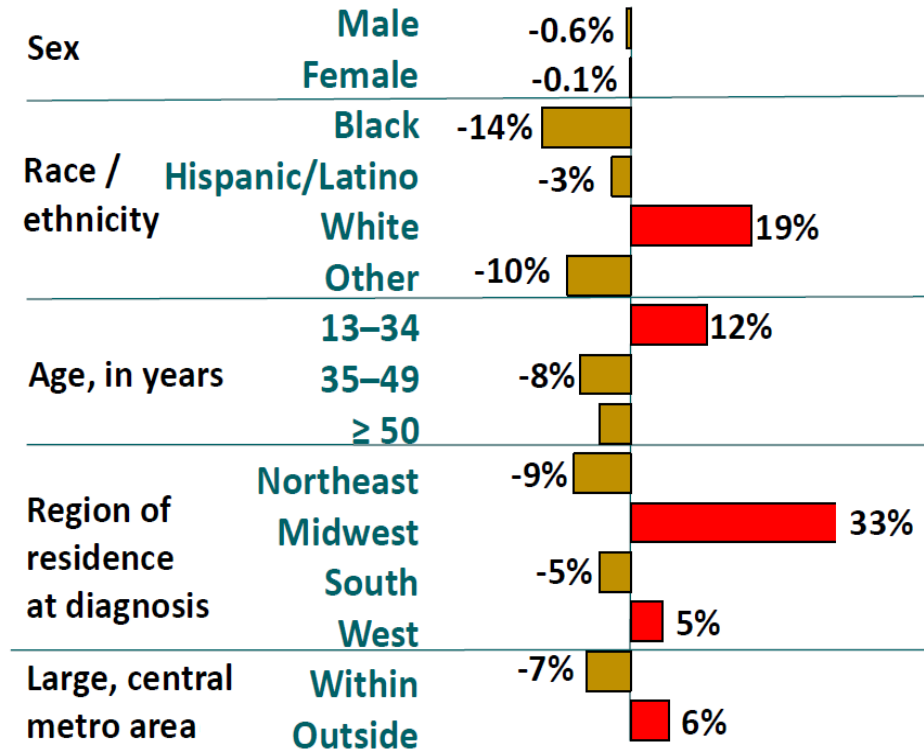


Polling Question

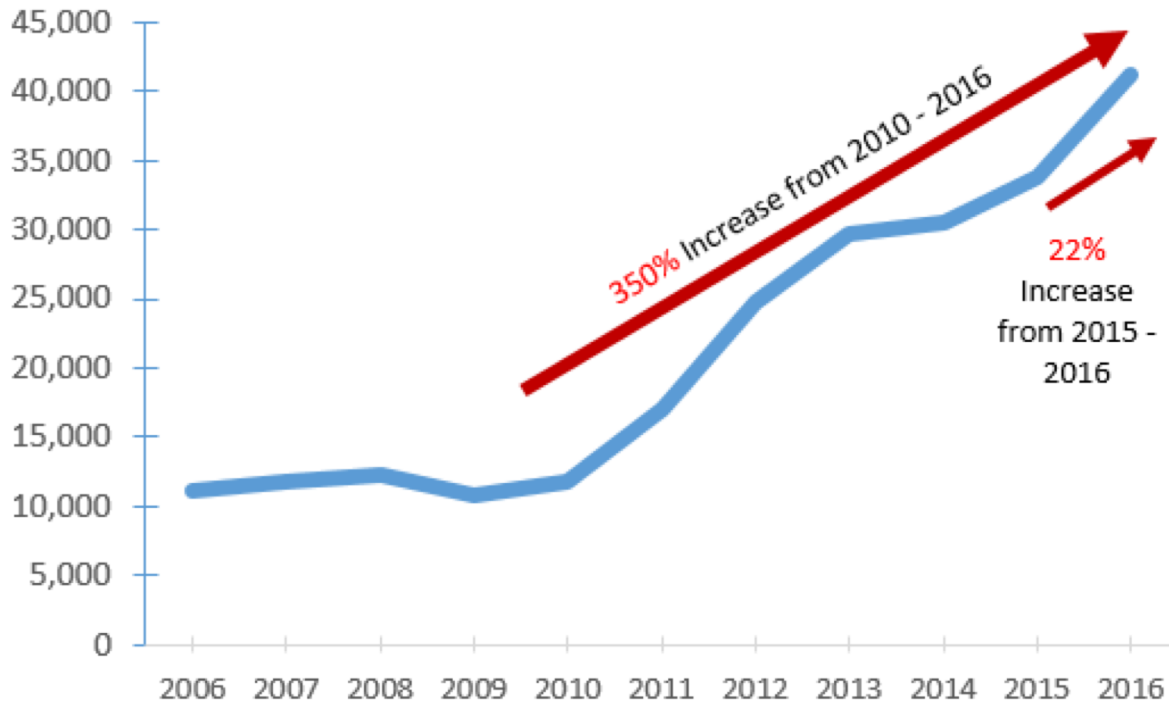
Vulnerable Counties and Jurisdictions Experiencing or At-Risk of Outbreaks



Differential Changes in HIV Diagnoses Among Persons Who Inject Drugs - 2014 vs. 2016

