HIV+HEP

POLICY INSTITUTE

October 23, 2026

SUBMITTED ONLINE: https://www.cms.gov/medicare-coverage-database/view/ncacal-public-comments.aspx?ncaId=325

JoAnna Baldwin
Acting Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
Mailstop S3-02-01
7500 Security Boulevard
Baltimore MD 21244

Dear Ms. Baldwin:

On behalf of the **HIV+Hepatitis Policy Institute**, an organization advocating for quality and affordable healthcare for people and communities affected by HIV, viral hepatitis, and other serious and chronic health conditions, we thank you for the opportunity to comment on CMS's update of the National Coverage Determination (NCD) for hepatitis C screening. In June 2021, HIV+Hep, along with the National Viral Hepatitis Roundtable, Caring Ambassadors Program, NASTAD, and The AIDS Institute, formally requested this reconsideration [1], and we are grateful that CMS has initiated the process.

The current NCD was finalized in 2014 and reflects the treatment landscape, testing technology, and evidence of more than a decade ago. Since that time, curative direct-acting antivirals (DAAs) have become the standard of care, CDC and USPSTF have recommended universal adult screening, and new rapid, point-of-care and self-testing technologies have emerged. Telehealth, now used far more widely than in 2014, allows people screened in community and correctional settings to access treatment without a traditional in-person office visit. Together, these changes have transformed the potential for broad access by Medicare beneficiaries to screening and curative treatments.

The March 2020 USPSTF recommendation for universal screening of adults 18-79 is the foundation of the National Coverage Analysis. The current NCD, issued in 2014, only

addresses “high-risk” adults and those who were born between 1945 and 1965. Many years have passed since the USPSTF recommendation was updated, and CMS’s NCD must now follow. As you do this, we urge CMS to ensure expanded coverage is implemented in ways that benefit the greatest number of Medicare beneficiaries. Therefore, we urge CMS to (1) not limit screening to primary care settings; (2) allow for self- and home-based testing as they become available; and (3) not require documentation of risk to access repeat testing.

Hepatitis C and the Medicare population

Hepatitis C in Medicare is not primarily a disease of people aged over 65. An analysis of Medicare claims found that only 28 percent of beneficiaries with chronic hepatitis C qualified on the basis of age alone, while 63 percent qualified due to disability. They averaged 57 years of age, 14 years younger than other beneficiaries, and carried a much heavier burden of comorbidities [2].

Failure to screen and delayed screening fall hardest on Medicare and other public programs. Untreated infection progresses silently towards cirrhosis, liver cancer, and transplantation, and when it is found, people are more likely to have aged into Medicare or qualified through disability, with the costs of advanced liver disease falling heavily on Medicare, Medicaid, and correctional health systems. Yet Medicare is well positioned to turn a diagnosis into a cure, with the highest rate of viral clearance of any payer in CDC’s clearance cascade [3].

The evidence shows that broader screening is cost-effective. In the DETECT Hep C randomized trial in three hospital emergency departments, offering testing to every patient identified more infections than testing only those reporting risk factors [4]. Modeling based on the trial found that universal ED screening diagnosed and cured more infections and prevented more deaths than risk-based or no screening, and that no screening was more costly than universal screening [5].

Do not limit screening to primary care settings

The current NCD covers screening only when it is ordered by the beneficiary’s primary care provider in a primary care setting. **We urge CMS to cover screenings ordered or furnished by any Medicare-enrolled provider in any clinically appropriate setting**. This should include, at a minimum, safety-net settings such as federally qualified health centers and Ryan White, rural, and homeless health clinics; mobile vans and other street outreach settings; hospital inpatient, outpatient, and emergency departments; health department and sexual health clinics; syringe services and other harm reduction programs; pharmacies; correctional facilities and reentry programs; and community-based organizations. Retaining a setting restriction imposes an insurance barrier on beneficiaries who may face out-of-

pocket costs as well as providers who cannot count on payment, and prevents Medicare from screening the beneficiaries who are hardest to reach.

