



Combating the Silent  
Epidemic of Viral Hepatitis  
**Action Plan for the Prevention,  
Care & Treatment of Viral Hepatitis**

Interagency Implementation Progress Report

Year 1

May 2011–April 2012



This report was prepared under the direction of the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services (HHS). Information contained in the report was provided by the Viral Hepatitis Leads from various HHS agencies, the Department of Veterans Affairs and the Bureau of Prisons, Department of Justice. Ms. Corinna Dan, R.N., M.P.H., Viral Hepatitis Policy Advisor in OHAIDP coordinated development of this report. Ms. Antigone Dempsey, M.Ed., Ms. Kelly Stevens, and Ms. Deborah Finette of Altarum Institute and Mr. Steve Holman, MBA, all working under contract to OHAIDP, assisted OHAIDP staff in compiling and formatting the report.

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September 2012

# Preface

## September 2012

Just over a year ago, in May 2011, it was my honor to release *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis* (Action Plan), which presented robust and dynamic steps for improving viral hepatitis prevention and the care and treatment provided to infected persons. The Action Plan also helps move the nation toward achieving Healthy People 2020 goals, the first Healthy People initiative to include an objective for increasing viral hepatitis awareness among infected persons.

In the year since the release of the Action Plan, an impressive array of actions has been undertaken by offices and agencies within the U.S. Department of Health and Human Services and by our colleagues at the Department of Justice's Federal Bureau of Prisons and the Department of Veterans Affairs' Veterans Health Administration. The Action Plan has fostered enhanced engagement and unprecedented collaboration of diverse partners across the federal government. Galvanized by the Action Plan, these federal partners have brought together expertise and tools to better coordinate our fight against this deadly disease. One important outcome is that we have generated significant awareness of the silent epidemic of viral hepatitis among both the public and health care providers.

I want to commend and thank my colleagues from across the participating federal agencies who actively responded to the Plan's ambitious call to action for better education, treatment, and prevention and who have all been working to implement the strategies detailed in the Action Plan. In particular, I want to express gratitude to the members of the Viral Hepatitis Action Plan Implementation Group, the representatives of 15 agencies and offices who have been conferring regularly over the past year to guide and advance implementation of the Action Plan and serving as advocates for the Action Plan within their respective agencies and offices. I would also like to thank Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases, and the Director of the Office of HIV/AIDS and Infectious Disease Policy at the Department of Health and Human Services for his leadership on the efforts to implement the Action Plan. He and his team have been key to the progress that we have made during this first year of the Action Plan.

In coming years, we shall build on the solid foundation established during this first year of Action Plan implementation, continuing to strengthen our cross-agency collaborations, sharpening the focus of our activities, and working to expand the reach of our programs. While the strategies and steps detailed in the Action Plan will continue to guide the federal efforts on viral hepatitis, to be successful in achieving our aims, the support and participation of nonfederal stakeholders is critical. State and local health departments, nonprofit education and advocacy organizations, pharmaceutical and diagnostics industry partners, medical and behavioral health care providers, and community advocates all play an important role in addressing viral hepatitis. We know that it will take new partnerships and creative strategies to meet the needs of all persons living with or at risk for viral hepatitis. Working together, we truly can be a nation committed to combating the silent epidemic of viral hepatitis.

Sincerely yours,



Howard K. Koh, M.D., M.P.H.  
Assistant Secretary for Health

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## Excerpt from Presidential Proclamation on World Hepatitis Day 2011

**M**y Administration has also released a comprehensive Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis. The plan brings together expertise and tools across government to coordinate our fight against this deadly disease. Our goal is to reduce the number of new infections, increase status awareness among people with hepatitis, and eliminate the transmission of hepatitis B from mothers to their children.

The first step toward achieving these goals is raising public awareness of this life-threatening disease. We must work to reduce the stigma surrounding hepatitis and to ensure that testing, information, counseling, and treatment are available to all who need it. The hard work and dedication of health care professionals, researchers, and advocates will help bring us closer to this goal .... I encourage citizens, government agencies, nonprofit organizations, and communities across the Nation to join in activities that will increase awareness about hepatitis and what we can do to prevent it.

—President Barack Obama  
World Hepatitis Day Proclamation  
July 28, 2011

## Background

On May 12, 2011, the U.S. Department of Health and Human Services (HHS) issued *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis* (Action Plan). The Action Plan details more than 150 actions to be undertaken over the course of several years by agencies and offices across HHS and partners at the Federal Bureau of Prisons (FBOP) and the U.S. Department of Veterans Affairs (VA) that will improve the prevention, diagnosis, and treatment of viral hepatitis in the United States.

The Action Plan put a spotlight on this silent epidemic and its growing impact in the United States, where as many as 5.3 million persons are living with chronic hepatitis B or C infection and millions more are at risk of infection. While viral hepatitis has been addressed by various federal research, prevention, care, and treatment programs, much of this work has been conducted independently, sometimes in isolation from other related efforts. Following the Institute of Medicine's (IOM) 2010 report, *Hepatitis and Liver Cancer*, which recommended steps to reduce the threats posed by hepatitis B and hepatitis C, Dr. Howard Koh, Assistant Secretary for Health, convened an interagency workgroup composed of subject matter experts from various HHS agencies to review the IOM recommendations and develop a comprehensive strategic viral hepatitis action plan that would:

- Address IOM recommendations for viral hepatitis prevention, care, and treatment;
- Set forth actions to improve viral hepatitis prevention and ensure that infected persons are identified and provided care and treatment; and
- Improve coordination of all activities related to viral hepatitis across HHS and promote collaborations with other government agencies and nongovernmental organizations.

Critical input into the Action Plan was also provided by stakeholders from other federal agencies; professional societies; and state, local, and community partners. The actions presented in the Action Plan represent efforts to be undertaken in calendar year 2011, 2012, or 2013. Some of the actions outlined in the Plan can be accomplished by using existing resources through improved coordination and integration, while others are subject to the availability of funds.

Following the Action Plan's release, agencies and offices across HHS began working to implement the actions assigned to them in the Action Plan. To support these efforts, HHS convened a Viral Hepatitis Action Plan Implementation Group (VHIG) and charged it with coordinating, supporting, and overseeing activities related to the Action Plan. The VHIG comprises representatives from across HHS and other federal agencies and is chaired by Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases. Members of the VHIG have met numerous times over the first year of the Action Plan and served as point persons within their respective agencies and offices on matters related to the Action Plan. The VHIG also established a separate Education Work Group to coordinate focused activities related to patient and provider education on viral hepatitis. Read more about the action plan at <http://aids.gov/hepatitis>.

## Viral Hepatitis Implementation Group Members:

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## Introduction

This report features brief highlights of progress made during the first year of implementing the *Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis*. Compiled by the HHS Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), the report documents actions, as reported by the federal partners engaged in implementing the Action Plan, that were initiated and/or completed between May 2011 and April 2012. Note that this includes several agencies and offices that were not specifically tasked in the Action Plan but nonetheless are engaged in its implementation. This expanded participation enhances the cross-agency efforts to pursue the Action Plan's goals.

The Action Plan's six priority areas are the organizing framework for this report. Within each priority area, the Action Plan established specific goals that are used to categorize the progress highlights reported by the participating agencies and offices.

A list of acronyms and abbreviations used in this report is found in Appendix A for reference.

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### Federal Partners in Implementing the Action Plan for the Prevention, Care and Treatment of Viral Hepatitis

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#### U.S. Department of Health and Human Services

- Agency for Healthcare Research and Quality
- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- Food and Drug Administration
- Health Resources and Services Administration
- Indian Health Service
- National Institutes of Health
- National Vaccine Program Office
- Office of HIV/AIDS and Infectious Disease Policy
- Office of Minority Health
- Office of the Assistant Secretary for Health
- Office of the National Coordinator for Health Information Technology
- Office of the Surgeon General
- Office on Women's Health
- Substance Abuse and Mental Health Services Administration

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#### U.S. Department of Justice

- Federal Bureau of Prisons

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#### U.S. Department of Veterans Affairs

- Office of Public Health
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## Priority 1 Educating Providers and Communities to Reduce Health Disparities

**GOAL 1.1** Build a U.S. health care workforce prepared to prevent and diagnose viral hepatitis and provide care and treatment to infected persons.

### Centers for Disease Control and Prevention (CDC)

#### 2011 Actions

- Assess medical and health education materials and programs on viral hepatitis and draft plans to improve quality and distribution.

**Progress:** CDC co-chaired the Education Work Group tasked with an OHAIDP initiated project to inventory, review, and post online all federally developed public and health care provider education materials related to viral hepatitis in collaboration with the VHIG. CDC led work with the National Prevention Information Network (NPIN) to catalog and post the inventory online. A new banner for viral hepatitis was added to the NPIN page, highlighting that there are education materials available on the site. This effort was completed in April 2012.

- Work with academic institutions and educational organizations to develop and promulgate standardized viral hepatitis curricula for students in postgraduate medical, dental, nursing, physician's assistant, alternative medicine, and other allied health schools.

**Progress:** CDC has funded the University of Alabama at Birmingham School of Public Health and Medical School to assess existing curricula in medical schools and will use the information to develop standardized content that can be integrated into existing training programs. This effort is in progress with an anticipated completion in September 2012.

#### 2012 Actions

- Conduct qualitative and quantitative research designed to understand the knowledge, skills, abilities, and attitudes of providers with regard to prevention, care, and treatment of viral hepatitis.

**Progress:** CDC conducted a small qualitative research study on primary care providers' attitudes about testing for viral hepatitis. This effort was completed in May 2011.

- Work with specialty medical organizations (e.g., the Infectious Diseases Society of America (IDSA), the American Association for the Study of Liver Diseases (AASLD)) to develop and disseminate guidelines for the evaluation, management, and treatment of viral hepatitis.

**Progress:** CDC has funded the University of Washington at Seattle to work with International Antiviral Society to develop and disseminate Web-based training modules for the evaluation, management, and treatment of viral hepatitis. This effort is in progress with an anticipated completion in September 2012.

## Federal Bureau of Prisons (FBOP)

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### 2011 Action

- Assess medical and health education materials and programs on viral hepatitis and draft plans to improve quality and distribution.

**Progress:** FBOP updated its *Clinical Practice Guidelines for Evaluation and Treatment of Hepatitis C and Cirrhosis* to include the use of hepatitis C virus (HCV) protease inhibitors in the treatment of chronic HCV genotype 1 infection and provided it to all FBOP health care providers. In addition, the updated guidelines are available to the general public and to federal inmates through established procedures. Other documents were updated to standardize and better facilitate the process for evaluating the appropriateness of hepatitis C treatment for the patient and to aid in the review of pertinent material which aims to improve patient outcomes. These activities were completed in March 2012.

## Health Resources and Services Administration (HRSA)

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### 2011 Actions

- Assess medical and health education materials and programs on viral hepatitis and draft plans to improve quality and distribution.

**Progress:** HRSA has assessed relevant materials available from the various HRSA bureaus and offices, including online and printed resources, and has shared them with NPIN for inclusion in the inventory of federal materials on viral hepatitis for patients and providers. Relevant materials have been shared and are now available via NPIN.

HRSA is working with and supporting CDC in the creation of a viral hepatitis curriculum, which, once available, HRSA will disseminate through its grantees, listservs, and networks. To aid in this effort, within HRSA, the Office of Global Health Affairs (OGHA) will review the Action Plan and create a supporting document that highlights the state of viral hepatitis in the U.S. Affiliated Pacific Islands (USAPI). An overview of the state of viral hepatitis in the USAPI is anticipated to be completed by August 2012. OGHA will develop cultural awareness materials to assist with the development of curriculum and training materials for providers in the USAPI. OGHA will also create a database containing USAPI viral hepatitis resources and HRSA resources to assist in the response to viral hepatitis in the USAPI. To help with the overarching development and quality of the educational curriculum and materials, OGHA will provide information specifically on the state of viral hepatitis in the USAPI. These efforts are in progress with an anticipated completion in April 2013.

- Train all health care providers in HHS-sponsored clinical programs (e.g., Federally Qualified Health Centers and clinics receiving funds associated with the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act) to deliver viral hepatitis vaccination, early detection, testing, management of alcohol and other cofactors, and treatment.

**Progress:** In January 2012, HRSA held a national Webinar on viral hepatitis B and C with health center grantees, primary care associations, and national organizations. Topics covered included viral hepatitis epidemiology, hepatitis treatment guidelines, the Action

Plan, care and treatment of hepatitis B for Asian and Pacific Islander populations, hepatitis C care and treatment for homeless individuals, and the Project Extension for Community Healthcare Outcomes (ECHO) telehealth models of expanding capacity to deliver hepatitis care. In addition, between July 1, 2010, and June 30, 2011, the Ryan White AIDS Education and Training Centers (AETC) provided 3,572 trainings across the Nation focusing on hepatitis, with 34,396 health care providers trained. Thirty-five percent of those trainees (more than 7,000 providers) were nurses or advanced practice nurses, and 16 percent (more than 3,000 providers) were physicians. Forty-one percent of all providers trained on hepatitis topics were minorities, including Blacks, Asians, and Hispanics.

