

# **Raising the Profile, Raising Your Voice**

**A Primer on Viral Hepatitis  
Policymaking and Programs  
at the Federal Level**



The National Alliance of State & Territorial AIDS Directors (NASTAD) represents the nation's chief state health agency staff who have programmatic responsibility for administering HIV/AIDS and viral hepatitis health care, prevention, education and supportive service programs funded by state and federal governments. NASTAD represents the Adult Viral Hepatitis Prevention Coordinators as a part of our membership.

NASTAD strengthens state and territory-based leadership, expertise, and advocacy and brings them to bear in reducing the incidence of HIV and viral hepatitis infections and on providing care and support to all who live with HIV/AIDS and viral hepatitis. NASTAD's vision is a world free of HIV/AIDS and viral hepatitis.

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NASTAD would like to thank Gilead Sciences, Inc. for their generous support in creating this document.

For more information on NASTAD's work on viral hepatitis policy and programs and a listing of Adult Viral Hepatitis Prevention Coordinators, go to [www.NASTAD.org](http://www.NASTAD.org)

Julie M. Scofield, Executive Director  
Amna Osman, *Michigan*, Chair

June 2011

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# Introduction

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This *Primer* provides a comprehensive overview of the federal legislative and regulatory processes that support viral hepatitis programs nationwide. This document is an update of the *Primer* published in 2007. It is intended for advocates and interested persons at all levels of policy experience who wish to better understand how national policy impacts funding and program decisions for viral hepatitis prevention, treatment, research and care programs. This *Primer* also documents the challenges and unmet needs of viral hepatitis programs to help you in advocating for an adequate federal response. We hope this document will assist advocates in finding their voice to raise the profile of viral hepatitis with policy makers.

## **What is NASTAD's role in viral hepatitis?**

NASTAD represents the Adult Viral Hepatitis Prevention Coordinators (AVHPCs) as a subcomponent of NASTAD's Viral Hepatitis Technical Assistance Program established in 2000. The program provides guidance and technical assistance to strengthen state and local health departments' capacity to develop, maintain and enhance comprehensive viral hepatitis programs.

NASTAD has been integrally involved with developing and supporting national viral hepatitis policy and advocacy through its Viral Hepatitis Public Policy Program. NASTAD founded and continues to lead and operate the Hepatitis Appropriations Partnership (HAP) since 2004. The coalition was renamed from the Hepatitis C Appropriations Partnership (HCAP) in 2010 to better reflect the work of the coalition. HAP is a national coalition that includes community-based organizations, public health and provider associations, national hepatitis and HIV organizations, and diagnostic,

pharmaceutical and biotechnology companies from all over the country. HAP works with policy makers and public health officials to increase federal support for hepatitis prevention, testing, education, research and treatment. NASTAD is a founding member of the [National Viral Hepatitis Roundtable \(NVHR\)](#), a national coalition of organizations working in viral hepatitis advocacy, policy and programs, and of the grassroots coalition Hepatitis C Advocates United! NASTAD also actively participates in the [National Task Force on Hepatitis B: Focus on Asian and Pacific Islander Americans](#), providing regular policy updates and assisting with advocacy capacity building. NASTAD has a long history working with HIV advocates as part of the Fair Pricing Coalition (FPC), and in 2010 joined hepatitis advocates in the creation of the FPC Hepatitis Work Group, which engages with pharmaceutical companies prior to the release of hepatitis therapies to influence affordable and fair pricing. Finally, NASTAD is a founding member of the [World Hepatitis Alliance](#), the organizing body for World Hepatitis Day and lead hepatitis coalition seeking World Health Organization (WHO) engagement on hepatitis.

## **What can I do?**

Whether you are a novice or an experienced advocate on viral hepatitis, this *Primer* will show that there are many ways you can get involved. Just by being a constituent, you represent an important voice on viral hepatitis that is often not heard and is missing in the national dialogue in Washington, DC. While national advocates can bring their perspectives and expertise to the Administration and Congress, elected officials seek to meet the needs of their constituents. This is why it is so important that you take action to educate your Representative and Senators on viral hepatitis

and actions they can take to improve the federal response.

This *Primer* is designed to help you understand the various funding mechanisms and policies that influence viral hepatitis programs. It can be an overwhelming task to grasp the full picture on your own. That is why we designed this *Primer* to provide you with information on how to advocate effectively and provide information on the federal landscape to aid you in your advocacy efforts. To provide you with in-depth and detailed information on how to improve your advocacy skills, please see NASTAD's *Viral Hepatitis Advocacy Toolkit* available at [www.NASTAD.org](http://www.NASTAD.org).

# Overview

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## What is Viral Hepatitis?

“Hepatitis” means inflammation of the liver. Hepatitis is most often caused by one of several viruses, such as hepatitis A virus (HAV), hepatitis B virus (HBV), or hepatitis C virus (HCV), and these are referred collectively as “viral hepatitis.” Even though these viruses are similarly named, they are unique from one another and have distinct molecular characteristics and epidemiology, especially with respect to their modes of transmission, chronicity and impacted populations.

### Discovery

HAV was the first hepatitis virus to be identified in the middle of the 20th century

with a preventive vaccine developed in 1995. It is transmitted orally from ingestion of contaminated fecal matter that can be present in food and water in addition to insufficient bathing and washing and through sexual activity. Unlike hepatitis B and C, hepatitis A does not lead to lifelong infection and is rarely fatal among healthy individuals in developed countries. In its acute phase, it typically manifests flu-like symptoms that self-resolve within a matter of weeks. Once infected a person remains immune for life.

HBV was first identified in 1963 with a preventive vaccine developed in 1981. HBV is transmitted in bodily fluids and blood, and is often transmitted from sexual activity, from

## Overview of Disease Burden

In 2007, the Centers for Disease Control and Prevention estimated that 43,000 Americans were newly infected with HBV and 17,000 with HCV. Further, these diseases impose a chronic disease burden on Americans with over 5 million people living with lifelong HBV or HCV infection and 65-75 percent do not know it. Viral hepatitis is the leading cause of liver disease, liver cancer, liver transplantation and premature death in about 15,000 Americans annually. It is also one of the leading causes of death in Americans co-infected with hepatitis and HIV where as many as 25-33 percent of HIV-positive Americans are living with HCV and 10-15 percent with HBV. In addition, chronic viral hepatitis disproportionately affects racial and ethnic communities. African Americans have the highest rate of acute hepatitis B infections in the United States. African Americans and Hispanics have higher rates of hepatitis C infection than Caucasians. Finally, chronic hepatitis B is a leading cause in death in Asian Americans, with as many as 1 in 10 living with chronic hepatitis B.

Chronic hepatitis B and C infections cost the United States approximately \$16 billion each year. If left unchecked, the projected direct and indirect cost in the next decade of just the current hepatitis C epidemic—not including the hepatitis B epidemic—is \$85 billion. Especially given that baby boomers account for two out of every three cases of chronic hepatitis C, we know millions of Americans will be progressing in their liver disease and aging into Medicare within the decade.

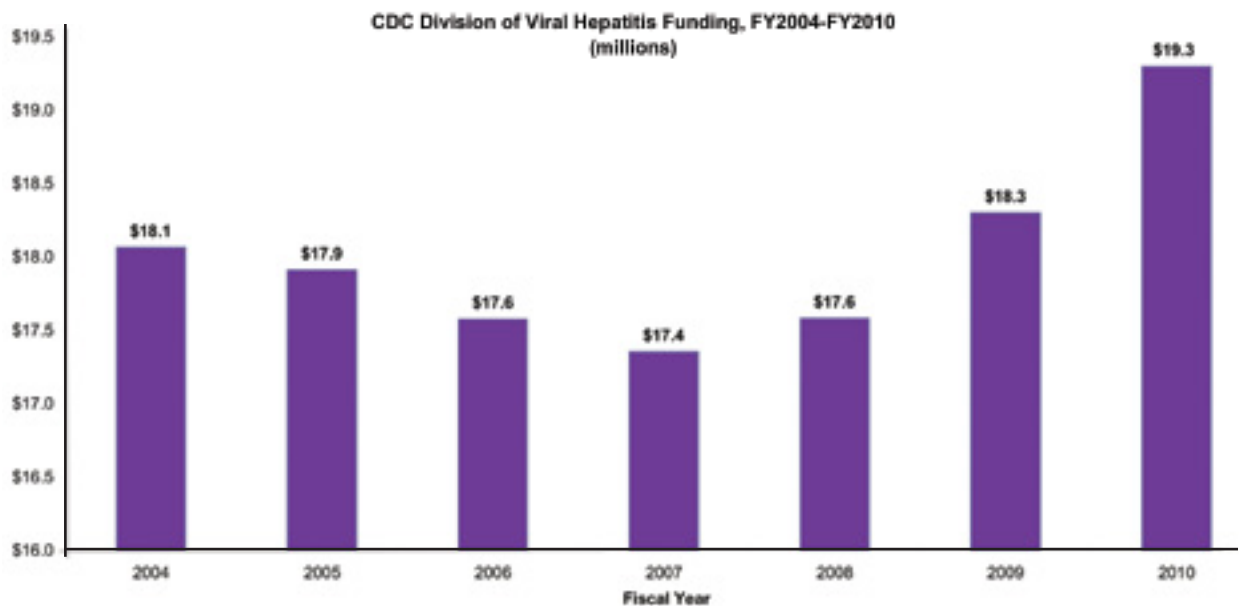
mother-to-child during birth and through the reuse of injection drug equipment. There has been a significant decrease in HBV among newborns and children, largely due to universal childhood vaccination recommendations since 1991 and ongoing routine vaccination at birth and as part of school entry requirements. Despite success in preventing HBV among young people, higher rates of HBV continue among at-risk adults including African Americans (particularly in the southern U.S.) Alaska Natives, Asian Pacific Islanders, immigrants from high endemic countries such as Asia and Africa, gay and bisexual men and other men who have sex with men, Latinos and persons who inject drugs. The best way to prevent HAV and HBV infection is by getting vaccinated.

HCV was first identified in 1988 and was responsible for many of the non-A and non-B hepatitis infections that were occurring through blood transfusions until an effective test for HCV was developed to screen the blood supply in 1992. No vaccine has been developed for HCV and it continues to be the most common blood-borne, chronic viral disease in the United States, with a high prevalence among baby boomers and drug users. Currently, most new

HCV infections occur among persons who inject drugs. There is some evidence that HCV can be spread sexually, though more research is needed. There have been cases of sexually transmitted HCV among HIV-infected gay men in Europe and several U.S. cities.

## Overview of the Federal Response

Despite the significant disease burden and the ramifications in mortality and cost, viral hepatitis is one of the most underfunded and neglected diseases. Unfortunately, we do not know how much the federal government is spending to address viral hepatitis as there is currently no official inventory of programs and resources. The only dedicated federal funding that Congress appropriates to viral hepatitis is \$19.3 million dollars provided to the Centers for Disease Control and Prevention (CDC). While not funded directly by Congress, we suspect that there are millions being spent on care through Medicare, Medicaid, Community Health Centers, the Ryan White Program, the Veterans Health Administration and Federal prisons. Funding at CDC for viral hepatitis is \$6 million less than it was in FY2001 when it



was funded at a high of \$25 million. Only recently have there been nominal increases. Due to the inadequate funding to prevent viral hepatitis infection and lack of focus in treating infected Americans, thousands of preventable infections and deaths continue to occur.

In addition to a lack of federal resources, there is also a lack of coordination at the federal level. To address this, the Department of Health and Human Services (HHS) Assistant Secretary for Health established a Viral Hepatitis Interagency Working Group to develop an HHS Action Plan to better coordinate activities across the Department. While this is a vast improvement, this effort does not include other federal Departments such as the Department of Veterans Affairs or the Department of Justice. The HHS Viral Hepatitis Action Plan includes the following areas of focus: educating providers; strengthening surveillance; better care, screening, and treatment; encouraging appropriate vaccinations to reduce the incidence of hepatitis B; reducing drug use; and protecting health workers from infections.

### **Federal Recommendations**

To combat the HBV and HCV epidemics in the United States, the CDC developed *Recommendations for Prevention and Control of Hepatitis C Virus Infection (HCV) and HCV-Related Chronic Disease* in 1998 and *Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection* in 2008, and the *National Hepatitis C Prevention Strategy* in 2001. The National Institutes of Health convened Consensus Development Conferences on the *Management of Hepatitis B* in 2008 and on the *Management of Hepatitis C* in 1997 and 2002, in addition to developing the *Action Plan for Liver Disease Research*. These recommendations and guidelines provide a framework for HBV and HCV prevention, education, control, research, and medical management referral programs.

### **Independent Recommendations**

In January 2010, the Institute of Medicine (IOM) issued a report on the federal response entitled *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C* (2010) that recommended the public health response to the hepatitis epidemics be significantly ramped up. The report issued 22 recommendations, most of which would directly impact state and local health departments, in addition to highlighting issues that warrant further investigation and opportunities for collaboration between the public and private sectors. The report outlined the consequences of the lack of funding as the following:

- Americans do not know how to prevent infection;
- Americans do not have adequate access to preventive services;
- Chronically infected Americans do not know that they are infected;
- Providers do not know how to manage infected patients;
- Actual disease burden remains unknown because there is no national chronic surveillance system;
- There remains insufficient understanding about the extent and seriousness of this public-health problem overall.

