NATIONAL ADAP MONITORING PROJECT
ANNUAL REPORT
MODULE THREE
ADAP Coverage of Hepatitis Treatments

MARCH 2012

Prepared by

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The National ADAP Monitoring Project is one component of NASTAD's National ADAP Monitoring and Technical Assistance Program which provides ongoing technical assistance to all state and territorial ADAPs. The program also serves as a resource center, providing timely information on the status of ADAPs, particularly those experiencing resource constraints or other challenges, to national coalitions and organizations, policy makers, industry members, and state and federal government agencies. NASTAD received support for the National ADAP Monitoring and Technical Assistance Program in 2011 from the following companies: Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, Janssen Therapeutics and ViiV Healthcare. NASTAD also receives funding to provide technical assistance to ADAPs through a Training and Technical Assistance Cooperative Agreement with the Health Resources and Services Administration (HRSA).

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MODULE THREE: HIV/AIDS AND VIRAL HEPATITIS CO-INFECTION

Millions of Americans are at risk for hepatitis A virus (HAV), hepatitis B virus (HBV) and hepatitis C virus (HCV) infection and millions more are living with chronic viral hepatitis. In 2009 alone, there were an estimated 21,000 new HAV infections, 38,000 new HBV infections and 16,000 new HCV infections in the United States.[1] It is estimated that there are 1.4 million Americans living with chronic HBV and 3.9 million living with chronic HCV. Due to the absence of a national chronic viral hepatitis surveillance system, it is believed that these estimates are much lower than the actual burden of disease. While both HAV and HBV are vaccine-preventable and there exist longstanding recommendations to vaccinate at-risk adults, coverage rates among adult populations such as gay/bisexual and other men who have sex with men (MSM), persons who inject drugs (IDU) and persons living with HIV remain low. These low vaccination rates are alarming as millions of Americans remain needlessly unvaccinated and susceptible to disease. Also alarming are statistics which indicate that up to one half of Americans infected with HBV are unaware of their status while three quarters infected with HCV are unaware of their status.

On May 12, 2011, in response to an Institute of Medicine Report on Hepatitis and Liver Cancer, the Department of Health and Human Services (HHS) released an Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis (HHS Action Plan). The HHS Action Plan is a critical foundation for mounting an aggressive response to address the rising number of hepatitis-related deaths in the U.S. According to an analysis of mortality trends performed by CDC, viral hepatitis mortality rates have increased substantially in the U.S. over the past decade.[2] At present, only 25-35 percent of people living with chronic viral hepatitis are aware of their infection.[3] Full implementation of the HHS Action Plan could result in an increase in the proportion of those who know their HBV and HCV infections, reduce the number of new HCV infections and eliminate mother-to-child transmission of HBV.

It is estimated that up to 15 percent of people living with HIV are co-infected with HBV and up to 30 percent are co-infected with HCV. Further, viral hepatitis is the leading cause of non-AIDS-related death in people co-infected with HIV and viral hepatitis.[4] Co-infection increases the progression to liver disease and can occur without symptoms. As screening for viral hepatitis increases, the demand for care and treatment services is likely to grow for both mono-infected and HIV co-infected individuals.

VIRAL HEPATITIS AND THE RYAN WHITE PROGRAM

Coverage of viral hepatitis services for persons living with HIV is allowable through the Ryan White Program and the AIDS Drug Assistance Program (ADAP). Some services (e.g., testing) are allowable through Ryan White clinical services and access to HAV/HBV vaccines and HBV/HCV drugs are allowable expenditures through ADAPs for co-infected individuals. Coverage of vaccines and HBC/HCV drugs on ADAP formularies varies across the country as states determine locally what services, vaccines and drugs will be covered.

With increasing mortality associated with viral hepatitis co-infection, it is increasingly important for persons living with HIV and viral hepatitis to have access to viral hepatitis treatments. Currently, not all states include HAV/HBV vaccine or HBV/HCV drugs on their ADAP formularies. Twenty-six states provide HAV/HBV vaccines, 27 states provide at least one medication for HBV and 28 states provide at least one medication for HCV. Equally important is the coverage of diagnostic testing to diagnose viral hepatitis infection and to monitor disease progression and treatment outcomes. Only nine states cover at least one type of viral hepatitis diagnostic service through ADAP.

WHY ALL STATES DO NOT COVER VIRAL HEPATITIS SERVICES

There are several reasons states may not include viral hepatitis vaccines and medications. Given state budget constraints and the current ADAP crisis, some jurisdictions have not provided viral hepatitis services and/or included HBV/HCV drugs on their formularies. In some jurisdictions, as a method of cost

containment, viral hepatitis medications have been removed from the ADAP formulary. Finally, some states have not covered viral hepatitis services and medications because the demand from providers and persons living with HIV/AIDS has not warranted it.

For states with viral hepatitis services covered through the Ryan White Program and ADAPs, there has not been a substantial uptake in utilization of the HAV/HBV vaccine and/or HBV/HCV drugs. This is due to a number of factors, including a general lack of understanding of viral hepatitis among health care providers and persons at risk of co-infection. However, AIDS Education and Training Centers (AETCs) and others are working to educate HIV-treating clinicians about the importance of evaluating and treating co-infected patients.

Providers have also indicated that accessing the HAV/HBV vaccine through an ADAP pharmacy, as opposed to in a clinic, makes it difficult to deliver this important preventive vaccine.

Additionally, it can be challenging for persons with underlying mental health or substance use issues to undergo HCV treatment, which often exacerbates existing mental health complications. Some clinicians are also resistant to treat HCV in co-infected persons due to the need for increased case management and support for these patients. Finally, some clinicians and patients are monitoring HCV progression and waiting for new therapies to become available. New treatments that have currently become available present similar side effects that must be managed and will have to be added into the existing standard of care of HBV/HCV drugs.

VIRAL HEPATITIS RECOMMENDATIONS FOR PERSONS LIVING WITH HIV

The Centers for Disease Control and Prevention recommend that persons living with HIV should receive the following viral hepatitis services:

- Testing for hepatitis B
- Testing for hepatitis C
- Vaccination against hepatitis A
- Vaccination against hepatitis B (if susceptible)

TREATMENT ADVANCES

There are many drugs undergoing development that, once approved, will improve current HBV and HCV therapies. The majority of development has focused on improving HCV treatment. Two new direct-acting antivirals (protease inhibitors) were FDA approved in 2011. In clinical trials, the two new drugs, telaprevir (brand name, Incivek) and boceprevir (brand name, Victrelis) have significantly increased HCV cure rates from 40 percent to as high as 80 percent and decreased treatment duration from 48 weeks to 24 weeks.

Approval of these treatments for co-infected persons is expected at a later date. Much of the drug development data focuses on mono-infection. Data on drug safety, efficacy and tolerability, including drug resistance and drug interactions of new HCV drugs with current HIV drugs, is currently limited. In one clinical trial however, a direct-acting antiviral found 74% of people co-infected had undetectable HCV viral loads 12 weeks after treatment ended.

While telaprevir and boceprevir show great promise for persons living with mono- or co-infection of HCV, it is important to note that they must be used in combination with the current standard of care for HCV which includes pegylated interferon and ribavirin. ADAPs that choose to provide these new treatments, therefore, will need to continue to cover these existing therapies if they wish to provide the full standard of care for these patients.