Non-traditional settings are key to reaching people most likely to have undiagnosed hepatitis C, including people who use drugs, people who are unhoused, and people who have been released from incarceration. Many are poorly connected or not at all connected to primary care or traditional health care, but are reached very effectively through emergency departments and trusted community-based organizations. This population is large and growing, with an estimated 3.7 million people who inject drugs in the United States in 2018, more than five times a previous estimate for 2011 [6]. Because hepatitis C is part of a syndemic with HIV and substance use, settings that address these conditions together are particularly efficient screening sites. One model estimated that from 2015 to 2019, injection drug use was associated with 120,000 overdose deaths, 17,000 new HIV infections, and 144,000 new hepatitis C infections [7]. Researchers have noted that U.S. payers generally do not cover HCV screening outside primary care, even though non-traditional settings successfully identify infections in high-prevalence vulnerable populations [8].

Hospital emergency departments are an important example of a non-traditional setting. Many people with undiagnosed HCV use emergency departments as their only regular point of contact with the health system. In the DETECT trial, offering testing to all emergency department patients found more infections than risk-based testing [4], and modeling based on the trial found universal screening cost-effective [5]. Emergency departments are also a clear example of a setting where providers may not have an ongoing relationship with a patient, yet which is a critical, cost-effective setting for diagnosis of HCV.

The evidence from community settings is equally strong. A systematic review and meta-analysis found that approaches that simplify testing, including opt-out screening, point-of-care antibody testing, and reflex RNA testing, significantly improved testing, and that integrated care and patient navigation improved treatment uptake [9]. In rural New Hampshire and Vermont, a community-designed testing program engaged people who inject drugs who had been poorly served by more traditional health care [10].

A setting-neutral NCD is also consistent with the CDC recommendation that anyone who requests hepatitis C testing should receive it, even if no risk is disclosed [11].

Telehealth is extending what screening can achieve outside the primary care setting

The wider availability of telehealth has changed hepatitis C care models in ways that make the NCD's setting restriction even harder to justify. Until recently, a positive result in a community setting usually meant a referral to a specialist, and many patients were lost to

follow-up at this stage. Innovative programs now can combine screening in community and street settings with treatment delivered remotely, so that a person can be tested, diagnosed, and started on curative treatment without ever stepping into a specialist's office.

Berkshire Harm Reduction in Massachusetts has fully integrated HCV testing and treatment into its harm reduction services using telehealth, a model the state's Department of Public Health highlights in its hepatitis C best practices toolkit [12]. Clients are screened at the syringe services program, positive antibody tests lead to RNA confirmatory testing, pre-treatment labs are drawn onsite, the prescriber sees the client by a telehealth visit including an assessment for PrEP, and a specialty pharmacy delivers the medication to the program, with a navigator supporting adherence and follow-up.

In a randomized trial in rural northern New England, Baystate Health and Tufts University found that mobile telemedicine at syringe service sites was associated with higher rates of treatment initiation and viral clearance among rural people who inject drugs than traditional care [13].

Correctional systems have used the same approach in a setting where the unmet need is substantial, and where screening and linkage before release can mean that Medicare beneficiaries, who lose their coverage while incarcerated, are already diagnosed and on a path to curative treatment after release. Roughly 1.4 million people were held in federal and state prisons in 2019 [14], with 15.2 percent of people in state prisons estimated to be HCV seropositive and 8.7 percent of people in state prisons living with viremic hepatitis C, nearly nine times the prevalence in the general population [15]. Since 2010, the University of Illinois at Chicago has partnered with the Illinois Department of Corrections to provide HIV and hepatitis C specialty care by telehealth in state prisons [16], and a telehealth treatment protocol in the Virginia Department of Corrections reported a 97 percent cure rate among over 600 people completing treatment [17]. California's provision of opt-out testing to everyone entering state correctional facilities without regard to known risk factors has improved equitable access to treatment, particularly for people who use drugs [18].

Each of these models begins with screening outside the primary care setting. **We urge CMS to clarify that screening is covered when ordered by a clinician seeing the patient remotely by telehealth**.

Repeat screening, risk, and stigma

Many people are reluctant to disclose substance use or other stigmatized practices to their providers. **We urge CMS not to reinforce stigma by requiring beneficiaries to attest to, or clinicians to document, these risk factors as a condition of repeat screening**.