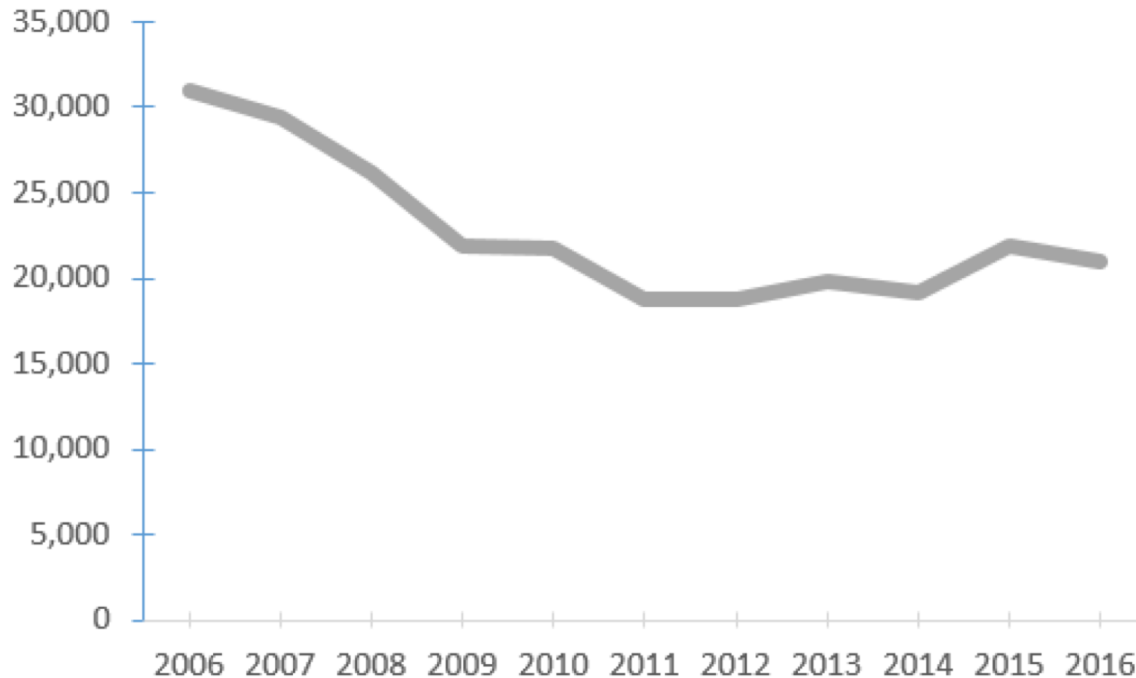


Steep Hepatitis C Increases



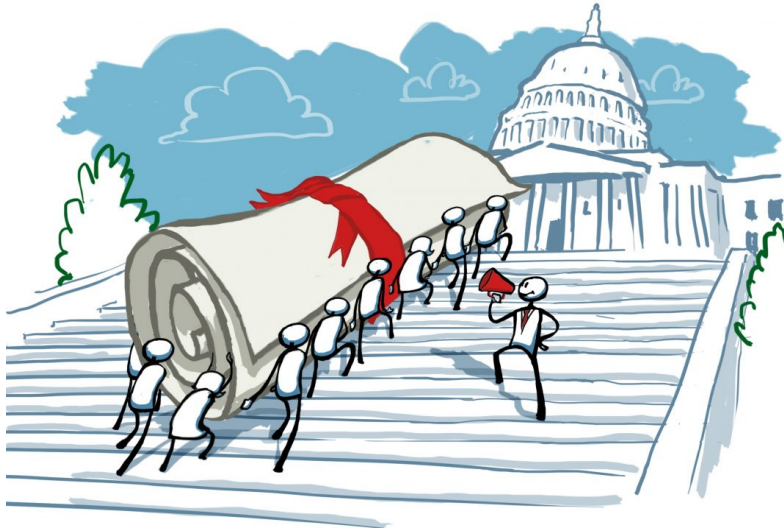
- 350% increase in new HCV cases from 2010-2016
- 22% increase in 2016
- 70+% of new cases due to injection drug use
- Large number of the new cases among young adults
- HCV remains the leading infectious disease killer in the U.S.

End of Reduction in Hepatitis B Cases



- Reversal of long-time reduction in new HBV cases
- 20% increase in 2015
- First increase in 10 years
- Spike in new cases in the Appalachian region

Eliminating Opioid Related Infectious Diseases Act of 2018



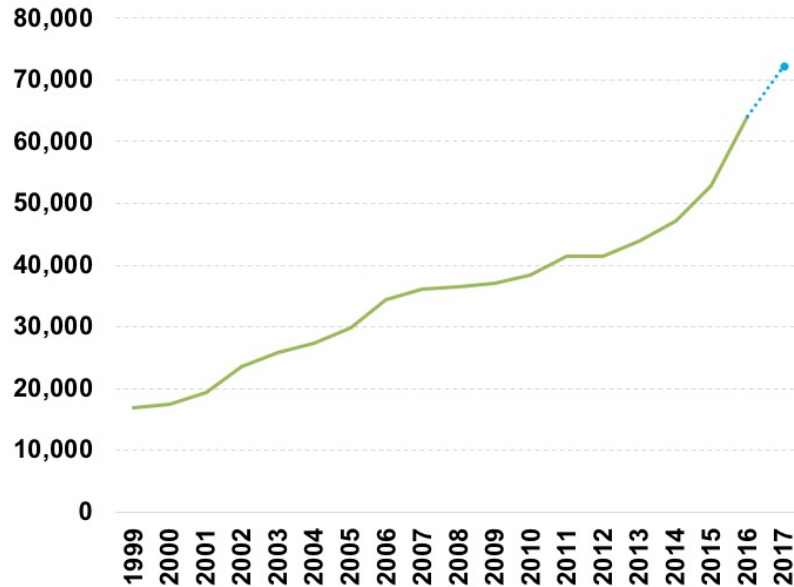
- Introduced in March 2018 by Reps. Leonard Lance (R-NJ) and Joseph Kennedy III (D-MA)
- Senate version introduced by Sens. Todd Young (R-IN), Tammy Baldwin (D-WI), and Edward Markey (D-MA)
- Authorizes \$40 million a year over five years to the CDC
- Enables state and local governments and others to respond to the growing number of opioid-related cases of infectious diseases, such as HIV and hepatitis
- Grantees can use the resources for surveillance, testing, prevention, and linkage to care and treatment for infectious diseases

Eliminating Opioid Related Infectious Diseases Act of 2018 – Updates

- Included in the **“SUPPORT for Patients and Communities Act” (H.R.6)**, the House the opioid package
 - Passed the House in June 2018
- Included in the **“Opioid Crisis Response Act of 2018” (S.2680)**, the Senate opioid package
 - Passed the Senate in September 2018
- House and Senate now must reconcile differences between the bills

Opioid Crisis Response Act of 2018

Total U.S. Drug Deaths



- Reauthorizes the State Targeted Response grant program
- Authorizes new grant program at SAMHSA for creation of Comprehensive Opioid Recovery Centers
- Encourages development of best practices for recovery housing
- Authorizes grant program to implement policies and procedures to individuals who have experienced an opioid overdose
- Expands access to Medication-Assisted Treatment