In September 2010, the *American Association for the Study of Liver Diseases (AASLD)* and the *Trust for America's Health (TFAH)* issued a report, *HBV & HCV: America's Hidden Epidemics*, calling for action to be taken to transform how the country deals with viral hepatitis – to help identify millions of Americans who do not know they are living with chronic forms of hepatitis and to ensure access to treatment for all who need it, to prevent even more Americans from becoming infected. Building off of the IOM recommendations, this report identifies specific policies that can be leveraged to increase hepatitis support such as through health reform and through collaborative and integrative work with other federal programs.

# The United States Congress

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Congress has a number of roles in the federal response to viral hepatitis. These include providing funding for programs, passing authorizing legislation to direct federal agencies and the private sector to take specific actions, and to provide oversight of the Administration's activities.

## Congressional Leadership

The House and Senate leadership are critical to the legislative functioning of the House and Senate. The leaders of the majority party in each chamber have enormous discretion over when a bill is deliberated and voted on. The leadership also decides who chairs congressional committees and approves of new Members to committees. In choosing these positions, party loyalty can often take precedence over seniority. Indeed, leadership can offer as well as remove a Member from a committee assignment.

The House leadership consists of the Speaker of the House ("Speaker") who presides over the entire chamber. The Speaker is second in presidential line of succession, after the Vice President and before the President pro tempore of the U.S. Senate. The Constitution permits the House of Representatives to select its Speaker as the presiding officer. Each party nominates a candidate and whoever receives a simple majority of the votes is elected. The Speaker is often too busy to physically preside over the House at all times and will often delegate presiding duty to other members of the majority party.

The respective parties elect the Majority Leader and the Minority Leader. Both the Majority and Minority Leaders have deputies called "whips," whose job it is to try to maintain party unity on important votes by corraling and

counting votes. The Members from each party meet to discuss issues of concern and for informational briefings via the Republican Conference and the Democratic Caucus. The Conference Chairs for each party reside over their respective conference's meetings and are selected by their party.

The Senate leadership also consists of Majority and Minority Leaders who are the "floor managers." The Majority and Minority Leaders are the elected spokespeople on the Senate floor for their respective parties, having been elected by their fellow Senators of the same party. The purely ceremonial presiding officer of the Senate is the Vice President of the United States who does not physically preside over the Senate. This task is given to the Senate Majority Leader who like the Speaker of the House is often too busy to preside and delegates this duty to another member of the majority party. The Vice President cannot introduce legislation or participate in debates and votes only in the rare occasion of a tie.

## Congressional Funding Process

The federal budget lays out federal revenues and spending, as well as new policy and program initiatives across all federal programs for a fiscal year that runs from October 1 to September 30 of a given year. The Congressional funding or budget process is actually a number of processes that evolve separately and occur with varying degrees of coordination. They include: the budget resolution, reconciliation, authorizations and appropriations which are each described further below. The federal budget contains two types of program funding: mandatory spending for entitlement programs (the largest are Medicare, Medicaid and Social Security) and discretionary spending for defense and most

other programs such as viral hepatitis. For more information on this process, the [House](#) and [Senate](#) Budget Committees provide informative primers on the budget process.

### **Budget Resolution**

After the President's budget request is released in February (see Administration section), the House and Senate Budget Committees prepare a budget resolution that lays out spending amounts for the fiscal year, which includes funding for priority policy initiatives by the President and the Congress. Although it does not have the force of law, the budget resolution is a central part of the budget process in Congress and is targeted for completion by mid-April. The budget resolution is the blueprint for broad spending and tax decisions that will be made during the balance of the year. The budget resolution is a "concurrent" congressional resolution, not an ordinary bill, and therefore is not subject to Presidential signature or veto. It also requires only a majority vote to pass, and its consideration is one of the few actions that cannot be filibustered in the Senate. The budget resolution is supposed to be passed by April 15, but it often takes longer and occasionally Congress does not pass a budget resolution. If that happens, the previous year's budget resolution stays in effect. The budget resolution's spending distribution is primarily implemented through two processes: reconciliation and appropriations.

### **The "Pay-As-You-Go" or "PAYGO" Rule**

While the budget resolution sets the spending limit on discretionary programs, it does not set spending limits on mandatory spending that consist of entitlements such as Medicaid and Medicare. The House and Senate therefore have a rule called "Pay-As-You-Go" or "PAYGO" that requires all entitlement increases and tax cuts to be fully offset or deficit-neutral. For instance, a funding bill that increases Medicaid or Medicare spending would have to

be compensated for by reducing the amount spent elsewhere in mandatory and/or discretionary spending, and/or by raising taxes to increase revenue.

The PAYGO rule is independent of the budget process and gives any Senator or Representative the power to raise a "point of order" or objection against any bill that proposes increased entitlement spending or decreased taxes without demonstrating offsets. House rules allow PAYGO to be easily waived. However in the Senate, an objection under PAYGO amounts to a filibuster and must be waived by at least 60 Senators. The PAYGO rule is established in law that requires it to be reauthorized from time to time. It was established in law from 1990 to 2002 and most recently in February 2010.

### **Budget Reconciliation**

Once the House and Senate agree on a budget resolution, an optional directive may be included known as budget reconciliation. Budget reconciliation (sometimes called OBRA – Omnibus Budget Reconciliation Act) instructs authorizing and appropriations committees to produce legislation by a specific date that meets certain spending or tax targets set by the budget resolution. If a committee fails to produce this legislation, the Budget Committee Chair generally has the right to offer floor amendments to meet the reconciliation targets; a threat which usually produces compliance. The authorizing and appropriations committees must provide the Budget Committee with legislative language that rewrites parts of their programs to reconcile the actual outcome in spending with what is called for in the budget resolution. The Budget Committees combine the legislative language which is then brought before the full House and Senate for a vote. Under reconciliation, amendments and floor debate are limited. In the Senate where debate is traditionally unlimited, reconciliation limits debate to 20

minutes and needs only a simple majority of 51 Senators for passage, making it filibuster-proof.

While reconciliation enables Congress to bundle together several different provisions affecting a broad range of programs and streamline its passage, it also faces the “Byrd rule” named after former Senator Byrd of West Virginia. The Byrd rule only applies to the Senate and allows a point of order to be raised to any provision of (or amendment to) the reconciliation bill that is deemed non-germane to the purpose of the amended entitlement or tax law, or violates PAYGO. If a point of order is raised under the Byrd rule, the offending provision is automatically stripped from the bill unless at least 60 Senators vote to waive the rule, making a filibuster possible on the specific provision. This makes it difficult to include any policy changes in the reconciliation bill unless they have direct fiscal implications.

### **Appropriations**

The budget resolution includes a total amount of spending known as the Section 302(a) of the Budget Act that is allocated to the Appropriations Committee. The Appropriations Committee then divvies up the total allocation to its 12 subcommittees. This second-level distribution is provided for under Section 302(b), so the sub-allocations are known as the “302(b)s.” The subcommittee allocations will determine the overall spending levels for the Labor-Health and Human Services-Education Appropriations bill and the Military Construction and Veterans Affairs and Related Agencies Appropriations bill, which include funding for viral hepatitis programs. The House and Senate can, and often have, different 302(b)s for the individual appropriations bills which must be reconciled later in the appropriations process. Once the appropriations subcommittees have their 302(b) allocations, the appropriations bills can be drafted for consideration by the subcommittees. In anticipation of the drafting of the

appropriations bills, each Member of Congress submits to the appropriations subcommittees request letters that prioritize their funding requests. There are project and programmatic letters. The project letter is specific to requests within a Member’s state or district and contains specific funding projects known as earmarks. In any given year, the leadership in Congress can decide not to include earmarks in the appropriations bills. The programmatic letter is specific to authorized funding streams for federal agencies. Therefore a request to increase hepatitis funding at the CDC’s Division of Viral Hepatitis is a program request. The subcommittee staff often prioritize spending based on the amount of Member requests they receive for a particular federal program. Committee leadership set internal deadlines for Member requests that are entered into a central database at the Appropriations Committee. This is a key point in the federal funding process where support for viral hepatitis programs can be demonstrated.

When the 12 appropriations bills are taken up in regular order they are first considered and passed by their respective subcommittee, passed individually in full committee, and then brought to the full House and Senate for floor consideration. Although the House and Senate draft separate appropriations bills, the Constitution requires that spending bills originate in the House. After an appropriations bill has been passed in both the House and Senate, the bill is then referred to a conference committee where the differences between the two bills can be reconciled. To fast-track spending legislation, Chairs of the House and Senate Appropriations Committees or Subcommittees will pre-conference a bill so that the bills are reconciled prior to floor passage to obviate the need to conference. The bill is then passed in both chambers and sent to the President for signature or veto.

Although Congress is required to complete action on all 12 appropriations bills by the end of the fiscal year on September 30, it rarely meets this deadline. In recent years, the appropriations process has finished well into the new fiscal year often due to the intense political nature of spending legislation. Since most government programs must continue to operate even if funds have not been appropriated, Congress will pass a continuing resolution (referred to as a “CR”) to temporarily fund government programs at the prior year’s levels or some other agreed-upon level until appropriations measures are passed and signed into law. Congress often enacts a number of short-term resolutions to prevent the government from shutting down at the beginning of a new fiscal year on October 1st. Due to the press of time at the end of a legislative session or intense political pressure to finish the process, several appropriations bills can be combined in an “omnibus” bill to fund the remainder of the fiscal year. For more information, please see the Congressional Appropriations Committees section.

### **Authorizations**

Congress may pass freestanding authorization bills, outside the reconciliation process, that may change tax or entitlement law. Although such measures are not part of reconciliation, they remain subject to the spending and revenue levels established in the budget resolution. Authorizations are legislation that establish, continue, or modify an agency or program, and authorize the enactment of appropriations for that purpose. Although House and Senate rules generally prohibit unauthorized appropriations, both provide exceptions in their respective rules and the prohibition itself may be waived. Authorizations may be temporary or permanent, and their provisions may be general or specific, but they do not themselves provide funding in the absence of appropriations committee action. Unless it changes an

entitlement program (such as Social Security or Medicare), authorizing legislation does not actually have a budgetary impact. For example, the Viral Hepatitis and Liver Cancer Control and Prevention Act (HR 3974, S 3711) introduced in the 111th Congress authorizes \$90 million to be spent in FY2011 and FY2012 with subsequent increases. However, even if the bill is to become law, none of those funds are available until the annual Labor-HHS-Education appropriations bill — which includes viral hepatitis spending — sets the actual dollar level for viral hepatitis funding for the year.

## **Congressional Committees**

Standing committees or fixed committees are generally organized to parallel the major departments and agencies of the executive branch. Since viral hepatitis programs are heavily concentrated across agencies within the Department of Health and Human Services (HHS), the most significant congressional committees of jurisdiction are those that oversee this Department.

### **Congressional Appropriations Committees**

House and Senate Appropriations Committees are typically the largest and most powerful committees in Congress. Traditionally, an assignment to this committee often boosts the Member’s ability to engage in project spending to bring federal spending back home to their district or state. This kind of spending is on the decline due to the negative press these projects have received in recent years. On program funding, committee members can influence funding amounts for specific programs at federal agencies, as well as for specific activities within programs.

There are 12 standing subcommittees within the Appropriations Committee. The Subcommittee on Labor, Health and Human

Services, Education, and Related Agencies in the House and Senate is the most significant Subcommittee for viral hepatitis spending. This bill funds viral hepatitis prevention programs as well as for health and behavioral services.

Typically once a subcommittee has received its 302(b) allocation, it begins holding hearings with federal officials and external stakeholders to collect relevant witness testimony and ask probing questions. This process allows advocates to weigh-in through organizational sign-on letters, testimony for the record and an opportunity to testify at the hearing if selected.

### **Congressional Authorizing Committees**

When an authorizing committee or subcommittee favors a legislative measure, it usually takes four actions:

1. Asks relevant executive agencies for written comments on the legislation.
2. Holds hearings to gather information and views from non-committee experts. During hearings, witnesses summarize submitted statements and respond to questions from Members.
3. Meets to consider legislation and alter it through the amendment process known as a “mark-up.”
4. Passes legislation out of subcommittee and full committee and is then referred to other committees of jurisdiction, and/or then sent to the full House or Senate for consideration. The Committee will release at this time a committee report describing the legislation’s purpose and provisions and the work of the committee thereon, including hearing proceedings and votes on amendments.

The influence of committees over legislation extends to the enactment into law. A committee that considers a bill will manage the full chamber’s deliberation on it. Also, its Members will be appointed to any conference committee created to reconcile differing versions of the legislation in the House and Senate.

In the House, the Energy and Commerce Committee has jurisdiction over Medicaid, Medicare Part B and D, the Food and Drug Administration’s (FDA) drug approval process, and discretionary public health programs, including CDC, Health Resources and Services Administration (HRSA) such as the Ryan White Program and the Substance Abuse and Mental Health Services Administration (SAMHSA) programs. The House Ways and Means Committee has jurisdiction over the entire Medicare program, Part A, B, C and D, which provides hepatitis B vaccines and hepatitis medications for the elderly and the disabled. The House Education and Labor Committee has jurisdiction over workforce issues that involve healthcare such as employee benefits, workforce initiatives, welfare, workers’ compensation, and family and medical leave. The House Veterans’ Affairs Committee has jurisdiction over the Veterans Health Administration (VA) and the VA health care system, which is the largest federal provider of hepatitis C treatment services.

