Memo:	House Human Services Committee
From:	Vermont Medical Society Jessa Barnard, Executive Director Jill Sudhoff-Guerin, Communications and Policy Manager
Date:	March 14, 2023
Re:	H.222, Removing Barriers to MOUD

On behalf of the 2,600 physician and physician assistant members of the Vermont Medical Society (VMS), we would like to express our strong support for Sections 8, 9 and 10 of Draft 2.3 of H.222 (We will be referring to the new sections). Removing barriers like step therapy and time-consuming prior authorization for medications for opioid disorder (MOUD) can prevent costly delays when patients are ready to take that critical, first step to recovery and alleviate unnecessary administrative burdens on clinicians providing treatment.

Section 8 – Step Therapy:
VMS has heard the Committee discussion that the concern leading to Section 8 is not provider behavior, but rather preventing payers from requiring patients to "fail first" or document adverse effects from one medication before being prescribed another medication for opioid use disorder. This practice by payers is often referred to as "step therapy." VMS opposes step therapy payer policies, which can result in delayed access to appropriate medication, patients dropping out of treatment, and subjecting patients to adverse side effects. VMS suggests that language preventing these policies can be added to statute already discussing step therapy (8 VSA 4089i), or in the section on prior authorization for MOUD (18 V.S.A. § 4754)
Amend 8 VSA 4089i as follows:

(e)(3) Notwithstanding (e)(1) a health insurance or other health benefit plan offered by an insurer or by a pharmacy benefit manager on behalf of a health insurer that provides coverage for prescription drugs shall not utilize a step therapy, "fail first," or other protocol that requires documented trials of a medication, including but not limited to one documented through a "MedWatch" (FDA Form 3500), before approving a prescription for the treatment of substance use disorder.

Section 8 & 9 – Telehealth and Updating Opiate Treatment System Language:
Section 8 of the bill proposes amendments to state statute creating Vermont's opiate treatment system. VMS does believe it is appropriate to make several modifications to this statute. First, as our system of care for opiate use disorder has evolved to treat OUD like other health conditions, some of this language has become overly prescriptive and prevents the Department of Health from modifying rules regarding treatment as the evidence changes. Other aspect of the language unnecessarily stigmatize MOUD, for example, suggesting medication should be tapered as soon as possible and highlighting discharge from care – which can be addressed in rule or practice policy. VMS suggests removing much of the language and deferring to VDH rules (found at https://www.healthvermont.gov/sites/default/files/documents/pdf/2023%20E-Rule.MAT%20Rule.Final_.annotated.pdf).

Second, VMS recommends that this section of statute address the ability to prescribe MOUD via telehealth. This is an area of federal regulation currently undergoing rapid change – with rules pending both with

SAMHSA[1] (regarding OTPs or hubs) and the DEA[2] (regarding OBTPs or spokes) regarding the status of prescribing via telehealth after the end of the federal public health emergency in May. Both of the rules recognize the value of ongoing access to care using remote means. For example, in recommending ongoing induction via audio-visual or audio-only telehealth by OTPs, SAMHSA finds:[3]

Recent research has demonstrated that telehealth can be an effective tool in integrating care and extending the reach of specialty providers, and that among those requiring treatment with buprenorphine, there are high levels of satisfaction with the use of telehealth services. Additionally, there are no significant differences between telehealth and in-person buprenorphine induction in the rate of continued substance use, retention in treatment or engagement in services. Research also shows that there is no significant difference in client and provider ratings of therapeutic alliance when using telehealth technology platforms. In the face of an escalating overdose crisis and an increasing need to reach remote and underserved communities, making the buprenorphine telehealth flexibility permanent is of paramount importance.

VMS members strongly support ongoing prescribing of MOUD via telehealth. Given federal regulation in this area, and the fact that federal rules are undergoing revision, VMS recommends allowing prescribing via telehealth at the state level as long as prescribers are following federal law and regulation. We have reflected this in section (5), below.

Our recommendations are as follows:

18 V.S.A. § 4752, Opioid ~~addiction~~ use disorder treatment system

(a) The Departments of Health and of Vermont Health Access shall establish by rule a regional system of opioid use disorder ~~addiction~~ treatment.

(b) The rules ~~shall include the following requirements~~ may address requirements for pharmacological treatment, including initial assessments, ongoing follow-up, provider education and diversion prevention.

~~(1) Patients shall receive appropriate, comprehensive assessment and therapy from a physician or advanced practice registered nurse and from a licensed clinical professional with clinical experience in addiction treatment, including a psychiatrist, master's- or doctorate-level psychologist, mental health counselor, clinical social worker, or drug and alcohol abuse counselor.~~

~~(2) A medical assessment shall be conducted to determine whether pharmacological treatment, which may include methadone, buprenorphine, and other federally approved medications to treat opioid addiction, is medically appropriate.~~

~~(3) A routine medical assessment of the appropriateness for the patient of continued pharmacological treatment based on protocols designed to encourage cessation of pharmacological treatment as medically appropriate for the individual treatment needs of the patient.~~

(4) Controlled substances for ~~use in federally approved pharmacological~~ treatment~~sing~~ ~~for~~ opioid use

[1] https://public-inspection.federalregister.gov/2022-27193.pdf. The rule proposes to allow initiation of buprenorphine via audio-only or audio-visual telehealth technology, and methadone via audio-visual telehealth, if an OTP physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via telehealth.

