Federal and State Policy Update

Combined PPG and PCPG Meeting
May 13, 2015 | Tampa, FL

Michael Ruppal, Executive Director
The AIDS Institute
Policy Update
Federal / State

- Budget and Appropriations
- Ryan White Program
- Health Reform
- State Policy
Budget & Appropriations – FY15

Fiscal Year 2015 (FY15) (Began 10/1/14)

- Federal Budget October 1 to September 30
- Virtually level funding for HIV/AIDS
- Congress rejects Ryan White Part C/D consolidation
Budget & Appropriations – FY16

- FY16
  - TAI Co-chairs the AIDS Budget & Appropriations Committee (ABAC)
    - Provide much of the staff support
    - Maintain tracking chart (hand-out)
  - 114th Congress
    - Republican majority
    - Many new members and staff
    - New Committee Leadership & Membership
      - Updating health staff contacts
# AIDS BUDGET AND APPROPRIATIONS COALITION

**FY2016 Appropriations for Federal HIV/AIDS Programs**  
_February 10, 2015_  
_(Increases/decreases from previous fiscal year are shown in parentheses.)_

<table>
<thead>
<tr>
<th>HHS PROGRAM</th>
<th>FY2012 Final</th>
<th>FY2013 Operating</th>
<th>FY2014 Enacted</th>
<th>FY2015 Enacted</th>
<th>FY2016 President’s Request</th>
<th>FY2016 Coalition Request</th>
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</thead>
<tbody>
<tr>
<td><strong>CDC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total - HIV, Hep, STD, TB line</td>
<td>$1.158 b</td>
<td>$1.096 b</td>
<td>$1.121 b</td>
<td>$1.118 b</td>
<td>$1.162 b (+$44.0 m)</td>
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<td>HIV Division of Prevention</td>
<td>$782.3 m (+$4.0 m)</td>
<td>$738.6 m (-$43.7 m)</td>
<td>$757.6 m (+$19.0 m)</td>
<td>$755.7 m (-$1.9 m)</td>
<td>$762.0 m (+$6.3 m)</td>
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<tr>
<td>DASH - HIV School Health</td>
<td>$32.0 m (+$10.2 m)</td>
<td>$30.5 m (+$1.5 m)</td>
<td>$31.2 m (+$0.7 m)</td>
<td>$31.1 m (+$0.1 m)</td>
<td>$37.4 m (+$6.3 m)</td>
<td>$50.0 m (+$18.9 m)</td>
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<td>Viral Hepatitis</td>
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<td>$31.4 m (-$1.0 m)</td>
<td>$31.4 m (+$0.0 m)</td>
<td>$31.3 m (-$0.1 m)</td>
<td>$62.8 m (+$31.5 m)</td>
<td>$62.8 m (+$31.5 m)</td>
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<td>STD Prevention</td>
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<td>$159.7 m (+$8.1 m)</td>
<td>$157.7 m (+$2.8 m)</td>
<td>$157.3 m (-$0.4 m)</td>
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<td>$212.0 m (+$54.7 m)</td>
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<td><strong>HRSA</strong></td>
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<tr>
<td>Ryan White Program Total</td>
<td>$2.302 b (+$55.0 m)</td>
<td>$2.249 b (+$143.4 m)</td>
<td>$2.319 b (+$70.1 m)</td>
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<td>$2.523 b (+$54.0 m)</td>
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<td>Part A</td>
<td>$671.3 m (+$5.6 m)</td>
<td>$624.3 m (-$47.0 m)</td>
<td>$655.9 m (+$31.6 m)</td>
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<td>Part B: Care</td>
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<td>Part B: ADAP</td>
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<td>Part F: AETCs</td>
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<td>$33.6 m (+$50.0 m)</td>
<td>$33.6 m (+$50.0 m)</td>
<td>$34.5 m (+$0.9 m)</td>
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</tbody>
</table>
Budget & Appropriations – FY16

- Holding line on community asks
- Wrote & organized sign-on letter to President
  - 148 groups signed
- President’s Budget
  - Maintain current funding levels
  - Double Investment in Hepatitis at CDC
  - Slight increases for HIV and DASH at CDC
  - Again proposes Part C/D consolidation
- Wrote & Organized Sign-on letter to Congress
Budget & Appropriations – FY16

