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# Integrating Hepatitis Services into HIV Programs

## Setting the Federal Policy Stage

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*USCA 2015*  
*Washington, DC*  
*September 10, 2015*

# Agenda – Setting the Stage

- Questions to consider in this session
- Brief overview of hepatitis and HIV co-infection
- Opportunities to respond in Ryan White programs
- What ADAPs are doing – focus on HCV treatment
- Health care funding source: Reimbursement for hepatitis testing under health care reform

# Questions to Consider

How are HIV programs in your state supporting hepatitis care?

- Curative HCV treatments on ADAP formularies
- Wrap around coverage to help with cost-sharing for insured clients
- Promising steps to improve your state's response to HIV-Hepatitis co-infection

How are Ryan White and CDC grantees addressing co-infection?

- Testing, counseling, vaccination, treatment
- Tracking and reporting of incidence and treatment data on co-infection
- Stakeholder collaboration – behavioral health, justice system

# Viral Hepatitis Overview

- Chronic infectious disease that if untreated can lead to serious liver conditions including cancer and cirrhosis
- Estimated 3.5 million in U.S. with HCV
  - 3 out of 4 people unaware of infection
  - 15,000 deaths annually
  - Curable with new direct-acting agents (DAAs)
- 1.5 million in U.S. with HBV
  - Can be avoided with vaccination
- 25% or more of people living with HIV have HCV
- 5-10% of people living with HIV have HBV

# Hepatitis Treatment is HIV Care

- Institute of Medicine 2010 Recommendations
  - HRSA and CDC should “provide resources and guidance to integrate comprehensive viral hepatitis services” into HIV care settings
- Viral Hepatitis Action Plan
  - Promote screening
  - Monitor rates of testing for hepatitis in HIV population
  - Support safety net providers to care for people with hepatitis
- HIV Guidelines
  - Test for and treat viral hepatitis
  - Counsel regarding risk of acquiring and transmitting
  - Vaccinate for HBV

# Ryan White Provisions

- Ryan White authorities currently extend resources for hepatitis care only for co-infected HIV clients
  - Ryan White law does not require ADAPs to cover treatment for viral hepatitis
- Provisions in 2006 reauthorization clarify intent to address co-infection
  - Through client representation Part A Planning Councils
  - Use of Part B funds for co-infection service coordination
  - Part C providers must provide hepatitis counseling

# Ryan White Provisions

- During 2009 reauthorization process, Congress acknowledged resource needs for co-infection
  - “Unfortunately, coverage for diagnostics, monitoring, treatment and vaccination against viral hepatitis is not uniformly available through state AIDS Drug Assistance Programs (ADAPs), due to funding shortfalls.” (Committee Report)
- Legislatively, 2009 law retained status quo for co-infection care



# Ryan White Today

- Current provisions on hepatitis are outdated and limited
  - Curative HCV treatments, approved since last 2009 reauthorization, are now standard of care
  - Risk of co-infection growing in emerging IDU populations
  - Health care reform brings enhanced resources and flexibility for grantees to improve responses to co-infection



February 13, 2015

Dear Ryan White HIV/AIDS Program Part B AIDS Drug Assistance Program Colleagues:

The treatment of hepatitis C virus (HCV) is rapidly evolving. New oral medications have greatly improved the outcomes of individuals with hepatitis C infection by achieving sustained viral suppression for the majority of people who complete treatment. These new regimens are not only more efficacious, but are better tolerated and are of shorter duration. In addition, studies suggest that individuals with HIV who are co-infected with HCV and utilize the new oral medications have similar rates of HCV viral suppression as those with HCV mono-infection.<sup>1</sup>

New HCV treatments are an important development as there are as many as one quarter of individuals with HIV infection in the United States that are also infected with HCV; HCV co-infection rates among HIV infected injection drug users is even higher with as many as 80 percent being co-infected.<sup>2</sup> HIV/HCV co-infected individuals have higher rates of progression to end-stage liver disease including fibrosis, cirrhosis and hepatocellular carcinoma. Even when HIV is virally suppressed, those with HIV/ HCV co-infection have higher rates of advanced liver fibrosis, cirrhosis, non-hepatic organ dysfunction and overall mortality compared with individuals that are HCV mono-infected. However, co-infected individuals that achieve sustained virologic response to hepatitis C treatment have lower rates of end-stage liver disease as well as lower rates of mortality related to liver disease.<sup>3</sup>

These advances in hepatitis C treatment underscore the importance of identifying those with HIV/HCV co-infection and getting their HCV infection treated. As per the [DHHS Guidelines for the Uses of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents](#), all HIV infected individuals should be screened for HCV and those at high risk for acquiring HCV should be screened annually. Individuals with HIV/HCV co-infection should receive appropriate counseling on avoiding transmission to others as well as avoiding alcohol and other liver-toxic substances. HIV/HCV co-infected individuals also need to be screened for hepatitis B and for immunity to hepatitis A and appropriately vaccinated for both. It is also important that those with HIV/HCV co-infection be evaluated for and receive treatment for hepatitis C.