Opioid Funding

- \$6 billion in new opioid funding agreed to in February as part of budget deal
- Plus \$500 million already approved in the 21st Century Cures Act
- FY18 Omnibus Appropriations bill included more than \$3 billion
 - SAMHSA (\$1.4 billion)
 - New State Opioid Response Grant program (\$1 billion)
 - Mental Health Block Grant (\$160 million increase)
 - NIH - opioid addiction research (\$500 million)
 - CDC - opioid overdose prevention, surveillance, and improving state prescription drug monitoring programs (\$350 million)
 - HRSA - improving access to addiction treatment in rural and other underserved areas, including funding Rural Communities Opioid Response grants (\$415 million)

Rural Communities Opioid Response – Planning grants

- Grantees will receive up to \$200,000 for one year
- Used to develop plans to implement opioid use disorder prevention, treatment, and recovery interventions designed to reduce opioid overdoses among rural populations
- Award 75 grants
- Initiative is part of a multi-year Rural Communities Opioid Response
- Ryan White HIV/AIDS clinics and HIV and HCV prevention organizations able to apply



Funding for Domestic HIV Programs



Polling Question

President's Proposed FY18 Cuts

- Proposed cuts
 - CDC HIV Prevention: -\$148 m
 - CDC STD Prevention: -\$22 m
 - NIH AIDS Research: -\$550 m
 - SAMHSA Minority AIDS Programs: -\$17 m
 - HOPWA: -\$26 m
- Proposed Program Eliminations
 - Ryan White AETCs: -\$34 m
 - Ryan White SPNS: -\$25 m
 - Teen Pregnancy Prevention Program: -\$101 m
 - HHS Secretary's Minority AIDS Initiative Fund: -\$54 m



Congress' Proposed FY18 Cuts

- House

- Proposed cuts
 - SAMHSA Minority AIDS Programs: -\$17 m
- Proposed Program Eliminations
 - Teen Pregnancy Prevention Program: -\$101 m
 - Title X Family Planning: -\$286 m
 - SMAIF: -\$116 m
- “Sexual Risk Avoidance” Abstinence-Only: +\$5 m

- Senate

- Proposed cuts
 - HOPWA: -\$26 m
- “Sexual Risk Avoidance” Abstinence-Only: +\$10 m



Final FY18 Appropriations

- **All proposed cuts and eliminations were not agreed to**
- **Most domestic HIV/AIDS programs level funded**
- **Increases**
 - CDC STD Prevention: +\$5 m
 - CDC Division of Viral Hepatitis: +\$5 m
 - HOPWA: +\$19 m
 - NIH Total: +\$3 b

 - \$10 m increase to “Sexual Risk Avoidance” Abstinence-Only Programs

President's Proposed FY19 Cuts

- Proposed cuts
 - CDC HIV Prevention: -\$40 m
 - CDC STD Prevention: -\$5 m
 - CDC Viral Hepatitis Prevention: -\$5 m
 - NIH AIDS Research: -\$89 m
 - HOPWA: -\$45 m
- Proposed Program Eliminations
 - Ryan White AETCs: -\$34 m
 - Ryan White SPNS: -\$25 m
 - SMAIF: -\$54 m
 - SAMHSA MAI: -\$116 m
 - Teen Pregnancy Prevention: -\$101 m



Congress' Proposed FY19 Cuts

- House
 - Proposed Program Eliminations
 - Teen Pregnancy Prevention Program: -\$101 m
 - Title X: -\$287 m
 - “Sexual Risk Avoidance” Abstinence-Only: +\$5 m
- Senate
 - “Sexual Risk Avoidance” Abstinence-Only: +\$10 m

Proposed FY19 Increases

- New CDC Initiative
 - President: +\$40 m
 - House: +\$20 m
 - Senate: +\$5 m
- SAMHSA Reducing IDU/HIV, Hepatitis
 - President: +\$150 m
- HOPWA
 - House: +\$18 m



Current Appropriations Status



- House & Senate Passing Spending Bills
- Combining Bills into “Minibuses”
- Fiscal Year Ends October 30th
- Labor HHS expected to pass in time
- Some federal agencies will be on a Continuing Resolution until after mid-term election
- Labor HHS proposed cuts rejected

**Affordable Care
Act and Access to
Care and
Treatment**

A dark, irregular ink blot with splatters on a white background. The blot is roughly circular but has jagged, feathered edges. The color is a deep, dark brown or black. There are several smaller, lighter brown splatters around the main blot, particularly towards the top and right sides. The overall effect is that of a fresh ink spill or a hand-drawn shape.

Polling Question

Threats to the Affordable Care Act

- Navigator funding cuts
- Shortened enrollment periods
- Elimination of Cost-Sharing Reduction (CSR) payments
- Individual mandate penalty repealed
- Essential Health Benefit (EHB) benchmark changes
- Association health plans (AHPs)
- Short-term limited duration plans
- Medicaid 1115 waivers
- Pre-existing condition protections

Copay Accumulator Programs and Access to Rx

Instituted by insurers and pharmacy benefit managers (PBMs) that prevent manufacturer copay assistance contributions from counting towards a beneficiary's deductible and maximum out-of-pocket spending limits.