In the Senate, the Health, Education, Labor and Pensions Committee has jurisdiction over the FDA’s drug approval process, biomedical research and development, and public health, including CDC, HRSA, the Ryan White Program and SAMHSA. The Senate Finance Committee has jurisdiction over the Medicaid and Medicare programs. The Senate Veterans’ Affairs Committee has jurisdiction over the Veterans Health Administration and the VA health care system.

Other committees such as the House Committee on Oversight and Government Reform (OGR) do not have a direct appropriation or authorization impact but play an important role in oversight of the Administration and its agencies. OGR is the main investigative committee in the House and has subpoena power to call in witnesses. The House Committee on Oversight and

Government Reform recently has held two hearings to examine the federal response to the hepatitis epidemics. In 2004, Chairman Tom Davis (R-VA) held the hearing “Stalking a Furtive Killer: A Review of the Federal Government’s Efforts to Combat Hepatitis C,” In 2010, Chairman Ed Towns (D-NY) held the hearing “Viral Hepatitis: The Secret Epidemic.” The Senate Committee on Homeland Security and Governmental Affairs’ Permanent Subcommittee on Investigations serves a similar oversight function.

Both the [House](#) and [Senate](#) websites contain a variety of information that is useful in learning about individual Members of Congress, committees, caucuses, status of legislation, House and Senate calendars, floor procedure, “how a bill becomes a law,” and “how to write your Representative and Senators.”

## Congressional Caucuses

A congressional caucus is a group of Members that meet to pursue common legislative objectives. The largest caucuses are the party conferences. These are the [House Democratic Caucus](#) and [House Republican Conference](#) in the House and the [Senate Democratic Caucus](#) and [Senate Republican Conference](#) in the Senate.

The minority caucuses are particularly active on health issues, including viral hepatitis. The Congressional Black Caucus (CBC) represents African-American Members that is open to both chambers but is traditionally made up exclusively of democrat Representatives. The Congressional Hispanic Caucus (CHC) represents Hispanic Members. The Congressional Asian Pacific American Caucus (CAPAC) is for Asian American and Pacific Islander American Members and those who represent districts with large API communities. The LGBT Equality Caucus represents both LGBT-identified Members and Members who support equal rights for LGBT people. Issue-specific caucuses are lesser known and can range from the Progressive Caucus to the Prevention Caucus. All caucuses meet regularly in private closed sessions to set legislative agendas and select committee members and chairs. In addition, many caucuses create separate foundations and charities to support caucus-specific priorities.

# The Administration

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## Executive Office of the President (EOP)

The power of the executive branch is vested in the President. The President appoints the Cabinet and oversees the various agencies and departments of the federal government. The Cabinet includes the Vice President and, by law, the heads of 15 executive departments — the Secretaries of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, Housing and Urban Development, Interior, Labor, State, Transportation, Treasury, Veterans Affairs and the Attorney General. Under President Obama, Cabinet level rank is also accorded to the Administrator of the Environmental Protection Agency, the Director of the Office of Management and Budget, the White House Chief of Staff, Chair of the Council of Economic Advisors, U.S. Ambassador to the United Nations and the U.S. Trade Representative. The Executive Office of the President (EOP) provides administrative support to all of these officials in addition to other key offices and councils.

### Office of Management and Budget

The Office of Management and Budget (OMB), as part of the executive office of the President, plays an integral role in the Administration's funding decisions for viral hepatitis programs. OMB's predominant mission is to assist the President in overseeing the preparation of the federal budget and to supervise its administration in executive branch agencies. In helping to formulate the President's spending plans, OMB evaluates the effectiveness of agency programs, policies, and procedures, assesses competing funding demands among agencies, and sets funding priorities.

OMB has undertaken performance evaluations of select HHS programs as part of the President's agenda for reforming the management of the government and improving the performance of federal programs. Each agency is evaluated quarterly by the OMB on five initiatives. These initiatives are: Strategic Management of Human Capital; Competitive Sourcing; Improved Financial Performance; Expanded Electronic Government; and Budget and Performance Integration. Another key OMB responsibility is legislative clearance and coordination of all agency communications with Congress, including testimony and draft legislation. Further, OMB is tasked with communicating Executive Orders and Presidential Memoranda to agency heads and officials. OMB increasingly serves an important political role to provide justifications for cost-savings and cost-benefits to any fiscal impact an Administration priority initiative may have on the economy.

### President's Budget

The release of the President's budget, which lays out the funding priorities of the Administration, is the starting point for deliberations on federal funding for a given fiscal year. Current law requires the President to submit a budget no earlier than the first Monday in January, and no later than the first Monday in February. Typically, Presidents submit budgets on the first Monday in February. In inaugural years of new Administrations, the President's budget is typically released later. Further, the release of the President's budget does not preclude a President from issuing further budget amendment proposals to Congress later in the appropriations process. Although this budget does not have the force of law, it is a comprehensive examination of federal revenues

and spending, including any initiatives recommended by the President, and is the start of extensive interaction with Congress. After receiving the President's budget request, Congress generally holds hearings to question Administration officials about their requests and then develops its own budget resolution. (As described in the Congressional Funding Process Section)

### **Councils and Committees**

Three councils – the Domestic Policy Council, the National Economic Council, and the National Security Council, make key policies at the White House. EOP councils and committees support the Administration's policy priorities by formulating and developing national policy recommendations. Presidents establish and modify councils and committees in order to leverage the expertise of staff dedicated to certain issue areas. For instance, the Domestic Policy Council is the most relevant council for public health issues such as viral hepatitis.

The Domestic Policy Council (DPC) oversees major domestic policy areas such as education, health, housing, welfare, justice, federalism, transportation, environment, labor and veteran's affairs. Recently, the White House Office on Health Reform was created by President Obama and is part of the DPC. The Office of National AIDS Policy (ONAP), the Office of National Drug Control Policy (ONDCP), the Council on Environmental Quality (CEQ) and the Office of Faith-Based and Community Initiatives (OFBCI) are also affiliated with the Domestic Policy Council. ONAP is the lead office on both mono-infection of hepatitis and co-infection with HIV and internally champions hepatitis within the DPC and White House. ONAP has worked to increase hepatitis funding in the president's budget and works to highlight hepatitis co-infection within its role as lead developer and implementer of the National HIV/AIDS Strategy (NHAS). ONAP helped

secure President Barack Obama's recognition letter on World Hepatitis Day in 2009 and 2010.

The Domestic Policy Council's formal membership includes the Cabinet Secretaries and Administrators of federal agencies that affect the issues addressed by the DPC. The DPC also works to ensure that domestic policy initiatives are coordinated and consistent throughout federal agencies. Finally, the DPC monitors the implementation of domestic policy, and represents the President's priorities to other branches of government.

The Administration makes public policy through a variety of vehicles including the following:

### **Proclamations**

Proclamations are formal public announcements often relating to ceremonial or celebratory occasions that are typically non-controversial, do not have any significant legal or fiscal ramifications and are aimed at activities outside government. In viral hepatitis advocacy, a Presidential Proclamation could be formal recognition of World Hepatitis Day or National Viral Hepatitis Awareness Month.

### **Executive Orders**

Executive orders have the force of law and are generally used to direct an agency or official to take a specific action or establish or modify an agency. It can range from the creation of a Department such as the establishment of Homeland Security Department under former President George W. Bush. It can also include institution or retraction of policy. For example the Mexico City Policy or global gag rule has been instituted and rescinded depending on the President since 1984. The policy requires all non-governmental organizations that receive

federal funding to refrain from performing or promoting abortion services, as a method of family planning, in other countries.

## Statements of Administration Policy (SAPs)

The President will issue SAPs on pending legislation in Congress to demonstrate support or opposition for legislation in total or regarding specific provisions. A SAP can influence the final outcome of legislation particularly in achieving modifications to the pending legislation that are consistent with the Administration's goals. For legislation that must pass such as Appropriations bills, SAPs are generally used to comment on specific funding amounts and provisions to bolster support for the Administration's fiscal priorities in the final version of the bill.

## Federal Regulations

While laws provide the framework, federal agencies develop rules to spell out the details and operationalize the provisions of law. Since federal regulations implement laws and are legally binding, the Administrative Procedures Act requires federal agencies to allow the public to participate in the development of federal rules and regulations. The most common way for the public to participate is through commenting on proposed regulations. The agencies within the Department of Health and Human Services (HHS) write nearly all of the regulations that impact viral hepatitis programs.

Regulations can be found in the [Federal Register](#) which is published every working day and serves to notify the public of all government rules, notices, Presidential documents, grant applications, meetings and hearings. This open access to information enables one to participate in the decision-making process by submitting written

comments. Any person, organization, or health department may submit written comments on a proposed rule or an interim final rule with comment period. All proposed rules and public comments are available on a separate [regulations website](#). All federal grant information is also available on a separate [website](#). Further, grant procurement specific to HHS can be found [here](#) and on an [extensive search database](#).

Despite its relatively straightforward format the rulemaking process can drag on for years and is often subject to political pressures from a variety of sources. Agency administrators, who are political appointees of the President, often strive to fulfill the Administration's policy objectives as they develop regulations to implement federal laws. Interested parties can meet with agency officials to discuss their concerns prior to submitting written comments, and can petition agencies to develop or withdraw regulations. Stakeholders can also ask Congress to intervene to change regulations, since federal agencies are generally responsive to Congress. Members of Congress are not always aware of concerns or support for agency rules and regulations, and are often willing to intervene if a regulation is contrary to Congressional intent in passing the legislation or contrary to the mission of the agency.

### Administrative Agencies

Programs addressing viral hepatitis reside in several agencies of the federal government. The greatest concentration of federal viral hepatitis programs is housed within HHS. The Department of Veterans Affairs, through the Veterans Health Administration and the VA health care system, provide a significant amount of care and treatment to eligible veterans living with hepatitis C through their VA National Hepatitis C Program.

Below are profiles of the administrative agencies with the most significant portions of the federal viral hepatitis portfolio.

# The Department of Health and Human Services

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## Office of the Secretary

The leadership of the Department of Health and Human Services resides in the Office of the Secretary. The HHS Secretary is a cabinet-level position who must be appointed by the President and confirmed by the Senate. The Office of the Secretary is immediately supported by a number of Assistant Secretaries and Offices including the Assistant Secretary for Health (ASH), the Office of Inspector General and the Office for Civil Rights.

## Assistant Secretary for Health

The ASH is the senior advisor on public health and science issues to the Secretary of Health and Human Services and oversees the U.S. Public Health Service (PHS). The ASH oversees twelve offices and the Commissioned Corps including the Office of the Surgeon General (OSG), the Office of Minority Health (OMH), the Office of Disease Prevention and Health Promotion (ODPHP), Office of Healthcare Quality (OHQ), the Office of HIV/AIDS Policy (OHAP) and the National Vaccine Program Office (NVPO). The Office of the ASH includes a Deputy Assistant Secretary for Infectious Disease that seeks to coordinate federal government activities on infectious disease, including viral hepatitis.

The ASH is also responsible for the development of Healthy People 2020 that provides a framework for prevention for the nation. It is a statement of national health objectives designed to identify the most significant preventable threats to health and to establish national goals to reduce these threats. It includes objectives for viral hepatitis prevention. In addition the ASH oversees several councils and committees including the Presidential Advisory Council on HIV/AIDS

(PACHA). The ASH also convenes the Interagency Work Group on Viral Hepatitis that is charged with the development and implementation of the *HHS Viral Hepatitis Action Plan*.

## HHS Interagency Work Group on Viral Hepatitis

Created by the ASH in 2010, the work group's goal is "to accelerate progress towards the prevention of viral hepatitis and associated disease in the U.S." Its charge is "to develop and implement an HHS strategic plan to improve the coordination of viral hepatitis activities within HHS, respond to recommendations of the Institute of Medicine (IOM), and set and achieve goals toward the prevention of viral hepatitis and associated disease in the U.S." The work group is co-chaired by the Senior Policy Advisor to the ASH and the Director of the Centers for Disease Control and Prevention's (CDC) Division of Viral Hepatitis. It involves staff from CDC in addition to the Center for Medicaid and Medicare Services (CMS), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Indian Health Services (IHS), the National Institutes of Health (NIH), the National Vaccine Program Office (NVPO) and the Substance Abuse and Mental Health Services Administration (SAMHSA). It is made up of the following five sub-working groups with two internally appointed co-leads:

- Increasing Community Awareness and Provider Education
- Improving Clinical Prevention, Care and Treatment Services
- Preventing Viral Hepatitis Transmission through Vaccination
- Strengthening Surveillance for Viral Hepatitis
- Preventing Blood Borne Transmission (IDU and HAI)

## **Surgeon General**

The Surgeon General is our nation's chief spokesperson on matters of public health and medicine, and serves as special advisor to the President, HHS Secretary, the Congress and the general population on hazards to health, disease prevention and health promotion, based on the best available scientific evidence. The Surgeon General is appointed by the President and must be confirmed by the Senate. The Surgeon General also chairs the National Prevention, Health Promotion, and Public Health Council that is charged with developing an annual National Prevention and Health Promotion Strategy.