Even with the approval of these new medications, successful treatment of HCV will continue to be fairly complex. Drug effectiveness can be limited by a number of factors including the person's genetics, the type of genotype or subtype of HCV, drug contraindications and the potential for drug resistance. As well, new treatments must be closely managed to ensure adherence as they may present new side effects such as anemia, rash and depression that are in addition to the side effects caused by medications in the current standard of care. While these new treatments will likely change the HCV treatment paradigm, new treatments will also likely pose new challenges, including the high cost of treatments that potentially result in a cure for people infected with HCV.

RESOURCES

In 2011, the Health Resources and Services Administration (HRSA) released *A Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIVA quick reference guide for clinicians in the diagnosis, evaluation, and treatment of HCV in the setting of HIV primary care.*

Treatment Action Group monitors HCV treatments in development. Information can be found in their Hepatitis C Treatment Pipeline Report.

NASTAD has produced a basic fact sheet on viral hepatitis co-infection which can be found on the NASTAD website.

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[1] http://www.cdc.gov/ncidod/diseases/hepatitis/resource/PDFs/disease_burden.pdf
[2] http://www.medpagetoday.com/MeetingCoverage/AASLDMeeting/29552
[3] http://www.cdc.gov/hiv/topics/msm/index.htm
[4] Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection. MMWR 2008; September 19, 2008;57(RR-8) http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5708a1.htm
http://www.cdc.gov/ncidod/diseases/hepatitis/resource/PDFs/disease_burden.pdf
[5]http://www.cdc.gov/hepatitis/Populations/hiv.htm

MODULE THREE: DETAILED FINDINGS

AIDS Drug Assistance Programs (ADAPs) provide life-saving HIV treatments to low income, uninsured, and underinsured individuals living with HIV/AIDS in all 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, the Federated States of Micronesia, Guam, the Northern Mariana Islands, Republic of Palau and the Republic of the Marshall Islands. In addition, some ADAPs provide insurance continuation and Medicare Part D and Medicaid wrap-around services to eligible individuals. ADAPs are a component of the federal Ryan White Part B Program that provides necessary medical and support services to low income, uninsured and underinsured individuals living with HIV/AIDS in all states, territories and associated jurisdictions.

The *Annual Report* of NASTAD's National ADAP Monitoring Project is based on a comprehensive survey of all ADAPs. This 17th release of the *Annual Report* updates prior findings with data from ADAP's fiscal year 2011[1] as well as provides a detailed snapshot of data from the month of June 2011. This module of the *Annual Report* reflects the latest available data and discusses recent policy and programmatic changes affecting ADAPs.

To provide interested stakeholders with more timely information, NASTAD is releasing the 2012 National ADAP Monitoring Project *Annual Report* in several modules. Detailed information related to ADAP budgets, client enrollment and utilization, client demographics, prescription distribution and payment methods, expenditures and prescriptions filled, insurance coordination, program eligibility, and program management and administration are included in Module One. Module Two highlights detailed information on ADAP coordination with Medicare Part D, ADAP coordination with Pre-existing Condition Insurance Plans (PCIPs) and ADAP coordination with the CMS Section 1115 Waiver process. This module includes updated information on ADAP inclusion of hepatitis treatments. The three modules will be combined into a final, comprehensive report.

A comprehensive survey was sent to all 58 jurisdictions[2] that received federal ADAP earmark funding in FY2011; 52 responded (see Methodology on page 9). A supplemental survey was sent to all 58 jurisdictions in January 2012; 48 responded. Most data included in this report are from FY2011, June 2011 and December 2011, unless otherwise noted. Detailed findings from the survey are included below. Tables and charts depicting the data follow the detailed findings and a glossary of key terms used throughout this report is also included.

ADAP AND HEPATITIS B TREATMENT

Hepatitis B medications available on some ADAP formularies include Adefovir Dipivoxil (Hepsera), Entecavir (Baraclude), Interferon Alfa-2b (Intron A), Lamivudine (Epivir-HBV, Zeffix, Heptodin), Peginterferon alfa-2a (Pegasys) and Telbivudine (Tyzeka, Sebivo).

- In June 2011, 28 ADAPs covered at least one of these medications for HBV on their formularies (see Chart 1 and Table 1).

- ADAPs filled 260 hepatitis B treatment prescriptions for 234 clients in June 2011. In FY2010, ADAPs filled 3,170 hepatitis B prescriptions (see Table 2).

ADAP AND HEPATITIS C TREATMENT AND DIAGNOSTICS

HCV is classified as an HIV-related opportunistic infection, due to the relatively high co-infection rate of HIV and HCV.[3] Because there is no national funding source specifically for HCV treatment, most of the burden for treating co-infected patients has fallen on ADAPs and other Ryan White programs. Hepatitis C medications available on some ADAP formularies include Interferon Alfa-2b (Intron A), Recombinant Interferon Alfa-2a (Roferon), Consensus Interferon (Infergen), Peginterferon Alfa-2a (Pegasys), Peginterferon Alfa-2b (PEG-Intron), Recombinant Interferon Alfa-2a (Roferon), Ribavirin, Incivek (Telaprevir) and Victrelis (Boceprevir).

- In June 2011, 28 ADAPs covered at least one of these medications for HCV on their formularies (see Chart 2 and Table 3), compared to 23 ADAPs in December 2010.

- ADAPs filled 289 hepatitis C treatment prescriptions for 174 clients in June 2011. In FY2010, ADAPs filled 3,702 hepatitis C prescriptions (see Table 4).

- Nine ADAPs reported providing coverage for hepatitis C diagnostics in June 2011 (see Table 5), including:
    - Nine ADAPs covered HCV screening.
    - Seven ADAPs covered qualitative HCV RNA.
    - Eight ADAPs covered quantitative viral load.
    - Six ADAPs covered HCV genotype.

ADAP AND HEPATITIS VACCINES

Hepatitis A and B vaccines are recommended for those at high risk for and living with HIV (see Chart 3 and Table 6).[4]

- Twenty-six ADAPs covered the hepatitis A and B combination vaccine in June 2011. Twenty-two ADAPs covered this vaccine in December 2010.

- Twenty-six ADAPs covered the hepatitis A vaccine in June 2011. Twenty-one ADAPs covered this vaccine in December 2010.

- Twenty-six ADAPs covered the hepatitis B vaccine in June 2011. Twenty-one ADAPs covered this vaccine in December 2010.

KEY DATES IN THE HISTORY OF ADAPS

1987: First antiretroviral (AZT, an NRTI) approved by the FDA; Federal government provides grants to states to help them purchase AZT, marking beginning of federally funded, state-administered "AZT Assistance Programs."

1990: ADAPs incorporated into Title II of the newly created Ryan White CARE Act.

1995: First protease inhibitor approved by FDA, and the highly active antiretroviral therapy (HAART) era begins.

1996: First reauthorization of CARE Act—federal ADAP earmark created; first non-nucleoside reverse transcriptase inhibitor (NNRTI) approved by FDA.