- Congressional “Hill” Visits
  - ABAC, HAP, ADAP, Friends of HRSA & CDC
- Documents Preparation
- Congressional Briefing
  - Hosted and organized by The AIDS Institute
- Press Releases
- “Dear Colleague” letters
- Testimony for the Record
- Congressional Hearings
Budget & Appropriations – FY16

○ A roller coaster of a year
  ✔ Homeland security appropriation
    • Demonstrates intraparty splits
  ✔ Budget
    • President - break spending caps
    • House & Senate Rep – cut social services
    • Resolution?

○ Long year ahead before passage of a bill and signed by the President
For Immediate Release: 02.02.15

Media Contact: Carl Schmid: (202) 669-8267 cschmid@theaidsinstitute.org

PRESIDENT OBAMA’S BUDGET MAINTAINS STRONG COMMITMENT TO DOMESTIC HIV & HEPATITIS PROGRAMS
Proposes to Double CDC’s Investment in Hepatitis Prevention

Washington, DC – “The budget President Obama released today demonstrates his strong commitment to ending infectious diseases by increasing funding for HIV and hepatitis prevention at the CDC and maintaining funding for lifesaving HIV health care and medications for those who cannot afford them in the United States,” commented
Budget Highlights

- Ryan White HIV/AIDS Program $2.3 billion
- AIDS Drug Assistance Program (ADAP) $900.3 million
- Again - eliminate funding for Part D (serves women, infants, children, and youth) redirect to RW Part C
- Increasing HIV funding to CDC by $12.6 million for a total of $799 million
- The Budget focuses HIV resources on implementing evidence-based interventions and focusing on those people who are at highest risk for HIV, including gay men, African Americans, and young people.
Ryan White Program

- Focus on continued funding & ACA implementation
- Reauthorization not an immediate priority
- Part B Supplemental Analysis
  - ✔ Wrote & organized community sign-on letter to HRSA
    - 38 groups signed
- Ryan White Work Group Meeting
  - ✔ Beginning to address issues
  - ✔ TAI taking lead on supplemental funding
  - ✔ Educate members of congress on Program
- HHS Assist. Secretary for Planning and Evaluation (ASPE) Studies
- Georgetown University O’Neil Institute
- 25th Anniversary
Number and Percentage of HIV-Infected Persons Engaged In Selected Stages of HIV Care, US

1,032,800
86%

478,433
40%

441,661
37%

361,764
30%

HIV+ Ryan White Program Clients Who Received RW-Funded Medical Care

- Seen for at least 1 Medical Care Visit: 317,458 (100%)
- Retained in HIV Medical Care: 260,950 (82%)
- Achieved Viral Suppression: 230,475 (73%)

Ryan White Program Services

- Case Management
- Medical Care
- Medications
- Oral Health
- Treatment Adherence
- Food Bank
- Psychosocial Support
- Linguistics Outreach
- Transportation
- Health Education Risk Reduction
- Legal
- Housing
- Referrals
- Premium/Cost Sharing Assistance
- Substance Abuse Treatment

The AIDS Institute
**HIV Prevalence and Incidence, 1980-2010**

- People living with HIV
- New HIV Infections

Approx. 50,000 new infections annually.

**HIV Incidence by Age, 2010**

- 13-24: 26%
- 25-34: 31%
- 35-44: 24%
- 45-54: 15%
- 55+: 5%

**Estimated New HIV Infections by Route of Transmission, 2010**

- MSM: 64%
- Heterosexual: 25%
- IDU: 8%
- MSM-IDU: 3%

**Estimated Rate of New HIV Infections, 2010, by Gender and Race/Ethnicity**

- Male:
  - Black: 103.6
  - Hispanic: 45.5
  - White: 15.8
- Female:
  - Black: 38.1
  - Hispanic: 8.0
  - White: 1.9

**Sources**

Number and Percentage of HIV-Infected Persons Engaged In Selected Stages of HIV Care, US