## **Office of Minority Health (OMH)**

The Deputy Assistant Secretary for Minority Health heads the Office of Minority Health with the mission of improving the health status of racial and ethnic minorities, eliminating health disparities and achieving health equity in the United States. OMH funds disease-specific and health equity activity to state and local entities, works with health programs to ensure culturally and linguistically competent systems of prevention and care, and convenes expert panels to forge federal recommendations and strategies to eliminate health disparities. OMH works closely with sister agencies within HHS and their minority health representatives.

In 2006, OMH convened and funded the National Task Force on Hepatitis B Expert Panel that developed the Goals and Strategies to Address Chronic Hepatitis B to lay out a national action agenda to eliminate hepatitis B in Asian Americans, Native Hawaiian and other Pacific Islander communities. Key elements include increasing national awareness of the disproportionate impact, engaging stakeholders and expanding the infrastructure needed to reduce the risk of chronic hepatitis B infection and its long-term complications. Further, OMH collaborates with community stakeholders to organize national public

awareness events around National Viral Hepatitis Awareness Month and World Hepatitis Day.

## **National Vaccine Program Office (NVPO)**

The National Vaccine Program Office (NVPO) has the responsibility for ensuring the collaboration among agencies of national vaccine and immunization initiatives. Using the National Vaccine Plan, NVPO works to prevent infectious diseases through immunization. NVPO seeks to limit adverse reactions to vaccines and ensure that minimal gaps in federal planning for vaccines and immunizations occur.

## **Office of Consumer Information and Insurance Oversight (OCIIO)**

With the passage of the Affordable Care Act (ACA), HHS created the Office of Consumer Information and Insurance Oversight (OCIIO) to ensure private industry compliance with the new insurance market rules, such as the prohibitions on rescissions and on pre-existing condition exclusions. OCIIO assists states with medical loss ratio rules, insurance rate reviews and the newly created state-based insurance exchanges by maintaining a database on insurance options. Further, OCIIO administers ACA's temporary high-risk pool program and the early retiree reinsurance program.

## **Office of the Assistant Secretary for Financial Resources (ASFR)**

The Office of the Assistant Secretary for Financial Resources (ASFR) is the main budgetary office of HHS. It provides guidance to the HHS Secretary on all aspects of financial management, grants and the American Recovery and Reinvestment Act (ARRA or Recovery Act) coordination. All HHS audits must be performed and cleared through ASFR. Within ASFR, the Office of Budget plays a lead role in analyzing Congressional budget actions and appropriations legislation, providing guidance and technical assistance to HHS operating

divisions in addition to developing the HHS budget that is sent to OMB and the Congress.

### **Office of Health Reform (OHR)**

The Office of Health Reform (OHR) is the lead HHS Office on the Department's compliance and implementation of the Affordable Care Act. In close coordination with the White House Office of Health Reform and the HHS Office of the Secretary, OHR coordinates and develops Department-wide health reform activity, provides analysis of health reform activities and coordinates HHS outreach and interaction with stakeholders on health reform. The HHS website on health reform is a useful resource.

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

The Agency for Healthcare Research and Quality (AHRQ) is the health services research arm of HHS. AHRQ is the lead agency charged with supporting research designed to improve the quality of health care, reduce its cost and broaden access to essential services. AHRQ's programs seek to bring science-based information to medical practitioners and to consumers and other health care purchasers. AHRQ supports improvements in health outcomes; develops strategies to strengthen quality measurement and improvement; identifies strategies to improve health care access, foster appropriate use, and reduce unnecessary expenditures; improve the quality of health care; promote patient safety and reduce medical errors; and advance the use of information technology for coordinating patient care and conducting quality and outcomes research.

Historically, AHRQ had funded a project to improve specialty care of hard-to-reach persons living with chronic hepatitis C in rural areas called Project ECHO. It was a three-year grant that supported rural physicians' co-management of patients with chronic HCV in New Mexico using

telehealth. Other than Project ECHO, AHRQ's viral hepatitis portfolio remains very limited.

### **U.S. Preventive Services Task Force (USPSTF)**

AHRQ convenes the U.S. Preventive Services Task Force (USPSTF) and AHRQ's Prevention and Care Management Portfolio provides ongoing administrative, research, technical, and dissemination support to the Task Force. The USPSTF is an independent panel of non-Federal experts in prevention and evidence-based medicine and is composed of primary care providers such as internists, pediatricians, family physicians, gynecologists/obstetricians, nurses, and behavioral health specialists. The USPSTF conducts scientific evidence reviews of a broad range of clinical preventive health care services (such as screening, counseling, and preventive medications) and develops recommendations for primary care clinicians and health systems.

Recommendations issued by the USPSTF are intended for use in the primary care setting. The USPSTF recommendations present health care providers with information about the evidence behind each recommendation, allowing clinicians to make informed decisions. The USPSTF reviews the evidence, estimates the magnitude of the benefit and harm for each preventive service, reaches consensus about the net benefit for each preventive service, and issues a recommendation. The Task Force grades the strength of the evidence from "A" (strongly recommends), "B" (recommends), "C" (no recommendation for or against), "D" (recommends against), or "I" (insufficient evidence to recommend for or against). USPSTF recommendations have formed the basis of the clinical standards for many professional societies, health organizations and medical quality review groups. Under the Affordable Care Act (ACA), USPSTF recommendations of preventative services rated at an "A" or "B" are automatically covered at no cost to the patient under private insurance and over time for Medicare and Medicaid.

## USPSTF's Recommendations on Viral Hepatitis

- **Grade: A Recommendation**
  - Strongly recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit (February 2004, June 2009)
- **Grade: D Recommendation**
  - Recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection (February 2004)
  - Recommends against routine screening for hepatitis C virus (HCV) infection in asymptomatic adults who are not at increased risk (general population) for infection. (March 2004)
- **Grade: I Recommendation**
  - Found insufficient evidence to recommend for or against routine screening for HCV infection in adults at high risk for infection (March 2004)

For more information, please go [here](#) for a full listing of USPSTF's recommendations

## Centers for Disease Control and Prevention (CDC)

The CDC, as an agency of HHS, is recognized as the lead federal agency for protecting the public health and safety of people, providing credible information to enhance health decisions and promoting health through strong partnerships. CDC is tasked with national-level disease surveillance, first-response and other prevention-related activities. CDC's top level organizational components include the Office of the Director, the Office of Public Health Preparedness and Response, Office of State, Territorial, Local and Tribal Support, the National Institute for Occupational Safety and Health and the Center for Global Health. Most relevant to hepatitis is the Office of Infectious Diseases that includes the National Center for Immunization and Respiratory Diseases (NCIRD) and the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP).

### Office of Infectious Diseases (OID)

The mission of the Office of Infectious Diseases

is to lead, promote, and facilitate science, programs, and policies to reduce the burden of infectious diseases in the U.S. and globally. The director of OID serves as the principal advisor to the CDC Director on infectious disease issues and provides strategic leadership to the three infectious disease centers.

### National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP)

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) provides national leadership in preventing and controlling the infectious diseases of HIV, viral hepatitis, sexually transmitted diseases, and tuberculosis. National Center staff work in collaboration with governmental and non-governmental partners at community, state, national, and international levels, applying integrated multidisciplinary programs of research, surveillance, technical assistance, and evaluation. The National Center in recent years has focused its priorities on program collaboration and service integration (PCSI), health inequities, addressing the

underlying social determinants of health that drive acquisition of infectious disease and where appropriate, using a sexual health framework to address some of these public health issues. The Division of Viral Hepatitis (DVH) is located within the National Center.

### **Division of Viral Hepatitis (DVH)**

The central focus of the Division of Viral Hepatitis (DVH) is the prevention, control and elimination of viral hepatitis infections in the U.S. and to assist the international public health community in these activities. DVH provides funding for staff to promote the integration of viral hepatitis into HIV/AIDS, STD and other programs and services to address the prevention needs of individuals at high risk for viral hepatitis. DVH funds adult viral hepatitis prevention coordinators in 49 states, the District of Columbia and five large metropolitan areas to provide management, networking and technical expertise for successful integration of hepatitis prevention and control activities into existing public health programs. DVH supports limited viral hepatitis surveillance through the Emerging Infections Program in seven jurisdictions: Colorado, Connecticut, New York City and New York, Oregon, Minnesota, and San Francisco, CA. DVH funds a small amount of research on epidemiology, new diagnostics and therapies, and practical applications in the healthcare setting for improving screening and testing. DVH supports limited education, networking and training grants, and technical assistance support to health departments. DVH funds and works on the global hepatitis epidemic through international partnerships and the World Health Organization.

Where the AVHPC resides within their health department structure varies. More than one half are located organizationally within the HIV/AIDS program. Others are located organizationally in the STD, TB, immunization or communicable disease programs. This often facilitates cross-program collaboration and

integration of hepatitis services into other areas of public health. Due to limited funding for health department hepatitis programs, collaboration and integration are essential to the provision of the most basic services.

To combat the HBV and HCV epidemics in the United States, the CDC developed *Recommendations for Prevention and Control of Hepatitis C Virus Infection (HCV) and HCV-Related Chronic Disease* in 1998 and *Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection* in 2008, and the *National Hepatitis C Prevention Strategy* in 2001 in response to a request by the Secretary of the Department of Health and Human Services for a comprehensive plan for the prevention and control of hepatitis C. DVH develops and updates its own strategic plan every five years with the most recent iteration through 2015. DVH also updates the CDC's guidelines for identifying, counseling and testing persons at risk for viral hepatitis infection. DVH is a key partner in the ASH's Interagency Work Group on Viral Hepatitis and key developer of the *HHS Viral Hepatitis Action Plan*. Further, DVH developed a professional judgment (PJ) budget at the request of Congress estimating an approximate need of at least \$300 million for a robust viral hepatitis program. Funds to fully implement any of these strategies have not been provided by Congress.

### **National Center for Immunization and Respiratory Diseases (NCIRD)**

The Immunization Services Division (ISD) under NCIRD awards grants through Section 317 of the Public Health Service Act and the Vaccines for Children (VFC) program to assist state and local health departments in purchasing vaccines and in planning, developing, and conducting immunization programs. This includes vaccines for hepatitis A and B. There is no adult-specific hepatitis vaccination program within ISD. ISD however does fund "Perinatal Hepatitis B Coordinators" in 67

## The Adult Viral Hepatitis Prevention Coordinators

Health departments were first funded by CDC's Division of Viral Hepatitis (DVH) in 2000 to provide coordination of services for individuals at risk for and infected with hepatitis C. In 2007, DVH redefined the role of health department "HCV Coordinators" to focus more broadly on adult hepatitis, creating the position of the Adult Viral Hepatitis Prevention Coordinator in 49 states, the District of Columbia and five cities – Chicago, IL, Houston, TX, Los Angeles, CA, New York City, NY, Philadelphia, PA – with a total funding level of approximately \$5 million per year (or an average award of \$90,000.) With the current level of federal funding, health departments cannot support these and other core public health services such as hepatitis outreach and education, screening and testing, hepatitis A and B vaccination for high-risk adults, or medical management and drug therapy. There is almost no funding for a surveillance system to capture the prevalence and incidence of these diseases. The CDC DVH cooperative agreements with health departments only provide funding for one full-time position and some travel. Because of this, there is no funding for community-based organizations to provide these and other services.

AVHPC responsibilities include:

- Public and provider education in addition to training for professionals;
- Oversight of counseling, testing, and referral services, partner services, community planning and capacity building;
- Developing a viral hepatitis prevention plan;
- Integration of core viral hepatitis prevention services into existing programs;
- Immunization of hepatitis A (HAV) and hepatitis B (HBV) of at-risk adults (immunization of infants is covered by the perinatal HBV program);
- Work with infection control for hepatitis exposure in medical settings;
- Work with substance abuse treatment programs for persons who use injection- or non-injection illicit drugs;
- Work with populations in high-risk settings such as the incarcerated and those accessing services at STD and HIV clinics, and homeless shelters;
- Services for HIV-infected persons, including HAV/HBV vaccination of all susceptible persons and testing to identify HIV-infected persons with chronic HBV/HCV infection;
- Assistance with primary health care services for the uninsured and underinsured;
- Administrative and fiscal management of hepatitis services.

## CDC/HRSA Advisory Committee (CHAC) on HIV and STD Prevention and Treatment

The CHAC is a committee made up of health experts from the federal government and the private and public sector to advise the HHS Secretary, CDC Director and HRSA Administrator on a full range of issues including objectives, strategies, policies and priorities for HIV and STD prevention, care and treatment efforts. The HHS Secretary appoints two co-chairs to serve two to four year terms. The CHAC encourages strong inter-agency collaboration across the spectrum of prevention and care.

While the CHAC does not list hepatitis in its name, CHAC has included hepatitis in its meetings since DVH's position was moved under the National Center. Given the importance of inter-agency collaboration to improve hepatitis program activity across CDC and HRSA, CHAC has informally created a subcommittee on hepatitis that will ensure hepatitis is part of regular updates in the CHAC's advisory role to HHS, CDC and HRSA leadership.

jurisdictions included in a larger immunization cooperative agreement to grantees. Perinatal Hepatitis B Coordinators work primarily with physicians and hospitals to ensure that pregnant women with hepatitis B are identified and that appropriate medical care is given to their babies to prevent the spread of HBV. In addition, the position supports ongoing universal hepatitis B vaccination efforts of newborns in their jurisdiction. They are accessible to the public as a valuable resource of information for viral hepatitis and can answer questions regarding hepatitis B immunization schedules and vaccine funding.