2000: Second reauthorization of CARE Act. Changes for ADAPs include: allowance of insurance purchasing and maintenance; flexibility to provide other limited services (e.g., adherence support and outreach); and creation of ADAP supplemental grants program.

2003: NASTAD's ADAP Crisis Task Force formed to negotiate with pharmaceutical companies on pricing of antiretroviral medications; first fusion inhibitor approved by FDA.

2004: President's ADAP Initiative (PAI) announced, allocating $20 million in one-time funding outside of the ADAP system to reduce ADAP waiting lists in 10 states.

2006: Third reauthorization of the CARE Act, now called, "Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006" or the "Ryan White Program." Changes for ADAP include: new formula for determining state awards, which incorporates living HIV and AIDS cases; new minimum formulary requirement; and an increase in the ADAP Supplemental set-aside and changes in eligibility and matching requirements.

2007: New minimum formulary requirement effective July 1; first CCR5 antagonist and integrase inhibitor approved by FDA.

2009: Fourth reauthorization of the Ryan White Program. The reauthorization was for four years and included several technical changes.

2010: Patient Protection and Affordable Care Act (PPACA) signed into law. ADAP emergency funding announced by the Obama Administration, allocating $25 million in funding to address ADAP waiting lists and cost-containment measures.

2011: ADAP emergency funding continued at $40 million. In December 2011, President Obama announced an additional $35 million for ADAPs to address ADAP waiting lists and cost containment measures. Awards from this funding will be available to states based on a competitive application. It is currently expected that awards will be made in Summer 2012.

METHODOLOGY

Since 1996, NASTAD's National ADAP Monitoring Project has surveyed all jurisdictions receiving federal ADAP earmark funding through the Ryan White Program. In FY2011, 58 jurisdictions received earmark funding and were surveyed; 52 responded. American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Republic of Palau, and U.S. Virgin Islands did not respond; these jurisdictions represent less than one percent of estimated living HIV and AIDS cases.

NASTAD surveyed all jurisdictions receiving federal ADAP earmark funding through the Ryan White Program to request supplemental and updated information in January 2012; 48 responded. Alaska, American Samoa, Delaware, District of Columbia, Federated States of Micronesia, Guam, Kansas, Northern Mariana Islands, Republic of Palau and U.S. Virgin Islands did not respond; these jurisdictions represent two percent of estimated living HIV and AIDS cases in the U.S.

The annual survey requests data and other program information for a one-month period (June and December), the current fiscal year, and other periods as specified. After the survey is distributed, NASTAD conducts extensive follow-up to ensure completion by as many ADAPs as possible. Data used in this report are from June 2011 and FY2011, unless otherwise noted.

All data reflect the status of ADAPs as reported by survey respondents. It is important to note that some program information may have changed between data collection and this report's release. Due to differences in data collection and availability across ADAPs, some are not able to respond to all survey questions. Where trend data are presented, only states that provided data in relevant periods are included. In some cases, ADAPs have provided revised program data from prior years and these revised data are incorporated where possible. Therefore, data from prior year reports may not be comparable for assessing trends. It is also important to note that data from a one-month snapshot may be subject to one-time only events or changes that could in turn appear to impact trends; these are noted where information is available. Data exceptions specific to a particular jurisdiction are provided in the notes section on relevant charts and tables.

CHARTS AND TABLES

Charts for each major finding and tables, with data provided by states, are included in this module.

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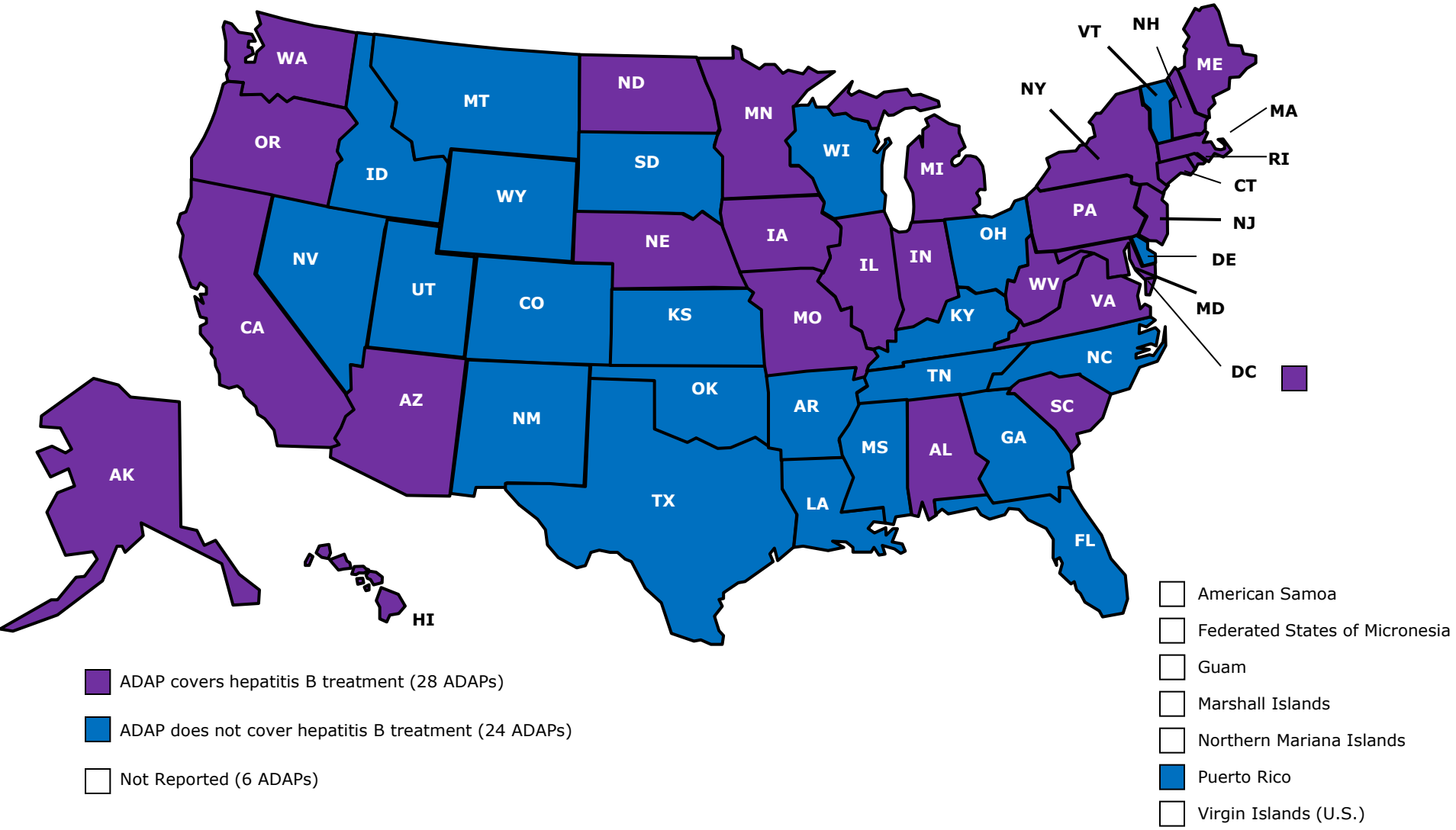
[1] FY2011 refers to ADAP fiscal year 2011 and encompasses data from April 1, 2011 through March 31, 2012.
[2] For the purposes of this *Report*, "jurisdiction" or "state" refers to all entities that receive a federal ADAP earmark award.
[3] Centers for Disease Control and Prevention, "Frequently Asked Questions and Answers About Coinfection with HIV and Hepatitis C Virus." Available at http://www.cdc.gov/hiv/resources/qa/HIV-HCV_Coinfection.htm (accessed April 15, 2011).
[4] Centers for Disease Control and Prevention, "Sexually Transmitted Diseases Treatment Guidelines, 2006." *MMWR*, Vol. 55, September 2006.

