Federal Policy Update

Carl Schmid
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Carl Schmid
Deputy Executive Director
The AIDS Institute
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
1. Grab your phone
2. Go to www.menti.com
3. Enter the code 927382 and vote!
Polling Question

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<tr>
<th>Category</th>
<th>Male</th>
<th>Female</th>
<th>Hispanic/Latino</th>
<th>Black</th>
<th>White</th>
<th>Other</th>
<th>Northeast</th>
<th>Midwest</th>
<th>South</th>
<th>West</th>
<th>Large, central metro area</th>
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<td>Age, in years</td>
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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
• 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
• 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

- 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
$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)
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
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
• 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
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
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
<table>
<thead>
<tr>
<th>Plan</th>
<th>Details</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambetter</td>
<td>Based on personal communication, currently allows the use of copayment assistance cards and they can be applied to the member’s deductible.</td>
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</tr>
<tr>
<td>Florida Blue</td>
<td>We reserve the right not to apply 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. Based on personal communication, currently not applying the copay accumulator program</td>
<td><a href="#">BlueSelect Silver 1443 Schedule of Benefits</a> Page 47</td>
</tr>
<tr>
<td>Health First</td>
<td>Based on personal communication, currently do not permit copay cards to count towards the members deductible.</td>
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</tr>
<tr>
<td>Molina</td>
<td>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 will not apply toward any Deductible or the Annual Out-of-Pocket Maximum under Your Plan.</td>
<td><a href="#">2018 Molina Healthcare of Florida, Inc. Agreement and Individual Evidence of Coverage</a> Page 72</td>
</tr>
</tbody>
</table>
• 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

<table>
<thead>
<tr>
<th>Month</th>
<th>Consumer</th>
<th>Manufacturer Co-pay Card</th>
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<tbody>
<tr>
<td>January</td>
<td>$0</td>
<td>$3,050</td>
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<tr>
<td>February</td>
<td>$0</td>
<td>$50</td>
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<tr>
<td>March</td>
<td>$0</td>
<td>$50</td>
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<tr>
<td>April - December</td>
<td>$0</td>
<td>$450 ($50/month)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$0</td>
<td><strong>$3,600</strong></td>
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<tr>
<td><strong>Total collected by Insurance Plan</strong></td>
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<td><strong>$3,600</strong></td>
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# Medication Costs with Co-pay Accumulator

<table>
<thead>
<tr>
<th>Month</th>
<th>Consumer</th>
<th>Manufacturer Co-pay Card</th>
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<tbody>
<tr>
<td>January</td>
<td>$0</td>
<td>$3,090</td>
</tr>
<tr>
<td>February</td>
<td>$180</td>
<td>$2,910</td>
</tr>
<tr>
<td>March</td>
<td>$2,870</td>
<td>$0</td>
</tr>
<tr>
<td>April - December</td>
<td>$450 ($50/month)</td>
<td>$0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$3,500</strong></td>
<td><strong>$6,000</strong></td>
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<tr>
<td><strong>Total collected by Insurance Plan</strong></td>
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<td><strong>$9,500</strong></td>
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</table>
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 1\textsuperscript{st}

• 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
Part B & ADAP Supplementals Awards

*Excludes states that did not receive Part B supplemental or ADAP supplemental.*
Parts A-D Multiplied by Total Cases

(Above/Below the Median)

Median Funding per Case: $2,240
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
• 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.
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
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
Midterm Election

– Changes in the Congress
  • Leadership
  • Committee Chairs and Members
  • New Members and Staff

President Trump
Thank You

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