The VFC program serves children and adolescents up to age 19 without insurance, those eligible for Medicaid, American Indian/Alaska Native children, and children who are underinsured and receive care through Federally Qualified Health Clinics and Rural Health centers. Through the VFC program, federally purchased vaccines are distributed to public health clinics and enrolled private providers, enabling vaccination of all eligible children.

The Section 317 Immunization Grant Program provides vaccines for children, adolescents and adults who primarily present at local health departments for immunization services but are not eligible for the VFC program. The Section 317 program is a discretionarily funded program that primarily serves children whose parents are unable to fully afford vaccinations. The majority of program funds are dedicated to routine childhood immunization programs, leaving a gap in coverage among adult programs. In previous fiscal years, CDC had identified funds through program cost savings in the Section 317 Vaccine Program, allocating \$20 million in FY2008 and \$16 million in FY2009 and FY2010 for one-time purchase of the hepatitis B vaccine for at-risk adults. While this initiative did not support any infrastructure or personnel for health departments to deliver the vaccine, it was an unprecedented expansion of the vaccine for adults. State immunization programs determine whether vaccinating adults at risk for hepatitis A and B infection are a priority for their jurisdiction.

## Perinatal Hepatitis B Coordinators

CDC's Immunization Services Division (in the National Center for Immunization and Respiratory Diseases) funds Perinatal Hepatitis B Coordinators in 67 jurisdictions (includes 50 states, the District of Columbia, eight directly-funded cities - Chicago, Detroit, Houston, Los Angeles County, New York City, Philadelphia, San Antonio and Washoe County, NV, and eight territories. Funding for this position is included in a larger immunization cooperative agreement to grantees. The current level of federal funding for perinatal HBV programs is insufficient to adequately prevent transmission of HBV from an infected mother to her newborn, provide treatment to the infected mother, and provide screening and vaccine to a mother's sexual and household contacts. Even with the availability of hepatitis B vaccines, about 43,000 new acute HBV infections still occur each year. CDC estimates that each year about 1,000 newborns are perinatally infected, which puts them at risk for premature death from HBV-related liver disease.

Perinatal Hepatitis B Coordinator responsibilities include:

- Identifying all HBV-positive women;
- Conducting case management of all identified infants at risk of acquiring perinatal HBV infection;
- Reporting of HBV-positive infants and providing appropriate care to infants born to mothers of unknown HBV status;
- Developing a state plan to put into practice a universal reporting mechanism with documentation of maternal HBV test results for all births; and
- Working with hospitals to achieve universal birth-dose coverage and documentation of the birth dose in an immunization information system.

### Advisory Committee on Immunization Practices (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is charged with providing advice and guidance to HHS and CDC leadership regarding the most appropriate selection of vaccines and related agents for effective control of vaccine-preventable diseases among children, adolescents and adults. ACIP consists of 15 experts in fields associated with immunization, who have been selected by HHS and CDC leadership, and 8 ex officio members who represent other federal agencies with responsibility for immunization programs, in addition to 26 non-voting representatives of liaison organizations that bring related

immunization expertise. ACIP maintains the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program. While the committee reports to the HHS Secretary, HHS Assistant Secretary for Health and the CDC Director, it is currently supported by the Office of the Director within the National Center for Immunization and Respiratory Diseases (NCIRD). Meetings are held three times each year and are open to the public unless deemed otherwise.

## **Office of Minority Health and Health Disparities (OMHD)**

The Office of Minority Health and Health Disparities (OMHD) aims to accelerate CDC's health impact in the U.S population and to eliminate health disparities for vulnerable populations as defined by race/ethnicity, socioeconomic status, geography, gender, age, disability status, risk status related to sex and gender, and among other populations identified to be at-risk for health disparities. OMHD coordinates CDC activity with White House Executive Orders and HHS Departmental Initiatives related to minority health, supports Cooperative Agreements for research and professional development that have a CDC-wide impact, reports on the health status of vulnerable populations, and initiates strategic partnerships with governmental as well as external stakeholders for increasing the science and professional practice of improving minority health. Given that chronic liver disease and cirrhosis are top 10 killers among American Indian/Alaska Native Population, Asian Americans and Hispanic/Latino Populations, there remains great opportunity to strengthen OMHD's work to eliminate these health disparities.

## **Centers for Medicare and Medicaid Services (CMS)**

The Centers for Medicare and Medicaid Services (CMS) oversees the three largest public insurance programs: Medicare, Medicaid and the Children's Health Insurance Program (CHIP). CMS' vision is to achieve a modernized and transformed health care system and has a significant role in the implementation of the Affordable Care Act. CMS also sets clinical laboratory quality standards under the Clinical Laboratory Improvement Amendments (CLIA).

Medicare and Medicaid are the two largest public insurance programs that provide health care to approximately 90 million Americans and will expand further with implementation of the Affordable Care Act and the aging baby boomer population. Medicare, Medicaid and CHIP account for the greatest spending of the national budget with defense and homeland security spending in second. Both Medicaid and CHIP require matching payments from states. The Medicare program finances health care services for elderly people and people with disabilities and is funded solely by the federal government. Medicare also offers a prescription drug benefit to beneficiaries. The Medicaid program finances health services for eligible low-income persons and is jointly funded by federal and state governments. Both Medicare and Medicaid, as entitlement programs, finance healthcare services to eligible persons living with or at risk for hepatitis, including testing, diagnostics, vaccines and medication.

For persons living with hepatitis, navigating the Medicare and Medicaid systems is challenging because both systems operate under the auspices of a complex set of rules and definitions that are constantly being updated and redefined. The number of people living with liver disease caused by chronic viral hepatitis and of their coverage on Medicare and Medicaid are unknown.

### **Medicare**

In general, all persons 65 years of age or older who have been legal residents of the U.S. for at least 5 years are eligible for Medicare. Persons under 65 who are disabled and have been receiving either Social Security benefits or the Railroad Retirement Board disability benefits for at least two years are eligible. Persons on Social Security Disability who are on dialysis for end stage renal disease or need a kidney transplant, or have amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease) are also eligible.

Medicare is divided into four different parts.

- Part A or “Hospitalization” covers hospital services and bills;
- Part B or “Major Medical” covers doctors’ bills;
- Part D or “Prescription Drug Coverage” covers prescription drugs;
- Part C or “Medicare Advantage” covers all the above bills in a managed care plan.

Part A typically does not come with a monthly premium: most patients, or their spouses, have paid Medicare-related income tax for a sufficient period of time in their lifetime to receive free coverage. Parts B, C and D have varying costs depending on the patient plan, income level and marriage status. The Parts do not pay for all of a covered person’s medical costs such as premiums, deductibles and copayments, which the covered individual must pay out-of-pocket.

Patients have the option of enrolling in a variety of plans: for example, the most basic Medicare plan is administered directly by the federal government and covers only Part A. In contrast, a plan administered by a Medicare-approved private insurance company (like a Medicare Advantage Plan outlined under Medicare Part C that is usually an HMO or PPO) provides a range of extra coverage at costs that may differ from the federally administered coverage of a direct plan. A third option allows Medicare to be paid for and administered through a Medicare Health Plan that is not a Medicare Advantage Plan. Plans in this category include Medicare Cost Plans, Demonstration/Pilot Programs, and Programs of All-inclusive Care for the Elderly (PACE).

### **Medicare Part D and the Donut Hole**

Medicare Part D went into effect on January 1, 2006 and expanded affordability of prescription drugs to close a gap in coverage among Medicare beneficiaries. Unlike Medicare Parts A and B, Part D coverage is not standardized. For instance, plans can choose which drugs (or

even classes of drugs) they wish to cover and at what level (or tier) they wish to cover it. Part D plans require a deductible or some other out-of-pocket expense like tiered copayments for initial drug coverage. Once this is met, the plan will then require some percentage of the drug costs up to a coverage limit. Once this initial coverage limit is reached, the beneficiary must pay the full cost of the prescription drugs up until the total out-of-pocket expenses reach a certain amount. This coverage gap of when someone is forced to pay the full cost of the drug is known as the “Donut Hole.” The donut hole is expected to be gradually eliminated by 2020 through a combination of measures including drug discounts and a gradual decrease in the catastrophic coverage threshold under health reform. It is unknown how Medicare Part D and the donut hole have impacted people living with chronic viral hepatitis.

### **Medicaid**

Although Medicaid was created under the federal Social Security Act, “Medicaid” is not one, but fifty separate programs that are overseen and implemented by each state. Some states do not even refer to the Medicaid programs they administer by the name of Medicaid, but by state-specific names such as “MediCal” in California, “Georgia Better” in Georgia, or “TennCare” in Tennessee. While the federal government provides some basic requirements for determining eligibility for coverage and benefits to be provided, each state can expand Medicaid beyond the federal eligibility income level. As a result of this flexibility, each state’s Medicaid program covers a slightly different group of people with widely varying sets of benefits. For example, benefits that go beyond the federally mandated minimum that are covered by some Medicaid programs include chiropractic care, podiatry, preventive care, and speech and occupational therapy.

To qualify for Medicaid in most states, a patient must meet a set of financial criteria designed to determine if they qualify for need-based eligibility. Typically, these criteria are the same as, or only slightly different from, the financial requirements that qualify an individual to receive Supplemental Security Income (SSI). The patient must also be declared disabled according to Social Security's definition of disability and have less than \$2,000 (\$3,000 for couples) in countable assets.

The administration of Medicaid benefits in some states is done through contracting managed care plans. It can be the case that the only option in a state is an HMO-type plan, which limits the choice of medical providers and requires that a primary care physician direct all of one's care. In addition, there are federal programs which are not part of Medicaid itself but are administered by Medicaid offices. These plans will pay for dual-eligibles who also have Medicare premiums, deductibles and co-payments. A dual-eligible is someone who is qualified for and enrolled in both Medicare and Medicaid such as a low-income and disabled adult who is at least 65 years old, or a disabled individual enrolled in both systems. As Medicare and Medicaid are entitlements, a dual-eligible must be able to receive both services.

In addition to Medicare and Medicaid, CMS administers the Demonstration to Maintain Independence and Employment (DMIE) grant program established by the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA). The purpose of the demonstration is to cover individuals who have a specific physical or mental impairment that, without medical assistance, has the potential to lead to disability. DMIE considers both hepatitis C and HIV/AIDS severe physical or mental impairments that are covered under their grant programs.

## **Clinical Laboratory Improvements Act (CLIA)**

CMS, through the Division of Laboratory Services, regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvements Act (CLIA). In total, CLIA covers approximately 200,000 laboratory entities and seeks to ensure quality laboratory testing. With the approval of rapid testing technology by the FDA, diagnostic companies have sought and received a CLIA waiver to allow testing to occur in non-lab settings such as a clinic or community-based organization. Waived tests are defined as simple laboratory examinations and procedures that are cleared by the FDA for home use, employ methodologies that are so simple and accurate that mistakes are unlikely and negligible, or pose no reasonable risk of harm to the patient if performed incorrectly. CLIA waivers have been granted for rapid HIV tests and will likely be granted for rapid HCV tests as well.

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

The Health Resources and Services Administration (HRSA) directs national health programs which improve the health of the nation by assuring quality health care to underserved, vulnerable and special-need populations and by promoting appropriate health professions workforce capacity and practice, particularly in primary care and public health. HRSA oversees the nation's community health centers and provides support for the health workforce. HRSA is made up of six Bureaus and the most relevant to viral hepatitis are the Bureau of Primary Health Care and the HIV/AIDS Bureau.

## **Bureau of Primary Health Care (BPHC)**

The Bureau of Primary Health Care (BPHC) provides national leadership in developing, coordinating, evaluating and assuring access to comprehensive preventive and primary health care services and improving the health status of the nation's underserved and vulnerable populations. In doing so, BPHC administers the Consolidated Health Center Program, which funds a national network of more than 3,400 community health centers and clinics, migrant health centers, health care for the homeless centers, public housing primary care centers and school-based health centers. BPHC also maintains a Uniform Data System that issues quality improvement measures for grantees and collects patient-level and disease-specific information from community health centers.

Within BPHC is the Division of Health Center Development (DCHD). DCHD provides leadership and direction, including tactical planning for the development and expansion of new health centers, health systems infrastructure, and pharmacy services. Within DCHD is the Office of Pharmacy Affairs that assists states in expanding the number and types of organizations that participate in the 340B drug pricing program. The 340B program provides discounts on drugs to participating HRSA grantees in order for grantees to reach more eligible patients. The 340B discount affects the cost of a drug to the HRSA grantee and not to the patient. Participation in the program results in significant savings for grantees, estimated to be 20 to 50 percent off the cost of drugs.

Under the Affordable Care Act, community health centers will receive an infusion of \$11 billion over five years. This is an opportunity to expand vaccination, screening and education on hepatitis. There are a limited number of community health centers that are providing services to people with viral hepatitis. BPHC

can play a leadership role in providing technical assistance to health centers to expand their services.