AIDS Drug Assistance Programs (ADAPs) have an important role in providing access to medications for people living with HIV, including those with HCV co-infection. When feasible, ADAPs are encouraged to add hepatitis C medications to their formularies. For those living with both HIV and HCV, providing access to hepatitis C medications improves the overall health outcomes for people living with HIV who are served by the Ryan White HIV/AIDS Program.

Sincerely,

Laura W. Cheever /s/

Laura W. Cheever, M.D., ScM  
Associate Administrator

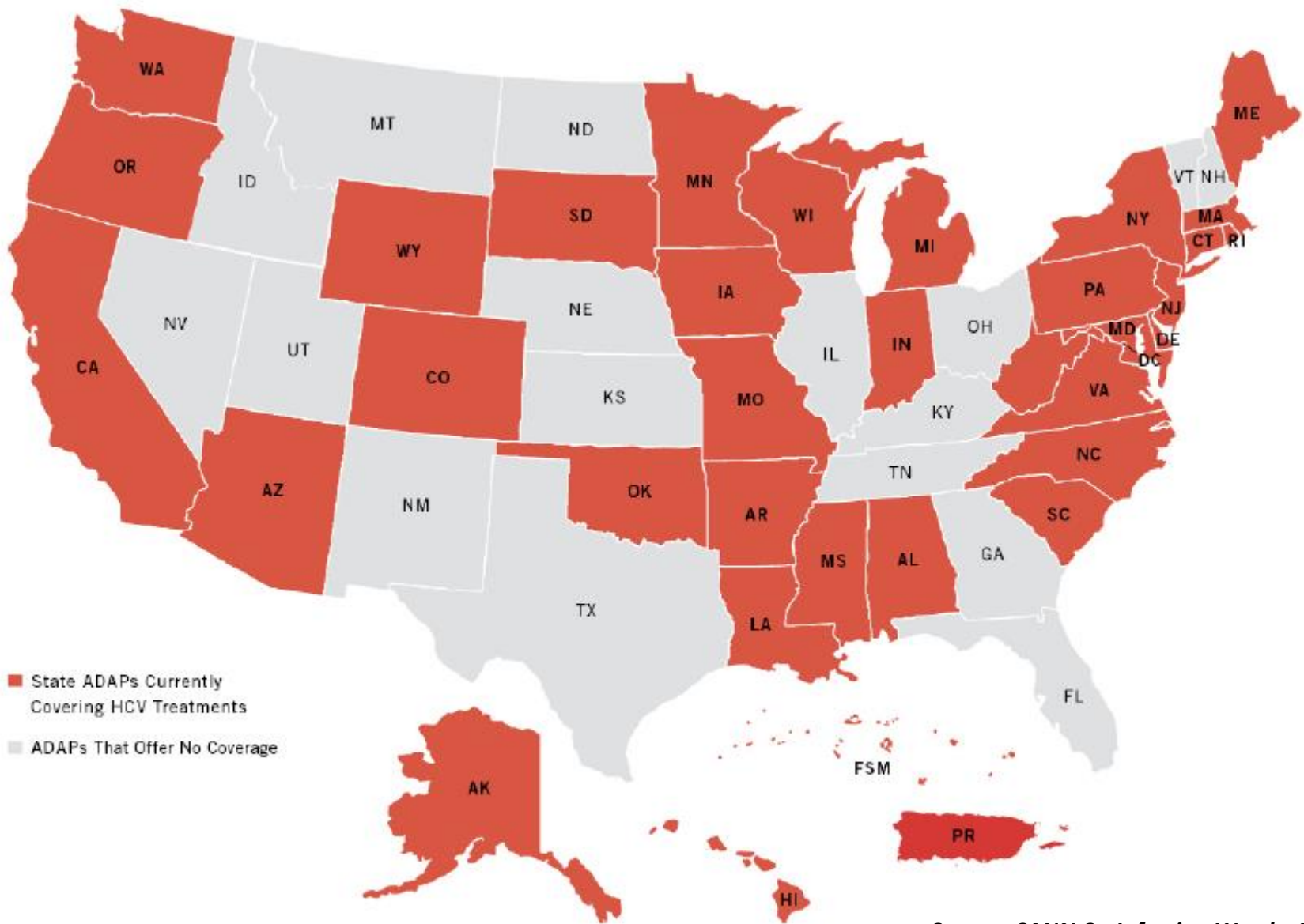
# HRSA Letter to ADAPs

## February 13, 2015

- Benefits of new HCV treatments
- HIV clients should be screened, counseled, and vaccinated as appropriate.
- “AIDS Drug Assistance Programs (ADAPs) have an important role in providing access to medications for people living with HIV, including those with HCV co-infection. When feasible, ADAPs are encouraged to add hepatitis C medications to their formularies.”

# ADAP Formularies

- NASTAD ADAP Monitoring – Online database
  - TAI Analysis August 2015
  - 16 states have no HBV treatment on formulary
  - 26 states do not cover HBV vaccine
  - 22 states have no HCV treatment on formulary
  - 19 states cover older non-DAA treatments
- CANN Monthly Report - Co-Infection Watch
  - August 2015 report ([tiicann.org/co-infection watch](http://tiicann.org/co-infection-watch))
  - 36 states not covering DAAs
  - 17 states have no HCV treatment on formularies



- State ADAPs Currently Covering HCV Treatments
- ADAPs That Offer No Coverage

Source: CANN Co-Infection Watch, August 2015

# ADAP Trends

- Coverage for HCV treatment varies by state
  - ADAP formularies can fluctuate over time