- Work with academic institutions and educational organizations to develop and promulgate standardized viral hepatitis curricula for students in postgraduate medical, dental, nursing, physician's assistant, alternative medicine, and other allied health schools.

**Progress:** HRSA, primarily through the Bureau of Primary Health Care (BPHC) and the HIV/AIDS Bureau (HAB), is working with and supporting CDC and others in the creation of a viral hepatitis curriculum, which, once available, HRSA will disseminate through its grantees, listservs, and networks.

## 2012 Actions

- Conduct qualitative and quantitative research designed to understand the knowledge, skills, abilities, and attitudes of providers with regard to prevention, care, and treatment of viral hepatitis.

**Progress:** HRSA lacks the resources to conduct such research. HRSA is willing to partner with stakeholder groups who may be able to conduct such research.

- Develop clinical decision aids as a component of electronic medical records (EMR) to support appropriate prevention, care, and treatment related to viral hepatitis.

**Progress:** HRSA is implementing EMRs and meaningful use in stages across all Federally Qualified Health Centers and Ryan White Part C Grantees. When clinical decision aids are available, HRSA will support their use in the EMRs. This effort is currently in progress with an anticipated completion in December 2013.

- Work with specialty medical organizations (e.g., IDSA, AASLD) to develop and disseminate guidelines for the evaluation, management, and treatment of viral hepatitis.

**Progress:** HRSA worked closely with the National Institutes of Health to ensure that the HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents were updated to include drug-drug interactions between directly acting agents for HCV treatment and antiretrovirals. The updated guidelines are posted on AIDSinfo ([www.aidsinfo.nih.gov](http://www.aidsinfo.nih.gov)) and were disseminated via the HAB biweekly e-mail to grantees, the HAB weekly update to project officers, and the AETCs to Ryan White providers. HRSA remains involved in the review and updating of the guidelines, including the section on HIV/HCV co-infection.

HRSA has disseminated AASLD guidelines to health center project officers. The AASLD guidelines were also shared with grantees during the national Webinar on viral hepatitis, referenced previously. When further guidelines, programs, educational materials, and tools are available, HRSA will disseminate through its networks. This effort is ongoing.

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## Indian Health Service (IHS)

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### 2011 Action

- Train all health care providers in HHS-sponsored clinical programs (e.g., Federally Qualified Health Centers and clinics receiving funds associated with the Ryan White CARE Act) to deliver viral hepatitis vaccination, early detection, testing, management of alcohol and other cofactors, and treatment.

**Progress:** IHS has undertaken a number of provider training activities focusing on viral hepatitis, including the following:

- In December 2010, the IHS National HIV/AIDS Program began a partnership with the Office of Minority Health Resource Center and the Seattle Indian Health Board to develop a training series integrating HIV and hepatitis services in urban settings to be completed in late 2012.
- Since 1999, the Alaska Native Tribal Health Consortium (ANTHC) Web site has provided information for providers on managing hepatitis B and C patients. This includes protocols on treating patients with acute and chronically elevated liver function tests. These resources are updated quarterly and the next update is planned for completion by June 2012.
- IHS is finalizing plans to expand trainings for providers on hepatitis and HIV care integration. Beginning in August 2012, IHS will launch an expanded partnership with the University of California San Francisco HIV Care Warmline to provide focused technical assistance to HIV providers in the IHS system to enhance viral hepatitis integration in IHS facilities.
- Finally, the IHS has a goal to certify all obstetric hospitals as Baby-Friendly by December of 2013. The Baby-Friendly® Hospital Initiative (BFHI) is a quality improvement effort to increase breastfeeding rates, thereby creating a healthy start on life and preventing childhood obesity. The Initiative is a global effort to implement practices that protect, promote, and support breastfeeding. The Ten Steps to Successful Breastfeeding outline what facilities should do as they seek certification. Included in this process is the education of facility employees on appropriate considerations for hepatitis A, B, and C in relation to breastfeeding. Online BFHI staff education is available for IHS employees to support dissemination of these practices.

All these efforts are ongoing.

## National Institutes of Health (NIH)

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### 2011 Action

- Work with academic institutions and educational organizations to develop and promulgate standardized viral hepatitis curricula for students in postgraduate medical, dental, nursing, physician's assistant, alternative medicine, and other allied health schools.

**Progress:** NIH is providing expert advice; however, this initiative is being led by CDC.

### 2012 Action

- Work with specialty medical organizations (e.g., IDSA, AASLD) to develop and disseminate guidelines for the evaluation, management, and treatment of viral hepatitis.

**Progress:** Guidelines for therapy of hepatitis C (genotype 1) were published by AASLD in October 2011 (*Hepatology*, 54(4), 1433–1443). The guidelines were developed with significant input from staff of the Intramural Research Program of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). These guidelines were widely disseminated and are available on the AASLD Web site. Guidelines for hepatitis C care will evolve quickly as new agents are approved in the next 1–5 years. Additionally, NIH representatives, including ones from the National Institute of Allergy and Infectious Diseases (NIAID) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), participated in developing updated HHS guidelines for antiretroviral use in HIV-infected persons, including hepatitis B virus (HBV)-co-infected individuals. The guidelines for adults and adolescents were released in April 2012

(<http://www.aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0/>); for infants and children, in August 2011

(<http://www.aidsinfo.nih.gov/guidelines/html/2/pediatric-treatment-guidelines/0/>); and for pregnant women, in September 2011

(<http://www.aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0/>). NIH representatives, including ones from NIAID and NICHD, are also participating in developing updated guidelines for prevention and treatment of opportunistic infections such as viral hepatitis in HIV-infected adolescents and adults (release expected in October or November 2012) and in HIV-infected and -exposed children (release expected in August 2012).

## Office of the Assistant Secretary for Health (OASH)

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Though not tasked in the Action Plan as a lead agency for any actions under this goal, OASH's OHAIDP undertook several activities in support of it, including the following:

OHAIDP co-chaired the Education Work Group and initiated a project to inventory, review, and post online all federally developed public and health care provider education materials related to viral hepatitis in collaboration with the VHIG. This effort was completed in April 2012.

OASH presented during a number of national and international conferences to increase awareness of the Action Plan; the work of HHS and federal partners to implement the Action Plan; and the need to better prepare the health care workforce to prevent, diagnose, and provide care and treatment to persons infected with viral hepatitis. These conferences have

included the annual meeting of the American Association for the Study of Liver Disease and the International Conference on Viral Hepatitis (International Association of Physicians in AIDS Care). These efforts are ongoing.

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### **Substance Abuse and Mental Health Services Administration (SAMHSA)**

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#### **2011 Action**

- Begin implementation of the viral hepatitis educational curriculum in drug-treatment centers (e.g., Addiction Technology Transfer Centers (ATTC)) to educate providers serving priority populations.

**Progress:** SAMHSA's 14 ATTCs have begun developing and implementing curricula that address hepatitis screening and prevention activities. Additionally, SAMHSA's project to Enhance Substance Abuse Treatment Services to Promote Healthy Lifestyles through Addressing Hepatitis Infection among Intravenous Drug Users (IDU) has provided hepatitis A virus (HAV)/HBV vaccine and HCV test kits to opioid treatment programs (OTP) that treat primarily racial- and ethnic-minority populations with HIV or at risk for exposure to hepatitis infection. In December 2011, a best-practices Treatment Improvement Protocol (TIP), Addressing Viral Hepatitis in People with Substance Use Disorders (SUD), was published and publicized through SAMHSA's March 2012 blog post. All 1,260 SAMHSA-certified OTPs were made aware of the TIP. These efforts are ongoing.

#### **2012 Action**

- In collaboration with behavioral, mental health, and social service provider organizations, networks, and groups, develop and disseminate training materials and programs on viral hepatitis prevention, care, and treatment.

**Progress:** SAMHSA's Center for Substance Abuse Treatment (CSAT) participated in meetings of the Federal Training Centers Collaborative (FTCC) to increase knowledge of HIV, hepatitis, and substance abuse. SAMHSA provided information to the FTCC on substance abuse and hepatitis. In addition, CSAT provided grants to 17 medical residency programs across the country responsible for formulating and disseminating screening, brief intervention, and referral to treatment (SBIRT) technology through curriculum development and training of local communities in SBIRT implementation. The curricula address the intersection between injection drug use and hepatitis. These efforts are ongoing.

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### **Department of Veterans Affairs (VA)**

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Though not tasked in the Action Plan as a lead agency for any actions under this goal, VA undertook several activities in support of it, including the following:

VA conducts a bimonthly Webinar series open to all hepatology and infectious disease clinical teams, primary care teams, and mental health and SUD providers from VA medical centers on best practices and standards of care in hepatitis care and treatment. This activity started in 2010 and will be ongoing through fiscal year (FY) 2013.

VA conducted a 300-person face-to-face meeting for frontline VA clinicians providing HCV care in September 2011 to educate providers on prescribing new triple therapy for HCV and managing patients on treatment. Participation at this meeting included representatives from CDC and FBOP.

VA is providing specific training for both pharmacists and mental health professionals in hepatitis care. Pharmacists are currently being trained at regional “boot camps.” VA has provided specialized training for 340 clinical pharmacists in hepatitis C care since May 2011. The face-to-face meetings will continue into FY 2013. The goal of these activities is to increase the number of hepatitis C treaters and to establish well-trained multidisciplinary teams to care for Veterans with hepatitis C.

VA is also developing an HIV/HCV Psychology Postdoctoral Fellowship Program, designed to train clinical psychologists to manage the unique mental health and substance use comorbidities frequently found in patients infected with HIV and/or HCV. VA has hired a director of the program and funded four new positions for HIV/HCV Psychology Postdoctoral Fellow for FY 2013–2015.

All of these efforts are ongoing.

**GOAL 1.2** Decrease health disparities by educating communities about the benefits of viral hepatitis prevention, care, and treatment.

**Centers for Disease Control and Prevention (CDC)**

**2011 Actions**

- Conduct formative research with populations at risk for HBV and HCV infection to understand knowledge, attitudes, and behaviors related to testing, care, and treatment of chronic viral hepatitis.

**Progress:** CDC has conducted formative research with populations at risk for HCV infection with the goal of understanding their knowledge, attitudes, and behaviors related to testing for chronic viral hepatitis. This effort was completed in 2011.

- Develop a national educational campaign and pre-test campaign materials with members of the target audience.

**Progress:** CDC has developed and pre-tested materials for the Know More Hepatitis campaign to encourage those at risk for chronic HCV to get tested. Plans have been developed to launch the first phase of this campaign in May 2012. CDC is planning on a national education campaign targeting Asian Americans and will conduct the associated formative research in 2013. These efforts are in progress and will continue through the remainder of 2012 and into 2013.

## 2012 Actions

- Launch a pilot project in several U.S. cities to create and test educational messages, materials, and strategies to be used for a national campaign.
- Partner with regional, state, local, and tribal organizations for the planning and implementation of a national education campaign.
- Award community grants designed to reach specific at-risk populations with culturally sensitive and linguistically appropriate evidence-based interventions.

**Progress:** Limited resources within the CDC have prohibited the launch of a pilot campaign as well as the issuing of community grants to educate at risk populations.

- Collaborate with federal partners, private industry, and the media to designate May 19 as Hepatitis Testing Day in the United States.

**Progress:** A variety of activities have been planned to support May 19 as Hepatitis Testing Day. This effort is in progress with an anticipated completion in May 2012.

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## Indian Health Service (IHS)

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### 2011 Action

- Develop a national educational campaign and pre-test campaign materials with members of the target audience.

**Progress:** The IHS National HIV/AIDS Program is planning to disseminate appropriate Know More Hepatitis materials and messages from the CDC campaign. In addition, IHS is in the process of implementing two youth-centered health education programs inclusive of hepatitis prevention messages: one in partnership with the Office of Adolescent Health, the Office of Minority Health Resource Center, and CDC and another in partnership with Project Red Talon and CDC. These efforts are in progress with an anticipated completion in December 2013. The IHS National HIV/AIDS Program will also develop, in partnership with a viral hepatitis treatment team, broad-audience promotional materials to increase co-infection status awareness, knowledge, and care among clinicians as well as expanded materials for co-infected patients. All products will be tested during development. This effort will be initiated in November 2012.

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## National Institutes of Health (NIH)

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### 2012 Action

- Spur development of an annual global forum to promote communication and collaboration among diverse stakeholders (e.g., health ministries, nongovernmental organizations, academia, and industry).

**Progress:** NIH (specifically NIDDK and NIAID) held a research workshop on hepatitis E in the United States in March 2012 with participants reporting on findings throughout Asia, Europe, and the United States, as well as participation from the Food and Drug Administration (FDA), CDC, VA, the American Red Cross, and private industry. Several NIH

Institutes and centers are planning national or international workshops on topics related to viral hepatitis, such as a meeting on alcohol, viral hepatitis, and pancreatitis to be sponsored by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in September 2012 in Beijing, China.