[2] https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-flexibilities. Proposes to allow all renewals via telemedicine, and initial prescriptions for 30 days before an in-person examination is conducted.

[3] https://public-inspection.federalregister.gov/2022-27193.pdf (pages 25-26)

disorder ~~addiction~~ shall be dispensed only by:

(A) a treatment program authorized by the Department of Health; or

(B) a ~~physician or advanced practice registered nurse~~ health care provider who is not affiliated with an authorized treatment program but who meets federal requirements for use of controlled substances in the pharmacological treatment of opioid use disorder ~~addiction~~.

(5) Controlled substances for use in treatment of opioid use disorder may be prescribed via telehealth in accordance with federal requirements.

~~(5) Comprehensive education and training requirements shall apply for health care providers, pharmacists, and the licensed clinical professionals listed in subdivision (1) of this subsection, including relevant aspects of therapy and pharmacological treatment.~~

~~(6) Patients shall abide by rules of conduct, violation of which may result in discharge from the treatment program, including:~~

~~(A) provisions requiring urinalysis at such times as the program may direct;~~

~~(B) restrictions on medication dispensing designed to prevent diversion of medications and to diminish the potential for patient relapse; and~~

~~(C) such other rules of conduct as a provider authorized to provide treatment under subdivision (4) of this subsection (b) may require.~~

After reviewing the new language posted this morning in current Section 9, we are also comfortable with that approach, however do not think it should refer to prescribing of buprenorphine alone – rather it should refer to medications for use in the treatment of opioid use disorder. SAMHSA, for example, is drafting rules regarding to the prescribing of methadone via telehealth, and as described above we believe Vermont should allow the flexibility authorized under federal law or rule.

Section 10 – Prior Authorization - MOUD Saves Lives

When people with opioid addictions initiate treatment, they significantly reduce their potential of relapsing back into opioid use and dying from an overdose. Yet, we know we need to reach more Vermonters. According to Vermont's Department of Substance Use February 2023 report the number of Vermonters dying by opioid overdose in 2022 was significantly higher than the 3-yr average. According to a January 2023 report from the Vermont Department of Health on 2021 Substance Use Disorder Treatment Initiation and Engagement, only 44% of patients diagnosed with a substance use disorder sought out one SUD treatment and only 23% continued treatment.

Patients struggling with OUD often have very small windows of opportunity when they have the courage and ability to seek out treatment. Therefore, more and more Vermont treatment clinicians strive to start same-day induction of MOUD, also referred to as medication-assisted-treatment (MAT), through a program called RAM, Rapid Access to MAT. This program was developed because *treatment timing can be critical* after patients are treated for an overdose in an ED. In the 24 to 72 hours it can take to get to a separate treatment center patients are vulnerable to another overdose, death, or changing their minds about whether they're ready to start treatment.

Prior Authorization Reforms

The majority of state Medicaid programs impose prior authorization (PAs) standards for some or all buprenorphine medications. According to a 2020 report, 17 states have laws that limit state-regulated

commercial plans from imposing prior authorization on MOUD, and 13 states and the District of Columbia *limit* Medicaid from doing so, including Vermont. A 2021, Journal of Managed Care Specialty Pharmacy white paper studied the impact of removing prior authorization for MOUD for Medicare Advantage patients and found that removal of PAs was followed by a decrease in opioid utilization, an increase in MAT initiation, and a 4% decline in relapse rates.

Vermont's Medicaid program provides payment/coverage for roughly 70 percent of all buprenorphine prescriptions in the state. In 2019, the Vermont Legislature adopted Act 43, which removed PAs for MOUD as long as the Hub dose is no higher than 24 mg and the Spoke dose does not exceed 16mg per day, which is within the U.S. FDA dosing recommendations. According to last year's testimony from the Department of Vermont Health Access (DVHA), Medicaid has made it a practice to remove prior authorization requirements for at least one dosage form for every class of MOUD: methadone, buprenorphine and naltrexone. We support putting this requirement in statute.

We have heard from our members that even slight modifications to Medicaid prior authorization for buprenorphine have made big differences in removing barriers to MOUD and reducing clinician burden. Therefore, we also support providing a "gold carding program" for clinicians who prescribe MOUD and meet a 90% approval rate. Gold card programs exempt from prior authorization those clinicians who have a high approval rate. DVHA has implemented Gold Card Programs in other areas of medicine and has found that they can have "success in improving clinical results and reducing administrative burden for health care professionals."

Act 43 required Medicaid to report on PAs for MOUD from 2020 to 2022 regarding:

a) Which medications required prior authorization;
b) How many prior authorizations requests the Department received and, of these, how many were approved and denied; and
c) The average and longest lengths of time the Department took to process a prior authorization request.

Here are the 3 reports:
MAT Prior Authorization Report, 2020
MAT Prior Authorization Report, 2021
MAT Prior Authorization Report, 2022

Over the last 3 years, there were a total of 9,256 prior authorization requests, 8,627 approvals and 629 denials. Which means **93.2% of the prior authorization requests were approved and only 6.8% were denied**.

We support the intent of this legislation to provide as much harm reduction as possible, which includes removing unnecessary barriers to life-saving treatment. We also understand that DVHA has responded to clinician feedback and worked to reduce PAs. As the next step in harm reduction we urge you to reduce PAs for MAT by expanding Vermont's current gold-carding programs.

Thank you for your consideration. For questions and clarifications contact Jessa Barnard at jbarnard@vtmd.org or Jill Sudhoff-Guerin at jsudhoffguerin@vtmd.org .