<table>
<thead>
<tr>
<th>Stage</th>
<th>Percent of All People with HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosed</td>
<td>86%</td>
</tr>
<tr>
<td>Engaged in Care</td>
<td>478,433</td>
</tr>
<tr>
<td>Prescribed ART</td>
<td>441,661</td>
</tr>
<tr>
<td>Virologically Suppressed</td>
<td>361,764</td>
</tr>
</tbody>
</table>


HIV+ Ryan White Program Clients Who Received RW-Funded Medical Care

- Seen for at least 1 Medical Care Visit: 100%
- Retained in HIV Medical Care: 82%
- Achieved Viral Suppression: 73%


Ryan White Program Services

- Casework Management
- Mental Health
- Medical Case Management
- Oral Health
- Medical Care
- Medications
- Premium/Cost Sharing Assistance
- Substance Abuse Treatment
- Psychosocial Support
- Transportation
- Health Education/Risk Reduction
- Legal Services
- Food Bank

State Decision on Medicaid Expansion

Health Reform

- Ensuring it works for people with HIV, hepatitis and other chronic conditions

- 2015 Enrollment & Re-enrollment
  - White House & HHS meetings
  - Movement by Ryan White clients?

- Key Patient Group Voice & Leader

- “I AM (Still) ESSENTIAL coalition
  - Broad coalition of disease groups with patient perspective
  - Focus mainly on Essential Health Benefits & Rx coverage
  - Administration proposed that every insurance plan had to only cover one drug per class
MORE THAN 2,500 PATIENTS AND ADVOCATES CALL ON HHS TO ENSURE ESSENTIAL HEALTH BENEFITS PROVIDE COMPREHENSIVE, QUALITY AND AFFORDABLE HEALTH CARE

Patient Protections Must Remain the Highest Priority Say ‘I Am Essential’ Campaign & Other Petition Signers in Response to HHS Essential Health Benefits Bulletin

Washington, DC (January 31, 2012) – National advocacy organizations for chronically ill and disabled patients will file a petition today at 3pm with Department of Health and Human Services (HHS) Secretary Kathleen Sebelius voicing concern about HHS’ approach to Essential Health Benefits in the department’s December 16 bulletin. The petition will also serve as public comments on the bulletin, which are due to HHS today.

So far, more than 2,500 patients and advocates from 49 states, the District of Columbia and Puerto Rico
For Immediate Release

December 18, 2012

Contact: Carl Schmid
The AIDS Institute
(202) 669-8267
CSchmid@TheAIDSInstitute.org

151 PATIENT GROUPS SEND LETTER TO HHS SECRETARY ON ESSENTIAL HEALTH BENEFITS PROPOSAL

The AIDS Institute, Arthritis Foundation, Easter Seals, National Alliance of Mental Illness, Parkinson’s Action Network, and others urge Secretary Sebelius to protect individual needs of patients

Washington, DC, December 18, 2012—One hundred and fifty-one patient groups delivered a joint letter to Secretary Kathleen Sebelius today, requesting improvements to the proposed Essential Health Benefits (EHB) rule issued by the Department of Health and Human Services (HHS) last month. The letter comes during the thirty-day comment period the department has offered before it finalizes rules for EHB coverage.

In its November 26 issuance, the HHS outlined the types of benefits, including those pertaining to prescription drugs, that insurance plans must cover beginning in 2014. Under the department’s proposed regulation, health plans must either cover one-drug per class or the same number of drugs as the state’s benchmark plan, whichever is greater.

The patient groups state in their letter to Secretary Sebelius that while the new rule marks an improvement from the “one-drug per class” proposal the department had previously advanced, it does not go far enough in safeguarding patient access to required medications. Because the rule only requires plans to meet a target number of drugs per class without regard to what actual drugs are covered, “plans can choose not to include certain necessary drugs for any reason, and still meet the requirements of EHB coverage,” the letter says.
Implementation Issues

- **Limited benefits**
  - Medications not covered on formularies
  - No process to include new Rx
  - Utilization management

- **High cost-sharing**
  - Use of co-insurance
  - HIV/AIDS Rx subject to coinsurance in about 55% of plans, with an average coinsurance of 35% (Avalere)
  - Placing all drugs in a class on highest tier (discrimination?)