NIH, through NIDDK and NIAID, also provides educational materials to promote public awareness about viral hepatitis, including awareness in at-risk groups, and highlighted related research and educational efforts pertaining to Hepatitis Awareness Month and World Hepatitis Day in May 2012, through the Web, social media, and other communication outlets. These efforts are ongoing.

NIH does education, outreach, and screening activities. Research on these areas also is conducted.

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### Office of Minority Health (OMH)

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#### 2011 Action

- Continue to promote May as “Hepatitis Awareness Month” in the United States and work with the media to communicate timely viral hepatitis messages.

**Progress:** As part of the official launch of Hepatitis B United, OMH, along with CDC and OHAIDP, presented on a Webinar with hepatitis B leaders and advocates on March 27, 2012, to promote partnership opportunities for the May 2012 national observance of Hepatitis Awareness Month. OMH highlighted the viral hepatitis related dimensions of the HHS Plan for Asian-American, Native Hawaiian, and Pacific Islander (AANHPI) Health and the National Partnership for Action. OMH has partnered with CDC to promote Hepatitis Awareness Month and increase awareness of perinatal transmission of hepatitis B from mother to child. These efforts are in progress with an anticipated completion in May 2012.

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### Office of the Surgeon General (OSG)

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#### 2011 Action

- Continue to promote May as Hepatitis Awareness Month in the United States and work with the media to communicate timely viral hepatitis messages.

**Progress:** OSG published a “Surgeon General’s Perspective” column on Hepatitis Testing Day and the importance of testing in the May–June 2012 issue of the journal *Public Health Reports*. This activity was completed in April 2012.

### Office on Women's Health (OWH)

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#### 2012 Action

- Continue to promote May as “Hepatitis Awareness Month” in the United States and work with the media to communicate timely viral hepatitis messages.

**Progress:** OWH has made plans to integrate hepatitis prevention into National Women's Health Week (May 13–19, 2012) activities, including prominent display on the OWH Web page of hepatitis education information and promotion of Hepatitis Testing Day (May 19) as well as the forthcoming online viral hepatitis risk assessment tool from CDC. These efforts are in progress with an anticipated completion in May 2012.

### Department of Veterans Affairs (VA)

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#### 2011 Actions

- Develop a national educational campaign and pre-test campaign materials with members of the target audience.
- Continue to promote May as Hepatitis Awareness Month in the United States and work with the media to communicate timely viral hepatitis messages.

**Progress:** VA is developing public health messaging to increase awareness of viral hepatitis among Veterans and VA staff across the system. VA is partnering with the CDC, in particular their Know More Hepatitis campaign, which will be adopted for VA dissemination. This effort is in progress with an anticipated completion in May 2012.

## Priority 2 Improving Testing, Care, and Treatment to Prevent Liver Disease and Cancer

GOAL 2.1 Identify persons infected with viral hepatitis early in the course of their disease.

### Agency for Healthcare Research and Quality (AHRQ)

#### 2011 Action

- Support U.S. Preventive Services Task Force (USPSTF) efforts to update guidelines for hepatitis C testing and treatment.

**Progress:** AHRQ is directed by statute to convene the USPSTF and to provide ongoing scientific, technical, and administrative support. In compliance with this requirement, AHRQ commissioned two Evidence-Based Practice Center (EPC) systematic evidence reports on HCV screening and treatment. AHRQ provided these reports to the USPSTF to assist the members in updating their recommendation on screening for hepatitis C infection. The USPSTF is expected to publish a draft recommendation statement on screening for hepatitis C in adults for public comment in the autumn of 2012. AHRQ has also ensured that experts from across HHS have been kept abreast of the progress of the USPSTF. AHRQ has posted draft EPC evidence reports on *Screening for Hepatitis C Virus Infection in Adults* and *Treatment for Hepatitis C Virus Infection in Adults: A Comparative Effectiveness Review* on its Internet site (<http://www.uspreventiveservicestaskforce.org/uspstf/uspshcpc.htm>). The final recommendation statement is expected to be posted in June 2013.

#### 2012 Action

- Develop and implement performance measures for hepatitis testing in HHS-sponsored health programs (e.g., community health centers, IHS clinics, HIV test sites).

**Progress:** AHRQ helped support a serial cross-sectional evaluation of the Hepatitis C Assessment and Testing Project (HepCAT). The HepCAT consists of two community-based interventions designed to increase HCV testing in urban primary care clinics in comparison with a baseline period. The first intervention (risk-based screener) prompted physicians to order HCV tests based on the presence of HCV-related risks. The second intervention (birth cohort) prompted physicians to order HCV tests on all patients born within a high-prevalence birth cohort (1945–1964).

## Centers for Disease Control and Prevention (CDC)

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### 2011 Action

- Revise CDC guidelines for hepatitis C testing and linkage to care and treatment.

**Progress:** CDC drafted and cleared recommendations for one-time HCV testing of persons born between 1945 and 1965. As of April 2012, the document is going through HHS review and clearance. CDC will issue a request for public comment in the *Federal Register*, on the revised recommendations, likely in May 2012. This activity is in progress with an anticipated completion in July 2012 and publication of the revised guidelines in the *Morbidity and Mortality Weekly Report*.

### 2012 Action

- Strengthen community-based programs providing testing and linkages to care, particularly those serving foreign-born populations.

**Progress:** CDC has begun a demonstration project aimed at identifying and targeting foreign-born populations from hepatitis B endemic countries who reside in the United States for screening, vaccination, and referral for care. Project sites in Philadelphia, PA, and Seattle, WA, have been identified, with three community-based organizations (CBO) participating in the demonstration project (the Hepatitis B Foundation in Philadelphia and the Hepatitis B Coalition and the Hepatitis Education Project in Seattle). Screening will begin in summer 2012 with an anticipated completion in August 2013.

## Health Resources and Services Administration (HRSA)

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### 2012 Action

- Promote HHS-recommended viral hepatitis testing as a standard of care in all federally sponsored primary care programs (e.g., community health centers, IHS clinics).

**Progress:** HRSA has presented on the cross-agency Action Plan in national meetings for health centers and Primary Care Associations. Additionally, the AASLD Practice Guidelines have been disseminated to all Health Center Program project officers

## Office of Minority Health (OMH)

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### 2012 Action

- Strengthen community-based programs providing testing and linkages to care, particularly those serving foreign-born populations.

**Progress:** OMH, in collaboration with the Association of Asian Pacific Community Health Organizations, conducted monthly calls with 20 organizations representing 10 cities with the highest concentration of AANHPI populations to work on hepatitis B activities. OMH developed a process to award 8–10 mini-grants to CBOs in cities with high concentrations of AANHPIs to replicate a city- and countywide model similar to San Francisco Hepatitis B Free in August 2012. The Hepatitis B United coalition, which includes HHS federal partners

such as OHAIDP, CDC, and OMH, will provide support and technical assistance to the funded CBOs. These efforts are ongoing and will continue through 2012.

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### Office of the Assistant Secretary for Health (OASH)

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#### 2011 Action

- To the extent possible, coordinate across agencies to ensure that guidelines for hepatitis B and hepatitis C testing, care, and treatment are aligned.

**Progress:** OHAIDP is working with the CDC Division of Viral Hepatitis (DVH) regarding the anticipated update to the CDC hepatitis C screening guidelines and with staff from AHRQ who work with the USPSTF regarding the current review of the USPSTF hepatitis C screening recommendations. OHAIDP is coordinating efforts to assess and coordinate materials and guidelines for viral hepatitis through VHIG, the federal cross-agency workgroup coordinating collaborative activities to implement and monitor the Action Plan. The CDC HCV screening guidelines are expected to be final in summer 2012 and the USPSTF HCV screening recommendations are expected to be final in 2013.

#### 2012 Action

- Develop a cross-agency process for identifying and eliminating barriers to the implementation of viral hepatitis testing and linkage of infected patients to care and treatment.

**Progress:** OHAIPD conducted a 1-day technical consultation with a group of approximately 45 experts and stakeholders on February 23, 2012, to examine approaches for implementing routine hepatitis B and C testing in health departments, jails and prisons, community health centers, and other primary care settings and CBOs. The consultation highlighted barriers, strategies, best practices, and models regarding implementation of routine testing for viral hepatitis. A final report from the consultation will be released in May 2012.

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### Substance Abuse and Mental Health Services Administration (SAMHSA)

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#### 2012 Action

- Implement HHS-recommended viral hepatitis testing as a standard of care in drug treatment programs.

**Progress:** SAMHSA's TIP, *Addressing Viral Hepatitis in People with Substance Use Disorders*, was finalized and released in February 2012. The CSAT discretionary HIV grantees, SAMHSA-certified OTPs, and State Substance Abuse Authorities were notified and made aware of recommendations pertaining to drug treatment. Plans are currently underway to implement recommendations outlined in the TIP.

The CSAT-funded ATTC for HIV, Hepatitis, and Substance Abuse conducted a conference on street-level intervention strategies for addiction, HIV/AIDS, and hepatitis on October 17–19, 2011, in Silver Spring, MD. The conference featured information on hepatitis testing in

substance abuse programs such as SAMHSA-certified OTPs (more than 1,250) that treat many individuals who are injecting or have injected drugs in the past.

An OTP medical education training course curriculum was reviewed by CSAT and will be revised to include additional information on HCV screening and testing and preventive services. An effort was initiated to revise OTP accreditation guidelines including sections on hepatitis prevention and referral services. All OTPs must be accredited and these guidelines help shape OTP infectious disease practices.

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### Department of Veterans Affairs (VA)

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#### 2012 Action

- Implement data elements (e.g., those concerning disease staging, hepatocellular carcinoma monitoring, comorbidity management) in EMRs to monitor hepatitis testing, care, and treatment in health care settings.

**Progress:** VA has clinical reminders available (a prompt in the EMR) to remind primary care teams to offer HCV screening and testing as indicated. These reminders have been in use for many years. In 2012, VA revisited the clinical reminder and has encouraged VA medical centers to increase use of the HCV clinical reminder.

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### GOAL 2.2 Link and refer persons infected with viral hepatitis to care and treatment.

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### Centers for Disease Control and Prevention (CDC)

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#### 2012 Action

- Identify and disseminate best practices for the prompt linkage of persons testing positive for viral hepatitis to needed care and treatment.

**Progress:** CDC began development of linkage to care interventions and will be formatively and rigorously evaluated over the next 2 years and completed by 2013.

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### Centers for Medicare & Medicaid Services (CMS)

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#### 2012 Actions

- Identify opportunities (e.g., those afforded by the Affordable Care Act) to improve the provision and coordination of comprehensive viral hepatitis services in public and private health plans.

**Progress:** CMS Medicare currently covers hepatitis B vaccines and their administration for certain beneficiaries at intermediate or high risk of contracting hepatitis B under Medicare Part B. Medicare also provides drug and vaccine coverage under Parts C and D. Part D drug coverage has become more affordable with coverage in the gap as provided by the Affordable Care Act. This effort is ongoing.

- Identify Medicaid options (e.g., Section 1115 waivers, health homes) to improve outreach and care coordination for HBV-infected women and their household contacts.

**Progress:** CMS's Centers for Medicaid and Children's Health Insurance Program Services and CDC have met to discuss this and determine how to leverage our authorities to effectively carry out this action. This activity is ongoing.

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### Federal Bureau of Prisons (FBOP)

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#### 2012 Action

- Develop and implement effective medical management models for use in priority populations.

**Progress:** In March 2012, FBOP published updated *Clinical Practice Guidelines for Evaluation and Treatment of Hepatitis C and Cirrhosis* to include the use of HCV protease inhibitors in treatment of chronic HCV genotype 1 infection. Other documents were updated to standardize and better facilitate the process for evaluating the appropriateness of hepatitis C treatment for the patient and to aid in the review of pertinent material that aims to improve patient outcomes. These action items are supplementary to the already established protocols of identifying inmates with hepatitis, upon intake, to be placed in chronic care clinics where they are routinely evaluated and managed as indicated. In addition, at intake and at other periods while incarcerated, risk factors for hepatitis are assessed, and appropriate hepatitis screening is conducted, as indicated in the FBOP Preventive Health Care Guidelines.

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### Health Resources and Services Administration (HRSA)

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#### 2012 Actions

- Create databases of testing and care referral services available in local areas.

**Progress:** HRSA was not able to initiate this action due to lack of resources.

- Develop and implement effective medical management models for use in priority populations.

**Progress:** In FY 2011, HRSA, through the Special Projects of National Significance program, awarded grants to 29 organizations across two separate cohorts (14 continuation and 15 new awards) to implement focused model interventions designed to increase access to and completion of HCV treatment for HIV-positive patients in Ryan White HIV/AIDS program funded clinical settings.