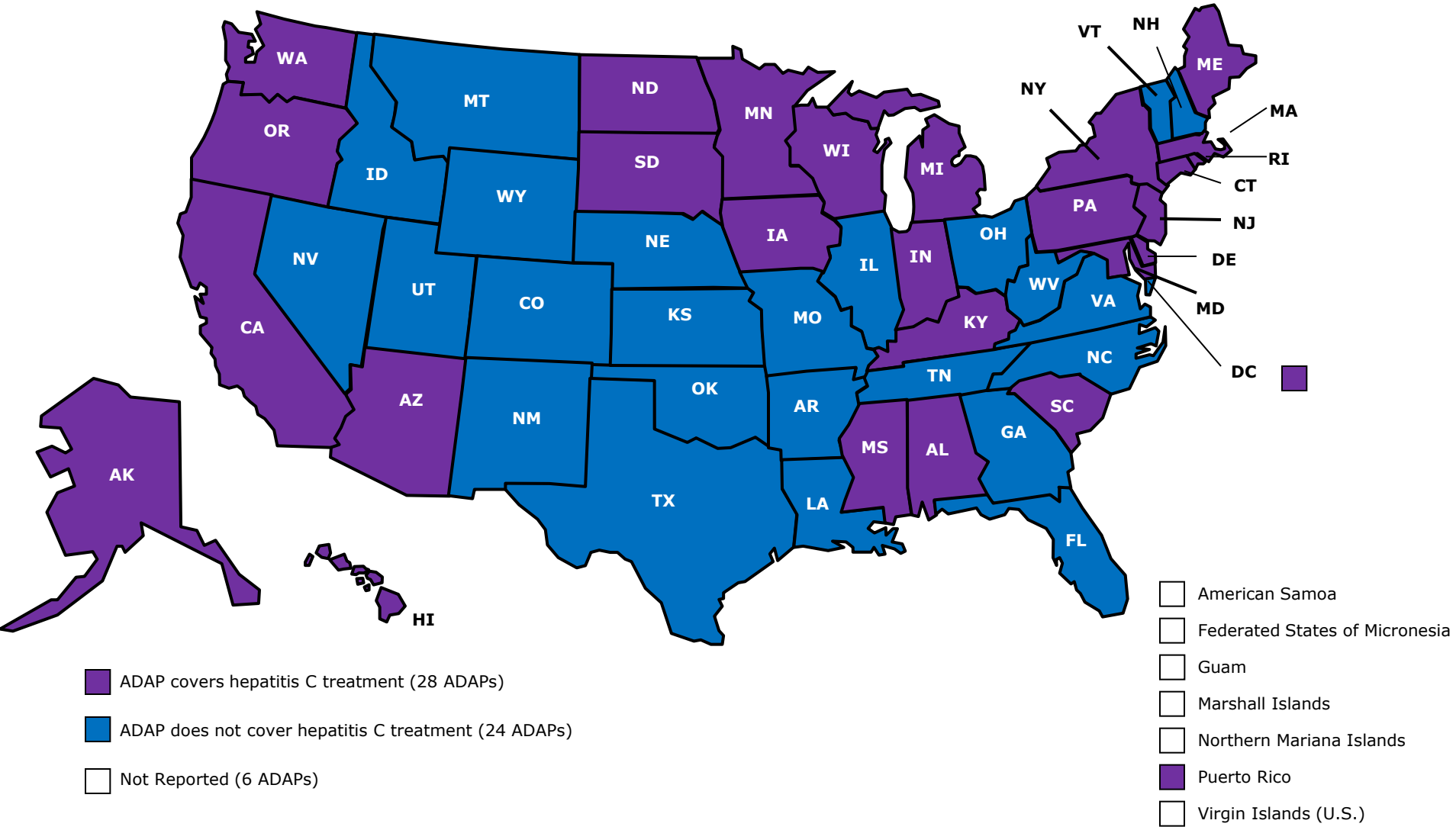
MODULE THREE: CHARTS

Chart 1: ADAP Coverage of Hepatitis B Treatment, June 2011



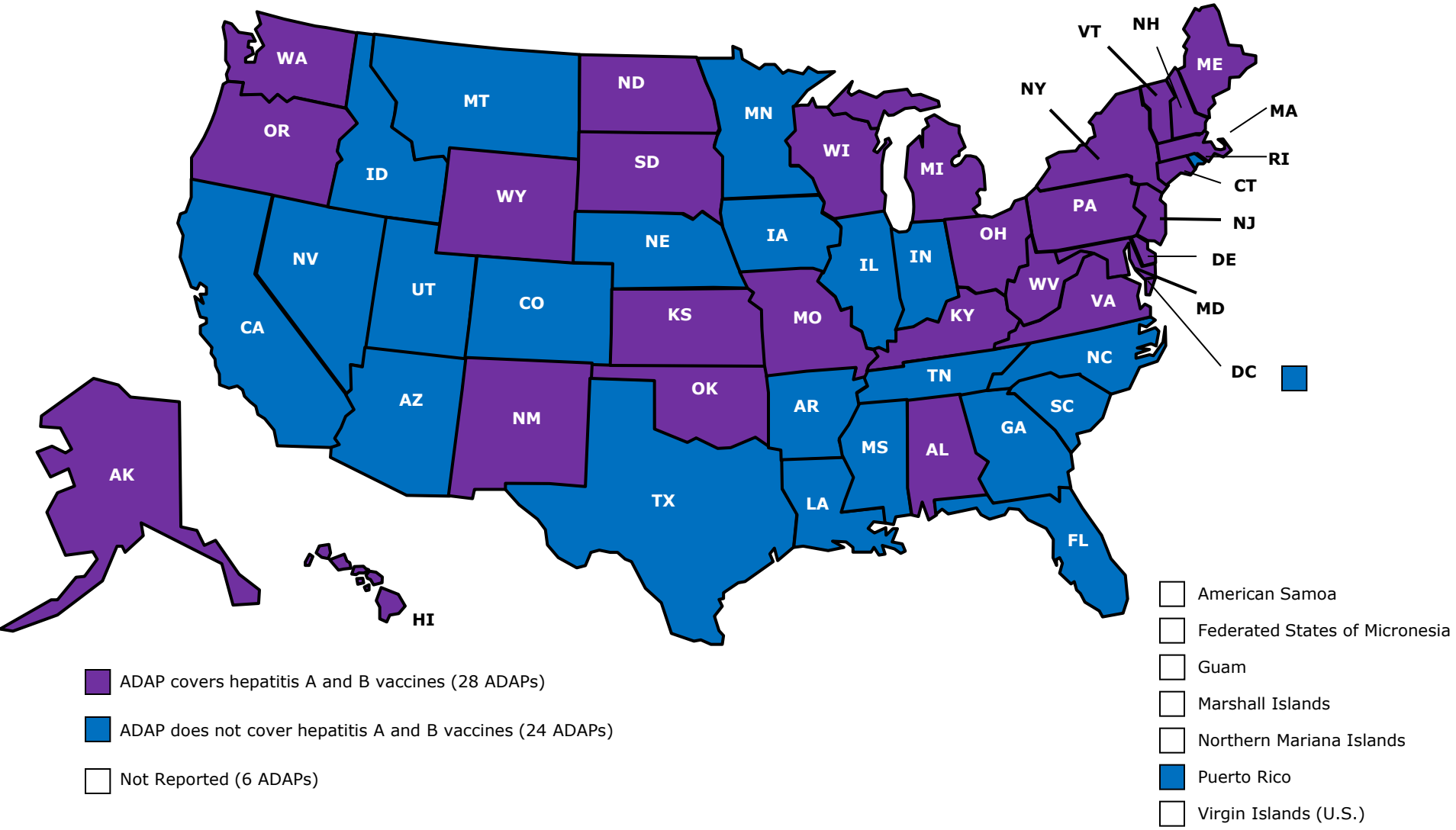
Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands did not report FY2011 data, but their federal ADAP earmark and ADAP supplemental awards were known and incorporated. Marshall Islands did not receive a federal ADAP earmark award in FY2011.