## **HIV/AIDS Bureau (HAB)**

The HIV/AIDS Bureau (HAB) administers the Ryan White Program that provides grants to states, cities, clinics, teaching hospitals, and other entities to provide primary care, medications and support services to persons living with HIV/AIDS. Ryan White Programs target people among whom HIV/HBV and HIV/HCV co-infection is prevalent such as the poor, people of color and current or former injection drug users. Further, there is a documented rise of sexual transmission of HCV among HIV-positive gay and bisexual men. Ryan White funds can be used to provide hepatitis A and hepatitis B vaccines and hepatitis testing, treatment and medical management services to co-infected individuals. Each state and eligible city determines what medications and services will be covered.

The Ryan White Program includes Part A that funds metropolitan areas and Part B that funds states and territories, including the state AIDS Drug Assistance Programs (ADAPs). ADAPs provide access to HIV-related medications including hepatitis A and hepatitis B vaccines and hepatitis treatments. Part C focuses on early intervention and primary care and Part D on comprehensive care and research for children, youth, women, and families. Part F includes funds for AIDS Education and Training Centers (AETCs) that provide training and information to health care providers, including treatment protocols for the co-infected. Part F also includes a dental services reimbursement program and the Special Projects of National Significance (SPNS). HAB has funded hepatitis specific SPNS projects to evaluate the effectiveness of the interventions to deliver HCV treatment among HIV-positive populations, and share best practice models.

## **AIDS Drug Assistance Programs (ADAPs)**

As of June 2009, ADAPs, which are administered by the states, provided the following:

- HBV treatments: covered by 25 states; of those 21 report covering three or more HBV drugs;
- HCV treatments: covered by 31 states; of those 25 report covering three or more HCV drugs;
- Hepatitis A and hepatitis B vaccines: covered by 27 states.

For more information on hepatitis treatment and vaccine coverage, please go to [www.NASTAD.org](http://www.NASTAD.org) to view NASTAD's *2010 National ADAP Monitoring Report*.

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

The mission of the Indian Health Service (IHS) is to raise the health status of the American Indian and Alaska Native people to the highest level possible. IHS also works to improve the Indian health care workforce which operates within the Indian Health Service, Tribal or Urban (I/T/U) programs. The IHS Division of Epidemiology functions as the leading office for disease epidemiology, prevention and control activities for general infectious and chronic diseases as well as the following specific health conditions: cancer, tobacco use, breast and cervical cancer, vaccine-preventable diseases, sexually-transmitted diseases and disease outbreaks.

Historically, IHS operated a Viral Hepatitis and Liver Disease Section that was staffed collaboratively by IHS and CDC's Division of Viral Hepatitis. Its goals were to conduct surveillance and study the epidemiology of viral hepatitis among Native Americans in addition to integrating viral hepatitis services into existing programs that served Native Americans. IHS funded a Viral Hepatitis Integration Project (VHIP) through the Minority AIDS Initiative in FY2006 to integrate and enhance

viral hepatitis screening and surveillance into HIV and STD services.

## **National Institutes of Health (NIH)**

The National Institutes of Health (NIH) conducts medical and behavioral research in its own laboratories, supports research in other institutions, and helps to train and inform the medical research community. NIH is composed of 27 subdivisions covering the whole of biomedicine.

NIH convenes many committees and advisory groups, the most relevant to viral hepatitis are the National Commission on Digestive Diseases and the Digestive Diseases Interagency Coordinating Committee (DDICC).

NIH convened Consensus Development Conferences on the Management of Hepatitis B in 2008 and on the Management of Hepatitis C in 1997 and 2002, in addition to developing the Action Plan for Liver Disease Research in December 2004. The *Action Plan* outlined major research goals for liver disease research. Included in the plan are 17 viral hepatitis specific goals including gaining a better understanding of the hepatitis B virus life cycle and hepatitis C disease process; evaluating the role of therapy; and expanding vaccine research to prevent transmission and/or mitigate disease progression.

## **National Center for Complementary and Alternative Medicine (NCCAM)**

The mission of the National Center for Complementary and Alternative Medicine (NCCAM) is to explore complementary and alternative healing practices and to educate medical researchers on these practices. NCCAM also funds related laboratory and clinical trials to study the effectiveness of complementary and alternative medicine

(CAM) therapies with hepatitis C. In response to the NIH consensus statement *Management of Hepatitis C* in 1997 and ongoing research on tolerability of hepatitis C treatment, NCCAM issued the report *CAM and Hepatitis C: A Focus on Herbal Supplements* (December, 2009). The report finds that CAM treatment has not yet been proven effective for treating hepatitis C or its complications and that CAM cannot replace conventional medical therapy for hepatitis C.

### **National Institute of Allergy and Infectious Diseases (NIAID)**

The National Institute of Allergy and Infectious Diseases (NIAID) is responsible for conducting and supporting basic research on infectious, immunologic and allergic diseases. According to NIAID, it has made groundbreaking contributions to the field of hepatitis research. NIAID scientists discovered the hepatitis A and E viruses, developed one of the first diagnostic tests for hepatitis A and were instrumental in the creation of the hepatitis A vaccine.

The NIAID Hepatitis Research Program supports research on viral hepatitis. Research goals include preventing new infections and creating safe and effective vaccines to prevent infection and disease by understanding the development of the hepatitis virus and its effect on the immune system.

In 2000, NIAID funded six sites as part of its Hepatitis C Cooperative Research Centers to identify components of the virus and the body's immune response as well as individual genetic factors that have a crucial impact on recovery, disease progression and the influence of alcohol use that amplify HCV damage. The clinical research emphasized studies in special populations heavily affected by HCV, such as African Americans who respond poorly to standard therapies. The effort was part of collaboration with NIDDK, NIDA and the NIH Office of Minority Health and Research.

### **National Institute of Drug Abuse (NIDA)**

The National Institute of Drug Abuse (NIDA) identifies the health aspects of and prevention and treatment methods for drug abuse and addiction. Injection drug use is a major mode of transmission of HCV and injection drug users represent the majority of new HCV cases. NIDA has responded to the recommendations of the 2002 National Institutes of Health *Consensus on Hepatitis C* with treatment for active drug users with HCV on a case-by-case basis. NIDA has conducted research on the outcomes of those recommendations in relation to the barriers for treatment experienced by injection drug users.

### **National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)**

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports research on diabetes, digestive diseases, kidney and urologic diseases, and metabolic and endocrine disorders. The National Digestive Diseases Information Clearinghouse (NDDIC) is a service of NIDDK and produces a series of information on viral hepatitis.

The Liver Disease Research Branch within NIDDK, as a partner in the trans-NIH *Action Plan for Liver Disease Research*, conducts research to determine useful and reliable means of prevention, treatment and control of viral hepatitis. In addition, it has a long tradition of training fellows for a career in academic hepatology under its Hepatology Fellowship Program. The program has made major contributions to both basic and clinical research in the field of liver diseases.

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

The Substance Abuse and Mental Health Services Administration (SAMHSA) is charged with improving the quality and reliability of prevention, treatment and rehabilitative services in order to reduce illness, death, disability and cost to society resulting from substance abuse and mental illness. SAMSHA addresses hepatitis through its HIV/AIDS related programs by increasing access to preventive and treatment services for those at risk due to drug and substance abuse. It is also expanding the capacity of community-based organizations to provide substance abuse prevention, HIV/AIDS prevention and hepatitis C prevention services. While SAMHSA highlighted hepatitis in its *Strategic Plan* for 2006 – 2011, it does not mention hepatitis in its most recent plan, *Leading Change: A Plan for SAMHSA's Roles and Actions 2011 – 2014*.

### **Center for Substance Abuse Prevention (CSAP)**

The Center for Substance Abuse Prevention (CSAP) within SAMHSA improves the accessibility and quality of services of substance abuse prevention services nationwide. While past and current funding and program activity is unknown, CSAP has a grant program within its Division of Community Programs around Substance Abuse, HIV & Hepatitis Prevention for Minority Populations and Reentry Populations in Communities of Color.

### **Center for Substance Abuse Treatment (CSAT)**

The Center for Substance Abuse Treatment (CSAT) within SAMHSA promotes the quality and availability of community-based substance abuse treatment services for individuals and families who need them. CSAT works with states and community-based groups to improve and expand existing substance abuse treatment

services under the Substance Abuse Prevention and Treatment Block Grant Program. CSAT also supports SAMHSA's free treatment referral service to link people with the community-based substance abuse services they need. In 2006, CSAT devoted one time funding for a hepatitis A and hepatitis B vaccination project for substance abuse treatment facilities. Not all states or facilities were eligible and no infrastructure funds were awarded.

# Department of Veterans Affairs (VA)

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The Department of Veterans Affairs (VA) provides federal benefits to over 25 million veterans and their families. Services provided include medical care, disability compensation or pensions, education and training, and research. The VA is the largest single source of health care services for persons with hepatitis C infection in the U.S.

## Veterans Health Administration (VHA)

The health programs under the VA are operated by the Veterans Health Administration (VHA). VHA is the nation's largest integrated health care system with an appropriation of more than \$47 billion, employs more than 239,000 staff at over 1,400 sites, including hospitals, clinics, nursing homes, domiciliaries, and Readjustment Counseling Centers in addition to providing graduate medical education and medical research.

### National Hepatitis C Program

In recognizing the disproportionate impact of hepatitis C among veterans, VHA operates a National Hepatitis C Program led by the Office of Clinical Public Health Programs, under the direction of the Public Health Strategic Health Care Group which includes the AIDS Information Center; Center for HIV Research Resources; Center for Quality Management in Public Health; Hepatitis C Resource Centers; HIV/ Hepatitis C Clinical Program Office; HIV/ Hepatitis C Prevention Program; HIV/ Hepatitis C Training/Education Program and the Smoke Free Program. The VHA Hepatitis C Program has used a comprehensive approach emphasizing clinical care and prevention through testing, counseling, research, and education. Beginning in 1998, the Under Secretary for Health outlined standards for

provider evaluation and testing for hepatitis C and conducted a nationwide surveillance activity testing over 26,000 veterans for hepatitis C in 1999. In January 1999, VHA established two Centers of Excellence in Hepatitis C located at the VA Medical Center Miami, FL, and the VA Medical Center, San Francisco, CA. In 2000, the Under Secretary for Health designated an additional \$20 million to be distributed to the 22 Veterans Integrated Service Networks (VISNs) for outreach, testing, counseling, and treating veterans with hepatitis C.

The program provides universal screening for risk of hepatitis C infection, testing and counseling for individuals at risk, education for patients and their families, and gives providers access to the best available information about hepatitis C. Further, the VA's hepatitis C program website is a source for both patients and providers to navigate services within the VA clinic system, track medical health records and find clinical trials. While not required by law, the VA maintains surveillance records at its clinics that depending on the individual clinic's discretion can be shared with public health agencies to incorporate into national and local surveillance. While not all veterans are eligible for care and this comprehensive care does not cover all the costs associated with long-term care of chronic hepatitis C and liver disease, many advocates look to the VA's hepatitis C program as a model of a national prevention and care program.

The VA issued its most recent directive (2007-022) on July 23, 2007 that defines the policies and programs relating to the VHA Hepatitis C Program through July 31, 2012. To view the directive and other VHA-specific policies, notifications and state of care on the program, please go to [www.hepatitis.va.gov](http://www.hepatitis.va.gov).

# Food and Drug Administration (FDA)

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The Food and Drug Administration (FDA) oversees the regulation of human and veterinary drugs, biological products, medical devices, the national food supply, cosmetics, products that emit radiation and most recently tobacco. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health. Most notably the FDA approves all diagnostics and therapies for their use that allows for drugs to be prescribed and used on public and private drug formularies and for sale over-the-counter commercially. The FDA is also responsible for recalling unsafe products, and monitoring abuse and fraud of off-label and non-approved products. You can find out more about hepatitis B and C approved treatments, including clinical trials and investigational drugs, at [www.FDA.gov](http://www.FDA.gov).

## **FDA Approval Process**

In the hepatitis pipeline of drug discovery and improvements, there are a number of phases that drugs must undergo to achieve approval by the FDA and thereby be available for use. The approval process is divided into: pre-clinical phase, Phase I, Phase II, Phase III which if successful leads to approval and Phase IV which deals with follow-up, retroactive studies, different treatment strategies and different populations on an approved drug. Each step of the way has to be approved by FDA. The cost of drug development is significant and the majority of drugs do not succeed to the next level let alone get approval. The time between the start of research to a drug's approval can take 8-15 years.

The pre-clinical phase is the basic research of novel drug therapy and need not occur if research is being done to alter an already existing drug. Initial development and testing tends to draw on academic literature and is done in a laboratory setting on live specimens and animals. Pre-clinical research is not conducted on humans. The pre-clinical phase takes on average 3-6 years and its cost is unknown. Phase I begins with small trials of limited dosing and duration on healthy humans who are usually not afflicted with the condition the drug is attempting to treat. This phase is primarily for testing the safety of the drug and its dosage. Phase I takes on average 1-2 years and can cost around \$100,000-\$1,000,000. Phase II allows for trials to test people who are afflicted and generally is a sample of over 100 to further test the drug's safety, dosage, duration and efficacy. Phase II takes on average 2-3 years and can cost around \$10-\$100 million. Phase III is similar to Phase II except that it can test over 1,000 people who are afflicted. Phase III takes on average 2-3 years and can cost around \$10 to \$500 million. Upon completion of Phase III, the FDA can approve the drug for its use and dosing for the general market. As mentioned, Phase IV deals with already approved drugs and is a way to streamline changes to an existing therapy for FDA approval. For more information about the treatment pipeline and about FDA, please go to [www.treatmentactiongroup.org](http://www.treatmentactiongroup.org).