HRSA also funded an Evaluation and Technical Assistance Center (ETAC) to provide clinical training and technical assistance on the implementation of HCV treatment models for patients within Ryan White-funded HIV primary care programs, conduct a rigorous evaluation of the demonstration models, and disseminate findings and lessons learned from implemented demonstration models. The ETAC will continue to provide clinical consultation through monthly multisite webinars. In addition, the ETAC will continue to assess the effectiveness, feasibility, and costs of the service delivery model for which each demonstration site is funded. From these assessments, the ETAC will identify which

model(s) of patient care best served HIV/HCV co-infected patients within a diverse set of communities and publish the findings with the goal of creating a replicable and sustainable model for integrating HCV treatment into Ryan White programs.

HAB was awarded the HHS Secretary's Minority AIDS Initiative funds in 2012 to expand the number of Telehealth Training Centers from three to nine starting in summer 2012. These multiyear projects target low volume providers to build capacity to identify and treat HIV with expansion focusing on hepatitis to be implemented throughout all AETC Telehealth Training Centers.

These efforts are in progress and ongoing.

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### Indian Health Service (IHS)

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#### 2012 Actions

- Identify and disseminate best practices for the prompt linkage of persons testing positive for viral hepatitis to needed care and treatment.

**Progress:** IHS facilities utilized telemedicine networks managed by the University of New Mexico (ECHO) and ANTHC (LiverConnect) to improve the care and treatment of persons living with hepatitis. The network of telemedicine doctors, nurses, and pharmacists has built a strong foundation for care and treatment in IHS sites. The results of a consensus conference in 2012 included a panel of experts representing OB/GYNs and other primary care providers and included the development of a simple algorithm for providers who care for pregnant women to provide prenatal screening and identify pregnant women who are hepatitis B surface antigen positive (HBsAg+). This protocol will be published in an OB/GYN journal in the spring of 2012.

**GOAL 2.3** Improve access to and quality of care and treatment for persons infected with viral hepatitis.

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### Centers for Medicare & Medicaid Services (CMS)

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#### 2012 Action

- Establish clinical quality measures to monitor performance.

**Progress:** CMS's Physician Quality Reporting System (PQRS) currently has nine measures related to hepatitis C that physicians and other eligible professionals can report in the PQRS Incentive Program. The measures include the following: (1) Testing for Chronic Hepatitis C: Confirmation of Hepatitis C Viremia, (2) Hepatitis C: RNA Testing Before Initiating Treatment, (3) Hepatitis C: HCV Genotype Testing Prior to Treatment, (4) Hepatitis C: Antiviral Treatment Prescribed, (5) Hepatitis C: HCV RNA Testing at Week 12 of Treatment, (6) Hepatitis C: Counseling Regarding Risk of Alcohol Consumption, (7) Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy, (8) Hepatitis C: Hepatitis A Vaccination in Patients with HCV, and (9) Hepatitis C: Hepatitis B Vaccination in Patients with HCV.

### **Health Resources and Services Administration (HRSA)**

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Though not tasked in the Action Plan as a lead agency for any actions under this goal, HRSA undertook several activities in support of it, including the following:

HRSA, along with SAMHSA, cosponsors the Center for Integrated Health Solutions (CIHS) to integrate behavioral health and primary care. In 2012, CIHS will develop resources for the prevention of hepatitis C. BPHC has ongoing discussions with homeless grantees and the National Health Care for the Homeless Council (a BPHC national cooperative agreement) on hepatitis prevention.

Hepatitis C and homelessness were highlighted in a Webinar in January 2012 to a national audience of health center grantees, primary care associations, national cooperative agreements, and BPHC staff. BPHC has been in discussion with Project ECHO on integrating behavioral health providers in the treatment team for hepatitis C. Project ECHO was highlighted in the national Webinar on viral hepatitis.

### **Indian Health Service (IHS)**

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#### **2012 Action**

- In accordance with clinical quality measures, develop clinical decision schema and other tools to ensure quality care for patients living with viral hepatitis.

**Progress:** In February 2011, LiverConnect was launched. It is updated bimonthly. This is a resource for providers, a forum to present patients, and a venue for the formal continuing medical education of providers. In addition, the Liver Disease and Hepatitis Program Patient Newsletter provided the latest research, latest treatment options, and information on biannual testing drives (liver function tests and viral load) for IHS grantees and clinicians. This is updated quarterly.

### **Office of the Assistant Secretary for Health (OASH)**

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#### **2011 Action**

- Coordinate the development of recommendations to guide the provision of care and treatment to persons living with viral hepatitis.

**Progress:** OASH will review all existing federally developed patient and provider materials relevant to the care and treatment of viral hepatitis to assess completeness and gaps. The findings of this assessment will be used to prioritize next steps in the development of recommendations to guide the provision of care and treatment to persons living with viral hepatitis and is expected to be completed in the summer of 2012.

## Office of Minority Health (OMH)

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### 2012 Action

- Improve linkage to care and treatment among persons infected with viral hepatitis.

**Progress:** All OMH grantees under the HIV/AIDS Health Improvement for Re-entering Ex-offenders (HIRE) and Linkage 2 Life (L2L) programs have integrated viral hepatitis prevention education and services with their HIV prevention programs. During the first quarter of FY 2012, a total of 1,487 individuals received counseling, testing, and referral (CTR) services for viral hepatitis and HIV under the HIRE program; 2,492 received CTR services for viral hepatitis and HIV under the L2L.

## Substance Abuse and Mental Health Services Administration (SAMHSA)

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### 2012 Action

- Develop “brief interventions for alcohol” training and disseminate via federally funded training centers and other partner organizations.

**Progress:** SAMHSA’s Center for Mental Health Services grant program, Primary and Behavioral Health Care Integration (PBHCI), supported grants to improve the physical health status of people with serious mental illness by supporting communities to coordinate and integrate primary care services into publicly funded community mental health and other community-based behavioral health settings. A number of PBHCI grantees reported that they conduct hepatitis testing as a routine part of primary care services.

CSAT’s SBIRT State Demonstration Grants offered screening, brief intervention and referral to traditional alcohol and other drug specialty treatment services in 12 states. The New York grantee has three sites specifically in HIV clinics which also have served hepatitis clients. Many of the states have offered services in clinics and emergency rooms serving the hepatitis population, among many others. CSAT SBIRT community grantees have promoted the collaborative connectivity between the primary care area and referral to specialty treatment including hepatitis.

CSAP supports extensive programs in alcohol education and training through various SAMHSA-funded substance abuse prevention and training programs as well as through the Drug Free Communities program, a collaboration funded by the Office of National Drug Control Policy and managed by SAMHSA.

## Department of Veterans Affairs (VA)

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### 2012 Actions

- In accordance with clinical quality measures, develop clinical decision schema and other tools to ensure quality care for patients living with viral hepatitis.

**Progress:** VA began to develop a standardized curriculum for the ECHO training model to support training and mentorship of providers in rural and underserved areas to promote the high

quality standards of care VA expects for diagnosis, care, and treatment for all Veterans with chronic hepatitis. This effort is in progress with anticipated completion in September 2012.

VA continues to collect information on hepatitis C quality measures and health outcomes on all Veterans with hepatitis C through VA's Hepatitis C Clinical Case Registry. These data are then used to provide feedback to VA medical facilities and VA providers on the quality of care that they are providing to Veterans with chronic hepatitis C. Quality improvement projects and interventions are then instituted to ensure a high standard of care for all Veterans across the United States. The annual reports on performance of HCV quality measures and health outcomes are posted on the VA intranet by facility, and a summary aggregate report is posted on the Internet for the public to view. This effort is ongoing.

- Develop "brief interventions for alcohol" training and disseminate via federally funded training centers and other partner organizations.

**Progress:** Since 2006, BAI training has been provided to 395 clinicians who care for Veterans with hepatitis C and alcohol abuse or dependence. Since May 2011, 37 clinicians have received the training, and another 37 will attend training in May 2012.

## GOAL 2.4 Advance research to facilitate viral hepatitis prevention and enhance care and treatment for infected persons.

### Agency for Healthcare Research and Quality (AHRQ)

#### 2012 Action

- Evaluate promising models of care to address the unique issues faced by priority populations affected by viral hepatitis.

**Progress:** AHRQ has commissioned an EPC evidence report on *Adherence to Hepatitis C Treatment Interventions: A Comparative Effectiveness Review*. A draft is expected to be available late in May 2012; after going through review at AHRQ, it will be posted for public comment and peer review by early July 2012.

In June 2011, AHRQ supported the University of New Mexico Health Sciences Center evaluation of their ECHO project. Project ECHO was designed to bring effective treatment for HCV infection to underserved areas via the transference of state-of-the-art medical knowledge to primary care providers and nurses.

### Centers for Disease Control and Prevention (CDC)

#### 2012 Action

- Conduct comparative research on culturally and ethnically sensitive approaches to and operations associated with viral hepatitis testing across diverse patient populations.

**Progress:** CDC began to develop studies designed to evaluate the effectiveness of testing and prevention messages for diverse patient populations. These studies will specifically

examine changes in knowledge and behavior after the provision of testing interventions. CDC's goal is to develop and disseminate evidence based interventions for hepatitis testing. This effort is in progress with an anticipated completion in 2013.

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### Food and Drug Administration (FDA)

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#### 2011 Action

- Support development of point-of-care assays to detect serological evidence of both exposure to viral hepatitis and active viral hepatitis infection.

**Progress:** In February 2011, FDA approved a supplement to the premarket approval application for the OraQuick HCV Rapid Antibody Test with an expanded indication for the use of fingerstick whole blood in the assay. Additionally, in November 2011, FDA granted a Clinical Laboratory Improvement Amendments (CLIA) waiver for the OraQuick HCV Rapid Antibody Test. This enabled the use of this test in point-of-care facilities with limitations such as that the test should not be used to make a final diagnosis of HCV infection, should not be used for screening blood donors or patients without signs or symptoms of HCV, and should be used only when prescribed by a physician.

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### National Institutes of Health (NIH)

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#### 2011 Actions

- Support development of point-of-care assays to detect serologic evidence of both exposure to viral hepatitis and active viral hepatitis infection.

**Progress:** In January 2012, NIH published a program announcement requesting applications in the area of rapid screening tests for all forms of viral hepatitis: PA-12-090 and -091, "New Technologies for Viral Hepatitis SBIR and STTR." Participating Institutes are NIDDK; the National Cancer Institute (NCI); the National Heart, Lung, and Blood Institute (NHLBI); NIAAA; NIAID; and NICHD. The NIH Clinical Center's Department of Transfusion Medicine has conducted studies related to serologic detection of viral hepatitis infection, including a transmission study in an animal model. This study is completed, and results published online in April 2012 (Busch et al., *Blood*, e-published April 12, 2012). The National Institute on Drug Abuse's (NIDA) Seek, Test, Treat, and Retain research paradigm is developing effective strategies to identify hepatitis infections sooner within vulnerable populations, including the criminal justice system, within integrated care clinics and drug treatment programs both foreign and domestic.

- Support investments in basic, translational, comparative, and effectiveness research to facilitate the discovery and development of effective and well-tolerated treatments for viral hepatitis and related disease resulting from chronic viral hepatitis infection (e.g., hepatocellular carcinoma).

**Progress:** Several NIH institutes and centers continue their ongoing support of basic and applied research on viral hepatitis, including primary and secondary prevention as well as treatment of the infection and its complications, such as hepatocellular carcinoma. The annual funding level for viral hepatitis research supported by NIH is approximately \$176

million (source: Research, Condition, and Disease Categorization FY 2011 combined actual spending for hepatitis A, B, and C).

The Hepatitis B Research Network, sponsored by NIDDK, initiated two prospective clinical trials and is about to launch a third such study evaluating the relative efficacy and safety of current therapies and their combination. NIDDK's Adult to Adult Living Donor Liver Transplantation (A2ALL) Cohort Study supports the exploration of pre-liver transplant HCV treatment strategies to prevent HCV re-infection following liver transplant. Additionally, data and samples from clinical research studies related to hepatitis C, such as A2ALL, Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis, and Pegylated Interferon +/- Ribavirin for Children With Hepatitis C, are available for future research through the NIDDK repository. The NICHD Maternal Fetal Medicine Network developed a study of hepatitis C in pregnant women that is in the final stages of development. A multicenter clinical trial of an herbal product, silymarin, for treatment resistant hepatitis C (National Center for Complementary and Alternative Medicine, NIDDK) was concluded in 2011, and results will be published in the *Journal of the American Medical Association*. The NIH Intramural program includes clinical research protocols on therapy of hepatitis B, C, and D (NIDDK) and in patients with HIV-HCV co-infection (NIAID).

In March 2012, NIH hosted a research workshop on hepatitis E in the United States, focusing on research opportunities in the diagnosis, prevention, and treatment of hepatitis E virus infection, which can cause severe acute as well as chronic hepatitis and cirrhosis. Research recommendations from the conference will be disseminated, and workgroups on specific issues have been formulated. Additional NIH research workshop topics related to viral hepatitis are being considered by the Institutes and Centers. Also, the International Maternal Pediatric Adolescent AIDS Clinical Trials group, led by NIAID with cofunding by NICHD and the National Institute of Mental Health, has established a new Hepatitis Scientific Committee charged with promoting viral hepatitis prevention and treatment protocols in pregnant women, infants, and children (with or without HIV co-infection) domestically and internationally.

