Public Comments
(In order of receipt):

1. Sarah Wakeman, MD

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I commend CEPAC for making treatment options for opioid use disorders the focus of the upcoming June public meeting. As highlighted in the ICER draft report "Management of Patients with Opioid Dependence: A Review of the Clinical, Delivery System, and Policy Options," opioid use disorder is a disease with a high prevalence and death toll. Reviewing evidence-based treatment options and discussing how to make such treatments immediately available to all patients with an opioid use disorder is of utmost importance.

The report highlights the strong evidence base for the treatment of opioid use disorder with the agonist medications, buprenorphine and methadone, and the less robust evidence for the antagonist medication, naltrexone. Overall, I agree wholeheartedly with the findings and emphasis of this report. The cost benefit calculations of maintenance treatment are particularly compelling and highlight that maintenance pharmacotherapy not only improves clinical outcomes, but also it is incredibly cost-effective. To further strengthen the argument for maintenance pharmacotherapy, I would add the following comments.

The report refers to pharmacotherapy for opioid use disorders as "medication-assisted treatment." This is a common way to describe the combination of pharmacotherapy and counseling in the treatment of substance use disorders. Yet, as this report highlights, the research has consistently demonstrated that opioid agonist treatment alone is effective in improving outcomes for patients with an opioid use disorder, regardless of whether they receive additional counseling. Continuing to use the term medication-assisted treatment implies that medication is an adjunct to treatment, when in fact the evidence has shown consistently that it is and should be first-line in the management of opioid use disorders. (1)

The report describes the effective dose range of methadone as 20-100 mg. Yet studies have demonstrated improved out comes with dosages of methadone higher than 100 mg for maintenance, both in terms of reduction in illicit opioid use (2), cocaine use (3), and treatment retention. (4) Similarly, although the common dosing guidelines for buprenorphine are 8-24 mg as

described in this report, a recent study found a linear relationship with treatment retention and buprenorphine dose, even up to a dose of 30-32 mg. (4) This suggests that patients on buprenorphine may have even better clinical outcomes with doses higher than those used in current practice.

This report importantly highlights the tremendous superiority of maintenance therapy versus a detoxification or tapering strategy. The clinical outcomes with nearly all detoxification protocols, regardless of duration, are poor. Importantly, not only is the rate of relapse high but the rate of death following a tapering strategy is markedly increased. A study by Kakko et al. in the Lancet demonstrated that 20% of patients randomized to detoxification as compared to maintenance were dead within one year. (5) Additionally, while this highlights that approximately 50% of patients on maintenance therapy at 1 year have no illicit drug use, the results are even better with longer treatment duration. As summarized by NIDA, a 12 year study of opioid-dependent patients on methadone found that illicit opioid use continued to decline progressively over time until year 6, when it stabilized at about 40% for "any" use and 25% for "daily" use, down from 100% who reported daily use prior to treatment. (6)

This report importantly highlights the many existing barriers that prevent patients with opioid use disorders from accessing pharmacotherapy. The barriers highlighted in this report are lack of insurance coverage for pharmacotherapy, inefficiency of referral pathways, regulatory barriers for physician practice, and patient factors such as geographic and financial limitations. These are all valid and important barriers. I would add to this list the arbitrary restrictions many treatment programs apply. Some treatment providers and programs mandate strict entry criteria for pharmacotherapy that are not evidence-based and serve only as an unnecessary barrier to life-saving treatment. Additionally, on the crucial issue of insurance coverage, although private insurers may "cover" methadone maintenance, the patient may be charged a co-pay (15-20 dollars generally) for each day's clinic visit. This co-pay rate is higher than the MassHealth rate of $10 daily for methadone. So at this co-pay rate the insurance company is essentially charging the patient more than the clinic would be charging the insurance company. This means that many patients with private insurance coverage realistically cannot access methadone maintenance due to the cost. Additionally, the dosage and treatment duration limits for Suboxone that some insurance companies impose are a barrier to the effective and evidence-based treatment approaches described above.

Lastly, I want to highlight the cost calculations this report makes for no treatment versus treatment. This is a particularly compelling argument for maintenance pharmacotherapy. As described here, the overall two-year societal costs for an untreated opioid-dependent individual are over $200,000, an amount that would pay for eight to ten years of maintenance treatment for an individual. This report rightly highlights that even accounting just for health care costs, maintenance pharmacotherapy more than pays for itself. The $32,000-$39,000 cost for two years of treatment from this analysis is completely offset by the estimated $40,000 in two-year health costs of a relapsed or dead patient.

The tragic loss of life to opioid addiction that we have watched play out in newspaper headlines across New England is made all the more devastating by the fact that effective treatment exists, can save lives, and is cost effective. The evidence reviewed in this report makes an irrefutable argument for the need for immediate policy changes to ensure greater access to long-term maintenance pharmacotherapy for all patients with opioid use disorders.

References:
1: Friedmann PD & Schwartz RP. Just Call it Treatment. Addiction Science & Clinical Practice 2012, 7:10
2: Fareed A, Casarella J, Roberts M, Sleboda M, Amar R, Vayalapalli S, Drexler K. High dose versus moderate dose methadone maintenance: is there a better outcome? J Addict Dis. 2009 Oct;28(4):399-405.
3: Peles E, Kreek MJ, Kellogg S, Adelson M. High methadone dose significantly reduces cocaine use in methadone maintenance treatment (MMT) patients. J Addict Dis 2006;25(1):43-50.
4: Hser Y et al.Treatment retention among patients randomized to buprenorphine/naloxone compared to methadone in a multi-site trial. Addiction, 109, 79–87.
5: Kakko J et al. 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: a randomised, placebo-controlled trialLancet 2003; 361: 662–68.
6: NIDA. http://www.drugabuse.gov/sites/default/files/pdf/partb.pdf

