April 1, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Comments on the Proposed Decision Memo for Screening for Hepatitis C Virus (HCV) in Adults (CAG-00436N)

Dear Administrator Tavenner:

We appreciate the opportunity to comment on the proposed National Coverage Determination (NCD) decision of the Centers for Medicare & Medicaid Services (CMS) regarding coverage of screening for hepatitis C virus (HCV) in adults (CAG-00436N). We are writing on behalf of the National Viral Hepatitis Roundtable (NVHR), a coalition of more than 250 organizations dedicated to the eradication of chronic viral hepatitis, and the Center for Health Law and Policy Innovation (CHLPI) of Harvard Law School.

We strongly support the decision for Medicare to cover HCV screenings for all high-risk adults and a single screening test for each adult born between 1945 and 1965.

This NCD is consistent with recommendations of both the Centers for Disease Control (CDC) and the United States Preventive Services Task Force (USPSTF). We thank you for your commitment to ending the HCV epidemic and for taking this important step towards helping to identify the estimated 75% of individuals who are living with HCV but do not realize they are infected.

However, we are concerned about the definition of “high risk” as it refers to “illicit” injection drug use. The word “illicit” has a negative connotation and stigma attached to it, which could deter some patients from obtaining screening. Because the use of the term “illicit” does not serve any substantive purpose in the context of the NCD, we join with other groups in recommending that the relevant language regarding “high-risk” be changed to “people who inject drugs, or people who have a previous history of injecting drugs,” and “people who have continued to inject drugs since the prior negative screening test.” Defining “high-risk” without using the term “illicit” would be in line with more recent testing and treatment guidelines, such as those published by the Centers for Disease Control (CDC), as
well as the American Association for the Study of Liver Disease (AASLD) and The Infectious Disease Society of America (IDSA). ¹

To ensure the maximum effectiveness of this coverage, we also urge CMS to include information about this HCV screening benefit in the “Welcome to Medicare” packet received by all new enrollees. This could be particularly effective given that many baby-boomers are not yet Medicare-eligible but will become new Medicare enrollees in the next few years.

In addition, we interpret this NCD to encompass HCV tests that have received CLIA waivers, including the HCV rapid test, and request that CMS provide clarity as to this point.

**We support the important role primary care practitioners can play in screening individuals and providing appropriate follow-up care and treatment for HCV.**

We agree with CMS regarding the important role of primary care practitioners in screening individuals for HCV and coordinating appropriate follow-up care and treatment. From the moment screening takes place, there are needs for case management and care coordination for individuals who have been diagnosed with HCV. Such needs include for instance, managing the logistics of helping patients access specialty care services and/or managing necessary follow-up work-ups, such as HCV RNA testing and ultrasounds. Much of this management may be performed or facilitated by primary care providers. In addition, new research also demonstrates that with appropriate support, primary care providers can successfully provide anti-viral treatment for some individuals, resulting in cure rates that are comparable to treatments provided in a specialist setting.¹

As such, the role of the primary care physician in both the initial screening process and in necessary follow up care and treatment can be a critical one. This role is underscored by numerous health reform provisions that support coordinated primary care models for individuals living with chronic illnesses, including those receiving care from Accountable Care Organizations and/or through new initiatives that specifically target dual-eligibles with complex medical conditions. For these reasons, we agree that HCV screening would ideally be done by primary care providers.

**However, given the scope of the epidemic and the urgent need to identify individuals in the Medicare population whose HCV-related liver disease requires immediate treatment to prevent development of complications and/or death, we strongly urge CMS to expand this coverage to screenings performed by practitioners in settings outside of primary care.**

This NCD comes at a critical juncture in the course of the HCV epidemic. New research has led to the development of medication regimens that can effectively cure HCV infection (produce sustained

virologic response (SVR)) in the majority of individuals, and additional all-oral regimens are expected to be approved in October of this year. At the same time, the majority of HCV-infected individuals in the baby-boomer cohort are unaware that they have developed chronic disease, and many of those individuals may not realize that they are also in danger from the development of cirrhosis or other complications caused by HCV. For instance, in 2007, over 15,000 people died from HCV related causes, more than the number of deaths cause by HIV/AIDS. New research suggests that even this high number may be an underestimate. Moreover, other models estimate that if left untreated, between 2030 and 2035, there will be a peak of “38,600 incident cases of end-stage liver disease; 3200 referrals for [liver] transplant; and 36,100 deaths.”

Only treatment can effectively prevent the development of potentially life-threatening liver disease and damage caused by HCV. Because most individuals in the baby-boomer generation have been living with HCV for 20 to 40 years, they cannot afford to wait any longer before being identified and linked to cure. Analysis of death records between 1992 and 2009 by the Massachusetts Department of Public Health for example, found that of those who died of HCV related causes in Massachusetts, 73% died within five years of diagnoses. These findings underscore the emergent need to diagnose infected individuals and get them into treatment.

