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To the Honorable members of the Joint Legislative Justice Oversight Committee,

Thank you for the opportunity to share an overview and update on the treatment of Vermont inmates who have Hepatitis C (HCV). This is an important topic and the attention from the committee on this issue has been valuable to our work. The Agency of Human Services (AHS), through our Department of Corrections (DOC), has an obligation to ensure that inmates receive health care that is consistent with "prevailing medical standards." 28 V.S.A. § 801. It is through this understanding that we have been working to implement treatment for inmates with HCV that includes direct acting antiviral (DAA) treatment (i.e., "cure" medications).¹

Changes in Medicaid Standard of Treatment

On December 4, 2017, DVHA sent an update to Medicaid providers that required "cure" medications to be considered regardless of F score.² Previously, only patients with a score of F2, F3, or F4 were considered candidates for "cure" treatment medications. While this was a change regarding when to consider use of "cure" medications, it was DOC's existing standard that all patients with chronic HCV be seen in Chronic Disease Clinic for ongoing medical monitoring and the development of a treatment plan.

DOC Processes for Determining HCV Treatment

Screening for HCV begins at intake, with confirmation of new diagnoses within seven days. Patients with HCV are seen by a medical provider within 14 days of admission unless extenuating circumstances exist. 28 V.S.A. § 801. Inmates newly-diagnosed with HCV are monitored for six months to see if they spontaneously "clear" the virus – this is the prevailing medical standard in the community. Patients with a known diagnosis of HCV are enrolled in the Chronic Disease Clinic and are seen every 3-6 months to monitor their condition. Medical providers, in consultation with UVM Medical Center Infectious Disease, review laboratory and other diagnostic information to determine when it is medically necessary to provide a treatment regimen that is in the best interest of the health of the patient. This determination is done regardless of F score, consistent with Vermont Medicaid's guidelines.

Of the total DOC patient population of 1,518 on 10/18/18, 153 or 10.1% came into custody with a known diagnosis of HCV.³ For those whose status is not known, HCV screening and confirmatory testing is conducted. Since the beginning of 2018, 385 HCV tests have been completed, which have resulted in the diagnosis of 35 new HCV cases. On average, 250

³ There have been some problems with the "current incarceration date" interface between the Offender Management System and the Electronic Health Record which may impact the accuracy of this information. Also, patients that self-report (either accurately or inaccurately) an HCV diagnosis upon intake may not always know when they were diagnosed and might not have records for verification purposes. In these cases, the HCV diagnosis may be entered as the date that the patient came into DOC custody.



¹ DAAs lead to a cure for HCV when the medications are taken as prescribed as measured by follow-up labs and "sustained viral response."

 $^{^{2}}$ F Score is a measure of fibrosis in the liver, as measured by a fibrosis ultrasound. F scores are integers and range from 0-4. 0 indicates no fibrosis and 4 indicates the presence of cirrhosis.

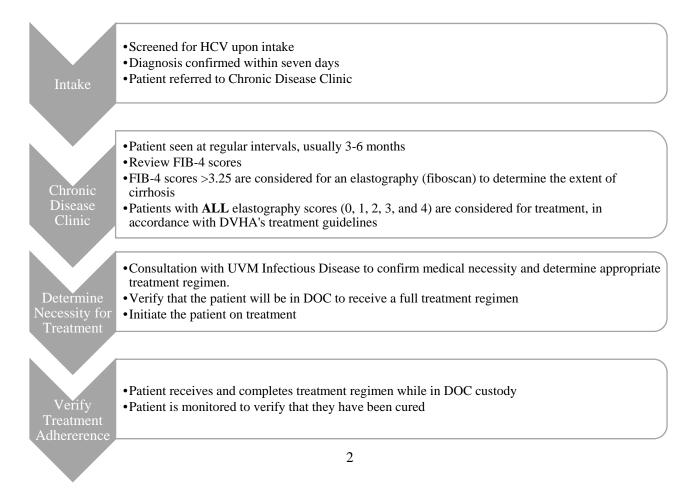
patients (including in-state and out-of-state populations) with HCV are in DOC custody per month. Of those, 24.8% (approx. 62 patients) will be in DOC custody long enough to receive a full HCV treatment regimen. Consistent with best practice, DOC continues patients on their HCV medications if they were on the medications upon intake.

In 2017, prior to the updated Medicaid Standard of Treatment, one patient was diagnosed and treated for HCV with direct acting antivirals which, when taken as prescribed, cure most patients with HCV. Under the updated Standard of Treatment, the number being newly treated increased to 10 in 2018 (one patient refused treatment). The remaining patients on the HCV "watchlist" are being considered for DAA treatment but have not yet received it because their FIB-4 scores are less than 3.25 – values less than 3.25 generally predict that fibrosis is not present. About 12% of patients are refusing diagnostic testing and treatment interventions. We are actively working to maximize the number of patients who receive this treatment, provider they meet all necessary criteria.

Challenges Regarding Length of Stay and Criteria for Successful Completion of Treatment

While we estimate that there are approximately 62 patients that have HCV and will be in DOC custody long enough to receive a course of treatment, they might not be always the same people over time. Further, even if those patients would be in long enough to receive the course of treatment, they may not meet the criteria for DAA treatment according to treatment guidelines. If a patient is expected to be in DOC custody for the length of time that treatment would require, that is not the only factor in determining a course of treatment. Disease progression, labs, imaging studies, other diagnostics, and case-by-case review by medical providers and infectious disease specialists are the cornerstones of "medical necessity" determinations in the DOC and the community.

In DOC, HCV treatment is not provided upon request. Nor is it provided upon request for any person seeking treatment outside of Corrections. The DOC's practice is the same as the community's practice in that patients with HCV are medically monitored to determine when it is appropriate to start the patient on one of the HCV "cure" medications.



It has been argued that DOC should treat patients in custody regardless of anticipated length of stay. To do so would not align with the treatment standard for people who are not in DOC custody. Medical providers strongly emphasize that patients be in a stable place in their lives where they will be able to comply with the full treatment regimen. There are risks to individual patients as well as to public health when treatment is not adhered to. For example, new strains of HCV for which there are no effective DAAs could develop and spread to the population.

Additional \$2M Investment

While we are treating patients with "cure" medications once they are determined medically necessary for the course of treatment, the additional \$2M requested at the September Joint Fiscal Committee from available funds in the FY2019 budget⁴, is meant to address a trend that we are seeing in the number of patients that are being treated at any given time, as well as to allow us to maximize treatment under the relatively new Medicaid Standard of Care. As the number of patients being treated increases, we can expect increased costs. The \$2M will help us address the need and goal to provide treatment to more patients over time.

The anticipated number of patients that are in DOC custody long enough to receive a full course of treatment of DAA is about 60 patients. Even with this additional investment in funds, there are still limiting factors since each is at a different stage within the overall treatment process and some may not meet the criteria that would result in treatment. This has nothing to do with funding availability. The standard is the same as in the community – not everyone diagnosed will be treated during a specific period of time because the medical standard takes into account much more than just the diagnosis and ability to complete the treatment regimen.

DOC has done a tremendous job wrapping their arms around this topic and making the connections needed in the medical community to support their implementation. We remain committed to treating inmates with HCV in accordance with standards that align with those in the community.

Sincerely,

Al Gobeille Secretary, Agency of Human Services

 $^{^4}$ Secs. C.106.2 and C.1000(a)(14) of Act 11 of the Special Session.