Chart 2: ADAP Coverage of Hepatitis C Treatment, June 2011



Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands did not report FY2011 data, but their federal ADAP earmark and ADAP supplemental awards were known and incorporated. Marshall Islands did not receive a federal ADAP earmark award in FY2011.

Chart 3: ADAP Coverage of Hepatitis A and B Vaccine, June 2011



Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands did not report FY2011 data, but their federal ADAP earmark and ADAP supplemental awards were known and incorporated. Marshall Islands did not receive a federal ADAP earmark award in FY2011.

MODULE THREE: TABLES

Table 1: ADAP Coverage of Hepatitis B Treatment, June 2011

State/Territory	Adefovir Dipivoxil (Hepsera)	Entecavir (Baraclude)	Interferon Alfa-2b (Intron A)	Lamivudine (Epivir-HBV, Zeffix, Heptodin)	Peginterferon alfa-2a (Pegasys)	Telbivudine (Tyzeka, Sebivo)
Alabama	Yes	Yes	Yes	--	Yes	--
Alaska	Yes	Yes	Yes	Yes	Yes	Yes
American Samoa	--	--	--	--	--	--
Arizona	--	--	--	Yes	--	--
Arkansas	--	--	--	--	--	--
California	--	--	Yes	--	Yes	--
Colorado	--	--	--	--	--	--
Connecticut	--	Yes	--	Yes	Yes	--
Delaware	--	--	--	--	--	--
District of Columbia	Yes	Yes	--	--	Yes	--
Federated States of Micronesia	--	--	--	--	--	--
Florida	--	--	--	--	--	--
Georgia	--	--	--	--	--	--
Guam	--	--	--	--	--	--
Hawaii	--	Yes	--	--	Yes	--
Idaho	--	--	--	--	--	--
Illinois	--	Yes	--	--	--	--
Indiana	Yes	Yes	Yes	Yes	Yes	Yes
Iowa	--	--	--	--	Yes	--
Kansas	--	--	--	--	--	--
Kentucky	--	--	--	--	--	--
Louisiana	--	--	--	--	--	--
Maine	Yes	Yes	--	Yes	Yes	Yes
Marshall Islands	--	--	--	--	--	--
Maryland	Yes	Yes	Yes	Yes	Yes	Yes
Massachusetts	Yes	Yes	Yes	Yes	Yes	Yes
Michigan	--	Yes	Yes	Yes	Yes	--
Minnesota	Yes	Yes	--	Yes	Yes	--
Mississippi	--	--	--	--	--	--
Missouri	Yes	Yes	--	Yes	--	Yes
Montana	--	--	--	--	--	--
Nebraska	--	Yes	--	--	--	--
Nevada	--	--	--	--	--	--
New Hampshire	Yes	Yes	--	Yes	--	Yes
New Jersey	Yes	Yes	Yes	Yes	Yes	Yes
New Mexico	--	--	--	--	--	--
New York	Yes	Yes	Yes	Yes	Yes	--
North Carolina	--	--	--	--	--	--
North Dakota	--	--	Yes	Yes	Yes	--
Northern Mariana Islands	--	--	--	--	--	--
Ohio	--	--	--	--	--	--
Oklahoma	--	--	--	--	--	--
Oregon	Yes	Yes	Yes	Yes	Yes	Yes
Pennsylvania	Yes	Yes	Yes	Yes	Yes	Yes
Puerto Rico	--	--	--	--	--	--
Republic of Palau	--	--	--	--	--	--
Rhode Island	--	--	Yes	--	Yes	--
South Carolina	--	--	--	Yes	Yes	--
South Dakota	--	--	--	--	--	--
Tennessee	--	--	--	--	--	--
Texas	--	--	--	--	--	--
Utah	--	--	--	--	--	--
Vermont	--	--	--	--	--	--
Virgin Islands (U.S.)	--	--	--	--	--	--
Virginia	--	--	--	Yes	--	--
Washington	Yes	Yes	Yes	--	Yes	--
West Virginia	--	--	--	Yes	--	--
Wisconsin	--	--	--	--	--	--
Wyoming	--	--	--	--	--	--
Total	**15**	**20**	**14**	**19**	**21**	**10**

Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands did not report FY2011 data, but their federal ADAP earmark and ADAP supplemental awards were known and incorporated. Marshall Islands did not receive a federal ADAP earmark award in FY2011.

Table 2: ADAP Utilization of Hepatitis B Treatment, June 2011 and FY2010

State / Territory	June 2011 Prescriptions Filled	June 2011 Number of Clients	FY2010 Prescriptions Filled
Alabama	1	1	39
Alaska	1	1	1
American Samoa	--	--	--
Arizona	1	1	10
Arkansas	--	--	--
California	0	0	0
Colorado	--	--	--
Connecticut	4	4	97
Delaware	--	--	--
District of Columbia	7	6	71
Federated States of Micronesia	--	--	--
Florida	--	--	--
Georgia	--	--	--
Guam	--	--	--
Hawaii	1	1	0
Idaho	--	--	--
Illinois	3	3	39
Indiana	4	4	42
Iowa	0	0	0
Kansas	--	--	--
Kentucky	--	--	--
Louisiana	--	--	--
Maine	2	1	14
Marshall Islands	--	--	--
Maryland	12	11	40
Massachusetts	11	11	119
Michigan	4	4	12
Minnesota	2	2	36
Mississippi	--	--	--
Missouri	3	3	14
Montana	--	--	--
Nebraska	0	0	0
Nevada	--	--	--
New Hampshire	1	1	3
New Jersey	13	11	266
New Mexico	--	--	--
New York	41	37	410
North Carolina	--	--	--
North Dakota	0	0	0
Northern Mariana Islands	--	--	--
Ohio	--	--	--
Oklahoma	--	--	--
Oregon	4	4	78
Pennsylvania	129	114	1,700
Puerto Rico	0	0	0
Republic of Palau	--	--	--
Rhode Island	0	0	3
South Carolina	5	3	27
South Dakota	--	--	--
Tennessee	--	--	--
Texas	--	--	--
Utah	--	--	--
Vermont	--	--	--
Virgin Islands (U.S.)	--	--	--
Virginia	0	0	0
Washington	4	4	54
West Virginia	7	7	95
Wisconsin	--	--	--
Wyoming	--	--	--
Total	**260**	**234**	**3,170**

Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands did not report FY2011 data, but their federal ADAP earmark and ADAP supplemental awards were known and incorporated. Marshall Islands did not receive a federal ADAP earmark award in FY2011.

