



Dear Chairmen Kennedy and Waxman:

The viral hepatitis community has worked together over the past several months to put forth recommendations at the federal level that focus on the prevention of viral hepatitis and improving treatment and care for those at risk of, or infected with, viral hepatitis. Hepatitis B, hepatitis C, HIV/AIDS, public health, and pharmaceutical and diagnostic stakeholders and advocacy organizations came together to develop core principles for ensuring adequate prevention of and coverage for viral hepatitis for your incorporation as you consider health reform. The *Chronic Viral Hepatitis and Health Care Reform* and the *Chronic Viral Hepatitis Prevention Principles* statements are the product of the work of this committed group of volunteers. They contain crucial recommendations for addressing the unmet needs of patients at risk of infection with or are currently infected with hepatitis B and C.

It is estimated that 5.4 million Americans are chronically infected with either hepatitis B or hepatitis C viruses, conditions that remain a leading cause of liver disease, cirrhosis, liver cancer and failure, liver transplantation and death. In fact, these chronic infections kill up to 15,000 Americans each year. In 2007 alone, the CDC estimates that 43,000 Americans were newly infected with hepatitis B and 17,000 with hepatitis C. At least 10 percent of people living with HIV/AIDS are also infected with hepatitis B and at least 25 percent with hepatitis C; liver disease caused by chronic viral hepatitis is now the most common cause of non-AIDS deaths of Americans living with HIV/AIDS. Unfortunately, it is believed that these estimates of acute and chronic hepatitis B and C are just the tip of the iceberg. Over half of those infected are unaware of their status. Alarming, it is estimated that the baby boomer population currently accounts for two out of every three cases of chronic hepatitis C. As this population continues to age, the consequences of undiagnosed infection will exact a heavy toll on the lives of this population and on the nation's private and publicly funded health care systems. It is estimated that this epidemic will impose billions of dollars in increased costs to private insurers and public systems of health care such as Medicare and Medicaid in addition to billions lost due to decreased productivity for the millions suffering from chronic hepatitis B and C.

The medical costs associated with care for viral hepatitis include:

- Screening blood test for hepatitis B: **\$8**.
- Hepatitis B vaccination: **\$60** for each of 3 vaccinations.
- Hepatitis B immune globulin for postexposure prevention: **\$400**.
- HBV treatment: **\$2,000 - \$16,000** per year.
- Screening blood test for hepatitis C: **\$8**.
- HCV treatment: **\$15,000 - \$25,000**, about 55% are cured.

The relative scarcity of access to these basic interventions, however, leads to enormous costs:

- End stage liver disease: **\$30,980 - \$110,576** per hospital admission.
- Liver transplantation: **\$314,000** (uncomplicated cases).
- HBV infections result in an estimated \$658 million in medical costs and lost wages annually.

- Without intervention, the HCV epidemic is expected to result in **3.1 million years of life lost** over the next decade. The projected direct and indirect costs of the current HCV epidemic, if left unchecked, will be over **\$85 billion for the years 2010 through 2019**.
- HCV-related deaths and long term complications are projected to increase dramatically by the year 2020 including increases in liver failure by 106 percent, liver cancer by 81 percent, and liver-related deaths by 180 percent.

National Viral Hepatitis Roundtable's Chronic Viral Hepatitis and Health Care Reform and Chronic Viral Hepatitis Prevention Principles

Please consider the following summary of the two principles statements below. The current efforts to reform the US health care delivery system offers important opportunities for addressing unmet needs and reducing the economic and social costs associated with untreated or undertreated viral hepatitis. It must provide expanded access to high-quality and comprehensive health care, guarantee access to affordable health care, especially for the chronically ill, address ongoing health disparities, and require accountability and continued investment in innovation, prevention and wellness care.

Two proposals currently under consideration could have immediate impact for people with viral hepatitis:

1. Expanding Medicaid for **all** low-income people, including childless adults, by eliminating current requirements that tie Medicaid to disability status would give at least half of all people living with viral hepatitis who are currently uninsured immediate access to health care through Medicaid.
2. Including a strong public plan option would help provide affordable access to comprehensive care for people living with viral hepatitis – at least 30 percent of whom are currently uninsured. This would offer a national standard for coverage and greater dependability, consistency and security for people with hepatitis than private plans, which can charge higher prices and/or close, merge or change benefits at will.

