State of California—Health and Human Services Agency
California Department of Public Health

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Ms. Paula Staley
Office of Prevention through Healthcare
Office of the Associate Director for Policy
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Mailstop D–28
Atlanta, Georgia, 30333

Attn: Health Risk Assessment Guidance

Dear Ms. Staley:

Thank you for inviting input regarding the development of health risk assessment (HRA) guidance as required by Section 4103 of the Affordable Care Act for use during the annual wellness visit authorized for Medicare and in other settings. We are writing to call your attention to issues of interest to Medicare beneficiaries and other populations living with or at risk for chronic hepatitis B virus (HBV) and chronic hepatitis C virus (HCV), referred to here as “viral hepatitis”.

As you may know, there are approximately 4.6 million people living with chronic viral hepatitis in the United States, yet most of these individuals do not know they are infected. Without timely diagnosis and treatment, one in four individuals with chronic HBV will die of liver disease, liver failure, or liver cancer. HCV is the leading cause of liver transplantation in the United States. Individuals born during 1945 through 1964 have a higher prevalence of HCV than does the general population and are beginning to age into eligibility for Medicare. Without changes in current HCV diagnosis and treatment practices, total annual HCV-related Medicare costs are expected to increase six-fold over the next 20 years, from $5 billion to $30 billion. These costs and complications can be averted through early screening and detection.

1. Content and Design

A. Risk Assessment Domains

The standardized HRA should include several key domains, which are consistent with current Medicare regulations as defined in 42 Code of Federal Regulations Section 410.16: medical, social, and family history. Within each of these domains, there are specific elements that, if included, could inform screening Medicare beneficiaries for chronic viral hepatitis and avert preventable complications from undetected chronic liver disease.

Specifically, to enable clinicians to implement Centers for Disease Control and Prevention (CDC) hepatitis C screening guidelines, we would advocate that the assessment of *"past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments"* include the question, "Did you ever receive a blood transfusion prior to 1992?", which would signal the need for HCV screening. Similarly, we would advocate that the assessment of "s*ocial history" -- "history of alcohol, tobacco, and illicit drug use"* -- include the question, "Have you or any of your partners ever injected drugs?", which would indicate the need for HBV and HCV screening for individuals with a history of injection drug use.

To implement CDC hepatitis B screening guidelines, we would advocate that the assessment of *"family history, including a review of medical events in the beneficiary's family, including diseases that may be hereditary or place the individual at risk"* include a question as to the patient's "country of birth", which would indicate HBV screening for patients born in countries where two percent or more of the population has chronic HBV infection.

To implement CDC hepatitis B screening guidelines, we would also advocate that the *"review of the beneficiary's medical and social history with attention to modifiable risk factors for disease"* include an assessment of sexual health, which would indicate HBV screening for men who have sex with men. The CDC 2010 STD treatment guidelines provide the following guidance for assessing sexual health and risk behaviors.

The Five P's: Partners, Prevention of Pregnancy, Protection from STDs, Practices, and Past History of STDs
1. Partners • "Do you have sex with men, women, or both?" • "In the past 2 months, how many partners have you had sex with?" • "In the past 12 months, how many partners have you had sex with?" • "Is it possible that any of your sex partners in the past 12 months had sex with someone else while they were still in a sexual relationship with you?" 2. Prevention of pregnancy • "What are you doing to prevent pregnancy?" 3. Protection from STDs • "What do you do to protect yourself from STDs and HIV?" 4. Practices • "To understand your risks for STDs, I need to understand the kind of sex you have had recently." • "Have you had vaginal sex, meaning 'penis in vagina sex'?" If yes, "Do you use condoms: never, sometimes, or always?" • "Have you had anal sex, meaning 'penis in rectum/anus sex'?" If yes, "Do you use condoms: never, sometimes, or always?" • "Have you had oral sex, meaning 'mouth on penis/vagina'?" For condom answers: • If "never:" "Why don't you use condoms?" • If "sometimes:" "In what situations (or with whom) do you not use condoms?" 5. Past history of STDs • "Have you ever had an STD?" • "Have any of your partners had an STD?" *Additional questions to identify HIV and viral hepatitis risk include:* • *"Have you or any of your partners ever injected drugs?" (emphasis added)* • "Have any of your partners exchanged money or drugs for sex?" • "Is there anything else about your sexual practices that I need to know about?"

Finally, to implement the Advisory Committee on Immunization Practices' adult immunization guidelines, we also recommend assessing the patient's vaccination history to identify whether vaccination against hepatitis A or HBV infection is indicated.