- Many consumers with chronic and complex conditions rely on manufacturer co-pay cards to defray the cost of their medications
- For HIV treatment, there are very few generic alternatives available to brand-name drugs and for PrEP and the new class of curative HCV treatment
- Co-pay accumulator policies – when applied to patients with no alternative – disrupt access to treatment

Copay Accumulator Language in Florida Qualified Health Plans

Plan		
Ambetter	<i>Based on personal communication, currently allows the use of copayment assistance cards and they can be applied to the member's deductible.</i>	
Florida Blue	<p>We reserve the right <u>not to apply</u> manufacturer or provider cost share assistance program payments (e.g., manufacturer cost share assistance, manufacturer discount plans, and/or manufacturer coupons) to the Deductible or Out-of-Pocket maximums.</p> <p><i>Based on personal communication, currently not applying the copay accumulator program</i></p>	<p>BlueSelect Silver 1443 Schedule of Benefits Page 47</p>
Health First	<i>Based on personal communication, currently <u>do not permit</u> copay cards to count towards the members deductible.</i>	
Molina	<p>Please note, Cost Sharing reduction for any prescription drugs obtained by You through the use of a discount card or coupon provided by a prescription drug manufacturer <u>will not apply</u> toward any Deductible or the Annual Out-of-Pocket Maximum under Your Plan.</p>	<p>2018 Molina Healthcare of Florida, Inc. Agreement and Individual Evidence of Coverage Page 72</p>

Patient Scenario for HIV Single Tablet Regimen (STR)

- **Plan annual OOP maximum: \$6,000**
- **Deductible (combined medical and Rx): \$3,000**
- **Drug cost sharing for preferred brand: \$50 after deductible**
- **Manufacturer co-pay assistance program annual maximum: \$6,000**
- **WAC monthly drug price: \$3,090**

Medication Costs *without* Co-pay Accumulator

	Consumer	Manufacturer Co-pay Card
January	\$0	\$3,050 Plan deductible met
February	\$0	\$50
March	\$0	\$50
April - December	\$0	\$450 (\$50/month)
Total	\$0	\$3,600
Total collected by Insurance Plan	\$3,600	

Medication Costs *with* Co-pay Accumulator

	Consumer	Manufacturer Co-pay Card
January	\$0	\$3,090
February	\$180	\$2,910 Manufacturer CAP max met
March	\$2,870 Plan deductible met	\$0
April - December	\$450 (\$50/month)	\$0
Total	\$3,500	\$6,000
Total collected by Insurance Plan	\$9,500	

Copay Accumulator Programs

- Lack of Transparency
 - Patients Surprised
- HIV Community Sent letter to all State Insurance Commissioners & Attorney Generals
 - Other patient groups follow
- Patient Groups need to Speak up
- Beneficiaries must be aware
 - Open enrollment begins November 1st
- Higher Out of Pocket Costs lead to lack of adherence