The limitation of coverage to screenings recommended by primary care practitioners in a primary care setting is inconsistent with Medicare regulations permitting the provision of preventive health assessments and care plan development in a broader array of settings.

We support the recommendation that the determination of whether an individual is “high-risk” for purposes of HCV screening ideally be made in conjunction with an assessment of the patient’s history, “typically part of an annual wellness visit and considered in the development of a comprehensive prevention plan” (p. 3). To this end, Medicare covers both an Initial Primary Preventive Exam (IPPE) and/or subsequent annual wellness visits (AWV) that include the creation of personalized prevention plan services (PPPS), and a health risk assessment (HRA). However, neither the IPPE or AWV are limited to performance by primary care providers or in primary care settings. Therefore, if the NCD is adopted as written, it is possible that a medical provider (or team of providers) could perform an enrollee’s IPPE or AWV but not have authorization to recommend an HCV screening. This could necessitate a separate appointment with a different provider for just that purpose, thwarting the stated goals of promoting care coordination and efficiency. By extending coverage of screening to a broader array of providers and settings, CMS could ensure that HCV screenings may be a part of these preventive service visits.

Limiting coverage to HCV screenings performed by a primary care practitioner in a primary care setting will miss key opportunities to screen baby-boomers and other at-risk individuals who access the health care system through other settings.

For example, a recent study published in the Morbidity and Mortality Weekly Report (MMWR) examined locations and reasons for initial testing for HCV infection among patients who received care at four different integrated health-care systems in the United States. This study found that while 60.4% of
patients were tested by a physician, one-third of the patients were tested in a location other than a physician’s office. As a result, the authors suggest that increasing testing in both physician’s offices and alternative locations could be important. Another study which looked specifically at HCV testing and linkage to care in minority populations found that 51.6% of non-Hispanic blacks, 52.7% of Hispanics, and 62.8% of American Indian/Alaska natives were tested in a setting other than in a physician’s office. As these data show, limiting coverage of HCV screening to primary care may miss infected individuals either in the baby-boomer cohort or among high-risk groups, particularly those in minority populations that may be at most risk for developing acute infection (American Indian/Alaska natives) and/or for dying from HCV-related illness (non-Hispanic blacks).

Recent research has also demonstrated the efficacy of HCV screenings of the baby-boomer cohort in emergency rooms, a location explicitly excluded for coverage by this NCD. For instance, HCV screening of baby-boomers in emergency departments has been successfully implemented at both the University of Alabama at Birmingham and at Texas Memorial Hermann Medical Center in Houston: 1259 individuals were screened at Alabama, with 11.1% testing positive for HCV antibodies; and 1421 baby boomers were tested at Memorial Hermann, with 9.9% testing positive.

In addition, it is well documented that injection drug users (IDUs), one of the groups most at risk for HCV, are less likely to seek health services in a primary care setting and more likely to enter the healthcare system through the emergency room or visits to an infectious disease provider. Reluctance to access primary care can also be driven by experiences of stigma, and therefore allowing providers with whom IDUs have established trusting relationships (such as infectious disease providers) to perform HCV screenings may be more likely to identify and diagnose all those at risk.

Finally, anecdotal evidence also suggests that some seniors have their main interactions with the healthcare system through their gastroenterologist, who they see for colonoscopies. Moreover, both infectious disease doctors and gastroenterologists often have particular expertise and experience in diagnoses, management and treatment of HCV, making both practices ideal settings for screening.

Limiting coverage to HCV screenings performed by a primary care practitioner in a primary care setting will hamper existing state and local provider-level efforts to screen and identify all baby-boomers living with HCV.

In light of recommendations by the CDC and USPSTF to implement non-risk based HCV screening among all baby-boomers, there are efforts underway in various state legislatures to pass laws that require medical providers to offer an HCV test to all individuals in the baby-boomer cohort. While some of these laws focus exclusively on primary care practitioners, others, such as the one most-recently passed in New York, require that both primary care providers and inpatient hospital settings offer HCV screening. This NCD would explicitly prohibit coverage of any screenings in the latter setting, potentially interfering with these efforts.

In addition to state legislation, many medical institutions are responding to the epidemic by implementing HCV testing prompts through electronic health records (EHR). For example, Beth-Israel
Deaconess Medical Center (BID) in Massachusetts has been an emerging leader in the use of EHR to help screen and diagnose individuals with HCV, and has developed a specific prompt for HCV testing of the 1945 to 1965 birth cohort. This prompt is on the patient dashboard and is seen by a network of about 5,500 providers. In the seven months since implementing this prompt, HCV screening of baby-boomers at BID has increased from 400 tests per month to about 1,260 tests per month.