## CDC Foundation

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Established by Congress, the CDC Foundation began operations in 1995 as an independent, non-profit to build partnerships with external non-Federal partners such as foundations and corporations. As a non-profit, CDC Foundation can receive private funds and work autonomously from certain restrictions that regulate the work of CDC.

### Viral Hepatitis Action Coalition (VHAC)

Beginning in 2009 with support from pharmaceutical and diagnostic partners, and ongoing community input, CDC Foundation created the Viral Hepatitis Action Coalition (VHAC) as a public-private venture to accelerate CDC-initiated projects designed to improve prevention and control of viral hepatitis. The proposed initial projects focus on the following:

- Increasing public awareness through a national education campaign;
- Improving HCV screening through evaluation of a population-based HCV screening;
- Improving HCV screening through implementation of rapid-HCV tests in sites to identify best practices;
- Developing assays to identify early HCV infection;
- Assembling evidence to update CDC's *Recommendations for Prevention and Control of Hepatitis C Virus (HCV)*; and
- Improving surveillance through the first comprehensive U.S. longitudinal observational cohort of 15,000 or more patients with chronic viral hepatitis known as the Chronic Hepatitis C and B Cohort Study (CHeCS).

# Institute of Medicine

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The Institute of Medicine (IOM) is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers. The National Academy of Sciences, along with the National Academy of Engineering, the National Research Council and the IOM collectively make up the “National Academies.”

Beginning in 2008, the Division of Viral Hepatitis, the Division of Cancer Prevention and Control, the Department of Health and Human Services Office of Minority Health, the Department of Veterans Affairs and the National Viral Hepatitis Roundtable commissioned the IOM for a report on viral hepatitis. Specifically, IOM was charged with developing evidence-based recommendations for the federal government to improve its response to viral hepatitis, highlight issues that warrant further investigations and identify opportunities for collaboration between the private and public sector. The IOM report, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C* (2010) found that the public health response to the hepatitis epidemics needs to be significantly ramped up. The report found that the general public, providers, those at-risk and/or living with chronic infection, and policymakers do not know about viral hepatitis. The report issued 22 recommendations, most of which would directly impact state and local health departments.

# Legislation

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To develop a public health response to viral hepatitis in the U.S., bills have been introduced in a number of Congresses. Thus far no action has been taken on them. Highlighted below are the most relevant pieces of legislation. To look up Congressional legislation including viral hepatitis-specific bills, please go to [www.thomas.gov](http://www.thomas.gov).

## **Viral Hepatitis and Liver Cancer Prevention and Control Act**

In an effort to combine past hepatitis B and C bills to forge a comprehensive viral hepatitis prevention, education, research and medical management referral program, Representatives Mike Honda (D-CA) and Charlie Dent (R-PA), and Senator John Kerry (D-MA), authored the Viral Hepatitis and Liver Cancer Prevention and Control Act. In addition to amending the Public Health Service Act to improve hepatitis services across the Department of Health and Human Services, the Act would expand the Substance Abuse and Mental Health Services Administration's (SAMHSA) authority to include hepatitis.

## **Supporting the goals and ideals of National Hepatitis Awareness Month and World Hepatitis Day Resolution**

Representatives Anh “Joseph” Cao (R-LA) and Mike Honda (D-CA), and Senator Dianne Feinstein, authored Congressional Resolutions to recognize the goals and ideals of World Hepatitis Day and National Hepatitis Awareness Month and to promote raising awareness of the risks and consequences of undiagnosed chronic hepatitis B and hepatitis C infections. Further it expresses support for a robust governmental and public health response to viral hepatitis domestically and globally.

## **Community AIDS and Hepatitis Prevention Act**

Representative Jose Serrano (D-NY) authored the Community AIDS and Hepatitis Prevention Act to ensure that no statute shall prohibit the use of federal funds to establish or carry out a program of distributing sterile syringes to reduce the transmission of blood borne pathogens, including the human immunodeficiency virus (HIV) and viral hepatitis. While the federal and District of Columbia funding bans on syringe exchange programs were lifted, Congress could still reinstate the funding ban in the absence of an expressed ban in statutory authority.

## **The Patient Protection and Affordable Care Act**

The Affordable Care Act became law in March 2010 and includes improvements in the health system to expand access to care for people living with viral hepatitis. The law ends discrimination based on health status that has been used to deny insurance to people with viral hepatitis. In 2014, access to coverage is increased through expansion of Medicaid up to 133 percent of the federal poverty level and availability of tax credits up to 400 percent of the poverty level for individuals and small groups to purchase insurance through state based insurance exchanges. In addition, many private insurance plans will be required to cover recommended preventive services like hepatitis A and B vaccine for at risk adults at no additional cost. In January 2011, Medicare will adopt a similar policy. The law also requires key investments in the health care workforce, a Prevention and Public Health Fund, Community Transformation Grants and for community health centers.

# Useful Links and Resources

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## ADMINISTRATIVE AGENCIES

### Federal Register

<http://www.gpo.gov/fdsys/>

### Cabinet Agencies

[www.whitehouse.gov/government/cabinet.html](http://www.whitehouse.gov/government/cabinet.html)

### Federal Grant Information

[www.grants.gov](http://www.grants.gov)

## HHS

### Department of Health and Human Services

[www.hhs.gov](http://www.hhs.gov)

### Office of Assistant Secretary for Health

[www.hhs.gov/ash/](http://www.hhs.gov/ash/)

### Office of the Surgeon General

<http://www.surgeongeneral.gov/index.html>

### Office of Minority Health

[www.omhrc.gov](http://www.omhrc.gov)

### National Vaccine Program Office

[www.hhs.gov/nvpo](http://www.hhs.gov/nvpo)

### Food and Drug Administration

[www.fda.gov](http://www.fda.gov)

### Health Reform Information

[www.healthcare.gov](http://www.healthcare.gov)

## AHRQ

### Agency for Healthcare Research and Quality

[www.ahrq.gov](http://www.ahrq.gov)

### U.S. Preventive Services Task Force

[www.ahrq.gov/clinic/uspstfix.htm](http://www.ahrq.gov/clinic/uspstfix.htm)

## CDC

### Centers for Disease Control and Prevention

[www.cdc.gov](http://www.cdc.gov)

### National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

[www.cdc.gov/nchhstp/](http://www.cdc.gov/nchhstp/)

### Division of STD Prevention

[www.cdc.gov/STD/](http://www.cdc.gov/STD/)

### Division of Viral Hepatitis

[www.cdc.gov/hepatitis/](http://www.cdc.gov/hepatitis/)

### National Immunization Program

<http://www.cdc.gov/vaccines/>

## CMS

### Center for Medicare and Medicaid Services

[www.cms.gov](http://www.cms.gov)

### Clinical Laboratory Improvements Amendments

[www.cms.gov/clia](http://www.cms.gov/clia)

## HRSA

### Health Resources and Services Administration

[www.hrsa.gov](http://www.hrsa.gov)

### Bureau of Primary Health Care

[www.bphc.hrsa.gov](http://www.bphc.hrsa.gov)

### HIV/AIDS Bureau

[www.hab.hrsa.gov](http://www.hab.hrsa.gov)

## IHS

### Indian Health Service

[www.ihs.gov](http://www.ihs.gov)

## NIH

### National Institutes of Health

[www.nih.gov](http://www.nih.gov)

### National Institute of Diabetes & Digestive & Kidney Diseases

[www.niddk.nih.gov](http://www.niddk.nih.gov)

### National Institute on Drug Abuse

[www.nida.nih.gov](http://www.nida.nih.gov)

### National Institute of Allergy and Infectious Disease

[www.niaid.nih.gov/default.htm](http://www.niaid.nih.gov/default.htm)

### National Center for Complimentary and Alternative Medicine

[www.nccam.nih.gov](http://www.nccam.nih.gov)

## **SAMHSA**

### **Substance Abuse and Mental Health Services Administration**

[www.samhsa.gov/](http://www.samhsa.gov/)

### **Center for Mental Health Services**

<http://www.samhsa.gov/about/cmhs.aspx>

### **Center for Substance Abuse Prevention**

<http://www.samhsa.gov/about/csap.aspx>

### **Center for Substance Abuse Treatment**

<http://www.samhsa.gov/about/csat.aspx>

## **VA**

### **Department of Veterans Affairs**

[www.va.gov](http://www.va.gov)

### **Public Health Strategic Health Care Group**

<http://www.publichealth.va.gov/about/pubhealth/index.asp>

### **National Hepatitis C Program**

[www.hepatitis.va.gov](http://www.hepatitis.va.gov)

## **NON-GOVERNMENTAL ORGANIZATIONS**

### **American Liver Foundation**

[www.liverfoundation.org](http://www.liverfoundation.org)

### **American Association for the Study of Liver Diseases**

[www.aasld.org](http://www.aasld.org)

### **Asian Liver Center, Stanford University**

<http://liver.stanford.edu/>

### **Association of Immunization Managers**

[www.immunizationmanagers.org](http://www.immunizationmanagers.org)

### **Center for the Study of Hepatitis C at Weill Medical College of Cornell University**

[www.hepccenter.org](http://www.hepccenter.org)

### **Harm Reduction Coalition**

[www.harmreduction.org](http://www.harmreduction.org)

### **Hepatitis A, B and C Prevention Programs**

[www.hepprograms.org](http://www.hepprograms.org)

### **Hepatitis B Foundation**

[www.hepb.org](http://www.hepb.org)

### **Hepatitis C Association**

[www.hepcassoc.org](http://www.hepcassoc.org)

### **Hepatitis C Caring Ambassadors Program**

[www.hepcchallenge.org](http://www.hepcchallenge.org)

### **Hepatitis C Support Project**

[www.hcvadvocate.org](http://www.hcvadvocate.org)

### **Hepatitis Education Project**

[www.hepeducation.org](http://www.hepeducation.org)

### **Hepatitis Foundation International**

[www.hepfi.org](http://www.hepfi.org)

### **Hepatitis Web Study**

[www.hepwebstudy.org](http://www.hepwebstudy.org)

### **Immunization Action Coalition**

[www.immunize.org](http://www.immunize.org)

### **Institute of Medicine**

[www.iom.edu](http://www.iom.edu)

### **Julia Spears Foundation**

[www.helpwithhepc.org](http://www.helpwithhepc.org)

### **Liver Health Today**

[www.liverhealthtoday.org](http://www.liverhealthtoday.org)

### **National AIDS Treatment Advocacy Project**

[www.natap.org](http://www.natap.org)

### **National Alliance of State & Territorial AIDS Directors**

[www.NASTAD.org](http://www.NASTAD.org)

### **National Association of Community Health Centers**

[www.nachc.org](http://www.nachc.org)

### **National Association of State Alcohol/Drug Abuse Directors**

[www.nasadad.org](http://www.nasadad.org)

### **National Coalition of STD Directors**

[www.ncsddc.org](http://www.ncsddc.org)

### **National Hepatitis C Advocacy Council**

[www.hepcnetwork.org](http://www.hepcnetwork.org)

### **National Viral Hepatitis Roundtable**

[www.nvhr.org](http://www.nvhr.org)

### **O.A.S.I.S. Clinic**

[www.oasisclinic.org](http://www.oasisclinic.org)

### **Trust for Americas Health**

[www.tfah.org](http://www.tfah.org)

### **Viral Hepatitis Action Coalition**

[www.cdcfoundation.org/vhac](http://www.cdcfoundation.org/vhac)