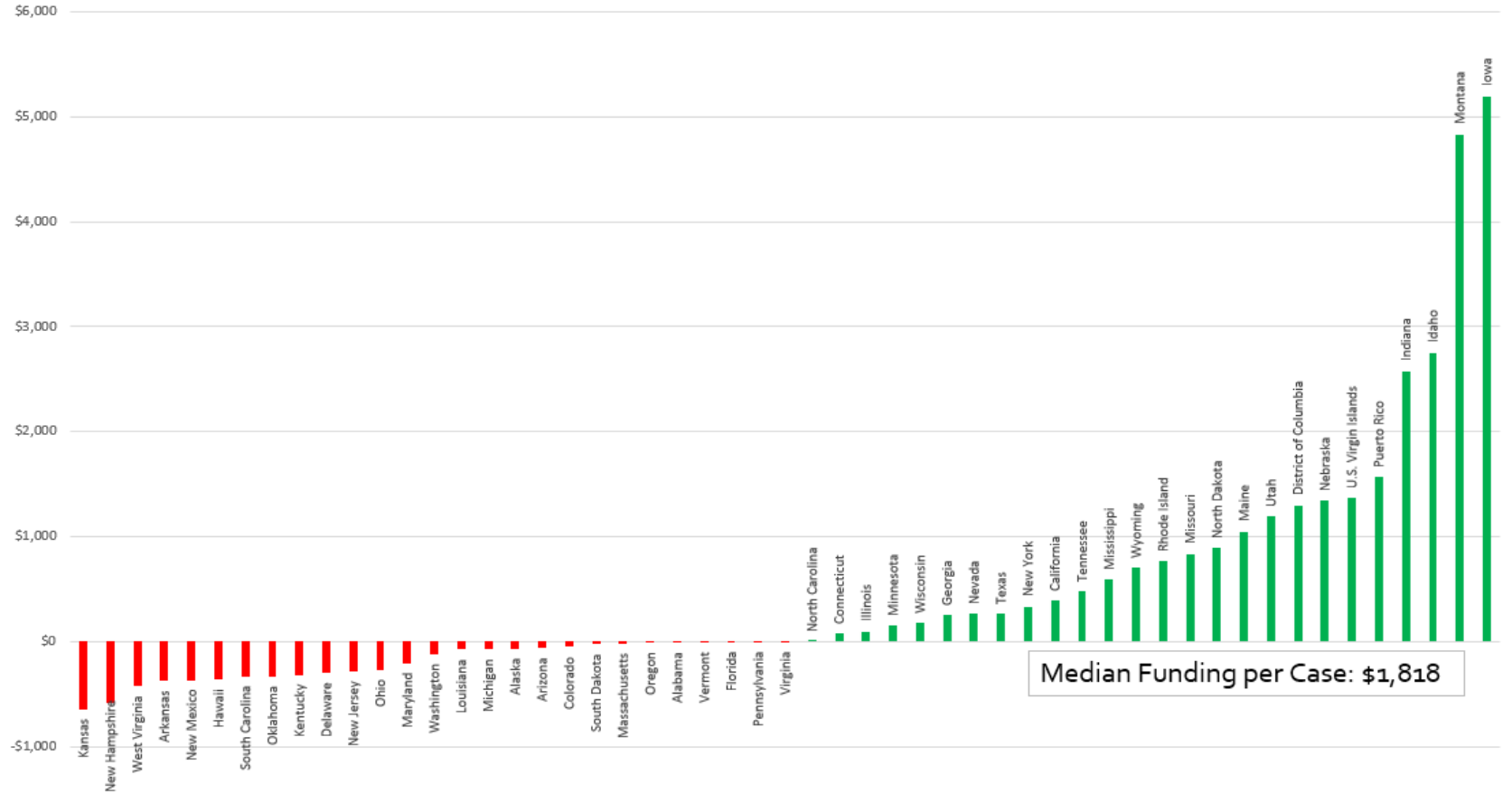
Ryan White Funding

Ryan White Program Funding

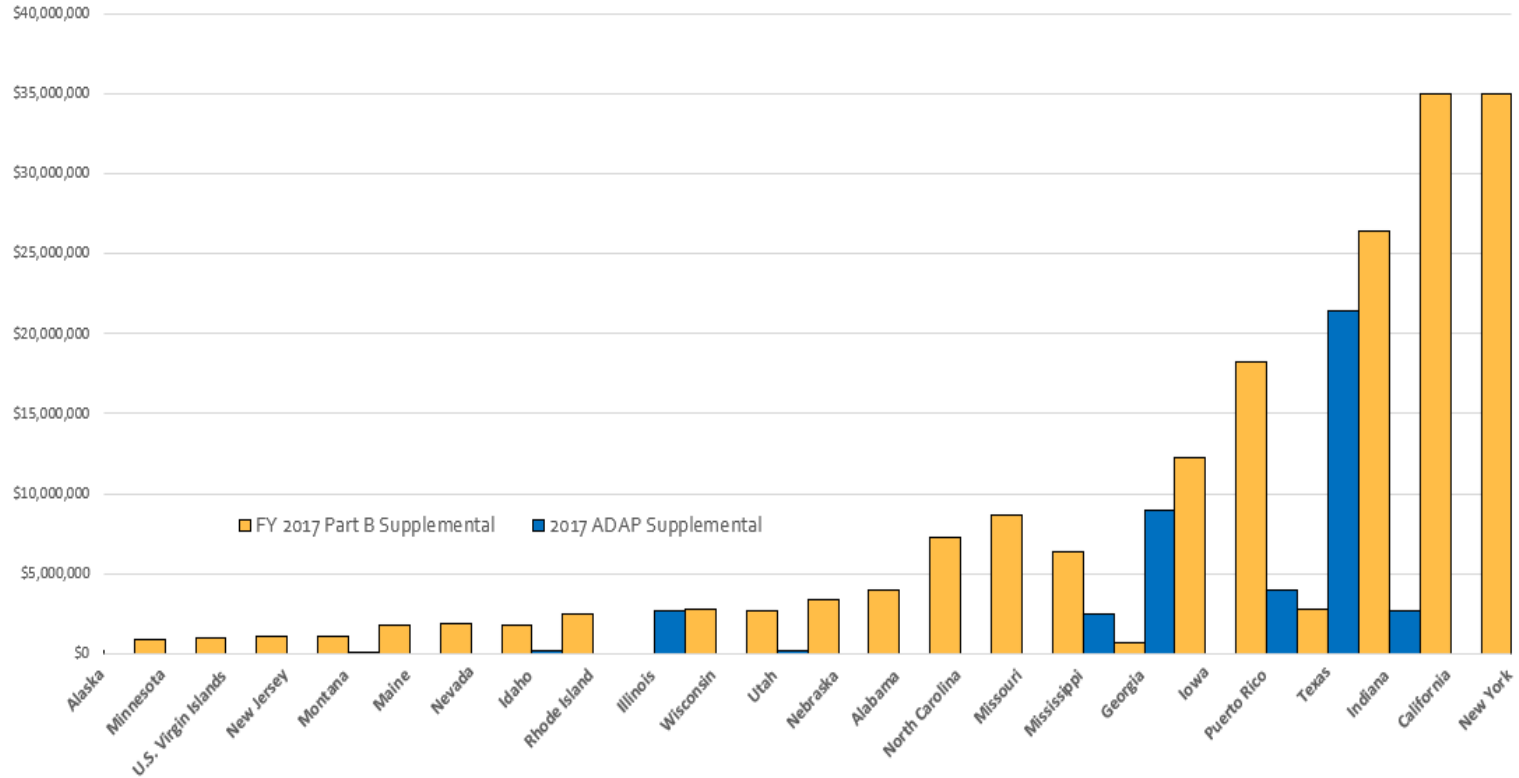
Is Ryan White Program funding distributed to areas most-in-need and following the epidemic?

- Examine all Part A, B, C and D funding per state and case counts
- Grants are based on formula, others based on need and who applies
- Part B Supplemental and C & D presence greatly impacts a state's total funding