- **Lack of transparency and uniformity**
  - Formularies difficult to access
  - Need for plan-finder tools
Utilization Management

Utilization Management of HIV/AIDS Medicines

- Exchange Plans
  - UM: 26%
  - No UM: 74%

- Employer Plans
  - UM: 8%
  - No UM: 92%

- Benchmark Plans
  - UM: 5%
  - No UM: 95%
I AM (Still) ESSENTIAL

For Immediate Release
December 19, 2014

Contact: Carl Schmid
The AIDS Institute
(202) 669-8267
CSchmid@TheAIDSInstitute.org

279 Patient Groups Applaud Proposed Changes to Essential Health Benefits
Coalition Endorses Additional Patient Protections and Urges Further Action against Discrimination

Washington, DC (December 19, 2014) – Today, the “I Am (Still) Essential” coalition of patient groups sent a letter signed by 279 organizations to Health and Human Services (HHS) Secretary Sylvia Mathews Burwell applauding the recently released Notice of Benefit and Payment Parameters for 2016 which, once finalized, define Essential Health Benefits (EHB) for Qualified Health Plans (QHPs) in the future under the Affordable Care Act (ACA). The letter detailed how the many positive changes in the proposed rule will improve the plans available to patients. The letter also suggests additional changes that will increase positive patient outcomes and urges the rule to be finalized without diminishing any of the proposed improvements.
Health Reform

- I Am (Still) Essential Letter to CMS on Rx formulary links not working
  - Press Release & Coverage
  - Fixed within 24 hours
- Notice of Payment & Benefit Parameters of Proposed Rule
  - Process to Review Rx Adequacy & New Rx
  - Improved Plan Transparency
  - Improved Exceptions Process
  - Prohibit Mail-order only Plans
  - Define Discrimination
Health Reform

- Proposed Rule
  - Rapid review and offer comments to press
  - Analysis & Draft Comments for “I Am (Still) Essential”
  - Seek Sign-on
    - 279 organizations signed on
  - Drafted and issued press release
    - Sent to Press, Administration, community and industry partners

- Draft Letter to Issuers
  - Also addressed discrimination by plans
  - Comments submitted by TAI
Health Reform

- Final Rule Issued
  - Positive outcomes
  - Press Statement by TAI
  - “I Am (Still) Essential” Press Release
    - Sent to press, administration, and database

- Meetings with Administration
  - Office of Health Reform
  - CCIIO
  - HHS
HHS Rule for Plans in the Future

- Improved Plan Transparency
- Improved Exceptions Process
- Prohibit Mail-order only Plans (2017)
- Define Discrimination “May be discrimination if a plan places all or almost all Rx to treat a certain illness or in one class on highest tier”
Discrimination Complaint

- Reviewed plans by 10 issuers in the State
- Most plans have a range of tiering and nominal cost-sharing for HIV drugs
- Four issuers placed every drug, including generics, on highest tier and had very large patient co-insurance (e.g. 40% or 50%)
- Appeared to be an effort to keep HIV patients from these plans
- Filed Discrimination Complaint with Office of Civil Rights
The AIDS Institute and National Health Law Program (NHeLP) filed complaint with HHS Office for Civil Rights on May 29, 2014 against 4 plans.

- Asking OCR to investigate and take corrective action
  - Against Florida plans
  - And others throughout country
Discrimination Complaint

○ Continues to receive media, community, industry and government attention

○ No formal response
  ✓ OCR staff working on it
  ✓ Addressed in rules and statements
  ✓ Submitted follow up letter to OCR in January
  ✓ Continue to urge Administration to take action
    • Press releases, press statements & PACHA public comments
Discrimination Complaint