NIDA funds several research projects domestically and internationally that focus on effective integration of hepatitis testing and care within opioid treatment programs.

## 2012 Actions

- In collaboration with industry, spur development of new tests (e.g., tests capable of distinguishing between acute and chronic hepatitis C, less costly alternatives to current HCV polymerase chain reaction testing).

**Progress:** NIH published a program announcement requesting applications in the area of developing assays that discriminate ongoing and active infection from recovery and immunity. PA-12-090 and -091, "New Technologies for Viral Hepatitis SBIR and STTR," was released in January 2012 (<http://grants.nih.gov/grants/guide/pa-files/PA-12-090.html> and <http://grants.nih.gov/grants/guide/pa-files/PA-12-091.html>). Participating Institutes are NIDDK, NCI, NHLBI, NIAAA, NIAID, and NICHD. This effort is slated for completion in January 2015.

- Revise eligibility criteria for the AIDS clinical trials network and other HIV-related clinical trials to expand studies of viral hepatitis treatment, including direct-acting antiviral therapies for patients with hepatitis C and patients co-infected with HIV and HCV.

**Progress:** NIH's AIDS Clinical Trials Group protocols are currently designed with flexible cutoff levels for liver function tests to avoid unnecessarily excluding those co-infected with HBV and HCV. In November 2011, the therapeutic clinical trials networks expanded their capacity to enroll persons infected with HCV and those co-infected with HCV and HIV.

- Conduct studies aimed at determining how genetics influence individual susceptibility to the development of chronic liver disease, cirrhosis, and liver cancer. Develop global collaborations for the conduct of basic research and clinical trials and for monitoring adverse events and antiviral mutations.

**Progress:** NIAID, NIDDK, and NCI supported several continuing studies on polymorphisms in the IL28b gene, which are shown to be associated with spontaneous elimination of HCV. Additional studies are focused on identifying specific polymorphisms in other genes (e.g., those in the interferon pathway) that may influence spontaneous and treatment induced HCV clearance. NCI supports and encourages research in hepatocellular carcinoma as a result of viral hepatitis infection. NCI recently released an Omnibus R21 Performance and Accountability Report (PAR) (PAR-12-145; <http://grants.nih.gov/grants/guide/pa-files/PAR-12-145.html>). This PAR permits exploratory and developmental research grant applications and will fill the void left by the recently expired Etiology, Pathogenesis, and Prevention of Hepatocellular Carcinoma R21 program announcement.

- Evaluate promising models of care to address the unique issues faced by priority populations affected by viral hepatitis.

**Progress:** NIH serves in an advisory capacity for this initiative.

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## Office of the Assistant Secretary for Health (OASH)

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### 2012 Action

- Coordinate development of a research agenda to better understand and address the multiple barriers for patients with co-occurring conditions.

**Progress:** In December 2010, OASH published a report titled *Multiple Chronic Conditions: A Strategic Framework*. The report contained recommendations for changes to the way our health system addresses chronic illnesses in the United States, from a single disease approach to a chronic care model emphasizing health care systems improvements, community support, self-management support, delivery design, decision support, and clinical information. This report will serve as the basis for future discussions about barriers to diagnosing and caring for persons with viral hepatitis and co-occurring conditions.

**Department of Veterans Affairs (VA)**

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Though not tasked in the Action Plan as a lead agency for any actions under this goal, VA undertook several activities in support of it, including the following:

VA has a long history of research in viral hepatitis with the goals of improving disease identification, chronic viral hepatitis management, access and equity. VA Office of Public Health collaborates closely with the VA Office of Research and Development's HIV & Hepatitis Quality Enhancement Research Initiative (QUERI) to develop and direct a coordinated research agenda including a number of research projects to improve quality of HCV care in VA.

## Priority 3 Strengthening Surveillance to Detect Viral Hepatitis Transmission and Disease

**GOAL 3.1** Build a network of state and local surveillance systems with sufficient capacity to monitor viral hepatitis transmission and disease.

### Centers for Disease Control and Prevention (CDC)

#### 2011 Actions

- Monitor the misclassification of viral hepatitis cases as a quality assurance measure.  
**Progress:** CDC examined and updated case definitions throughout the year. Changes to case definitions are planned to be released in the summer of 2012.
- Use aggregated EMRs to monitor performance measures of hepatitis testing, care, and treatment and associated health outcomes.  
**Progress:** CDC began conducting several studies to evaluate testing, care, and treatment of viral hepatitis. One study is evaluating current testing practices at four primary care sites and subsequently testing an intervention designed to increase testing and linkage to care. These studies will inform the development of performance measures. This effort is slated for completion in 2013.

#### 2012 Actions

- Identify current gaps in epidemiologic capacity and identify strategies to address them.
- Upgrade surveillance information technology to improve exchange of surveillance data among reporting sites (e.g., laboratories), state and local health departments, and CDC.  
**Progress:** CDC has been unable to initiate this action due to lack of sufficient funding.
- Conduct special studies to investigate emerging modes of transmission, identify new or rare forms of viral hepatitis, and evaluate access to care for persons living with viral hepatitis.  
**Progress:** CDC has funded activities in several health jurisdictions to examine increased incidence of acute HCV in young injection drug users, who typically started drug use with prescription oral opioid drugs (e.g., oxycodone). This effort is in progress and will be completed in November 2012.
- Pilot the use of EMRs in collaboration with health care systems to improve surveillance.
- Automate case detection of viral hepatitis using electronic records (e.g., electronic laboratory data and electronic health records from Medicare, Medicaid).  
**Progress:** CDC conducted analysis of national ambulatory care records (the National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey). This is an ongoing effort.

### Health Resources and Services Administration (HRSA)

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Though not tasked in the Action Plan as a lead agency for any actions under this goal, HRSA undertook activities in support of it.

All health centers under HRSA are now reporting on HCV and HBV testing and diagnoses. Data from 2011 will be available in the summer of 2012.

### Indian Health Service (IHS)

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#### 2012 Action

- Incorporate viral hepatitis diagnostic codes in federal EMR standards.
- Pilot the use of EMRs in collaboration with health care systems to improve surveillance.  
**Progress:** IHS completed the initial programming for an automated electronic surveillance system that will monitor 10 reportable conditions, including hepatitis C. Next steps are beta testing and data validation, which will begin May 2012. Additional hepatitis screening and support via the IHS EMR will be developed according to the results of the beta tests.

### Office of the National Coordinator for Health Information Technology (ONC)

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#### 2012 Action

- Incorporate viral hepatitis diagnostic codes in federal EMR standards.  
**Progress:** Viral hepatitis diagnostic codes (ICD-9 through 2013 and ICD-9, ICD-10, and/or Systematized Nomenclature of Medicine—Clinical Terms for 2014 and thereafter) are required for EMR certification under regulations 45 CFR 170 and are a proposed regulation for 2014 EMR certification. This effort was completed.

## GOAL 3.2 Monitor viral-hepatitis-associated health disparities.

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### Centers for Disease Control and Prevention (CDC)

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#### 2012 Actions

- Revise federal surveys to expand the monitoring of health disparities among target populations.
- Publish periodic reports on viral-hepatitis-associated health disparities.
- For a component of Viral Hepatitis Centers of Excellence, design and conduct state/local surveys of marginalized populations (e.g., foreign-born persons, those who were previously incarcerated, IDUs) experiencing health disparities caused by viral hepatitis.
- Gather data from nontraditional sources (e.g., U.S. Census data, clinical datasets, counseling and testing databases, health records from correctional settings).

**Progress:** CDC has not made additional progress on these actions due to inadequate resources and the discontinuation of the Racial and Ethnic Approaches to Community Health (REACH) program. The REACH Risk Factor Survey had gathered health-related information from about 25,000 minority persons annually in 28 communities across the United States. The survey contained questions about health, chronic diseases, diet, exercise, preventive services, and adult immunizations and was a vital source of data about viral hepatitis in minority communities.

**GOAL 3.3** Monitor provision and impact of viral hepatitis prevention, care, and treatment services.

**Agency for Healthcare Research and Quality (AHRQ)**

**2012 Action**

- Document and monitor the provision and impact of viral hepatitis care and treatment services.

**Progress:** AHRQ helped support a study that evaluated the relationship between adherence to HCV therapy and early and sustained virologic response, assessed changes in adherence over time, and examined risk factors for nonadherence. This retrospective cohort study was performed using the National Veterans Affairs Hepatitis C Clinical Case Registry. Results showed that among patients with HCV genotype 1 or 4, sustained response increased with higher adherence to ribavirin therapy over the second, third, and fourth 12-week intervals. Similar results were found for adherence to interferon therapy. This effort was completed in September 2011.

**Centers for Disease Control and Prevention (CDC)**

**2012 Action**

- Create public-private partnerships to establish observational cohort studies and other evaluations of persons in care for viral hepatitis.

**Progress:** The CDC Foundation currently funds the Chronic Hepatitis Cohort Study. This study began in March 2010 and will be continuing for the next 5–10 years. CDC also began conducting several other studies evaluating the care that newly identified persons receive in specific care settings, the studies will be completed in the summer of 2014.

**Federal Bureau of Prisons (FBOP)**

Though not designated in the Action Plan as a lead agency for any actions under this goal, FBOP undertook activities in support of it. FBOP recently began utilizing FBOP Regional Hepatitis Clinical Pharmacist Consultants in a team based medicine approach to disease state management. These consultants monitor treatment outcomes and provide recommendations on the management of side effects of therapy while maintaining cost effectiveness of hepatitis C treatment. Implementation of FBOP Regional Hepatitis Clinical Pharmacist Consultants began October 2011.

### Substance Abuse and Mental Health Services Administration (SAMHSA)

#### 2012 Action

- Gather data from nontraditional sources (e.g., U.S. Census data, clinical datasets, counseling and testing databases, health records from correctional settings).

**Progress:** SAMHSA began developing a methodological report that will compare a variety of behavioral health measures and specific health conditions (including hepatitis) across various federal data systems. Differences in sampling, data collection, and estimation procedures will also be assessed. These data systems include the National Survey on Drug Use and Health, National Health Interview Survey, National Health and Nutrition Examination Survey, Behavioral Risk Factor Surveillance System, and Medical Expenditure Panel Survey. This report is planned for completion and release in September 2012.

### Department of Veterans Affairs (VA)

#### 2012 Action

- Promote the development of systems to monitor where persons are tested for viral hepatitis and the quality of prevention and care services that they receive.

**Progress:** VA maintains a Hepatitis C Clinical Case Registry, which is a database of all Veterans in VA care with chronic hepatitis C. This allows VA to evaluate the impact of hepatitis care, treatment, and any disparities that may exist. By evaluating this information critically, VA is able to direct resources and quality improvement efforts in order to maximize quality of care. This is an ongoing activity.

**GOAL 3.4** Develop and implement new technologies and laboratory procedures to improve viral hepatitis surveillance.

### Department of Veterans Affairs (VA)

#### 2012 Action

- Upgrade NNDSS and other surveillance systems to enable the collection of viral hepatitis test results from various sources, including public health and commercial laboratories.

**Progress:** VA began to engage in surveillance efforts for HBV via population-based seroprevalence studies and future access to a new Clinical Data Warehouse in development. This effort is slated for completion in 2014.

## Priority 4 Eliminating Transmission of Vaccine-Preventable Viral Hepatitis

### GOAL 4.1 Eliminate mother-to-child transmission of hepatitis B.

#### Centers for Disease Control and Prevention (CDC)

##### 2012 Actions

- Expand the capacity of perinatal programs to ensure that all HBV-infected mothers are identified and linked to care, their newborns receive postexposure prophylaxis, and their household contacts are tested and, as appropriate, vaccinated and referred for care.
- In collaboration with professional organizations (e.g., APHL, the American Society of Clinical Pathologists), promote inclusion of pregnancy status on all electronic and paper reports of HBsAg+ test results sent by laboratories to clinicians.
- Identify and implement effective strategies to ensure that all neonates receive a birth dose of vaccine as the standard of care in hospitals and birthing centers.

**Progress:** CDC funded perinatal hepatitis B prevention programs (PHBPP) in 50 states, six cities, five territories, and the Freely Associated States. Program requirements included identifying HBsAg+ pregnant women, providing case management to their infants to ensure that post-exposure prophylaxis is received. Another program requirement is identifying household contacts and referring for vaccination as necessary. PHBPPs are funded through the 317 immunization funds. In 2008, 96 percent of identified infants born to HBsAg+ mothers received hepatitis B immune globulin and the first dose of hepatitis B vaccine within 1 calendar day of birth, and programs identified 9,681 household and sexual contacts. CDC and CMS are actively discussing how CMS can assist CDC in expanding the capacity of the PHBPP to eliminate mother-to-child transmission of hepatitis B.

