December 23, 2024

Center for Medicaid and Medicare Services
2024 Pre-Rulemaking Measure Review

Re: Measure Under Consideration # MUC2024-031: Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

Dear CMS:

Thank you for the opportunity to provide public comment on the draft Measures Under Consideration. I am writing to express concerns regarding # MUC2024-031: Hepatitis C Virus (HCV): Sustained Virological Response (SVR).

Hepatitis C is a viral infection of the liver that can cause serious liver disease, including cirrhosis, liver cancer, and death. Hepatitis C disproportionally affects populations often excluded from and discriminated against in health care settings and who thus often avoid seeking care, including people who use drugs, people who are or have been incarcerated, and people experiencing homelessness. Best practices for successful hepatitis C testing, care, and treatment including delivering low-threshold services in non-traditional settings, such as drug treatment programs, jails, mobile outreach and street medicine, supportive housing and shelters settings, and syringe services programs. Hepatitis C can also be effectively treated and cured in primary care settings, which may be more accessible than specialty care. Common barriers to care include cost, transportation, competing survival priorities (such as the need for housing, food, and clothing) along with fear of stigma. The Association for the Advanced Study of Liver Diseases (AASLD) recommends minimizing on-treatment appointments to reduce barriers to care.

Direct acting antiviral (DAA) medications for hepatitis C are highly effective, with cure rates of 90% or higher, including for people who use or inject drugs and people experiencing homelessness, particularly when supportive services such as patient navigation and incentives are available. Research, such as the SIMPLIFY study of hepatitis C treatment among people who use drugs, have shown high cure rates even with varied adherence. Yet the California Department of Public Health (CDPH) has received multiple complaints since the advent of DAAs about health care providers denying or delaying care for people who use drugs due to misinformed assumptions that people who use drugs cannot or do not adhere to their medications. This pattern prompted us to publish an Issue Brief aimed at dispelling these stigmatizing myths among health care providers and to recommend treatment for people who use drugs, without requirements for abstinence, in line with AASLD guidelines recommending that substance use should not preclude people from hepatitis C treatment, along with research and best practices. The issue brief can be accessed at https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/HCV-Tx-PWID-Brief.pdf; we are currently working on updating this document because we continue to receive complaints of healthcare provider stigma and discrimination.

From 2016-2018, the California Department of Public Health (CDPH) funded five programs across California to perform hepatitis C testing and linkage to care demonstration projects and then published our evaluation findings on our website (https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/HCV_Demo_Eval_Report_ADA.pdf). Funded projects specifically prioritizing reaching people who use drugs and people experiencing homelessness. In our funded projects, at least 818 program participants were known to have initiated hepatitis C treatment, among whom 657 (at least 80 percent) were known to have completed treatment. (Not all funded sites had the capacity to track treatment completion so the true proportion may have been higher.) Most importantly, 40 percent of those who were linked to care and treated had a known history of injection drug use. In our experience, only about seven or eight out of every ten people who completed treatment returned for post-treatment testing to assess for sustained virologic response (SVR), or evidence of virological cure. Yet clinical trials and real-world evidence has shown that DAAs are highly effective with a high rate of cure, even in individuals who have moderate levels of adherence. Many patient navigators reported that their program participants often felt better by the end of hepatitis C treatment and did not feel it was importance to get post-treatment testing for SVR. Research suggests that many of these individuals likely achieved virologic cure even if they did not return to the clinic for post-treatment SVR testing.

While I support the goal of increasing treatment for hepatitis C, I am concerned that implementing a quality measure focused on SVR could have the unintended consequence of increasing the likelihood that clinicians will favor treating patients for hepatitis C whom they perceive to be more likely to return for post-SVR testing—and exclude patients, such as people who use drugs or are experiencing homelessness—whom they perceive to be less likely to return for post-SVR testing. I also do not believe that an SVR measure would truly measure who had been cured—it would only measure who had been tested for SVR and would likely fail to capture 1-2 people cured for every 10 who are treated.

In May 2024, I participated in an HHS consultation on establishing quality measures related to viral hepatitis. At the end of that consultation, I agreed with the consensus of the group that a combined measure for hepatitis C testing and treatment initiation (but not SVR) would be the most appropriate measure for hepatitis C-related care quality in light of the dynamics I have highlighted here. This combined measure is already included in the 2024 Merit-Based Incentive Payment System (MIPS) quality measures list as Measure 400. I would recommend continuing to focus on that combined measure, which would incentivize providers to screen and treat marginalized populations rather than exclude them.

Thank you for your consideration.

Sincerely,

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(For identification purposes only; opinions are my own and do not necessarily represent the views of CDPH or its funders.)