  - States with rural populations and no ADAP coverage, including KY, TN, GA, FL, TX
  - 19 states cover older therapies only
  - 5 states cover Sovaldi, Olysio, Harvoni, VieKira: HI, MA, MN, NJ, WA
  - 4 states cover Sovaldi, Harvoni, VieKira: AZ, CO, IA, VA

*Source:* CANN Co-Infection Watch, August 2015

# ADAP Trends

- More information needed about coverage when ADAP-purchased insurance plans do not cover DAA
  - Colorado will, with prior authorization, if funds available (July 2015 Co-Infection Watch)
- Support and Coordination
  - Co-Infection Watch asks ADAPs if they refer co-infected clients to patient assistance programs (PAPs) for help with HCV
    - As of July 2015 report, only 14 report doing so
    - AR, CT, DE and PR report they do NOT refer to PAPs for HCV

*Source: CANN Co-Infection Watch, July 2015*

# Summary – Ryan White Programs

- Limited federal requirements for Ryan White grantees
- Clear direction that hepatitis testing, counseling, vaccinating and treatment are standard HIV care
- Significant potential with new HCV treatments to improve HIV outcomes
- Grantees should be encouraged to respond to new opportunities to full extent
- Health care reform brings additional resources

# Health Care Reimbursement

## Preventive Services Benefits

- ACA requires most public and private payers to cover, without cost-sharing, preventive services graded “A” or “B” by the U.S. Preventive Services Task Force (USPSTF).
- USPSTF recommendations for hepatitis testing:
  - One-time screening for Hepatitis C in persons born between 1945 and 1965 (“Baby Boomers”)
  - Screening for Hepatitis C in persons at high risk
  - Screening for Hepatitis B in persons at high risk
- “B” grades – high certainty of moderate or substantial benefit