- Florida Office of Insurance Regulation
  - Reached agreements with 4 issuers
  - Initially only for 2015, in one state and 3 of the agreements only impacts 4 brand Rx
    - Move generics to non-preferred generic tier
    - Capped co-pays for 4 HIV drugs at $200 (instead of 40% or 50% co-insurance)
    - No prior authorizations or step therapy for HIV drugs
    - Insurers had to meet with The AIDS Institute
  - Humana went further: Dropped all HIV drugs to no more than 10% of the cost (2016 too)
<table>
<thead>
<tr>
<th>QHP Issuer</th>
<th>Benefit Design</th>
<th>Cost-Sharing</th>
</tr>
</thead>
</table>
| **Ambetter** | • Most HIV drugs on Tier 1 or 2  
• 2 HIV drugs on Tier 4 | • Tier 1 copays range $10-$25 (after deductible in some plans)  
• Tier 2 copays range $50-$75 (after deductible in some plans)  
• Tier 4 coinsurance ranges 20-30%, with one plan instead using $250 copay (after deductible) |
| **Blue Cross** | • Most HIV drugs on Tier 1 or 2  
• Only 1 drug on Tier 3 without a generic or other alternate form on lower tier | • Tier 1 copays range $10-$25 (after deductible in some plans)  
• Tier 2 copays range $40-$70 (after deductible in some plans)  
• Tier 3 copays range $70-$100 |
| **Molina** | • Most HIV drugs on Tiers 1 and 2  
• 1 drug on Tier 3  
• 2 drugs on Tier 4 | • Tier 1 copay $20  
• Tier 2 copay $55  
• Tiers 3 and 4 require 30% coinsurance |
## Examples of Bad Florida Plans

<table>
<thead>
<tr>
<th>QHP Issuer</th>
<th>Benefit Design</th>
<th>Co-Insurance and Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoventryOne</td>
<td>• Tier 5 – All HIV Drugs, Including Generics</td>
<td>• 40% after $1,000 Rx deductible&lt;br&gt;• Most Require Prior Authorization&lt;br&gt;• Quantity Limits (e.g., no 90-day supply)</td>
</tr>
<tr>
<td>Cigna</td>
<td>• Tier 5 – All HIV Drugs, Including Generics</td>
<td>• 40-50% after deductible ranging $0 - $2,750&lt;br&gt;• 30-day supply limits</td>
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<tr>
<td>Humana</td>
<td>• Tier 5 - All HIV Drugs, Including Generics</td>
<td>• 40-50% after $1,500 deductible&lt;br&gt;• 30-day supply limits</td>
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<tr>
<td>Preferred Medical</td>
<td>• Specialty Tier- All HIV Drugs, Including Generics</td>
<td>• 40% co-insurance</td>
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</table>
Discrimination Complaint

- 2015 plans
  - TAI has reviewed plans for HIV & hepatitis Rx
  - Issuers continue to place Rx on highest tiers
    - More common for Hepatitis Rx
  - Pursuing additional complaints w/NHeLP
    - Planning one for hepatitis
    - Other states and disease groups
      - Sidley Austin pro bono firm

- Awaiting non-discrimination regulations
BIAS CLAIMS FOR INSURERS IN COVERAGE OF H.I.V.
By KATIE THOMAS MAY 29, 2014

Health care advocates said on Thursday that four insurers offering plans in the new federal marketplace discriminated against people with H.I.V. or AIDS by requiring them to pay high out-of-pocket costs for drugs to treat H.I.V., including generic medications.

Two groups, the AIDS Institute and the National Health Law Program, filed a complaint on Thursday with the Department of Health and Human Services’ Office for Civil Rights, saying the insurers had violated a provision in the new health care law that prohibits discriminating against consumers because of their medical conditions. They said the insurers had subjected people infected with H.I.V. to restrictions on medications that most patients take daily to keep the virus in check.......

Miaml Herald

COMPLAINANTS SAY HEALTH INSURERS USED HIGH DRUG CO-PAYS TO DISCOURAGE PEOPLE WITH HIV/AIDS FROM ENROLLING
BY PATRICIA BORNs May 29, 2015

Four Florida insurance companies offering Affordable Care Act policies are discriminating against people with HIV or AIDS, according to two health-rights organizations that plan to file a formal complaint with the federal government Thursday.