Yet administrators and providers at BID report that limiting Medicare coverage of HCV screening to primary care providers would be almost impossible to implement through their EHR system, largely because there would be no feasible means to limit the viewing of this prompt to only primary care providers. In the alternative, with such a large network of participating providers, they report that it would only increase confusion if attempts were made to limit testing to just primary care through education on utilization (i.e. without actually changing the system). BID is not alone in these efforts and such a limitation would likely have the same detrimental effect on other systems. These outcomes would be particularly senseless given that the goal of EHR systems is to ensure increased coordination among health care providers for a given patient. Using EHR, the enrollee’s primary care provider can easily see whether a patient has been screened for HCV and/or referred for additional follow-up if tested by a different provider within the system, and can assume facilitation of care coordination.

The secretary’s authority to authorize NCDs to designate “additional preventive services” is not limited to authorization of services performed only in a primary care setting.

CMS cites the “charge of the USPSTF” as the basis for its decision that referrals for HCV screening should be ordered by the primary care provider in a primary care setting. While the USPSTF does include in its mission a statement indicating that it makes recommendations for preventive services performed by primary care providers, the Secretary’s authority in this context is not so limited. Medicare covers a number of preventive services that are specifically defined by statute. The authority to add “additional preventive services” stems from the Medicare Improvements for Patients and Providers Act (MIPPA). This authority has never been limited either by the MIPPA or subsequently by the ACA, to designating preventive services that can only be provided by a primary care provider and/or in a primary care setting. Indeed, in two previous instances when the Secretary has added additional preventive services pursuant to this same authority and as recommended by the USPSTF, “Screening for the Human Immunodeficiency Virus (HIV) Infection,” (updated February 23, 2011), and “Counseling to Prevent Tobacco Use,” (implemented January 3, 2011), the services were not specifically limited to primary care.

CMS’s own analysis does not provide any data or studies to support its determination that these screenings must be done in a primary care setting.

Though there is no statutory or regulatory requirement that the Secretary limit HCV screening to primary care, there is also no analysis of data or research in the NCD that would justify why this service should be so limited. The CDC’s recommendations for screening both at-risk individuals and those in the baby-boomer generation, for example, are not limited to primary care. In addition, while the USPSTF
makes recommendations based on primary care populations, there is not an explicit requirement in the their recommendation that these screenings be performed by a primary care provider in a primary care setting. Nor is there a statutory requirement that services recommended by the USPSTF with an A or B grade rating be covered by insurers under only these circumstances.  

We thank you for considering our comments. We truly appreciate the efforts of CMS in initiating this NCD, and strongly support its goals of identifying individuals living with HCV and linking them to appropriate care and treatment. Medicare coverage of HCV screening for both at-risk adults and individuals in the baby-boomer cohort is a huge step forward towards ending the epidemic. Should you have any questions about these comments, or if we may be of any further assistance in this process, please contact Ryan Clary, Executive Director, NVHR at (415) 235-8593 or at rclary@nvhr.org, or Robert Greenwald, Executive Director and Clinical Professor of Law, Center for Health Law and Policy Innovation of Harvard Law School, at (617) 390-2584 or at rgreenwa@law.harvard.edu.

Sincerely,

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5 Regulations require that both the Initial Preventive Physical Exam (IPPE) and Annual Wellness Visits (AWVs) be performed by qualified health professionals, including physicians and/or other qualified non-physician practitioners. Physician in this context is defined by statute as a doctor of medicine or osteopathy, with no specification related to primary care as would be found in §1883(u)(6), §1833(x)(2)(A)(i)(I) or § 1833(x)(2)(A)(i)(II) of the Social Security Act. (See 42 CFR §§ 410.15-16).


See e.g. Cisneros GO1, Douaihy AB, Kirisci L. Access to Healthcare Among Injection Drug Users at a Needle Exchange Program in Pittsburgh, PA, J Addict Med. 2009 Jun; 3(2):89.


See e.g. 73 FR 69726 (Nov. 19, 2008); 75 FR 73170 (Nov. 29, 2010), and 42 CFR §410.64.


For instance, insurers may use “established techniques and the relevant evidence base” to implement “reasonable medical management techniques to determine the frequency, method, treatment, or setting” for a preventive service recommended by the USPSTF, ACIP, or HRSA to the extent not specified by those bodies. This regulation therefore implies that there is not a pre-established setting in which USPSTF guidelines must be implemented. (See 75 FR 41726 (Jul. 19, 2010), 41728-9; 45 CFR §147.130(a)(iv)(B)(4)(4)). Moreover, CMS has not provided any reference to a “relevant evidence base” with respect to its primary care restriction.