USPSTF recommends periodic screening of people with continuing risk for HCV [19], and, as discussed below, clinical guidelines now recommend at least annual screening for several groups, and every six months for dialysis patients [20, 21]. **We urge CMS to cover repeat screening at the frequencies recommended in current guidelines, rather than relying on a frequency restriction such as a once-a-year cap**. Requirements to elicit risk factors may deter exactly those people most in need of screening, and questions about substance use at triage often do not receive meaningful answers, as noted in commentary on the DETECT study [22]. AASLD/IDSA recommendations note that many people at greatest risk "do not readily report their highly stigmatized risk activities," and that 15-25 percent of people with previously undiagnosed HCV would be "missed by even perfect implementation of risk-based testing" [20]. There is substantial benefit to frequent testing. CDC researchers found that testing people who inject drugs every six months, combined with treatment, could reduce hepatitis C prevalence by up to 45 percent and related deaths by 42 percent over ten years, with a modest increase in total costs [23].

CMS should also replace references to persons at "high risk" with "increased risk" and align the definition of risk with CDC's current recommendations, which call for testing all persons with risk factors regardless of age or setting [11], rather than limiting "high risk" to injection drug use and transfusion before 1992. As we noted in our comments on the PrEP NCD, many people who would benefit from a preventive service do not see themselves as being at high risk, and some providers stigmatize those seen as high risk.

CMS also asked specifically for evidence related to screening intervals for those at increased risk. The evidence supports the frequencies set in current clinical guidelines rather than a fixed cap. AASLD/IDSA guidance recommends at least annual testing for people who inject drugs, men living with HIV who have condomless sex with men, and men on PrEP, with more frequent testing when risk warrants it. Given high reinfection rates of about 6 per 100 person-years, annual RNA testing is also recommended for people who continue to inject drugs after the completion of curative treatment [20, 24]. CDC already recommends testing every six months for hemodialysis patients [21], showing that a once-a-year limit is too low for some groups with ongoing exposure. **The NCD should cover repeat screening, including RNA testing after curative treatment, at the frequencies recommended in current clinical guidelines**.

Finally, **the NCD should cover screenings during each pregnancy**, as recommended by CDC, and, because CDC sets no upper age limit, **the NCD should at a minimum cover screening of beneficiaries 80 and older at the beneficiary's request** [11].

Allow for new testing modalities

Our 2021 request asked CMS to account for new testing modalities, including rapid point-of-care and self-tests. Conventional testing often requires multiple visits, as a reactive antibody test requires confirmatory RNA testing whose results often arrive after the patient is no longer on-site. Data show very substantial loss to follow-up, with only 62-68 percent of patients completing the full testing process when a second visit was required [25]. Point-of-care testing can make diagnosis and linkage to care possible in a single visit.

Self-testing and home collection offer similar advantages to beneficiaries with disabilities, those in rural areas or with limited access to transportation, and people who are discouraged by stigma. WHO recommended HCV self-testing in 2021 and prequalified the first HCV self-test in 2024 [26], and dried blood spot samples self-collected at home have been shown to detect HCV RNA [27]. The current NCD, however, limits screening coverage to FDA-approved or cleared laboratory tests and ties screening to a primary care visit. **We encourage CMS to allow the NCD to encompass FDA-authorized point-of-care, self-testing, and home testing as they become available, as well as to cover confirmatory RNA testing following any reactive screening result, including self-tests or rapid tests**.

Coverage must keep pace with scientific innovation and evidence-based guidelines

USPSTF and CDC both updated HCV screening recommendations in 2020, yet Medicare coverage still reflects the 2014 NCD. Our request for reconsideration was filed in June 2021, but this analysis will only be completed in June 2027. **When USPSTF or CDC updates HCV screening recommendations, or FDA authorizes new tests, those changes should be incorporated into Medicare coverage without delay**, just as the HIV pre-exposure prophylaxis NCD extends to any future FDA-approved PrEP drugs without requiring a separate NCD [28]. Medicare beneficiaries should not have to wait years for access to scientific innovation, especially for a curable disease that remains one of the deadliest infectious diseases in the United States [29].

Conclusion

CDC has reported that hepatitis C kills more Americans than sixty other notifiable infectious diseases combined [29], and it still contributes to over 11,000 deaths a year [30], even though it can be cured. Even now, over a decade after curative treatments have been available, CDC found that only one in three people with evidence of infection had been cured [3], and the number of US adults estimated to be living with HCV was 2.5 to 4 million in 2017-2020, a prevalence unchanged from 2013-2016 [31]. Many of the easiest people to reach, those in primary care and traditional health care settings, have already accessed curative treatment. We urge CMS to issue this NCD without setting restrictions so that as many Medicare beneficiaries as possible can access these curative treatments.