CDC also established a workgroup to focus to explore development of a specific screening test designed for pregnant women. A report of a positive test result would indicate that the result is from a pregnant woman. The lab workgroup's anticipated end date is 2014.

CDC submitted a facility-based hepatitis B birth dose measure to the National Quality Forum (NQF) for endorsement. NQF endorsed the facility-based hepatitis B birth dose coverage measure (#0475) on April 2, 2012, and no appeal was received. The next steps are to initiate activities to monitor and evaluate use of the measure for annual progress reporting and to conduct a second feasibility study to maintain the measure for the next 3-year review.

Perinatal hepatitis B prevention programs, supported by 317 immunization funds, conducted surveys during this project period (2008–2012) to determine whether birthing facilities in their jurisdictions have written policies and standing orders on administering a birth dose of hepatitis B vaccine prior to discharge.

### Centers for Medicare & Medicaid Services (CMS)

#### 2012 Action

- Identify all HBV-infected pregnant women by increasing laboratory reporting of pregnancy status on reports of HBsAg+ tests.

**Progress:** CMS's CLIA staff began discussion of opportunities and ways to increase laboratory reporting of pregnancy.

### National Institutes of Health (NIH)

#### 2012 Action

- In collaboration with partners, evaluate the efficacy and safety of antiviral prophylaxis in pregnant women with high viral loads to reduce the likelihood of disease transmission to their infants.

**Progress:** NICHD, in collaboration with CDC, will fund a grant to evaluate the efficacy of tenovir, an anti-hepatitis B antiviral drug, to reduce the risk of mother-to-child hepatitis B transmission.

## GOAL 4.2 Achieve universal hepatitis A and B vaccination for vulnerable adults.

### Federal Bureau of Prisons (FBOP)

#### 2012 Action

- Integrate hepatitis A and B vaccination as a standard of care in federal prevention and clinical programs that serve priority populations.

**Progress:** FBOP updated the Clinical Practice Guidelines for Preventive Health Care for hepatitis A and B vaccinations in July 2011. Proper medical practice necessitates that all cases are evaluated on an individual basis and that treatment decisions are patient specific.

### Health Resources and Services Administration (HRSA)

#### 2012 Action

- Integrate hepatitis A and B vaccination as a standard of care in federal prevention and clinical programs that serve priority populations.

**Progress:** HRSA developed and released performance measures on hepatitis B screening and vaccination. The hepatitis B screening measure is the percentage of patients, regardless of age, for whom hepatitis B screening was performed at least once since the diagnosis of HIV/AIDS or for whom there is documented infection or immunity. The hepatitis B vaccination measure is the percent of clients with HIV infection who completed the vaccination series for hepatitis B. Both measures are included in the recently developed

HAB HIV Performance Measure Module. This module is a voluntary tool available to Ryan White Program grantees to submit aggregate performance measure data on a quarterly cycle. All HRSA-supported health centers are expected to practice evidence-based care and follow national practice guidelines including vaccinations for hepatitis A and B. The HAB performance measures can be found at <http://hab.hrsa.gov/deliverhivaidsca/habperformmeasures.html>.

In January 2012, HRSA conducted a national webinar on viral hepatitis for community health center grantees and reviewed the importance of hepatitis A and B vaccinations among vulnerable adults such as Asian and Pacific Islanders and persons who experience homelessness. Health centers, like any primary care practice, will choose their own guidelines; however, BPHC endorses guidelines developed by CDC and NIH.

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### Indian Health Service (IHS)

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#### 2012 Action

- Identify strategies, including Affordable Care Act requirements, to expand access to and use of viral hepatitis vaccine in all primary care settings.

**Progress:** The IHS electronic health record provides clinical decision support for vaccines, including provider reminders for hepatitis A and B vaccination for all children and for adults who received a dose prior to 18 years of age. Work is under way to explore the feasibility of developing provider reminders for hepatitis A and B vaccination for unvaccinated patients diagnosed with hepatitis C infection and chronic liver disease. ANTHC has separate registries for patients with chronic hepatitis C and B that are programmed to generate letters every 6 months to remind patients that they are due for laboratory monitoring (liver function tests, alpha-fetoprotein levels, and HBV DNA where applicable). These letters include patient education handouts and are sent to providers in the field. The registry is updated quarterly with the next delivery planned for April 1, 2012.

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### Office of Minority Health (OMH)

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#### 2012 Action

- Integrate hepatitis A and B vaccination as a standard of care in federal prevention and clinical programs that serve priority populations.

**Progress:** OMH is implementing two HIV/AIDS demonstration programs that serve priority populations. One demonstration project, the HIRE Initiative serves federal and state reentrants that are living with or at high risk for HIV/AIDS. Current grantees coordinate HIV and viral hepatitis prevention, counseling, testing, and treatment services. Whereas the L2L Health and Social Service Resource Network demonstration program serves families living with HIV/AIDS that are in transition from incarceration and substance abuse treatment. All grantees under the HIRE (eight) and L2L (six) programs provide hepatitis screening as part of their outreach and intake efforts. In some cases, hepatitis vaccines were provided by the HRSA-funded or other network partner (HIRE and L2L grantees are primarily CBOs). These programs will conclude in August 2013.

## Department of Veterans Affairs (VA)

### 2012 Actions

- Integrate hepatitis A and B vaccination as a standard of care in federal prevention and clinical programs that serve priority populations.

**Progress:** VA's ongoing "Liver Health Initiative" (LHI) is a focused clinician training program aimed at changing clinician behavior in VA SUD clinics. This program was designed to educate SUD providers about the risk of viral hepatitis in the population whom they serve and to promote liver health and a comprehensive hepatitis prevention program in the Veteran SUD population. In addition, SUD programs are encouraged to provide hepatitis A, B, and C testing; appropriate vaccination against HAV and HBV; and appropriate linkage to medical care for viral hepatitis. VA also recommends hepatitis A and B immunization for previously unvaccinated adults who are at increased risk of contracting HAV infection or HBV infection and for any other adult who is seeking protection from HAV infection. This effort is ongoing and in collaboration with internal VA stakeholders.

**GOAL 4.3** Design and test new or improved viral hepatitis vaccines and determine the indications for their optimal use.

## Food and Drug Administration (FDA)

### 2011 Action

- Facilitate development of candidate hepatitis C vaccines designed to induce protective immune responses.
- Collaborate with partners to evaluate hepatitis E vaccination in highly endemic countries.

**Progress:** FDA conducted research to define the nature of protective immune responses to hepatitis C virus and how such immune responses can be induced by vaccines, in order to guide vaccine development. This effort is likely to continue until an effective vaccine is identified.

## National Institutes of Health (NIH)

### 2011 Actions

- Facilitate development of candidate hepatitis C vaccines designed to induce protective immune responses.

**Progress:** In 2011, NIAID supported planning efforts for a Phase I and II, double-blinded, randomized clinical trial to evaluate a new hepatitis C vaccine candidate. The goals of this trial are to evaluate the safety, immune response, and initial efficacy of a vaccine to prevent acute and chronic hepatitis C infection in uninfected adults who are at high risk of becoming infected with hepatitis C. The study began recruitment in February 2012.

- Estimate the U.S. and global burden of hepatitis E.

**Progress:** In March 2012, NIDDK and NIAID held a workshop on hepatitis E in the United States with partners at CDC, FDA, and others, which included sessions on assessing the U.S. and global burden of hepatitis E infection, as well as one on development and testing of vaccines, presented by a representative from the National Institute of Diagnostics and Vaccine Development in China, a country of high endemicity. Additionally, NIAID supported several intramural and extramural research projects on hepatitis E pathogenesis. Efforts related to this action are ongoing.

## 2012 Actions

- Expand research to develop more effective vaccine strategies against HAV and HBV.

**Progress:** NIAID is supporting studies focused on the development of an HBV vaccine that may be administered orally. This effort is ongoing. NCI SBIR is supporting development of another HCV vaccine that is intended to improve the sustained virologic response rate in patients being treated with current standard of care therapy for chronic HCV infection.

- Determine the persistence of the protective immune response to hepatitis B vaccination among persons vaccinated as infants, persons in older age groups, and adults with comorbidities (e.g., diabetes, liver disease, HIV, and obesity), and assess their need for a booster dose.

**Progress:** NIDDK's Intramural Research Program is supporting a study of the duration of long-term immunity after adult hepatitis B vaccination, which will reveal whether booster doses are needed. This study has now been completely enrolled, and results will be available within the next year.

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## National Vaccine Program Office (NVPO)

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### 2011 Action

- Work with IOM to assess the priority for the development of hepatitis C vaccines.

**Progress:** In response to a request from NVPO, IOM has begun to develop an evidence-based approach and methodology for identifying and prioritizing the needs for developing new vaccines of domestic and global importance. The draft analytical conceptual framework and model, along with recommendations on how to use this model for reviewing the catalog of preventive vaccines every 2–3 years, will be available for comment in May 2012. An IOM stakeholder meeting is planned for autumn 2012 to inform this draft conceptual model.

## Priority 5 Reducing Viral Hepatitis Caused by Drug Use Behaviors

**GOAL 5.1** Ensure that persons who inject drugs have access to viral hepatitis prevention, care, and treatment services.

### Centers for Disease Control and Prevention (CDC)

#### 2012 Action

- Identify and implement feasible options for integrating viral hepatitis prevention services with HIV prevention activities targeting IDUs and other populations at risk for both viral hepatitis and HIV.
- Strengthen technical assistance and training to help prevention programs integrate viral hepatitis and HIV prevention strategies.

**Progress:** CDC has completed the groundwork necessary to begin a demonstration study that will assess the use of HCV rapid tests in HIV testing settings. Two sites have been selected, and OMB approval has been acquired. Data collection is expected to begin in summer 2012 and end in April 2013. CDC expects to learn how the HCV rapid test fits into the context of HIV testing and how HCV rapid tests can be best implemented. Lessons learned from this demonstration study will inform subsequent studies that will evaluate the impact of prevention messages and test results on knowledge and behavior.

### Indian Health Service (IHS)

#### 2011 Action

- Disseminate evidence-based best practices through a new SAMSHA TIP to guide integration of drug treatment and hepatitis prevention, care, and treatment.

**Progress:** In March 2012, IHS began conducting an assessment of existing resources to disseminate evidence-based practices integrating drug treatment and hepatitis prevention, care, and treatment.

### Office of the Assistant Secretary for Health (OASH)

#### 2011 Action

- Disseminate evidence-based best practices through a new SAMSHA TIP to guide integration of drug treatment and hepatitis prevention, care, and treatment.

**Progress:** OHAIDP has promoted awareness of SAMHSA's evidence-based TIP to support the integration of drug treatment and hepatitis prevention, care and treatment through a blog post about the TIP on AIDS.gov and promoting that post via Twitter and Facebook as well as posting a link to it from the Action Plan page on AIDS.gov ([www.AIDS.gov/hepatitis](http://www.AIDS.gov/hepatitis)). This activity is completed.

### Office on Women's Health (OWH)

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Though not tasked in the Action Plan as a lead agency for any actions under this goal, OWH undertook activities in support of it, including the following:

- Integrate viral hepatitis prevention and care services as standard components of substance abuse and treatment programs.

**Progress:** OWH integrated new educational materials and information about viral hepatitis prevention for the recipients of grants under the OWH program for incarcerated women reentering their communities.

### Substance Abuse and Mental Health Services Administration (SAMHSA)

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#### 2011 Action

- Disseminate evidence-based best practices through a new SAMSHA TIP to guide integration of drug treatment and hepatitis prevention, care, and treatment.

**Progress:** SAMHSA completed the peer review and editing process in 2011 and released TIP 53: *Addressing Viral Hepatitis in People with Substance Use Disorders* in February 2012. The 132-page TIP was written to improve knowledge of HBV and HCV risk, testing, care, and treatment among providers of substance abuse treatment. SAMHSA promoted the release of this TIP via a blog post on AIDS.gov and the SAMHSA blog as well as in a "Dear colleague" letter to all 432 SAMHSA substance abuse treatment grantees. SAMHSA is developing dissemination plans with federal colleagues to extend the reach of this resource still further. This effort is ongoing.

#### 2012 Actions

- Identify and implement feasible options for integrating viral hepatitis prevention services with HIV prevention activities targeting IDUs and other populations at risk for both viral hepatitis and HIV.

**Progress:** SAMHSA's Center for Substance Abuse Prevention's (CSAP) Viral Prevention and Care Services has integrated HIV and hepatitis prevention strategies. The CSAT project to promote healthy lifestyles through addressing hepatitis infection among racial and ethnic IDUs provided 10 trainings to 336 opioid treatment program (OTP) medical and clinical staff on hepatitis prevention and integration services between May 2011 and April 2012.

- Strengthen technical assistance and training to help prevention programs integrate viral hepatitis and HIV prevention strategies.