Table 3: ADAP Coverage of Hepatitis C Treatment, June 2011

State/Territory	Interferon Alfa-2b (Intron A)	Recombinant Interferon Alfa-2a (Roferon)	Consensus Interferon (Infergen)	Peginterferon Alfa-2a (Pegasys)	Peginterferon Alfa-2b (PEG-Intron)	Peginterferon alfa-2a (Pegasys) + Ribavirin	Peginterferon alfa-2b (PEG-Intron) and Ribavirin	Interferon alfa-2b (Intron A) and Ribavirin	Recombinant Interferon Alfa-2a (Roferon) and Ribavirin	Incivek (telaprevir)	Victrelis (boceprevir)
Alabama	Yes	Yes	--	Yes	Yes	--	--	Yes	--	--	--
Alaska	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
American Samoa	--	--	--	--	--	--	--	--	--	--	--
Arizona	--	--	--	--	Yes	--	Yes	--	--	--	--
Arkansas	--	--	--	--	--	--	--	--	--	--	--
California	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	--	--
Colorado	--	--	--	--	--	--	--	--	--	--	--
Connecticut	--	--	--	Yes	Yes	Yes	Yes	--	--	--	--
Delaware	Yes	--	--	Yes	Yes	Yes	--	Yes	--	--	--
District of Columbia	--	--	--	Yes	Yes	--	--	--	--	--	--
Federated States of Micronesia	--	--	--	--	--	--	--	--	--	--	--
Florida	--	--	--	--	--	--	--	--	--	--	--
Georgia	--	--	--	--	--	--	--	--	--	--	--
Guam	--	--	--	--	--	--	--	--	--	--	--
Hawaii	--	--	--	Yes	Yes	Yes	Yes	--	--	--	--
Idaho	--	--	--	--	--	--	--	--	--	--	--
Illinois	--	--	--	--	--	--	--	--	--	--	--
Indiana	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Iowa	--	--	--	Yes	--	Yes	--	--	--	--	--
Kansas	--	--	--	--	--	--	--	--	--	--	--
Kentucky	--	--	--	--	--	--	Yes	--	--	--	--
Louisiana	--	--	--	--	--	--	--	--	--	--	--
Maine	--	--	Yes	Yes	Yes	Yes	Yes	--	--	Yes	Yes
Marshall Islands	--	--	--	--	--	--	--	--	--	--	--
Maryland	Yes	Yes	--	Yes	Yes	Yes	Yes	--	--	--	--
Massachusetts	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Michigan	Yes	--	--	Yes	Yes	Yes	--	Yes	--	--	--
Minnesota	--	--	--	Yes	Yes	Yes	Yes	--	--	--	--
Mississippi	--	--	--	--	--	Yes	--	--	--	--	--
Missouri	--	--	--	--	--	--	--	--	--	--	--
Montana	--	--	--	--	--	--	--	--	--	--	--
Nebraska	--	--	--	--	--	--	--	--	--	--	--
Nevada	--	--	--	--	--	--	--	--	--	--	--
New Hampshire	--	--	--	--	--	--	--	--	--	--	--
New Jersey	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
New Mexico	--	--	--	--	--	--	--	--	--	--	--
New York	Yes	Yes	--	Yes	Yes	--	--	--	--	--	--
North Carolina	--	--	--	--	--	--	--	--	--	--	--
North Dakota	--	--	--	Yes	Yes	Yes	Yes	--	--	--	--
Northern Mariana Islands	--	--	--	--	--	--	--	--	--	--	--
Ohio	--	--	--	--	--	--	--	--	--	--	--
Oklahoma	--	--	--	--	--	--	--	--	--	--	--
Oregon	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pennsylvania	Yes	--	Yes	Yes	Yes	Yes	Yes	Yes	--	--	--
Puerto Rico	--	--	--	Yes	Yes	--	--	--	--	--	--
Republic of Palau	--	--	--	--	--	--	--	--	--	--	--
Rhode Island	Yes	--	--	Yes	--	Yes	Yes	Yes	--	--	--
South Carolina	--	--	--	Yes	Yes	Yes	Yes	--	--	--	--
South Dakota	Yes	--	--	Yes	Yes	Yes	Yes	Yes	--	--	--
Tennessee	--	--	--	--	--	--	--	--	--	--	--
Texas	--	--	--	--	--	--	--	--	--	--	--
Utah	--	--	--	--	--	--	--	--	--	--	--
Vermont	--	--	--	--	--	--	--	--	--	--	--
Virgin Islands (U.S.)	--	--	--	--	--	--	--	--	--	--	--
Virginia	--	--	--	--	--	--	--	--	--	--	--
Washington	Yes	Yes	--	Yes	Yes	Yes	Yes	Yes	Yes	--	--
West Virginia	--	--	--	--	--	--	--	--	--	--	--
Wisconsin	Yes	--	--	Yes	Yes	Yes	Yes	Yes	--	--	--
Wyoming	--	--	--	--	--	--	--	--	--	--	--
Total	**16**	**10**	**8**	**25**	**24**	**22**	**20**	**14**	**7**	**6**	**6**

Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands did not report FY2011 data, but their federal ADAP earmark and ADAP supplemental awards were known and incorporated. Marshall Islands did not receive a federal ADAP earmark award in FY2011.