If you have any questions or comments, please contact Carl Schmid, HIV+Hepatitis Policy Institute at cschmid@hivhep.org or (202) 462-3042, or Kevin Herwig, HIV+Hepatitis Policy Institute at kherwig@hivhep.org or (617) 666-6634.

Sincerely,



Carl E. Schmid II
Executive Director

References

[1] HIV+Hepatitis Policy Institute, National Viral Hepatitis Roundtable, Caring Ambassadors Program, NASTAD, and The AIDS Institute. Request for reconsideration of NCD 210.13, Screening for Hepatitis C Virus in Adults. June 2021. https://www.cms.gov/files/document/id325c.pdf

[2] Characteristics of Medicare beneficiaries with chronic hepatitis C virus. ISPOR 18th Annual International Meeting, 2013. https://www.ispor.org/heor-resources/presentations-database/presentation/ispor-18th-annual-international-meeting/characteristics-of-medicare-beneficiaries-with-chronic-hepatitis-c-virus

[3] Wester C, et al. Hepatitis C Virus Clearance Cascade — United States, 2013–2022. MMWR 2023;72(26):716–720. https://www.cdc.gov/mmwr/volumes/72/wr/mm7226a3.htm

[4] Haukoos J, Rothman RE, Galbraith JW, et al. Hepatitis C Screening in Emergency Departments: The DETECT Hep C Randomized Clinical Trial. JAMA 2025;334(6):497–507. https://doi.org/10.1001/jama.2025.10563

[5] Czoty LMW, Munroe S, Stewart E, et al. Cost-Effectiveness of HCV Screening in Emergency Departments Using DETECT Hep C Trial Results. JAMA Internal Medicine, published online October 19, 2026. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2855588

[6] Bradley H, Hall EW, Asher A, et al. Estimated Number of People Who Inject Drugs in the United States. Clinical Infectious Diseases 2023;76(1):96–102. https://doi.org/10.1093/cid/ciac543

[7] Chiosi JJ, Mueller PP, Chhatwal J, Ciaranello AL. A multimorbidity model for estimating health outcomes from the syndemic of injection drug use and associated infections in the United States. BMC Health Services Research 2023;23(1):760. https://doi.org/10.1186/s12913-023-09773-1

[8] Choi et al. Cost-effectiveness analysis of emergency department-based hepatitis C screening and linkage-to-care program. BMC Health Services Research, 2024. https://pmc.ncbi.nlm.nih.gov/articles/PMC11523774

[9] Cunningham EB, Wheeler A, Hajarizadeh B, et al. Interventions to enhance testing, linkage to care, and treatment initiation for hepatitis C virus infection: a systematic review and meta-analysis. The Lancet Gastroenterology & Hepatology 2022;7(5):426–445. https://pubmed.ncbi.nlm.nih.gov/35303490/

[10] Perry AN, Eccles E, Bardach SH, et al. Getting to the Point: A Community-Designed, Low-Barrier Hepatitis C Testing and Treatment Program for People Who Inject Drugs in Rural America. Viruses 2025;17(12):1589. https://pmc.ncbi.nlm.nih.gov/articles/PMC12737676/

[11] Centers for Disease Control and Prevention. CDC Recommendations for Hepatitis C Screening Among Adults — United States, 2020. MMWR Recommendations and Reports 2020;69(No. RR-2):1–17. https://www.cdc.gov/mmwr/volumes/69/rr/rr6902a1.htm

[12] Massachusetts Department of Public Health. Hepatitis C Treatment Best Practices. https://www.mass.gov/info-details/hepatitis-c-treatment-best-practices

[13] Friedmann PD, et al. Mobile Telemedicine for Treating Chronic Hepatitis C Among Rural People Who Inject Drugs: A Randomized Clinical Trial. JAMA Network Open 2026;9(1):e2555125. https://doi.org/10.1001/jamanetworkopen.2025.55125

[14] Carson EA. Prisoners in 2019. Bureau of Justice Statistics, U.S. Department of Justice, 2020. https://bjs.ojp.gov/library/publications/prisoners-2019