Parts A & B Funding

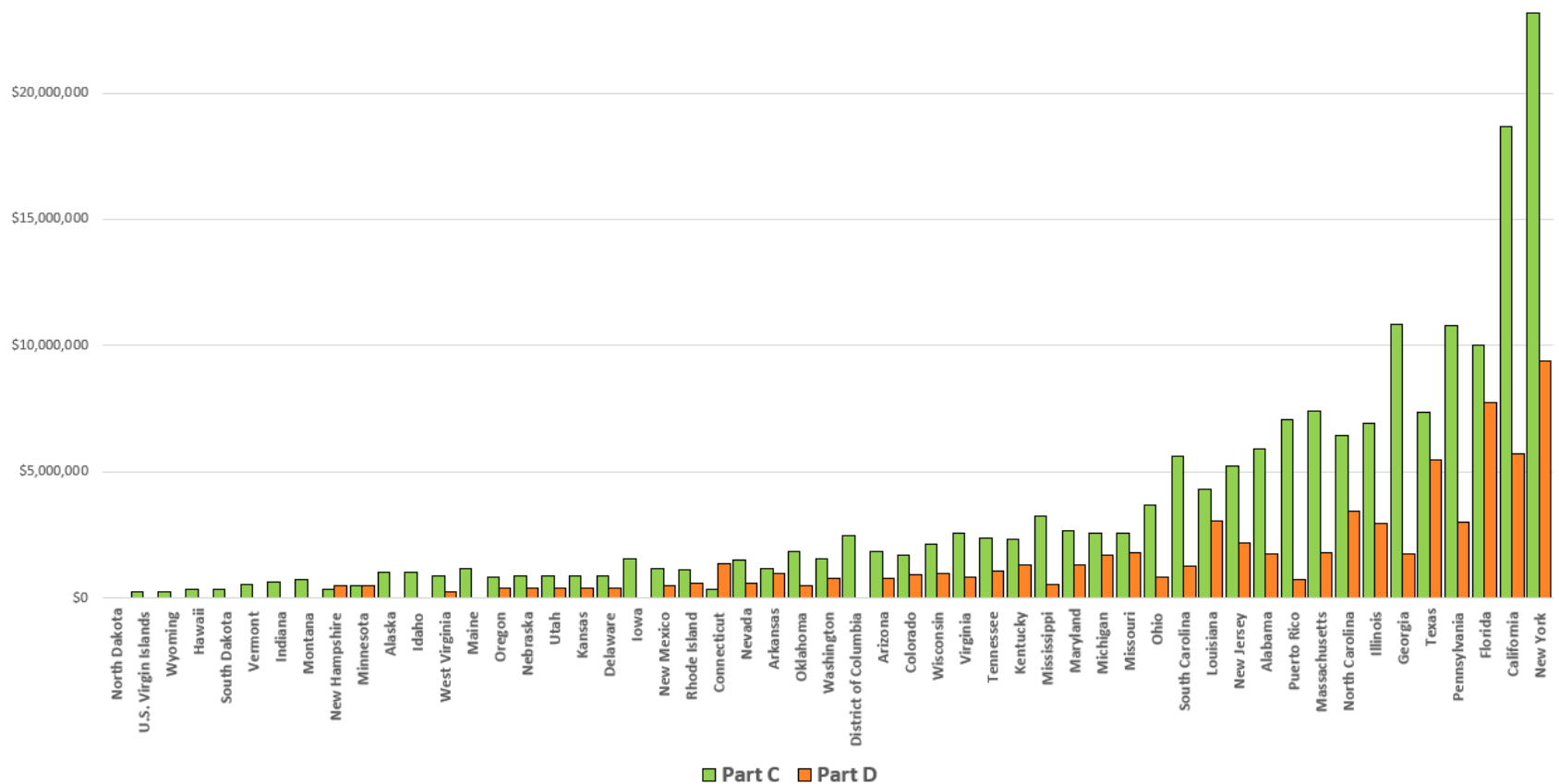


Part B & ADAP Supplementals Awards



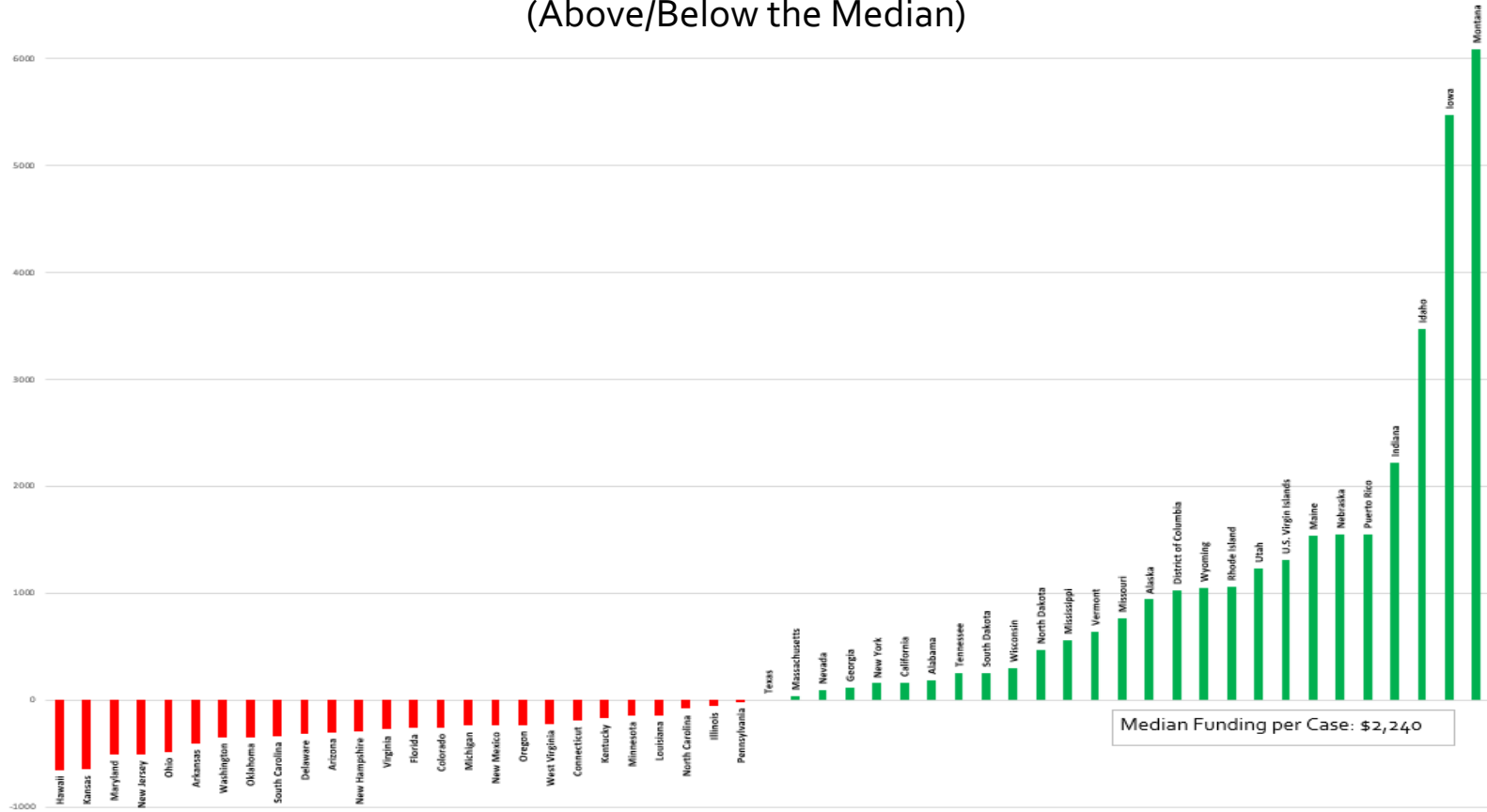
*Excludes states that did not receive Part B supplemental or ADAP supplemental