# Health Care Reimbursement

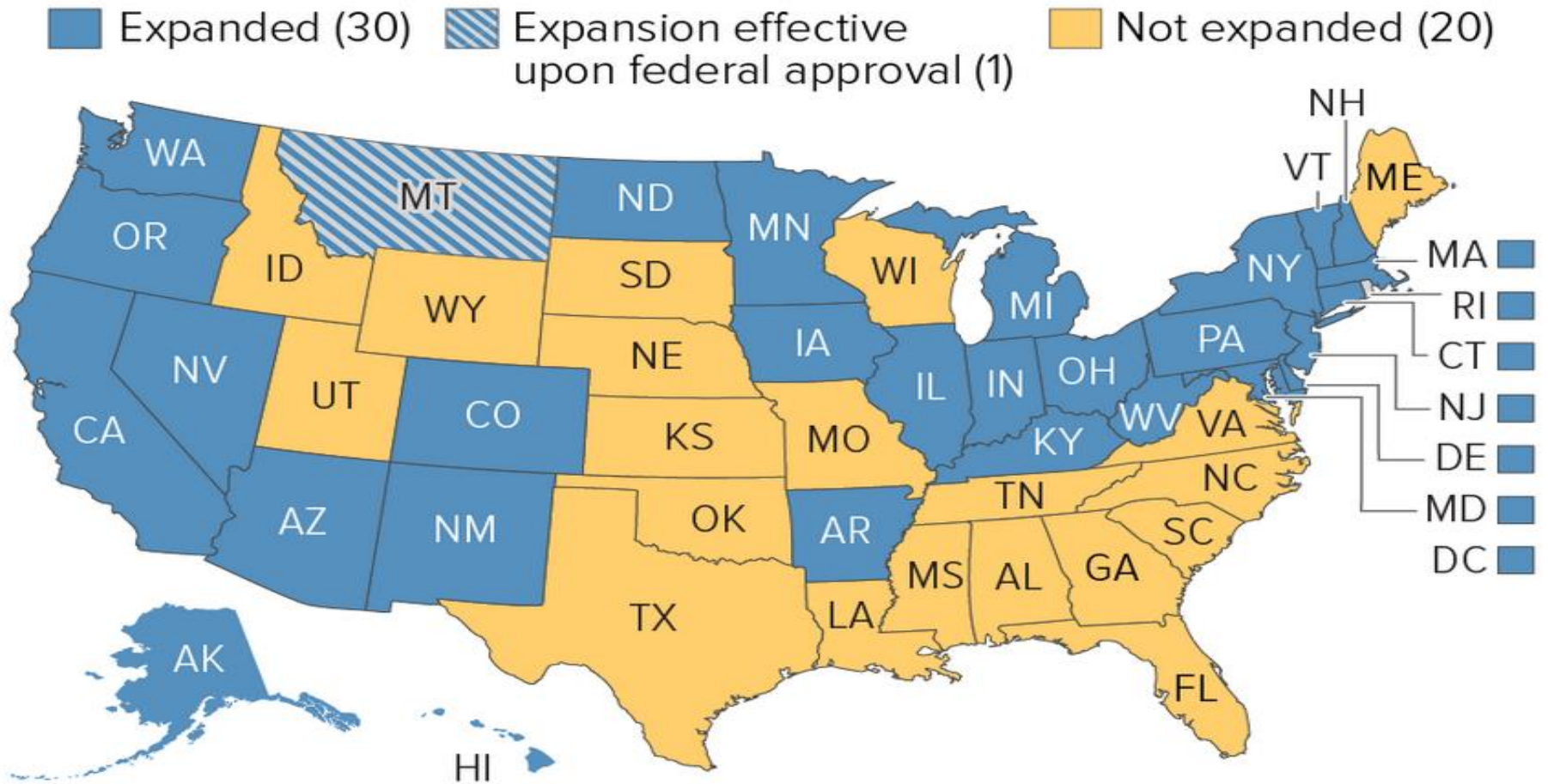
## Private plans must cover hepatitis screening

- Required since 2010 to cover USPSTF-recommended services without cost-sharing
- Applies to plans inside and outside Marketplace (unless grandfathered)

## Expanded Medicaid plans must cover hepatitis screening

- Required since 2014 to cover USPSTF-recommended services without cost-sharing
- 30 states have opted to expand

# Status of State Medicaid Expansion in 2015



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# Health Care Reimbursement

## Traditional Medicaid

- Hepatitis testing covered if medically-necessary as mandatory lab service
- In addition, under ACA, 1% increase in federal match to states that agree to cover all USPSTF-recommended preventive services, without cost-sharing
  - 11 states have been approved: CA, CO, DE, HI, KY, NH, NJ, NV, NY, OH, WI
  - Routine and risk-based hepatitis screening covered without cost-sharing

# Health Care Reimbursement

## Medicare

- Covers A & B preventive services after national coverage determination (Medicare Improvements for Patients and Providers Act of 2008)
- Without cost-sharing (ACA)
- For HCV Testing, Medicare finalized National Coverage Determination (NCD) in June 2014
  - Medicare now covers one-time HCV testing for boomers and risk-based testing annually without cost-sharing
- Advocates currently seeking NCD for risk-based HBV screening consistent with USPSTF

# Conclusion – Moving Forward

- Legislative and administrative initiatives needed to increase capacity to address HIV/Hepatitis co-infection
- Without Ryan White reauthorization
  - Report language in appropriations
  - HRSA activities to identify and promote best practices
  - State-level advocacy for ADAP formulary coverage
- Reauthorization – incentives and strategies to address co-infection through all Parts
- Opportunities for Ryan White and CDC grantees to integrate HIV and hepatitis responses
  - Local collaboration
  - Billing capacity

# THANK YOU

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