[15] Spaulding AC, Kennedy SS, Osei J, et al. Estimates of Hepatitis C Seroprevalence and Viremia in State Prison Populations in the United States. Journal of Infectious Diseases 2023;228(Suppl 3):S160–S167. https://pubmed.ncbi.nlm.nih.gov/37703336/

[16] Illinois Department of Corrections. Press release on the IDOC–University of Illinois at Chicago Telemedicine Pilot Program for HIV and Hepatitis C. July 27, 2010. https://www.illinois.gov/news/press-release.8689.html

[17] HCV treatment through telehealth highly effective regardless of DAA regimen (Virginia Department of Corrections; Digestive Disease Week 2020). Healio. https://www.healio.com/hepatology/hepatitis-c/news/online/%7B59d07ad0-f03d-4756-926e-477865d451bf%7D/hcv-treatment-through-telehealth-highly-effective-regardless-of-daa-regimen

[18] Ye Z, Lucas K, Furukawa NW, et al. Universal Opt-Out Hepatitis C Virus Testing and Treatment on Entry in California State Prisons. JAMA Internal Medicine, published online 2026. https://doi.org/10.1001/jamainternmed.2026.4041

[19] U.S. Preventive Services Task Force. Screening for Hepatitis C Virus Infection in Adolescents and Adults: Final Recommendation Statement. March 2, 2020. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening

[20] American Association for the Study of Liver Diseases and Infectious Diseases Society of America. HCV Guidance: HCV Testing and Linkage to Care. Last updated July 12, 2024. https://www.hcvguidelines.org/guidance/hcv-testing-and-linkage-to-care/

[21] Centers for Disease Control and Prevention. Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients. MMWR Recommendations and Reports 2001;50(RR-5):1–43. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm

[22] Coupet E, Hawk KF, D'Onofrio G. Emergency Department Hepatitis C Virus Testing—To Do or Not to Do? JAMA Internal Medicine, published online October 19, 2026. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2855593

[23] Zhu L, Furukawa NW, Thompson WW, et al. Potential Impact of Frequent Testing for Hepatitis C Virus Among People Who Inject Drugs Toward Hepatitis C Elimination in the United States. Clinical Infectious Diseases 2026;83(1):e38–e46. https://academic.oup.com/cid/article/83/1/e38/8202696. See also Zhu L, et al. Health and Economic Impact of Periodic Hepatitis C Virus Testing Among People Who Inject Drugs. JAMA Network Open, 2025. https://pmc.ncbi.nlm.nih.gov/articles/PMC12232219/

[24] Hajarizadeh B, Cunningham EB, Valerio H, et al. Hepatitis C reinfection after successful antiviral treatment among people who inject drugs: A meta-analysis. Journal of Hepatology 2020;72(4):643–657. https://pubmed.ncbi.nlm.nih.gov/31785345/

[25] Cartwright EJ, Patel P, Kamili S, Wester C. Updated Operational Guidance for Implementing CDC's Recommendations on Testing for Hepatitis C Virus Infection. MMWR 2023;72(28):766–768. https://www.cdc.gov/mmwr/volumes/72/wr/mm7228a2.htm

[26] World Health Organization. WHO prequalifies the first self-test for hepatitis C virus. News release, July 10, 2024. https://www.who.int/news/item/10-07-2024-who-prequalifies-the-first-self-test-for-hepatitis-c-virus

[27] Prinsenberg T, et al. Dried blood spot self-sampling at home is a feasible technique for hepatitis C RNA detection. PLoS ONE 2020;15(4):e0231385. https://pmc.ncbi.nlm.nih.gov/articles/PMC7156069

[28] Centers for Medicare and Medicaid Services. Decision Memo: Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection (CAG-00464N). https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=310

[29] Ly KN, et al. Rising Mortality Associated With Hepatitis C Virus in the United States, 2003–2013. Clinical Infectious Diseases 2016;62(10):1287–1288. https://pmc.ncbi.nlm.nih.gov/articles/PMC11089523/

[30] Centers for Disease Control and Prevention. 2023 Hepatitis C Surveillance Report. https://www.cdc.gov/hepatitis-surveillance-2023/hepatitis-c/index.html

[31] Hall EW, Bradley H, Barker LK, et al. Estimating hepatitis C prevalence in the United States, 2017–2020. Hepatology 2025;81(2):625–636. https://stacks.cdc.gov/view/cdc/169976