Specific elements in any health reform proposal to address the unmet needs of persons with viral hepatitis **MUST** include:

1. **Access to Comprehensive Prevention Services:** These include hepatitis A and B immunization, Hepatitis B and C screening programs, counseling to encourage individual behavior change, use of universal precautions in health care settings, safety standards for foods, water, waste disposal, and health education including patient education.
2. **Chronic Hepatitis B and C Testing:** At least two out of three patients with chronic viral hepatitis infection remain undiagnosed because of testing barriers. All individuals at risk should be tested.
3. **Hepatitis Vaccination:** Safe and effective vaccines exist to prevent hepatitis A and hepatitis B. All individuals considered to have at least one risk factor as designated by ACIP should be offered the vaccine. Persons with chronic viral hepatitis should be vaccinated for other vaccine-preventable hepatitis viruses to prevent additional liver infections. Persons with HIV/AIDS should be vaccinated against hepatitis A and B to prevent additional liver infections.
4. **Patient Education:** One of the primary obstacles to achieving successful chronic viral hepatitis treatment outcomes is lack of patient education. Patients are often anxious to initiate treatment without having a real understanding of the disease or treatment involved and lack guidance in the management of their chronic infection.

5. **Provider Education:** One of the major factors contributing to missed diagnoses of chronic viral hepatitis is the lack of health care provider awareness and education. Education would increase routine screening and testing of patients which should be offered independent of perceived risk factors, and support implementation of universal evidence-based management guidelines.
6. **Medical Care Services:** All patients with chronic viral hepatitis should be considered as candidates for therapy. No arbitrary exclusionary qualifications (e.g., race, ethnicity, gender, language, insurance status, active substance use, homelessness) should be allowed to substitute for the judgment of patients and their health care providers. These services must include primary medical care and access to specialty care.
7. **Mental Health and Substance Abuse Care:** Due to the very high rates of comorbid mental health and substance abuse issues faced by these patients, especially those with HCV, access to comprehensive mental health and substance abuse services are essential to providing the standard of care.
8. **Laboratory and Diagnostics:** Lack of accessible hepatitis B and C testing contributes to missed diagnoses, misdiagnoses, missed treatment opportunities, and mismanagement of patients on treatment. Wider availability of and reimbursement for HBV and HCV virus testing to confirm chronic infection following a positive test is urgently needed. All available diagnostic and prognostic tests must be available and reimbursed at the point of care.
9. **Formulary:** In all phases of pretreatment, treatment and follow up, patients should have access to all drugs necessary for the successful treatment of HBV and HCV (and side-effects associated with HCV treatments) and related co-morbidities and co-infections.
10. **Chronic Viral Hepatitis Guidelines:** The Department of Health and Human Services (DHHS) and the American Association for the Study of Liver Diseases (AASLD) should coordinate a process similar to the panel that develops and regularly updates the *Guidelines for the Use of Antiretroviral Agents in HIV infected Adults and Adolescents*. Public and private health plans should be required to follow existing CDC guidelines for viral hepatitis screening; the CDC's Advisory Committee on Immunization Practices (ACIP) guidelines for viral hepatitis immunization of infants and adults; and the National Institutes of Health (NIH) guidelines for chronic viral hepatitis management and care.

We hope you will address these key issues as you construct health reform legislation.

This principles document was created by a committee convened by the National Viral Hepatitis Roundtable. The National Viral Hepatitis Roundtable is a coalition of public, private, and voluntary organizations dedicated to reducing the incidence of infection, morbidity, and mortality from viral hepatitis in the United States through strategic planning, leadership, coordination, advocacy, and research. For additional information, please contact Martha Saly, Director, at 707.480.0596 or at mbsaly@nvhr.org.

The following organizations endorse the National Viral Hepatitis Roundtable's *Chronic Viral Hepatitis and Health Care Reform* and *Chronic Viral Hepatitis Prevention Principles* statements. The full documents are available at <http://www.nvhr.org>.

Sincerely,

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Association of Asian Pacific Island Community Health Organizations (AAPCHO)

Community Access National Network (CANN), Washington, DC

National Alliance of State and Territorial AIDS Directors (NASTAD)

cc/ Representative Nancy Pelosi, Speaker, US House of Representatives; Senator Harry Reid, Senate Majority Leader; Members of the Senate Finance and HELP Committees and the House Commerce and Labor Committees; Nancy Ann DeParle, Director, White House Office for Health Reform; Peter Orszag, Director, Office of Management and Budget; Dr. Thomas Frieden, Director, Center for Disease Control and Prevention; Kathleen Sibelius, Secretary, Department of Health and Human Services