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Addiction Medicine

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July 21, 2016

Mr. Thomas Leet  
Comprehensive Health Planner II  
MaineCare Services  
242 State St.  
11 State House Station  
Augusta, Maine 04333-0011

RE: Proposed Rule: MaineCare Benefits Manual, Chapters II and III,  
Section 65, Behavioral Health Services

Dear Mr. Leet,

On behalf of the American Society of Addiction Medicine (ASAM) and the Northern New England Society of Addiction Medicine (NNESAM), we are writing in response to the request for comments on the Proposed Rule: MaineCare Benefits Manual, Chapters II and III, Section 65, Behavioral Health Services.

ASAM and NNESAM are deeply concerned with the Proposed Rule's potential impact on access to evidence-based opioid addiction treatment in the state of Maine. Our nation as a whole is reeling from the disastrous effects of an epidemic of opioid addiction and overdose deaths, and Mainers in particular are suffering. In 2014, 216 Mainers lost their lives to opioid overdoses, up from 174 in 2013.<sup>1</sup> Sadly, many of these deaths could have been prevented through evidence-based treatment. Despite widespread stigma and negative personal beliefs about persons suffering from addiction or the effectiveness of treatment, the medical science is unequivocal: opioid addiction is a chronic disease of the brain and medication-assisted treatment is the gold standard treatment to help patients enter recovery.<sup>2</sup> At a time when opioid addiction is increasingly claiming lives, devastating families, and destroying communities, it is imperative that policymakers do everything in their power to increase access to evidence-based, life-saving care.

We are concerned that the Proposed Rule would do just the opposite by imposing additional requirements on providers of medication-assisted treatment without an accompanying increase in reimbursement rates. Moreover, the proposed rule lacks needed clarity and specificity regarding the difference between methadone treatment, provided in federally regulated opioid treatment programs (OTPs), and

office-based opioid addiction treatment with buprenorphine or naltrexone. Our specific comments are detailed below.

### Definitions

The Proposed Rule includes a revised definition of “Medication-Assisted Treatment (MAT)” which encompasses several medications used for the treatment of opioid addiction and alcohol withdrawal. However, it fails to distinguish between the very different clinical and regulatory aspects of the medications listed. For example, methadone is a Schedule II controlled substance and may only be dispensed through federally certified opioid treatment programs (OTPs), buprenorphine (Suboxone) is a Schedule III controlled substance and may be prescribed by certain qualified physicians in the office setting, and naltrexone (Vivitrol) is not a controlled substance and may be prescribed or administered by any physician in the office setting. Furthermore, nowhere in the Proposed Rule are “Medication-Assisted Treatment Facility” and “Medication-Assisted Treatment Program” defined, although those terms are used throughout. Accordingly, it is unclear to what types of clinics or practices the rule would apply.

The final rule should be explicit as to which parts apply only to OTPs, to any clinic or practice where patients are treated with controlled substances for addiction (including physicians’ offices where patients are prescribed buprenorphine), or to any clinic or practice where patients are treated for addiction and prescribed any of the medications listed in the current definition of “Medication-Assisted Treatment,” including non-controlled substances. It should clearly distinguish between requirements for each treatment setting, as each is subject to different federal, state, and state medical board regulations. Further, it should strive to align its requirements with current federal and state licensure requirements so as not to create conflicting or inconsistent criteria for licensure and reimbursement.

### Counseling Requirements

ASAM’s National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use (Guideline) recommends psychosocial treatment in conjunction with any pharmacological treatment of opioid addiction, but the recommendations differ depending on which medication a patient is receiving.<sup>3</sup> Regarding treatment with methadone, the Guideline states:

Psychosocial treatment is generally recommended for patients in treatment with methadone. Studies have found that psychosocial treatment in conjunction with methadone pharmacotherapy improves treatment effectiveness.

Regarding office-based treatment with buprenorphine, the Guideline states:

Clinicians who are prescribing buprenorphine should consider providing or recommending office-based or community-based psychosocial treatment. There is some research evidence that the addition of psychosocial treatment improves adherence and retention in treatment with buprenorphine; however, these findings are mixed.

However, it is important to note that the Guideline does *not* recommend any specific minimum hours to be completed, and the recommendation for psychosocial treatment for patients receiving

buprenorphine makes it clear that these services can be provided by the physician him or herself. The proposed rule's requirements for at least one hour of weekly counseling by a Masters Level Counselor or other licensed professional during the first 45 days, bi-weekly during the stabilization stage, and monthly thereafter are not supported by any evidence of effectiveness of this type of additional requirements,<sup>4</sup> and we anticipate they will erect a barrier to care, particularly for patients receiving office-based treatment. We strongly recommend that the counseling requirements in the final rule reflect the differences between the two treatment settings. Specifically, they should be expanded to allow physicians who provide office-based treatment to provide psychosocial treatment themselves. Further, we urge MaineCare to ensure that reimbursement rates for all treatment modalities are sufficient to support the requirements included in the final rule.