# Glossary

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<b>AASLD</b>	American Association for the Study of Liver Diseases	<b>IOM</b>	Institute of Medicine
<b>ACIP</b>	Advisory Committee on Immunization Practices	<b>NASTAD</b>	National Alliance of State & Territorial AIDS Directors
<b>AHRQ</b>	Agency for Healthcare Research and Quality	<b>NCCAM</b>	National Center for Complimentary and Alternative Medicine
<b>ASFR</b>	Office of the Assistant Secretary for Financial Resources	<b>NCHHSTP</b>	National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Prevention
<b>ASH</b>	Assistant Secretary for Health	<b>NCIRD</b>	National Center for Immunization and Respiratory Diseases
<b>AVHPC</b>	Adult Viral Hepatitis Prevention Coordinators	<b>NEDSS</b>	National Electronic Disease Surveillance System
<b>BPHC</b>	Bureau of Primary Health Care	<b>NETSS</b>	National Electronic Telecommunications System for Surveillance
<b>CAM</b>	Complementary Alternative Medicine	<b>NHANES</b>	National Health and Nutrition Examination Survey
<b>CAPAC</b>	Congressional Asian Pacific American Caucus	<b>NIAID</b>	National Institute of Allergy and Infectious Diseases
<b>CBC</b>	Congressional Black Caucus	<b>NIDA</b>	National Institute of Drug Abuse
<b>CDC</b>	Centers for Disease Control and Prevention	<b>NIDDK</b>	National Institute of Diabetes & Digestive & Kidney Diseases
<b>CHAC</b>	CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment	<b>NIH</b>	National Institutes of Health
<b>CHC</b>	Community Health Center	<b>NVAC</b>	National Vaccine Advisory Committee
<b>CHC</b>	Congressional Hispanic Caucus	<b>NVHR</b>	National Viral Hepatitis Roundtable
<b>CHIP</b>	Children's Health Insurance Program	<b>NVPO</b>	National Vaccine Program Office
<b>CLIA</b>	Clinical Laboratory Improvements Act	<b>OCIO</b>	Office of Consumer Information and Insurance Oversight
<b>CMS</b>	Centers for Medicare and Medicaid Services	<b>OGR</b>	Oversight and Government Reform Committee
<b>CR</b>	Continuing Resolution	<b>OHR</b>	Office of Health Reform
<b>DPC</b>	Domestic Policy Council	<b>OID</b>	Office of Infectious Diseases
<b>DVH</b>	Division of Viral Hepatitis	<b>OMB</b>	Office of Management and Budget
<b>EIP</b>	Emerging Infections Program	<b>OMH</b>	Office of Minority Health
<b>EOP</b>	Executive Office of the White House	<b>PACHA</b>	Presidential Advisory Council on HIV/AIDS
<b>FDA</b>	Food and Drug Administration	<b>PJ</b>	Professional Judgment (budgetary)
<b>FQHC</b>	Federally Qualified Health Center	<b>SAMHSA</b>	Substance Abuse and Mental Health Services Administration
<b>HAB</b>	HIV/AIDS Bureau	<b>SAPs</b>	Statements of Administration Policy
<b>HAV</b>	Hepatitis A virus	<b>TFAH</b>	Trust for America's Health
<b>HAP</b>	Hepatitis Appropriations Partnership	<b>USPHS</b>	US Public Health Service
<b>HBIG</b>	Hepatitis B immunoglobulin	<b>USPSTF</b>	US Preventive Services Task Force
<b>HBV</b>	Hepatitis B virus	<b>VA</b>	Department of Veterans Affairs
<b>HCC</b>	Hepatocellular Carcinoma	<b>VHA</b>	Veterans Health Administration
<b>HCV</b>	Hepatitis C virus	<b>VHAC</b>	Viral Hepatitis Action Coalition
<b>HHS</b>	Department of Health and Human Services	<b>VFC</b>	Vaccines for Children
<b>HIV</b>	Human Immunodeficiency Virus	<b>WHO</b>	World Health Organization
<b>HRSA</b>	Health Resources and Services Administration		
<b>IDU</b>	Injection-Drug User		
<b>IHS</b>	Indian Health Service		

# Addendum

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The following listing of key governmental personnel is current as of March 2011.

## ADMINISTRATION

### Melody Barnes

Director, Domestic Policy Council

### Nancy-Ann Min DeParle

Director, Office of Health Reform

### Jeffrey Crowley

Director, Office of National AIDS Policy

## OFFICE OF MANAGEMENT AND BUDGET

### Jack Lew

Director

### Barry Clendenin

Director, OMB Health Division

### Keith Fontenot

Branch Chief, OMB Health Financing Branch

### Marc Garufi

Branch Chief, OMB Public Health Branch

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Kathleen Sebelius

Secretary

### Dr. Howard Koh

Assistant Secretary for Health

### Dr. Ron Valdiserri

Deputy Assistant Secretary for Health for Infectious Diseases

### Dr. Regina Benjamin

Surgeon General

### Garth Graham

Deputy Assistant Secretary for Minority Health

### Bruce G. Gellin

Director, National Vaccine Program Office

### Jay Angoff

Director, Office of Consumer Information and Insurance Oversight

### Ellen Murray

Assistant Secretary, Office of the Assistant Secretary for Financial Resources

### Dr. Jeanne Lambrew

Director, HHS Office of Health Reform

## AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

### Dr. Carolyn Clancy

Director

### Dr. Bruce N. Calonge

Chair, U.S. Preventive Services Task Force (USPSTF):

## CENTERS FOR DISEASE CONTROL AND PREVENTION

### Dr. Thomas Frieden

Director

### Dr. Rima Khabbaz

Deputy Director, Office of Infectious Diseases

### Dr. Kevin Fenton

Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

### Dr. John Merman

Director, Division of HIV/AIDS Programs

### Dr. John Ward

Director, Division of Viral Hepatitis

### Dr. Ann Schuchat

Director, National Center for Immunization and Respiratory Diseases

### Dr. Lance Rodewald

Director, Immunization Services Division

### Tamara J. Kicera

Director, Office of Minority Health & Health Disparities

## CENTER FOR MEDICARE AND MEDICAID SERVICES

### Dr. Don Berwick

Administrator

### Jonathan Blum

Director, Medicare

### Cindy Mann

Director, Medicaid

### Dr. Richard Gilfillan

Acting Director, Center for Medicare and Medicaid Innovation

**HEALTH RESOURCES AND SERVICES  
ADMINISTRATION**

**Dr. Mary Wakefield**

Administrator

**Jim Macrae**

Associate Administrator, Bureau of Primary Health  
Care

**Dr. Deborah Parham Hopson**

Associate Administrator, HIV/AIDS Bureau

Acting Director, Office of Health Equity: Dr. Deborah  
Willis-Fillinger

**NATIONAL INSTITUTES OF HEALTH**

**Dr. Griffin P. Rodgers**

Acting Director, National Institute of Diabetes &  
Digestive & Kidney Diseases

**Dr. Nora D. Volkow**

Director, National Institute of Drug Abuse

**Dr. Anthony Fauci**

Director, National Institute of Allergy and Infectious  
Diseases

**Dr. Ruth L. Kirschstein**

Acting Director, National Center for Complimentary  
and Alternative Medicine

**SUBSTANCE ABUSE AND MENTAL HEALTH  
SERVICES ADMINISTRATION**

**Dr. Pam Hyde**

Administrator

**Dr. H. Westley Clark**

Director, Center for Substance Abuse Treatment

**Dennis O. Romero**

Acting Director, Center for Substance Abuse  
Prevention

**A. Kathryn Power**

Director, Center for Mental Health Services

**DEPARTMENT OF VETERAN AFFAIRS**

**Eric Shinseki**

Secretary

**Janet M. Durfee**

Chief Consultant, Public Health Strategic Healthcare  
Group

**Dr. Victoria Davey**

Chief Officer, Office of Public Health and  
Environmental Hazards

# Appendix

## The ABCs of Hepatitis

*Adapted from CDC's Hepatitis ABC Fact Sheet*

	<b>HEPATITIS A</b> is caused by the Hepatitis A virus (HAV)	<b>HEPATITIS B</b> is caused by the Hepatitis B virus (HBV)	<b>HEPATITIS C</b> is caused by the Hepatitis C virus (HCV)
<b>U.S. Statistics</b>	<ul style="list-style-type: none"> <li>Estimated 25,000 new infections in 2007</li> </ul>	<ul style="list-style-type: none"> <li>Estimated 43,000 new infections in 2007</li> <li>Estimated 1.2 million people with chronic HBV infection</li> </ul>	<ul style="list-style-type: none"> <li>Estimated 17,000 new infections in 2007</li> <li>Estimated 3.2 million people with chronic HCV infection</li> </ul>
<b>Routes of Transmission</b>	<p>Ingestion of fecal matter, even in microscopic amounts, from:</p> <ul style="list-style-type: none"> <li>Close person-to-person contact with an infected person</li> <li>Sexual contact with an infected person</li> <li>Ingestion of contaminated food or drinks</li> </ul>	<p>Contact with infectious blood, semen, and other body fluids, primarily through:</p> <ul style="list-style-type: none"> <li>Birth to an infected mother</li> <li>Sexual contact with an infected person</li> <li>Sharing of contaminated needles, syringes or other injection drug equipment</li> <li>Needlesticks or other sharp instrument injuries</li> </ul>	<p>Contact with blood of an infected person, primarily through:</p> <ul style="list-style-type: none"> <li>Sharing of contaminated needles, syringes, or other injection drug equipment</li> </ul> <p>Less commonly through:</p> <ul style="list-style-type: none"> <li>Sexual contact with an infected person</li> <li>Birth to an infected mother</li> <li>Needlestick or other sharp instrument injuries</li> </ul>
<b>Persons at Risk</b>	<ul style="list-style-type: none"> <li>Travelers to regions with intermediate or high rates of Hepatitis A</li> <li>Sex contacts of infected persons</li> <li>Household members or caregivers of infected persons</li> <li>Men who have sex with men</li> <li>Users of certain illegal drugs (injection and non-injection)</li> <li>Persons with clotting-factor disorders</li> </ul>	<ul style="list-style-type: none"> <li>Infants born to infected mothers</li> <li>Sex partners of infected persons or multiple sex partners</li> <li>Persons with a sexually transmitted disease (STD)</li> <li>Men who have sex with men</li> <li>Injection drug users</li> <li>Household contacts of infected persons</li> <li>Travelers to regions with intermediate or high rates of Hepatitis B</li> </ul>	<ul style="list-style-type: none"> <li>Current or former injection drug users</li> <li>Recipients of clotting factor concentrates before 1987</li> <li>Recipients of blood transfusions or donated organs before July 1992</li> <li>Long-term hemodialysis patients</li> <li>Persons with known exposures to HCV (e.g., healthcare workers after needlesticks, recipients of blood or organs from a donor who later tested positive for HCV)</li> <li>HIV-infected persons</li> <li>Infants born to infected mothers</li> </ul>
<b>Incubation Period</b>	15 to 50 days (average: 28 days)	45 to 160 days (average: 120 days)	14 to 180 days (average: 45 days)

<b>Symptoms of Acute Infection</b>	<b>Symptoms of all types of viral hepatitis are similar and can include one or more of the following:</b> • Fever • Fatigue • Loss of appetite • Nausea • Vomiting • Abdominal pain • Gray-colored bowel movements • Joint pain • Jaundice		
<b>Likelihood of Symptomatic Acute infection</b>	<ul style="list-style-type: none"> <li>• &lt; 10% of children &lt; 6 years have jaundice</li> <li>• 40%–50% of children age 6–14 years have jaundice</li> <li>• 70%–80% of persons &gt; 14 years have jaundice</li> </ul>	<ul style="list-style-type: none"> <li>• &lt; 1% of infants &lt; 1 year develop symptoms</li> <li>• 5%–15% of children age 1–5 years develop symptoms</li> <li>• 30%–50% of persons &gt; 5 years develop symptoms</li> </ul> <p><b>Note:</b> Symptoms appear in 5%–15% of newly infected adults who are immunosuppressed</p>	<ul style="list-style-type: none"> <li>• 20%–30% of newly infected persons develop symptoms of acute disease</li> </ul>
<b>Potential for Chronic Infection</b>	None	<ul style="list-style-type: none"> <li>• Among unimmunized persons, chronic infection occurs in &gt;90% of infants, 25%–50% of children aged 1–5 years, and 6%–10% of older children and adults</li> </ul>	<ul style="list-style-type: none"> <li>• 75%–85% of newly infected persons develop chronic infection</li> <li>• 15%–25% of newly infected persons clear the virus</li> </ul>
<b>Severity</b>	Most persons with acute disease recover with no lasting liver damage; rarely fatal	<ul style="list-style-type: none"> <li>• Most persons with acute disease recover with no lasting liver damage; acute illness is rarely fatal</li> <li>• 15%–25% of chronically infected persons develop chronic liver disease, including cirrhosis, liver failure, or liver cancer</li> <li>• Estimated 3,000 persons in the United States die from HBV-related illness per year</li> </ul>	<ul style="list-style-type: none"> <li>• Acute illness is uncommon. Those who do develop acute illness recover with no lasting liver damage.</li> <li>• 60%–70% of chronically infected persons develop chronic liver disease</li> <li>• 5%–20% develop cirrhosis over a period of 20–30 years</li> <li>• 1%–5% will die from cirrhosis or liver cancer</li> <li>• Estimated 12,000 persons in the United States die from HCV-related illness per year</li> </ul>
<b>Serologic Tests for Acute Infection</b>	<ul style="list-style-type: none"> <li>• IgM anti-HAV</li> </ul>	<ul style="list-style-type: none"> <li>• HBsAg in acute and chronic infection</li> <li>• IgM anti-HBc is positive in acute infection only</li> </ul>	<ul style="list-style-type: none"> <li>• No serologic marker for acute infection</li> </ul>





The White House  
Washington

May 19, 2010

I send warm greetings to all those observing World Hepatitis Day.

Millions of Americans are affected by viral hepatitis, and too many do not know they are infected. As a leading cause of liver cancer and related complications, viral hepatitis presents a major public health challenge at home and abroad. We must work together to raise awareness, increase access to services, improve preventive care, and end the silence surrounding this life-threatening illness so at risk and infected individuals can receive the assistance they need.

Across the United States, countless health care professionals, researchers, and advocates are working to achieve these goals, and our Nation's future is more hopeful because of their dedication. Their tireless efforts are bringing us closer to the day when words like "incurable" are no longer a part of our vocabulary.

On World Hepatitis Day, we renew our support for people living with hepatitis and their loved ones, and for those who are working to improve treatment and prevention. I wish you all the best as you join together to take action against this terrible disease.