The complaint by the AIDS Institute and the National Health Law Program — nonprofits advocating for the health rights of the poor and those living with chronic diseases — cites CoventryOne, Cigna, Humana and Preferred Medical for creating prescription-drug policies that the groups say discourage people with HIV/AIDS from enrolling in their Florida healthcare marketplace plans........
Developments Since Filing

- The AIDS Institute & HIV advocates in other states interested in filing more complaints
- Other disease groups also interested
- Await decision from Office of Civil Rights
- CMS still developing Sec. 1557 Regulations
- Continued media attention
2015 Plans

- CMS indicated they will utilize outlier tests with “more rigorous” review
- No evidence of changes between good and bad plans
  - Some plans worse
  - (co-insurance increased from 40% to $50%)
  - Cigna plans outside FL
- Continued advocacy & legal action necessary
Media

- Wall Street Journal (2)
- Washington Post (5)
- New York Times (3)
- Miami Herald (3)
- Bloomberg BNA (4)
- Roll Call (3)
- Austin American Statesmen
- Pink Sheet Daily
- Congressional Quarterly
- The Specialist
- The Edge (Boston) (2)
- Tampa Bay Times
- Inside Health
- Modern Health Care
- Inside Health (4)
- Politico (3)
- Business Week
- Kaiser News
- The Hill (3)
- Washington Blade
- Charlotte Observer
- Forbes
- National Law Journal
- Chicago Tribune
AETNA AGREES TO SIGNIFICANTLY REDUCE PATIENT COSTS
FOR HIV DRUGS NATIONWIDE
Sets Example for Other Insurers to Lower Costs so Patients Can Access Medications

Washington, DC – The AIDS Institute welcomes a major announcement by Aetna that it will significantly reduce patient costs for HIV medications nationwide in the qualified health plan marketplace.

“This is a major victory for people living with HIV who rely on medications to remain healthy,” commented Carl Schmid, Deputy Executive Director for The AIDS Institute. “We thank Aetna for recognizing that charging excessive co-insurance is wrong and harmful to people with HIV who cannot afford the cost of their medications.”

In its announcement, Aetna, along with its Coventry plans, will move all but one HIV drug (an injectable fusion inhibitor) from a specialty tier to either a generic or non-preferred brand tier, lowering patient cost-sharing to co-payments ranging between $5 and $100, after deductibles are met. Currently, Aetna places almost all HIV drugs on the highest tier and charges beneficiaries co-insurance as high as 50 percent. This results in patient cost-sharing of about $1,000 a month for some popular HIV drugs, making it almost impossible for patients to access their lifesaving medications.
Next Steps

- Adverse tiering is happening in other states and for other Rx classes
- 2015 plans no better than 2014, actually for some plans more Rx subject to co-insurance
- Opportunity for states and CMS to review 2016 plans
- Still awaiting decision from Office of Civil Rights
Florida Legislative Update

For PPG & PCPG Meetings

by Florida HIV/AIDS Advocacy Network (FHAAN)

May 12th, 13th & 14th
2015-2016 Budget & Allocations

- The Legislature adjourned before completing the budget bill
- They will return June 1st through June 20th for a Special Session on the budget; the Budget must be signed by July 1st per Florida’s Constitution
- The Senate and House are about $4 billion apart on their budgets
- The House and Governor Scott don’t want to expand Medicaid, but the Senate has a plan that would open Medicaid to more Floridians
- Neither House nor Senate has any cuts to HIV/AIDS programs
HIV Testing Legislation

- HB 321 sponsored by Representative Avila (R-Hialeah) and the partner bill SB 512 by Senators Thompson (Orlando) and Soto (Kissimmee):
  - Streamlines HIV testing & screening in traditional health care settings, Hospital emergency rooms, and private physician offices. Changes the written consent to informed consent; patient may “opt out”
  - Reporting and notification of positive test results is unchanged
  - Maintains patient notification in accordance with CDC guidelines
  - Passed the House 119 to 0, passed the Senate 39 to 0; the Bill now awaits authorization by Governor Scott
Right to Try Act

- HB 269 by Rep. Ray Pilon (Sarasota) and SB 1052 by Senator Jeff Brandes (St. Petersburg)
- Allows pharmaceutical companies to provide eligible patients with investigational products
- Eligible patient is defined as a person who has a terminal illness
- House Bill 269 passed the Senate 39 to 1 and the House 113 to 0
- Bill awaits authorization by Governor Scott
Join the Florida HIV/AIDS Advocacy Network at:
FHAAN@googlegroup.com