We understand reimbursement rates for OTPs in Maine were recently cut to a bundled payment of \$60 per member per week, which has been demonstrably insufficient to support extensive counseling services, and that a waiver has been granted to increase the patient-to-counselor ratio accordingly. We urge MaineCare to increase its reimbursement rates to OTPs so that recommended counseling can be provided to patients. Without an increase in reimbursement rates or a continuation of the waiver, it is expected that many OTPs will not be able to continue to operate in Maine. Such a change would be disastrous for the 4,000 Mainers currently receiving care at Maine's OTPs.

ASAM and NNESAM stand by our long-held assertion that treatment for addiction, including addiction involving opioid use, must be individualized to best meet the clinical and social needs of each patient. For many patients recovering from opioid addiction, methadone is the recommended and more effective treatment modality. For example, patients requiring intensive, frequent counseling and accountability reinforcements respond far better to methadone treatment with daily structure than to less intensive office-based treatment with buprenorphine or extended-release injectable naltrexone. Patients who decide to transition from methadone to buprenorphine must undergo a lengthy, often difficult process of physician-monitored methadone tapering, followed by buprenorphine induction and stabilization; those who transition to extended-release injectable naltrexone must be completely withdrawn from methadone. A forced, rapid transition will yield, at best, significant patient discomfort and destabilization and, at worst, relapse and death from overdose or withdrawal.

### Facility Operation

The Proposed Rule would require "Medication-Assisted Treatment Facilities" to be open at least six (6) days per week. Such a requirement would have a very different impact on an OTP than it would on an individual or group physician practice where patients with opioid addiction are treated and prescribed buprenorphine. Such a proposed requirement and its vastly different effects on different treatment settings underscores the need for very clear definitions to be included in the final rule. For OTPs, the proposed requirement would give welcome flexibility to close one day per week. For individual or group physician practices offering office-based opioid addiction treatment, such a requirement could be a strong disincentive to treating MaineCare members as it would likely require them to open an additional day each week. Again, we urge MaineCare to clearly differentiate between these treatment settings and types, and to carefully consider the differential impact that the Proposed Rule would have on access to each.

The Proposed Rule would also require facilities utilizing methadone to ensure that “tapering/withdrawal from medication is discussed with the patient during the first sixty (60) days of treatment and quarterly thereafter if not prompted earlier by client or other circumstances.” We oppose including such a requirement in the final rule as it is inconsistent with the chronic nature of the disease of addiction and the recommendation that treatment duration be determined by an individual’s response to treatment and a shared decision between the patient and his/her clinician. ASAM’s National Practice Guideline notes:

The optimal duration of treatment with methadone has not been established; however, it is known that relapse rates are high for most patients who drop out; thus long-term treatment is often needed. Treatment duration depends on the response of the individual patient and is best determined by collaborative decisions between the clinician and the patient.

Thus, quarterly discussions about tapering/withdrawal for all patients are not recommended and could convey to patients a subtle pressure to end or change what is an otherwise successful treatment.

#### Medical Records

The requirements under the Medical Records section of the Proposed Rule indicate that individual practitioners must follow the same intervals for completion of the initial service plan and updates to the service plan, that is, within seven (7) days of admission and at least every ninety (90) days thereafter. However, these intervals are inconsistent with those detailed under the Individualized Service Plan section, which states that individual practitioners must “reflect a treatment plan within the first seven (7) visits.” Again, we urge the final rule to clearly distinguish between the requirements for OTPs and individual physicians and to ensure the requirements within each category are internally consistent. The final rule could be clearer and more concise by combining the Medical Records and Individual Service Plan sections.

In conclusion, in order to ensure continued access to evidence-based and life-saving opioid addiction treatment in the state of Maine, we urge MaineCare to revise the Proposed Rule to clarify the distinctions between different treatment modalities and settings, and to ensure that the final requirements do not amount to uncompensated mandates that would make offering addiction treatment services to MaineCare members unsustainable.

Thank you for your consideration. We welcome the opportunity to work with MaineCare as the rule is finalized to ensure high-quality addiction treatment services are available and accessible to all members suffering from this disease.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Jeffrey Goldsmith", with a stylized flourish at the end.

R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM  
President, American Society of Addiction Medicine



Daniel Graubert, MD  
President, Northern New England Society of Addiction Medicine



Mark Publicker, MD, FASAM  
Past President, Northern New England Society of Addiction Medicine

cc: Kimberly A. Johnson, PhD, Director, Center for Substance Abuse Treatment, SAMHSA  
Mary Mayhew, Commissioner, Maine Department of Health and Human Services  
Richard McGreal, Associate Regional Administrator, CMS

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<sup>1</sup> Rudd RA, Aleshire N, Zibbell JE, and Gladden M. Increases in Drug and Opioid Overdose Deaths – United States, 2000–2014. *MMWR*. January 1, 2016 / 64(50);1378-82. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s\\_cid=mm6450a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w) Accessed July 13, 2016.

<sup>2</sup> World Health Organization. Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence. Available at: <http://apps.who.int/iris/handle/10665/43948>. Accessed July 13, 2016.

<sup>3</sup> American Society of Addiction Medicine. National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. June 1, 2015. Available at: <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24> Accessed July 14, 2016.

<sup>4</sup> Dugosh K, Abraham A, Seymore B, et al. A Systematic Review on the Use of Psychosocial Interventions in Conjunction with Medications for the Treatment of Opioid Addiction. *J Addict Med*. 2016;10: 93–103.