2. Madeleine Mongan

Deputy EVP, Vermont Medical Society

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In Vermont the rules for Medication Assisted Treatment (MAT Rules) that apply to OTPs also apply to OBOT providers who have 30 or more patients on narcotic replacement treatment. http://healthvermont.gov/regs/documents/opioid_dependence_rule.pdf (Page 1, Section 3 - Purpose) The MAT rules require a psychosocial assessment or referral for an assessment early in treatment. (page 17 of 24)

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Vermont has now **passed** legislation (S. 295) that requires pretrial screening and proposes to create programs, that will serve as screening, assessment and treatment alternatives to the criminal justice system for some individuals. Link to S. 295 as passed by House and Senate: http://www.leg.state.vt.us/docs/2014/bills/Passed/S-295C.pdf

Page 26 –The final version of the S. 295 does not require OBOT providers with fewer than 30 patients to ensure that their patients receive counseling. Instead it provides:

> "The Commissioner of Health shall adopt rules relating to medication-assisted therapy for opioid dependence for physicians treating fewer than 30 patients, which shall include a requirement that such **physicians ensure that their patients are screened or assessed to determine their need for counseling and that patients who are determined to need counseling or other support services are referred** for appropriate counseling from a licensed clinical professional or for other services as needed."

Page 26 S. 295 also requires the Department of Corrections to create a one year pilot project that will allow incarcerated individuals who were receiving medication assisted treatment before incarceration to continue treatment while incarcerated.

"The pilot project shall offer continued medication-assisted treatment for opioid dependence with methadone or buprenorphine and a prescribed taper as appropriate to incarcerated persons who were participating in medication-assisted treatment in the community immediately prior to incarceration."

Finally, S. 295 requires the Agency of Human Services to promulgate rules for physicians who prescribe buprenorphine for Medicaid patients that will require them to check the Vermont Prescription Monitoring System (VPMS) the first time they prescribe buprenorphine for a patient and at regular intervals thereafter. The law also requires the Agency to set dosage thresholds that may be exceeded only with prior approval of the Chief Medical Officer of the Vermont Medicaid agency, the Department of Vermont Health Access.

To implement this provision, DVHA will submit the following emergency rule to the Legislative Committee on Administrative Rules:

7502.7 Vermont Prescription Monitoring System (07/01/2014, 14-03E)

All Medicaid participating providers who prescribe buprenorphine or a drug containing buprenorphine to a Vermont Medicaid beneficiary must query the Vermont Prescription Monitoring System the first time they prescribe buprenorphine or a drug containing buprenorphine for the patient and no fewer than two times annually thereafter.

Dosage criteria, as described in the Provider Manual and approved by the Drug Utilization Review Board, may only be exceeded with prior approval from the Chief Medical Officer of the DVHA or designee.

3. Mark Parrino, MPA

President, American Association for the Treatment of Opioid Dependence (AATOD)

The CEPAC Report on Management Options for Opioid Dependence is certainly a comprehensive document. You referenced a number of the critical reports which document the benefits of maintenance treatment and I commend you for the comprehensive analysis.

I have a few minor comments, which are being tendered on behalf of the American Association for the Treatment of Opioid Dependence. The therapeutic dosage range for methadone maintenance treatment has generally been published between 80mg-120mg. the issue of dosage determination is captured in the SAMHSA Treatment Improvement Protocol #43, "Medication Assisted Treatment for opioid Addiction in Opioid Treatment Programs", (2005). "There is no single recommended dosage or even a fixed range of dosages for all patients. For many patients, the therapeutic dosage range of methadone may be in the neighborhood of 80-120mg per day, but it can be much higher, and occasionally, it is much lower." The point is that there are therapeutic benefits for some patients above 100mg per day of methadone maintenance treatment.

There is also a comment related to the section concerning New England State regulations on page 23. Your report indicates, "In Maine, counselors working at detoxification facilities or OTPs are unable to treat more than 50 patients at one time." This is not the case at the present time since the Maine State Opioid Treatment Authority altered these regulations, which have been in force before MaineCare had imposed a number of reductions in the weekly Medicaid reimbursement

rate for OTPs. The SOTA changed the regulation to allow 150 patients to be treated by any one counselor. In all candor, this was not seen as an improvement in treatment, and OTPs have subsequently been challenged by accreditation surveys with regard to compliance with federal regulation. The problems of Maine are quite critical with regard to supporting OTPs, which is very different when you compare policies in Vermont and Massachusetts.

Finally, there is a comment with regard to delivery models as noted on page 56. “Evidence is mixed on the benefits of psychosocial therapy and the management of opioid dependence. However, such counseling remains a standard component of Medication Assisted Treatment”. The key phrase here is “Medication Assisted Treatment” and the mixed results are not based on the benefits for the patient when effective counseling is combined with any one of the three federally approved medications to treat chronic opioid addiction. The Principles of Effective Treatment, which was published by the National Institutes on Drug Abuse in 2009, consistently makes the point that counseling and other treatment interventions, which are used to enhance the use of the federally approved medications to treat opioid addiction, leads to more effective treatment outcome for the individual patient. This also depends on the qualifications of the counselor providing such services. Obviously, the clinician needs to be well trained and knowledgeable about the field of opioid addiction treatment. The individual clinician’s attitude toward the patient is just as important. The real question is the quality of the counseling and the real and perceived benefits to the patient. It is not likely that a patient would benefit from counseling if the individual counselor lacks the essential knowledge of treatment of the patient or has a negative attitude toward the patient. This is where the mixed results generally come to surface.

In summary, your report certainly brings into account a number of the active debates in treating chronic opioid addiction. As has been noted, there is still an enormous stigma that this particular patient population faces in and out of treatment.