**Progress:** CSAP's Viral Prevention and Care Services have integrated HIV and hepatitis prevention strategies. The vast majority of CSAP's viral hepatitis and HIV prevention training and technical assistance have been group educational efforts such as trainings or Webinars. SAMHSA sponsored three workshops related to hepatitis prevention at the 2012 American Association for the Treatment of Opioid Dependence National Conference in April 2012. The attendees of the workshops learned about the benefits of integrating viral hepatitis screening, counseling, treatment, and vaccination in their OTPs.

### Department of Veterans Affairs (VA)

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#### 2012 Action

- Strengthen technical assistance to drug treatment providers to facilitate the integration and effective delivery of viral hepatitis prevention, care, and treatment services.

**Progress:** VA is committed to providing high-quality hepatitis care to all Veterans regardless of drug or substance use behaviors. VA has incorporated education around models of care delivery for Veterans with hepatitis C and ongoing substance use into ongoing training programs. This content is incorporated into trainings that VA does on end-stage liver disease, treatment of HCV, and the LHI trainings.

### GOAL 5.2 Mobilize community resources to prevent viral hepatitis caused by injection drug use.

### Centers for Disease Control and Prevention (CDC)

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#### 2012 Action

- Increase support for comprehensive and targeted disease prevention partnerships involving syringe service programs, state and local health departments, other government agencies (e.g., law enforcement), and community representatives.

**Progress:** The Funding Opportunity Announcement (FOA) for 2012 Prevention Public Health Fund funding of viral hepatitis testing and linkage to care activities will support proposals that emphasize collaboration in addressing prevention needs of persons who inject drugs (PWID). The grant announcement for the 2012–2015 Adult Viral Hepatitis Prevention Coordinator will also invite partnerships for PWID-focused prevention activities.

### Substance Abuse and Mental Health Services Administration (SAMHSA)

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#### 2012 Action

- Increase support for comprehensive and targeted disease-prevention partnerships involving syringe service programs, state and local health departments, other government agencies (e.g., law enforcement), and community representatives.

**Progress:** CSAT's project to enhance OTP treatment services to promote healthy lifestyles through addressing hepatitis infection among racial- and ethnic-minority IDUs provided training to medical and clinical staff on hepatitis prevention and integration services. CSAT began revising OTP accreditation guidelines to support the benefits of integrated hepatitis prevention and addiction treatment services. CSAT is supporting several workshops at the April 2012 American Association for the Treatment of Opioid Dependence conference that focused on integration of hepatitis prevention and addiction treatment services. As part of SAMHSA's Syringe Services Program (SSP) approved by Congress for FY 2011, 10 grantees collaborated directly with needle exchange programs for more than a year. In brief, more than 350 clients were enrolled into substance abuse treatment, and more than 85 percent finished their treatment program. These efforts (outside the SSP) are ongoing.

**GOAL 5.3** Provide persons who inject drugs with access to care and substance abuse treatment to prevent transmission and progression of disease.

**Substance Abuse and Mental Health Services Administration (SAMHSA)**

**2012 Action**

- Pilot different approaches to preventing persons from returning to injection drug use after successful clearance of HCV infections following antiviral therapy.

**Progress:** SAMHSA began exploring the use of the medication Vivitrol as a pharmacotherapeutic intervention to prevent relapse and support recovery from opioid use disorders among IDUs, including those with HCV and HIV infections. This effort is ongoing.

**GOAL 5.4** Expand access to and delivery of hepatitis prevention, care, and treatment services in correctional settings.

**Centers for Disease Control and Prevention (CDC)**

**2011 Action**

- Survey correctional facilities to assess current drug treatment and viral hepatitis prevention, care, and treatment services.

**Progress:** CDC surveyed correctional facilities to assess current drug treatment and viral hepatitis prevention, care, and treatment services. This effort is ongoing.

**Office of Minority Health (OMH)**

Though not tasked in the Action Plan as a lead agency for any actions under this goal, OMH undertook activities in support of it, including the following:

- Promote continuity of viral hepatitis care and drug treatment of inmates who are released from incarceration and are reentering the community.

**Progress:** OMH's HIRE program sought to improve the health outcomes for individuals reentering the mainstream population from federal and state prisons through a systems navigation approach. The HIRE Program provides access to HIV and viral hepatitis prevention and treatment services to the reentry population through stakeholder partnerships that develop and provide community-based HIV/AIDS-related services, transitional assistance, and substance abuse and mental health services for the reentry population. During the first quarter of FY 2012, a total of 163 HIRE participants were referred for drug treatment, and 1,909 were referred for other health care services. This effort will be completed in August 2012.

## Substance Abuse and Mental Health Services Administration (SAMHSA)

### 2012 Action

- Identify best practices to help correctional facilities improve drug treatment programs offering viral hepatitis testing, care, and treatment to incarcerated populations.

**Progress:** SAMHSA increased coordination with criminal justice activities within CDC by initiating plans to work with CDC's correctional health staff to review existing viral hepatitis testing protocols and to provide outreach to constituency groups such as the National Correctional Health Services Association and to the Association of State Correctional Administrators (ASCA) in conjunction with the National Association of State Alcohol and Drug Abuse Directors (NASADAD). CSAT staff met with ASCA and NASADAD on substance abuse treatment issues related to offender populations.

GOAL 5.5 Advance research to improve prevention of viral hepatitis among persons who use drugs.

## Centers for Disease Control and Prevention (CDC)

### 2011 Action

- Examine patterns of HCV transmission of among young IDUs infected with HCV.
- Expand prevention research to intervene and prevent HCV among young IDUs.

**Progress:** DVH and CDC recently hired an expert in injection drug use-related issues to lead young IDU efforts in the hepatitis program. CDC began examining the injection equipment sharing practices of 500 persons who inject drugs in upstate New York. These data will inform the development of prevention interventions for this population. The IDU expert is also working closely with staff in the Epidemiology Team as they collect field data on IDU use practices among PWIDs. This effort is slated for completion in spring 2013.

## National Institutes of Health (NIH)

### 2011 Action

- Examine patterns of HCV transmission of among young IDUs infected with HCV.

**Progress:** NIDA has funded a number of research studies on HCV among young injectors. Many of these studies are in progress. This effort is slated for completion in October 2015.

### 2012 Actions

- Expand comparative and effectiveness research to improve viral hepatitis prevention for IDUs.

**Progress:** NIDA has funded a number of research studies on prevention and treatment of HCV, as well as HIV/HCV in drug-abusing populations. NIDA is also in the process of issuing FOAs on (1) drug abuse aspects of HIV/AIDS and (2) cohort studies of HIV/AIDS and substance abuse, both of which include a focus on HIV/HCV co-infections in IDUs and non-IDUs. This effort is expected for completion in the fall of 2016.

- Determine the effectiveness of interventions to prevent non-injection drug users from initiating injection drug use.

**Progress:** NIH's research findings from the studies on HCV prevention and treatment in drug-abusing populations will support programs to prevent HCV transmission in these and other populations. This effort is slated for completion in October 2016.

- Develop collaborations with international partners to identify emerging trends in drug use and viral hepatitis transmission and to accelerate the development of effective prevention strategies.

**Progress:** NIH released the new US-China Program for Biomedical Collaborative Research Request for Application (RFA-AI-12-021; <http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-12-021.html>). NCI's area of interest is for applications focused on the links between infection and cancer important in the United States and China. Hepatitis B and C are highlighted as areas of particular interest. This effort is slated for completion in October 2016.

NIDA maintains a significant portfolio of international collaborations among U.S. researchers and colleagues located in India, Iran, Kazakhstan, Georgia, China, and Southeast Asia that strive to identify effective testing and prevention strategies among hepatitis mono-infected and HIV/HCV dually infected drug users. NIDA also supports research to identify hepatitis transmission risks within homeless and other drug abusing youth to identify effective behavioral modification strategies to alter risk behavior to prevent viral transmission and further abusive drug practices.

- Expand prevention research to intervene and prevent HCV among young IDUs.
- Assess the timing of serial HCV antibody testing of IDU cohorts to detect acute (or recent) infection.
- Conduct clinical trials of treatments for acute HCV to assess sustained viral clearance and their impact on prevention of secondary transmission among IDUs.

**Progress:** Related NIDA-funded studies are in progress with preliminary results anticipated in 2015. NIAID is currently supporting a Phase I and II, double-blinded, randomized clinical trial to evaluate a new hepatitis C vaccine candidate. The goals of this trial are to evaluate the safety, immune response, and initial efficacy of a vaccine to prevent acute and chronic hepatitis C infection in uninfected adults who are at high risk of becoming infected with hepatitis C (IDUs). The study began recruitment in February 2012. This goal is slated for completion in October 2015.

## Priority 6 Protecting Patients and Workers From Health Care-Associated Viral Hepatitis

GOAL 6.1 Reduce transmission of viral hepatitis to patients resulting from misuse of medical devices and drugs.

### Centers for Disease Control and Prevention (CDC)

#### 2011 Actions

- Enhance provider and purchaser education regarding limiting use of single-dose vials to only one patient to encourage increased uptake of prefilled syringes and right-sized medication vials.

**Progress:** CDC promoted education among manufacturers, providers, and purchasers as part of the Safer Designs for Safer Injections industry partner meeting and as part of ongoing activities relating to the One and Only Campaign. This effort is ongoing.

- Identify opportunities to improve infection control education, and expand requirements for continuing education and related competency certifications for health care providers.

**Progress:** The new CDC and Association of State and Territorial Health Officials Policy Toolkit for Healthcare-Associated Infection (HAI) Prevention outlines options relating to infection control education and certification. CDC has begun inventorying related state-level activities (e.g., a recent Nevada law requiring that health care providers attest to awareness of and training in CDC safe injection guidelines). These issues were discussed in December 2011 at the CDC-hosted Injection Safety: Insurance Stakeholders Meeting.

- Engage the affected industries to raise awareness of infection control standards, guidelines, and training needs.

**Progress:** In 2011, CDC published its *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care*, which specifies infection control standards and training needs. CDC, the Safe Injections Practices Coalition, and other partners have promoted the guide and accompanying checklist to affected professional groups, health care organizations, and governmental partners. Engagement with the insurance industry took place at CDC's December 2011 Injection Safety: Insurance Stakeholders Meeting.

#### 2012 Actions

- Encourage industry to develop reuse prevention equipment and/or devices that indicate prior use of injection equipment.

**Progress:** CDC, FDA, and CMS helped organize and participated in an industry meeting on this topic, sponsored by Premier Safety Institute and titled *Safer Designs for Safer Injections: Innovations in Process, Products, and Practices*. CDC's Division of Healthcare Quality Promotion (DHQP) is engaged in ongoing dialogue with industry partners on this topic in the context of the CDC-led Safe Injections Practices Coalition. This effort is in progress with an anticipated completion in 2013.

- Expand educational campaigns (including injection safety checklists) and infection control and regulatory guidance, and use campaigns and materials to promote safe use of syringes and injectable medications.

**Progress:** The CDC-led Safe Injection Practices Coalition continues to expand implementation of the One and Only Campaign. Examples of recent partners that have begun promoting safe use messages include the U.S. Air Force, HRSA, the Institute for Safe Medication Practices, and the North Carolina Department of Health. In July 2011, the Safe Injection Practices Coalition also launched a free continuing education activity on Medscape for health care providers titled *Unsafe Injection Practices: Outbreaks, Incidents, and Root Causes*, which has been completed by approximately 20,000 physicians and nurses. This effort is slated for completion in 2013.

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### Centers for Medicare & Medicaid Services (CMS)

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#### 2011 Actions

- Incorporate evidence-based infection control components into applicable health and safety standards.

**Progress:** The State Survey Agencies are currently pilot-testing a hospital infection control survey tool that includes specific questions dealing with needle sticks, sharps injuries, and other employee exposure events; postexposure evaluation and prophylaxis (if exposure events exist, the hospital evaluates and develops corrective action plans); and a hepatitis B vaccination series to all employees who have occupational exposure and postvaccination screening. This effort is in progress.

- Assist oversight authorities with ensuring the appropriate use of medical devices and the provision of associated training within health care settings.

**Progress:** CMS has conducted the Recent Survey and Certification Memos on Glucometers (Point of Care Devices) and Insulin Pens and established educational opportunities and training for surveyors to better assess injection safety as part of the infection control assessment in facilities. This effort is in progress.

The Survey and Certification Group clarified CMS policy on the use of single dose vials and has provided guidance to State Survey Agencies that the use of medication from single dose vials must not be used for more than one patient and, if observed during a health care facility survey, will be cited as an infection control deficiency. Medication from single dose vials may be repackaged in accordance with USP 797 standards, either within the facility or through a vendor. When a vendor is used, surveyors are instructed to ask for documentation on how the facility ensures that its vendor adheres to USP 797 standards.

## Food and Drug Administration (FDA)

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### 2011 Actions

- Issued draft guidance for Industry on the reprocessing of reusable medical devices in health care settings.

**Progress:** In May 2011, FDA issued the *Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*. Additionally, in June 2011, FDA held a public workshop on the reprocessing of medical devices; and in October 2011, FDA co-hosted, with the Association for the Advancement of Medical Instrumentation (AAMI), the Medical Device Reprocessing Summit.