Parts C & D Funding



Parts A-D

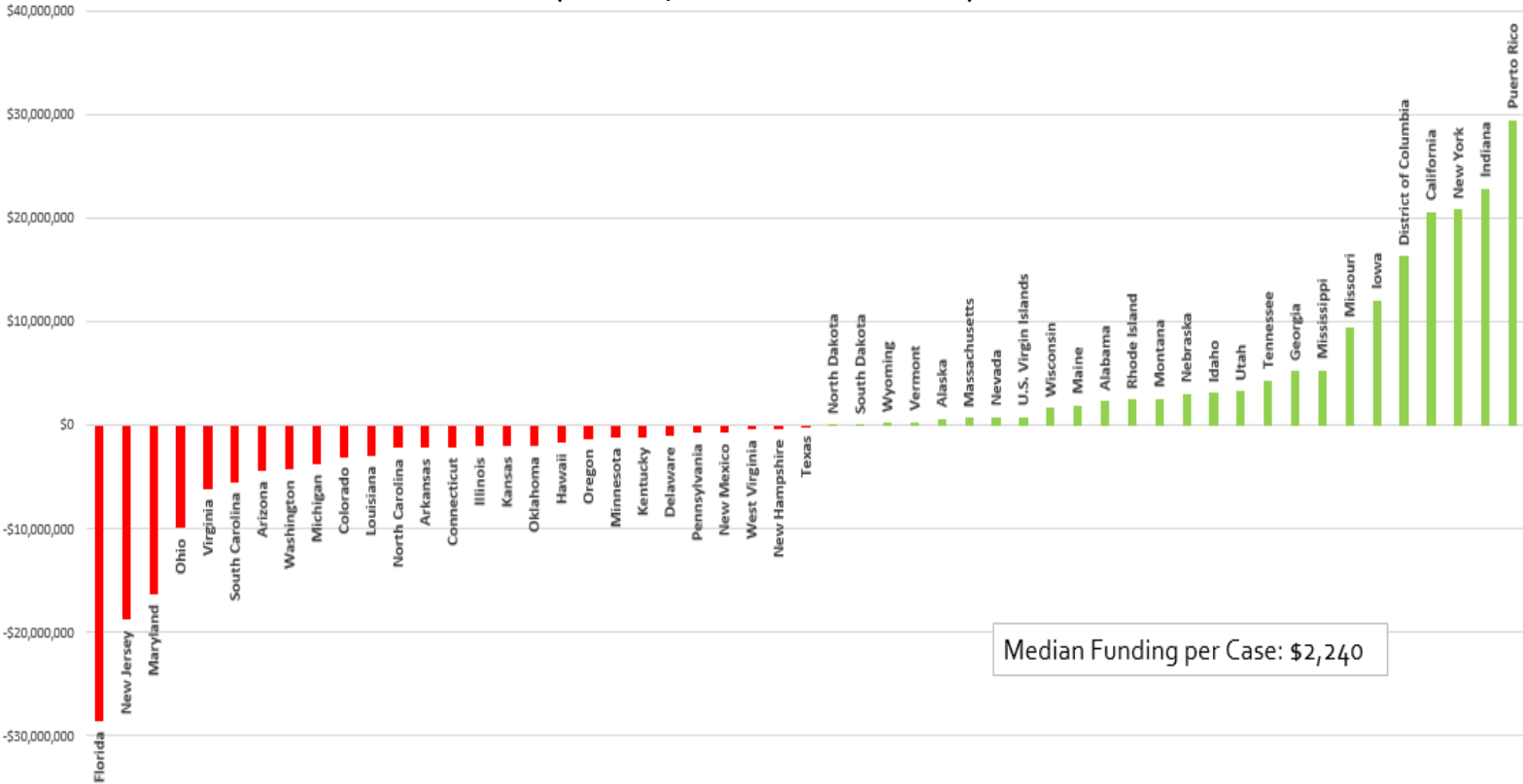
(Above/Below the Median)