Table 4: ADAP Utilization of Hepatitis C Treatment, June 2011 and FY2010

State / Territory	June 2011 Prescriptions Filled	June 2011 Number of Clients	FY2010 Prescriptions Filled
Alabama	2	2	78
Alaska	0	0	0
American Samoa	--	--	--
Arizona	0	0	5
Arkansas	--	--	--
California	52	46	773
Colorado	--	--	--
Connecticut	0	0	50
Delaware	0	0	15
District of Columbia	6	2	47
Federated States of Micronesia	--	--	--
Florida	--	--	--
Georgia	--	--	--
Guam	--	--	--
Hawaii	0	0	18
Idaho	--	--	--
Illinois	--	--	--
Indiana	2	1	31
Iowa	0	0	10
Kansas	--	--	--
Kentucky	--	--	--
Louisiana	--	--	--
Maine	0	0	7
Marshall Islands	--	--	--
Maryland	4	2	63
Massachusetts	7	7	90
Michigan	1	1	10
Minnesota	1	1	2
Mississippi	0	0	18
Missouri	--	--	--
Montana	--	--	--
Nebraska	--	--	--
Nevada	--	--	--
New Hampshire	--	--	--
New Jersey	30	13	127
New Mexico	--	--	--
New York	78	43	1,047
North Carolina	--	--	--
North Dakota	0	0	0
Northern Mariana Islands	--	--	--
Ohio	--	--	--
Oklahoma	--	--	--
Oregon	1	1	49
Pennsylvania	6	5	52
Puerto Rico	90	46	1,080
Republic of Palau	--	--	--
Rhode Island	0	0	3
South Carolina	1	1	25
South Dakota	3	1	3
Tennessee	--	--	--
Texas	--	--	--
Utah	--	--	--
Vermont	--	--	--
Virgin Islands (U.S.)	--	--	--
Virginia	--	--	--
Washington	1	1	16
West Virginia	--	--	--
Wisconsin	4	1	83
Wyoming	--	--	--
Total	**289**	**174**	**3,702**

Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands did not report FY2011 data, but their federal ADAP earmark and ADAP supplemental awards were known and incorporated. Marshall Islands did not receive a federal ADAP earmark award in FY2011.

Table 5: ADAP Coverage of Hepatitis C Diagnostics, June 2011

State/Territory	HCV Screening	Qualitative HCV RNA	Quantitative Viral Load	HCV Genotype
Alabama	--	--	--	--
Alaska	--	--	--	--
American Samoa	--	--	--	--
Arizona	--	--	--	--
Arkansas	--	--	--	--
California	--	--	--	--
Colorado	--	--	--	--
Connecticut	--	--	--	--
Delaware	Yes	Yes	Yes	Yes
District of Columbia	--	--	--	--
Federated States of Micronesia	--	--	--	--
Florida	--	--	--	--
Georgia	--	--	--	--
Guam	--	--	--	--
Hawaii	--	--	--	--
Idaho	--	--	--	--
Illinois	--	--	--	--
Indiana	Yes	Yes	Yes	Yes
Iowa	--	--	--	--
Kansas	Yes	Yes	Yes	--
Kentucky	--	--	--	--
Louisiana	--	--	--	--
Maine	--	--	--	--
Marshall Islands	--	--	--	--
Maryland	--	--	--	--
Massachusetts	--	--	--	--
Michigan	--	--	--	--
Minnesota	--	--	--	--
Mississippi	--	--	--	--
Missouri	--	--	--	--
Montana	--	--	--	--
Nebraska	--	--	--	--
Nevada	--	--	--	--
New Hampshire	Yes	Yes	Yes	Yes
New Jersey	--	--	--	--
New Mexico	--	--	--	--
New York	Yes	Yes	Yes	Yes
North Carolina	--	--	--	--
North Dakota	Yes	--	--	--
Northern Mariana Islands	--	--	--	--
Ohio	--	--	--	--
Oklahoma	--	--	--	--
Oregon	Yes	Yes	Yes	Yes
Pennsylvania	Yes	--	Yes	--
Puerto Rico	--	--	--	--
Republic of Palau	--	--	--	--
Rhode Island	--	--	--	--
South Carolina	--	--	--	--
South Dakota	--	--	--	--
Tennessee	--	--	--	--
Texas	--	--	--	--
Utah	--	--	--	--
Vermont	--	--	--	--
Virgin Islands (U.S.)	--	--	--	--
Virginia	--	--	--	--
Washington	Yes	Yes	Yes	Yes
West Virginia	--	--	--	--
Wisconsin	--	--	--	--
Wyoming	--	--	--	--
Total	**9**	**7**	**8**	**6**

Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands did not report FY2011 data, but their federal ADAP earmark and ADAP supplemental awards were known and incorporated. Marshall Islands did not receive a federal ADAP earmark award in FY2011.

Table 6: ADAP Coverage of Hepatitis A and B Vaccines, June 2011

State/Territory	Hepatitis A and B Combination Vaccine	Hepatitis A Vaccine	Hepatitis B Vaccine
Alabama	Yes	Yes	Yes
Alaska	Yes	Yes	Yes
American Samoa	--	--	--
Arizona	--	--	--
Arkansas	--	--	--
California	--	--	--
Colorado	--	--	--
Connecticut	Yes	Yes	Yes
Delaware	Yes	Yes	Yes
District of Columbia	--	--	--
Federated States of Micronesia	--	--	--
Florida	--	--	--
Georgia	--	--	--
Guam	--	--	--
Hawaii	Yes	Yes	Yes
Idaho	--	--	--
Illinois	--	--	--
Indiana	--	--	--
Iowa	--	--	--
Kansas	Yes	Yes	Yes
Kentucky	Yes	Yes	Yes
Louisiana	--	--	--
Maine	Yes	Yes	Yes
Marshall Islands	--	--	--
Maryland	Yes	Yes	Yes
Massachusetts	Yes	Yes	Yes
Michigan	--	Yes	Yes
Minnesota	--	--	--
Mississippi	--	--	--
Missouri	Yes	Yes	Yes
Montana	--	--	--
Nebraska	--	--	--
Nevada	--	--	--
New Hampshire	Yes	Yes	Yes
New Jersey	Yes	Yes	Yes
New Mexico	Yes	Yes	Yes
New York	Yes	Yes	Yes
North Carolina	--	--	--
North Dakota	Yes	Yes	Yes
Northern Mariana Islands	--	--	--
Ohio	Yes	Yes	Yes
Oklahoma	Yes	Yes	Yes
Oregon	Yes	Yes	Yes
Pennsylvania	--	Yes	Yes
Puerto Rico	--	--	--
Republic of Palau	--	--	--
Rhode Island	--	--	--
South Carolina	--	--	--
South Dakota	Yes	--	--
Tennessee	--	--	--
Texas	--	--	--
Utah	--	--	--
Vermont	Yes	Yes	Yes
Virgin Islands (U.S.)	--	--	--
Virginia	Yes	Yes	Yes
Washington	Yes	Yes	Yes
West Virginia	Yes	Yes	Yes
Wisconsin	Yes	Yes	Yes
Wyoming	Yes	--	--
Total	**26**	**26**	**26**

Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands did not report FY2011 data, but their federal ADAP earmark and ADAP supplemental awards were known and incorporated. Marshall Islands did not receive a federal ADAP earmark award in FY2011.

GLOSSARY

340B Drug Discount Program – The federal 340B Drug Discount Program, authorized under the Veterans Health Care Act of 1992, enables ADAPs to purchase drugs at or below the statutorily defined 340B ceiling price.

AIDS Drug Assistance Program (ADAP) - A state administered program authorized under Part B (formerly Title II) of the Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2009 (Ryan White Program) that provides Food and Drug Administration (FDA) approved medications to low-income individuals with HIV disease who have limited or no coverage from private insurance or Medicaid. ADAPs may also purchase insurance and provide adherence monitoring and outreach under the flexibility policy.

ADAP Crisis Task Force – A group of state ADAP and AIDS directors, convened by NASTAD, that negotiates with the manufacturers of HIV antiretrovirals and other high-cost medications to secure supplemental discounts/rebates benefitting all ADAPs.