- Review and take necessary action on the regulatory status of blood lancets.

**Progress:** FDA is currently reviewing the regulatory status of blood lancets. This effort is in progress.

- In collaboration with the U.S. Pharmacopeial Convention (USP), revise label content for medication vials.

**Progress:** FDA formed a workgroup of subject matter experts from various offices within the agency to discuss best practices and to establish acceptable and consistent labeling terminology for medication vials that is clear and understandable to users. This workgroup and USP conducted a collaborative, large-scale survey of health care providers in an attempt to identify the most effective labeling to discourage unsafe behaviors. FDA, USP, and CDC are now discussing (1) the harmonization of the definition of “single-dose vial,” (2) the circumstances that lead to the use of single-dose vials as multiple-dose vials, and (3) the necessary education to enhance the knowledge of health care providers. This effort is slated for completion in December 2012.

### 2012 Action

- Issue a draft guidance for industry addressing the validation of cleaning, disinfection, and sterilization of endoscopes.

**Progress:** FDA has decided not to issue an FDA draft guidance document for industry on endoscope reprocessing. Instead, FDA will partner with AAMI to develop a Technical Information Report (TIR) on endoscope reprocessing. The Task Force to draft the TIR was formed in November 2011 and is already working on the document.

**GOAL 6.2 Reduce iatrogenic transmission of viral hepatitis associated with blood, organs, and tissues.**

**Centers for Disease Control and Prevention (CDC)**

**2011 Action**

- Update policies to facilitate implementation of nucleic acid testing (NAT) for HCV among organ donors.

**Progress:** The CDC's Office of Blood, Organ, and Other Tissue Safety has drafted U.S. Public Health Service (PHS) guidelines for reducing transmission of HIV, HBV, and HCV in solid-organ transplantation. PHS agencies are finalizing the draft guidelines after a CDC-led review of public comments of the draft published in the *Federal Register* in September 2011. The guidelines will include recommendations for NAT screening for HCV in deceased and living donors. This effort is slated for completion in December 2012.

**Centers for Medicare & Medicaid Services (CMS)**

**2011 Action**

- Update policies to facilitate implementation of nucleic acid testing (NAT) for HCV among organ donors.
- **Progress:** CMS is working to align Organ Procurement Organization (OPO) survey guidance with Organ Procurement and Transplantation Network (OPTN) policies on hepatitis screening and testing and is in the process of completing the Interpretive Guidance for the OPO regulations. These guidelines will include a statement that the OPO must follow OPTN rules for the testing of all potential donors for infectious diseases, including HIV and hepatitis. The guidelines will also indicate that the OPO makes full disclosure of all test results to all transplant surgeons so that they may in turn share these results with the intended recipient. CMS also regulated blood transfusions in hospitals and served as a member of the committee which drafted the PHS Guideline for Reducing Transmission of HIV, HBV, and HCV through Solid Organ Transplantation. These efforts are ongoing.

**Food and Drug Administration (FDA)**

**2011 Actions**

- Engage manufacturers to promote development of rapid, high-sensitivity NAT systems for HBV and HCV.  
**Progress:** FDA anticipates completing the action in December 2012.
- Explore the development of new pathogen reduction technology by examining FDA's current regulatory approach.  
**Progress:** Development continues with respect to exploring new pathogen reduction technologies. This effort is ongoing.

## Office of the Assistant Secretary for Health (OASH)

### 2011 Action

- Undertake a coordinated cross-agency and public-private collaborative effort to collect, analyze, and share data on adverse events associated with the donation, processing, distribution, and transfusion and transplantation process.

**Progress:** OHAIDP has coordinated the following collaborative efforts:

*The National Blood Collection and Utilization Survey*, funded by HHS, offers a comprehensive analysis of collection and utilization of blood, blood products, and cellular therapies in the United States. The results of the survey are used to support important blood-related initiatives by the federal government as well as within the transfusion medicine community. This survey of hospitals, blood centers, and cord blood banks is conducted biennially. It solicits general information about the blood collection facility; transfusion service, or cord blood bank; and, depending on the specific activity of the facility, more specific data regarding blood collection, transfusion, cellular therapies, and product modification, including leukoreduction and irradiation.

*The HHS Blood Donor Hemovigilance Analysis and Reporting Tool (DonorHART™)* was developed to collect and analyze adverse events and reactions that occur during the blood donation process. The DonorHART™ system was developed under two OASH Small Business Innovative Research contracts with Knowledge Based Systems, Inc. of College Station, Texas. This system will provide analysis of factors (e.g., demographic, donation process-related, facility-related) correlated with reaction and event rates.

*The National Healthcare Safety Network (NHSN)* is a secure, Internet-based surveillance system that integrates and expands patient and health care personnel safety surveillance systems managed by DHQP. NHSN also includes a new component for hospitals to monitor adverse reactions and incidents associated with receipt of blood and blood products. Enrollment is open to all types of health care facilities in the United States, including acute care hospitals, long-term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long-term care facilities. This effort is ongoing.

## GOAL 6.3 Reduce occupational transmission of viral hepatitis.

### Food and Drug Administration (FDA)

#### 2011 Actions

- Release a joint safety alert and advisory recommending the use of blunt surgical needles for the suturing of fascia.

**Progress:** An FDA workgroup is in the process of finalizing the document. Release in December 2012 is expected.

## Indian Health Service (IHS)

### 2011 Action

- Identify barriers and develop strategies to address barriers to hepatitis B vaccination among health care workers and trainees.

**Progress:** IHS maintains the *Indian Health Manual* (<http://www.ihs.gov/ihtm/index.cfm>) which includes guidance for employee hepatitis B immunization, screening, and prophylaxis and educational material for employees in Chapter 12.

**GOAL 6.4** Enhance understanding of the preventable causes of viral hepatitis transmission in health care settings.

## Centers for Disease Control and Prevention (CDC)

### 2011 Actions

- Link state HAI programs to viral hepatitis surveillance programs.

**Progress:** DHQP and DVH have had ongoing discussions to identify opportunities and strategies for linking these programs. CDC promoted this interaction during the October 2011 HAI grantee meeting and will do so again at the June 2012 Council of State and Territorial Epidemiologists (CSTE) meeting. This effort is slated for completion in 2013.

- Develop and disseminate best practices for the investigation of potential cases of health care-associated viral hepatitis.

**Progress:** CDC developed, cleared, and posted a best-practices case investigation guide that incorporates feedback from selected health department partners. Next steps include promoting this investigation guide at the June 2012 CSTE meeting. This effort is slated for completion in 2013.

- Commission a study to evaluate purchasing practices of health care facilities to understand the patterns of use that contribute to poor compliance with recommended practices for the safe use of medical devices.

- Conduct site visits and/or focus groups to identify barriers to use of safety devices and single-patient medication vials.

**Progress:** While funding for this specific study has not been identified, CDC has given technical input to an FDA-sponsored study of injectable medication vial labeling that is being conducted by USP. In addition, focus groups conducted under the auspices of the New York State Health Department and DHQP have included a hypothesis-generating exploration of purchasing practices among clinicians and clinic managers. Focus-group studies funded by DHQP were conducted recently and included a hypothesis-generating exploration of barriers to use of safety devices and single-patient medication vials among clinicians and clinic managers. A report from the contractor conducting the focus groups is currently under review.

- Engage stakeholders to improve current practices related to narcotics security.

**Progress:** CDC co-authored a study detailing HCV transmission due to narcotics diversion in an April 2012 issue of *Annals of Internal Medicine*.

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### National Institutes of Health (NIH)

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- Support clinical trials to explore the safety and efficacy of technologies currently being used in other parts of the world.
- Support grants to promote the development of new processing technologies.

**Progress:** NHLBI continues its ongoing support of research on reduction or inactivation of pathogens, including hepatitis viruses, for blood and blood products such as red blood cells. For example, a study supported during the period is developing the use of photodynamic substances combined with the use of chemiluminescent compounds to generate light *in situ* for pathogen inactivation. This method overcomes the opacity of erythrocytes to UV light.

The NIH Clinical Center's Department of Transfusion Medicine completed a study, which has been submitted for publication, looking at whether peripheral blood mononuclear cells serve as a reservoir for HCV replication even in patients who have the serologic and molecular pattern of spontaneous or treatment-induced recovery from HCV infection.

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### Substance Abuse and Mental Health Services Administration (SAMHSA)

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#### 2011 Action

- Identify barriers and develop strategies to address barriers to hepatitis B vaccination among health care workers and trainees.

**Progress:** CSAT has begun drafting guidance to encourage grantees to consult with local health departments to perform testing and vaccinations of health care staff working in drug treatment programs.

## Appendix List of Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
AANHPI	Asian-American, Native Hawaiian, and Pacific Islander
AASLD	American Association for the Study of Liver Diseases
AETC	AIDS Education and Training Center
AHRQ	Agency for Healthcare Research and Quality (HHS)
ANTHC	Alaska Native Tribal Health Consortium
ASCA	Association of State Correctional Administrators
ATTC	Addiction Technology Transfer Center
A2ALL	Adult to Adult Living Donor Liver Transplantation
BFHI	Baby-Friendly® Hospital Initiative
BPHC	Bureau of Primary Health Care
CARE	Comprehensive AIDS Resources Emergency
CBO	Community-Based Organization
CDC	Centers for Disease Control and Prevention (HHS)
CIHS	Center for Integrated Health Solutions
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services (HHS)
CSAP	Center for Substance Abuse Prevention (HHS/SAMHSA)
CSAT	Center for Substance Abuse Treatment (HHS/SAMHSA)
CSTE	Council of State and Territorial Epidemiologists
CTR	counseling, testing, and referral
DHQP	Division of Healthcare Quality Promotion (HHS/CDC)
DVH	Division of Viral Hepatitis (HHS/CDC)
ECHO	Extension for Community Healthcare Outcomes
EMR	electronic medical record
EPC	Evidence-Based Practice Center
ETAC	Evaluation and Technical Assistance Center
FBOP	Federal Bureau of Prisons

## Appendix A: List of Abbreviations

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FDA	Food and Drug Administration (HHS)
FOA	Funding Opportunity Announcement
FTCC	Federal Training Centers Collaborative
FY	fiscal year
HAB	HIV/AIDS Bureau (HHS/HRSA)
HAV	hepatitis A virus
HBsAg+	hepatitis B surface antigen positive
HBV	hepatitis B virus
HCV	hepatitis C virus
HepCAT	Hepatitis C Assessment and Testing Project
HHS	U.S. Department of Health and Human Services
HIRE	HIV/AIDS Health Improvement for Re-entering Ex-offenders
HRSA	Health Resources and Services Administration (HHS)
IDSA	Infectious Diseases Society of America
IDU	intravenous drug user
IHS	Indian Health Service (HHS)
IOM	Institute of Medicine
LHI	Liver Health Initiative
L2L	Linkage 2 Life
NASADAD	National Association of State Alcohol and Drug Abuse Directors
NAT	nucleic acid testing
NCI	National Cancer Institute (HHS/NIH)
NHLBI	National Heart, Lung, and Blood Institute (HHS/NIH)
NHSN	National Healthcare Safety Network (HHS/CDC)
NIAAA	National Institute on Alcohol Abuse and Alcoholism (HHS/NIH)
NIAID	National Institute of Allergy and Infectious Diseases (HHS/NIH)
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development (HHS/NIH)
NIDA	National Institute of Drug Abuse (HHS/NIH)
NIDDK	National Institute of Diabetes and Digestive and Kidney Disorders (HHS/NIH)

NIH	National Institutes of Health (HHS)
NPIN	National Prevention Information Network
NQF	National Quality Forum
NVPO	National Vaccine Program Office (HHS)
OASH	Office of the Assistant Secretary for Health (HHS)
OGHA	Office of Global Health (HHS/HRSA)
OHAIDP	Office of HIV/AIDS and Infectious Disease Policy (HHS/OASH)
OMH	Office of Minority Health (HHS)
ONC	Office of the National Coordinator for Health Information Technology (HHS)
OSG	Office of the Surgeon General (HHS)
OTP	Opioid Treatment Program
OWH	Office on Women's Health (HHS)
PBHCI	Primary and Behavioral Health Care Integration
PHBPP	perinatal hepatitis B prevention program
PHS	Public Health Service
PQRS	Physician Quality Reporting System (HHS/CMS)
PWID	person who injects drugs
QUERI	Quality Enhancement Research Initiative
SAMHSA	Substance Abuse and Mental Health Services Administration (HHS)
SBIRT	screening, brief intervention, and referral to treatment
SSP	Syringe Services Program (HHS/SAMHSA)
SUD	substance use disorder
TIP	Treatment Improvement Protocol
USAPI	U.S. Affiliated Pacific Islands
USP	U.S. Pharmacopeial Convention
USPSTF	U.S. Preventive Services Task Force
VA	U.S. Department of Veterans Affairs
VHIG	Viral Hepatitis Action Plan Implementation Group