Median Funding per Case: \$2,240

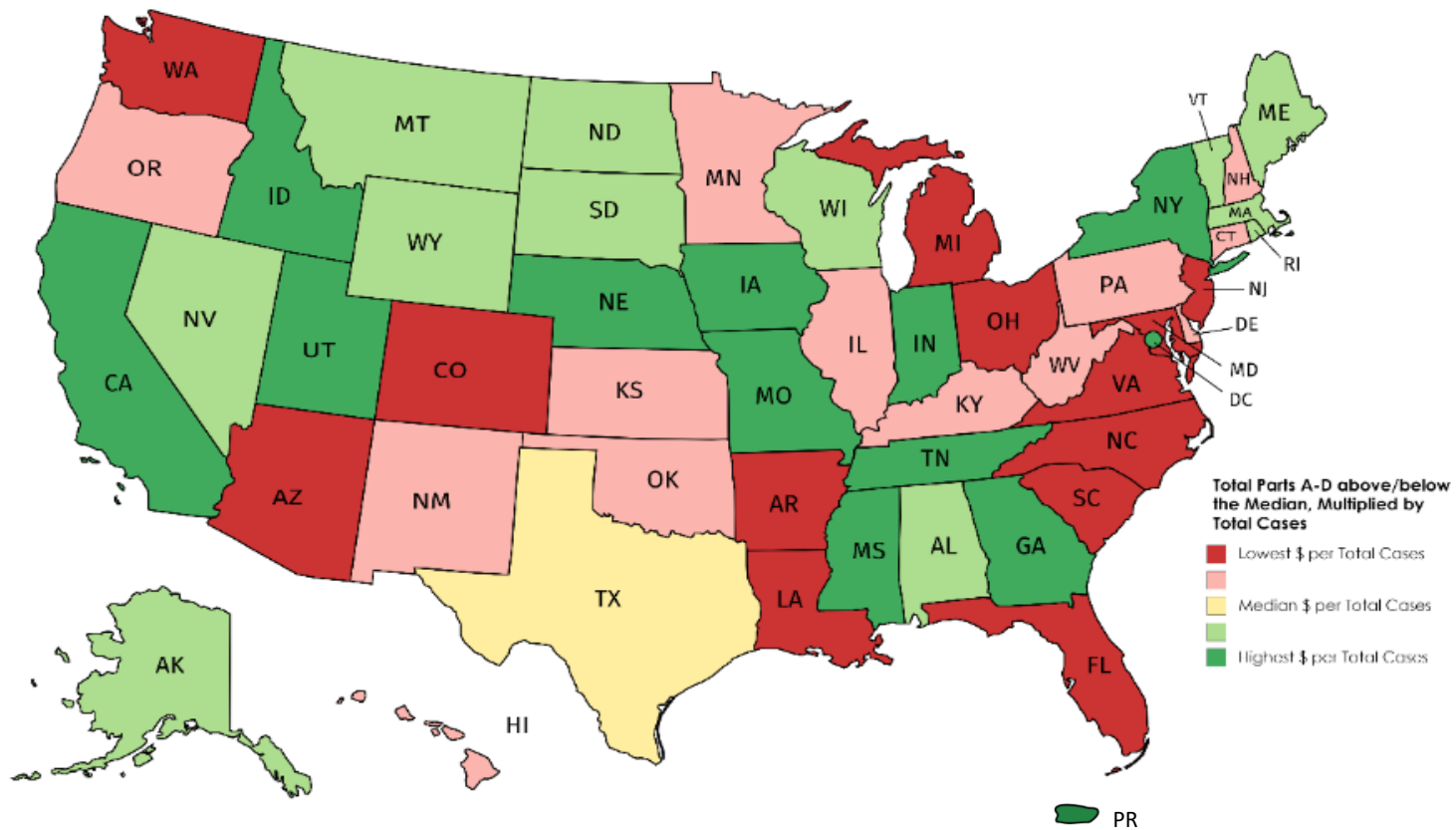
Parts A-D Multiplied by Total Cases

(Above/Below the Median)



Median Funding per Case: \$2,240

Total Part A-D Funding, Above/Below the Median, Multiplied by Total Cases



Part B Supplemental Awards (2017)

- OH, MA, the Marshall Islands, and American Samoa were not eligible
- 20 States applied
- \$218 million available; \$177.8 million awarded
- Highest awards:
 - NY: \$35m
 - CA: \$35m
 - IN: \$26.4m
- Recipients: AL, AK, GA, ID, IA, ME, MN, MS, MO, MT, NE, NV, NJ, NC, PR, RI, TX, US Virgin Islands, UT, WI

President Trump's Budget

- Proposes statutory changes to Parts A & B funding methodologies
 - No specifics provided
 - Allows for a data driven distribution to ensure funds are allocated to populations experiencing high or increasing rates of infections
 - Reduces burden on recipients and allows for better targeting of resources
- Increase HHS's ability to effectively focus resources for HIV care, treatment, and support needs in funded cities and states **based on need, geography, data quality, and performance.**

Changes to the Ryan White Program Funding to End the Epidemic

- Reauthorization unlikely in near future, so The AIDS Institute is focusing on improving distribution within current law
 - Supplementals and Parts C & D
- In the future, suggest distribution on case counts and other factors such as:
 - Death Rate
 - Viral Suppression Rate
 - Number of Clients using Ryan White Program
 - Insurance Coverage
 - Cost of care
 - Poverty Rate

Key Federal HIV/AIDS Players

Key Administration Officials



Alex Azar
Secretary of HHS



Adm. Brett Giror
Assistant Sec. for Health



Robert Redfield
CDC Director



Seema Verma
CMS Administrator



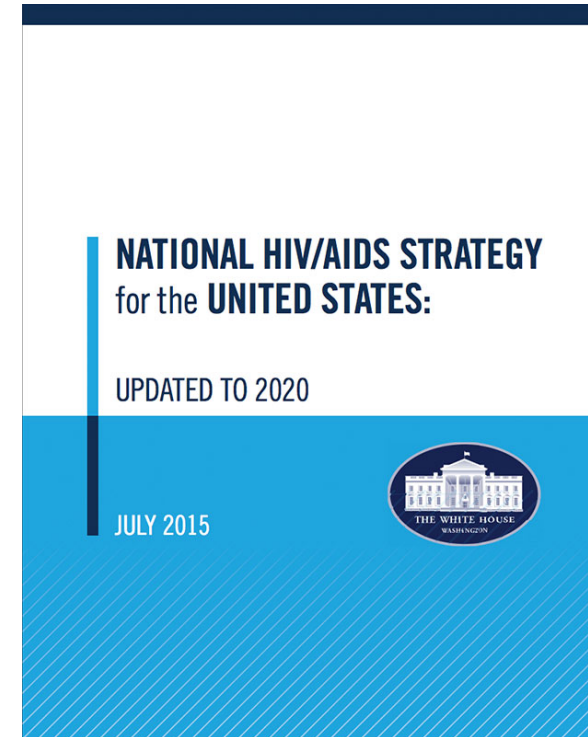
Katy Talento
Member, White House Policy Council



Joe Grogan
Associate Director, Health Program, OMB

National HIV/AIDS Strategy Update

- HHS Updating NHAS
 - Current one expires 2020
- Last updated in 2015
- First listening session held at USCA
- Additional opportunities for stakeholder input to be announced

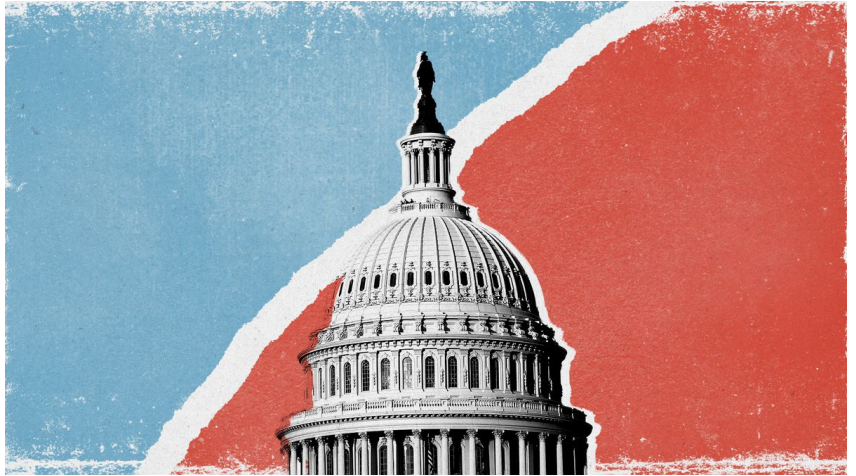


The Future

Midterm Election

- Changes in the Congress
 - Leadership
 - Committee Chairs and Members
 - New Members and Staff

President Trump



Questions / Answers

Thank You

Carl Schmid

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