B. Literacy and Cultural Appropriateness

In many cultures, discussing sexual health, sexual behavior, disease, and drug-using behaviors is taboo. In addition, people with a history of illicit drug use, and lesbian, gay, bisexual, and transgender individuals often experience discrimination from healthcare professionals in clinical settings. Foreign-born individuals also may fear discrimination, may not feel comfortable disclosing information as to their country of birth, and face language access barriers. In California, a task force comprising more than 40 primary care clinicians, infectious disease physicians, human immunodeficiency virus (HIV) care providers, and liver specialists, reported that primary care clinicians often do not have time to ask their patients extensive risk assessment questions.

For these reasons, one option for administering risk assessments is to organize the HRA to include statements such as “If any of the above statements apply to you, check yes”. This enables patients at risk for viral hepatitis to be flagged for screening without them having to disclose which specific risk behavior or demographic characteristic indicated the need for screening. Enclosed for your reference, you will find a sample patient-administered risk assessment developed by the California Viral Hepatitis Clinical Task Force, which was developed with these considerations in mind.

It is important that the HRA be translated into the languages most commonly spoken in the geographic area where a specific provider delivers care and be made available to patients who are members of high-risk ethnic populations (e.g., Asian and Pacific Islanders). Based upon prevalence data for HBV infection, translated languages should initially include Chinese, Korean, Vietnamese, Cambodian, Lao, and Hmong. HCV prevalence data suggest the need for translating materials into Vietnamese, Russian, and Spanish; however, this will vary by region. The HRA should also be culturally appropriate for these groups.

In order to facilitate shared decision-making between the patient and a provider, the HRA should inform a summary, delivered either in-person or by computer, of which screenings and vaccinations are recommended, based on the patient information provided. Patients can use this summary, along with information on the risks and benefits of the recommended screening and vaccination, to decide which services to utilize during their visit.

2. Mode of administration

The HRA should be accessible to patients via multiple venues. This includes kiosks and paper forms completed by the patient in physician waiting rooms. Additionally, online versions can be made available through health-related non-profit websites. A simple, downloadable, paper and electronic version of the HRA needs to be accessible at venues which are frequented by high-risk individuals, including methadone clinics and other drug treatment programs, syringe services programs, STD clinics and family planning sites, prisons and jails, community-based organizations that serve high-risk populations, primary care clinics, and federally qualified health centers. The HRA should include a section that is modifiable, so that organizations using the form can add their logos and other administrative information to the form for internal use.

Whether the HRA is completed electronically or on paper, healthcare organizations that use an electronic health record (EHR) should enter information from the HRA into the EHR as soon as the assessment is completed. Where possible, information from the

HRA can inform automated prompts for appropriate screenings for patients with risk factors identified through the HRA.

3. Primary care office capacity

Training on cultural, linguistic, and logistical considerations for administering HRAs and using information collected through these assessments in clinical practice can be conducted online or in-person, through networks of professional and healthcare organizations. There are also a number of potential community linkages to assist with prevention planning and follow-up care. National organizations focusing on education and linkages for people living with viral hepatitis include: the Asian Liver Center at Stanford University; Caring Ambassadors; Hepatitis B Foundation; Hepatitis C Support Project; Hepatitis Treatment Research and Education Center; and the National Viral Hepatitis Roundtable; among others.

The CDC National HIV and STD Testing Resources website (www.hivtest.org) is a potential venue for providing service referrals for hepatitis A and HBV vaccination; HBV and HCV testing; education and support groups; and linkages to care. Patients could easily be redirected to the site through a dummy URL, such as www.heptest.org, to access viral hepatitis-related service referrals.

4. Evaluation and quality assurance

In order to maintain the HRA up to date, CDC should periodically (every two to three years) issue an updated standard HRA, which incorporates recently released CDC screening and vaccination guidelines for various patient populations and risk groups.

Thank you very much for considering this input. Please do not hesitate to contact me at (510) 620-3177 with any questions or comments you may have.

Sincerely,

Gail Bolan MD

Gail Bolan, M.D., Chief
STD Control Branch

Enclosure: Hepatitis B and C: Patient Self-Administered Risk Assessment
Also, please see note on next page.

The following organizations have also endorsed this letter:

Caring Ambassadors Program
National Task Force on Hepatitis B: Focus on Asian Americans and Pacific Islanders
National Viral Hepatitis Roundtable
Association of Asian Pacific Community Health Organizations
California Hepatitis Alliance
Center for Health Improvement