ADAP Earmark - The amount of federal Ryan White Program, Part B dollars specifically designated by Congress through the annual appropriations process to ADAP for the federal fiscal year.

ADAP Supplemental Drug Treatment Grant – ADAP Supplemental grants are used for the purchase of medications by states and territories with demonstrated severe need to increase access to HIV/AIDS related medications. These grants must be used to expand ADAP formularies, target resources to reflect the changes in the epidemic, and enhance the ADAP's ability to remove eligibility restrictions. States must meet HRSA eligibility criteria in order to apply for ADAP Supplemental funds. The overall supplemental amount is mandated by law to be five percent of the congressionally appropriated ADAP earmark.

Back-billing – In some instances, ADAP covers an individual's prescription costs but later determines there is another payer source, for example, state Medicaid. Once it is certain that another payer should have covered a client's previous claims, the ADAP can request reimbursement for expenditures previously incurred or "back bill." Another scenario for back billing is when individuals apply and are eligible for Medicaid. Their eligibility coverage dates back three months PRIOR to the application date. ADAP covers the individual while they wait for their Medicaid eligibility determination and then "back-bills" Medicaid for any drugs or services they paid for during the interim wait time (see also pay and chase).

Co-payment - Some ADAPs pay the co-payments for ADAP formulary drugs, which can be a cost-effective way to help clients access medications through existing insurance coverage. In those states where ADAPs largely use their funding to purchase or maintain health insurance coverage, co-payments accounted for a much greater share of expenditures. Co-payments are a set amount an individual must pay upon receiving medical services or prescriptions. For example, there may be a $10 co-payment required each time a prescription is purchased at a retail pharmacy.

Cost-recovery - Reimbursement from third party entities such as private insurers and Medicaid.

Cost-sharing – The payment of a premium or fee by an enrolled ADAP client to the ADAP as a portion of the cost for medications and/or services received.

Deductible - The amount a health insurance beneficiary must pay before a third party payer begins to provide coverage for health services. Amounts can change from year to year. Some ADAPs pay this cost for eligible clients.

Direct Purchase States – ADAPs using this model centrally purchase and dispense medications through their own pharmacy or a single contract pharmacy services provider.

Dual Eligible – Individuals who are eligible for both Medicare and Medicaid.

Dual Purchaser – ADAPs using this model centrally purchase and dispense medications through their own pharmacy or a single contract pharmacy services provider and also bill drug manufacturers for the 340B Unit Rebate Amount for the number of units dispensed for clients accessing an insurance plan (public or private).

Formulary - ADAP drug list that establishes the number of drugs available within a therapeutic class for purposes of drug purchasing, dispensing and/or reimbursement. Effective July 1, 2007, all ADAPs were required to include at least one drug from each antiretroviral drug class. The minimum formulary requirement does not apply to multi-class combination products (not considered a unique class of drugs), drugs for preventing and treating opportunistic infections (OIs), hepatitis C treatments, or drugs for other HIV-related conditions (e.g., depression, hypertension, and diabetes).

- **Closed/restricted formulary** – allows only those drug products listed to be dispensed or reimbursed.
- **Open formulary** – covers all FDA-approved drugs prescribed by a physician with no restrictions or with restrictions such as higher patient cost-sharing requirements for certain drugs.
- **Tiered formulary** – also referred to as "step therapy" and is a cost containment measure that categorizes medications for a particular condition based upon their cost. For example, a tier one medication would be one that is lowest cost and recommended to be used first, unless there are medical restrictions for doing so. Tier two would be a different medication that is prescribed for the same condition as the tier one drug but is more expensive. Step therapy or tiered formularies are most commonly used by ADAPs with medications prescribed for depression, respiratory problems and opportunistic infections.

Hybrid states – A direct purchase state that utilizes an existing entity (e.g., University Hospital) to purchase and distribute ADAP drugs. The entity maintains a single drug inventory purchased at 340B prices. To secure the additional supplemental discounts negotiated by the ADAP Crisis Task Force, these ADAPs must submit rebate claims for any supplemental discount amounts.

Insurance Continuation - The payment of all or some combination of insurance premiums, co-pays, or deductibles for clients who have existing insurance policies through their current employment, Consolidated Omnibus Budget Reconciliation Act (COBRA) or other supplemental programs. HRSA allows ADAP funds to be used for insurance continuation with certain restrictions.

Insurance Purchasing - The purchase of new insurance policies through the insurance industry market, state high risk insurance pools or Pre-existing Condition Insurance Plans (PCIPs).

Part A funding - Provided to metropolitan jurisdictions, some of whom make local decisions to allocate funds to ADAPs.

Part B "base" - Formula-based funding to states (other than that earmarked for ADAP); some states choose to allocate some of this funding to ADAPs, but are not required to do so.

Part B supplemental funding – Funding to states with "unmet need;" some states choose to allocate some of this funding to ADAPs, but are not required to do so.

Patient Assistance Programs (PAPs) - Programs through which many pharmaceutical manufacturers provide free or greatly subsidized medications to indigent patients. To see information on pharmaceutical company co-payment assistance and patient assistance programs, please visit the Positively Aware website or the Fair Pricing Coalition's website.

Rebate states – ADAPs who pay retail pharmacies a pre-determined amount at the point of sale for drugs dispensed to ADAP clients. ADAP then bills drug manufacturers for the 340B Unit Rebate Amount for the number of units dispensed.

The Ryan White HIV/AIDS Treatment Modernization Act of 2009 - The Ryan White CARE Act, "Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2009", or "Ryan White Program" is the single largest federal program designed specifically for people with HIV/AIDS. First enacted in 1990, it provides care and treatment to individuals and families affected by HIV/AIDS. The Ryan White Program has five parts - **Part A** (formerly Title I) funds eligible metropolitan areas and transitional grant areas, 75% of grant funds must be spent for core services; **Part B** (formerly Title II) funds States/Territories, 75% must be spent for core services; **Part C** (formerly Title III) funds early intervention services, 75% must be spent for core services; **Part D** (formerly Title IV) grants support services for women, infants, children and youth and **Part F** comprises Special Projects of National Significance, AIDS Education & Training Centers (AETCs), Dental Programs and the Minority AIDS Initiative.

State funding - General revenue support from state budgets. States are not required to provide funding to their ADAPs (except in limited cases of matching requirements), although many have historically done so either over a sustained period of time or at critical junctures to address gaps in funding. Such funding is, for the most part, dependent on individual state decisions and budgets; even where states are required to provide a match of federal Part B Ryan White funds, they are not required to put this funding toward ADAP. The only exception to this is the ADAP supplemental, where states must provide a 1:4 match (or seek a waiver of the requirement, if eligible to do so).

True Out of Pocket Expenditures (TrOOP) – This is the amount of money that a Medicare Part D enrolled client will have to pay from their own money to reach the "catastrophic limit" making Part D the primary payer for medications. Payments for drugs, co-payments, and coinsurance made by the beneficiary, friends, family members, State Pharmacy Assistance Programs, charities and the Medicare low-income subsidy (LIS) count towards TrOOP costs. Payments for premiums, drugs not on plan formularies, costs incurred by the ADAP and payments by other types of insurance are not counted as TrOOP costs.