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December 18, 2015

Senator Eric L. Brakey, Chair
Representative Drew Gattine, Chair
Members, Joint Standing Committee on Health and Human Services
#100 State House Station
Augusta, ME 04333-0100

Dear Senator Brakey, Representative Gattine and Members of the Joint Standing Committee on Health and Human Services:

Attached is the report required by Public Law 2015, Chapter 267, Part SS. The Department of Health and Human Services (DHHS) was directed to convene a stakeholder group with the purpose of assisting in reviewing and making recommendations related to methadone treatment and report findings to the Joint Standing Committee on Health and Human Services.

If you have any questions or need additional information, please feel free to contact Nick Adolphsen at (207) 975-2838.

Sincerely,

Mary C. Mayhew
Commissioner

MCM/klv

Attachment

Methadone Treatment Stakeholder Group Report

Drafted for:

Joint Standing Committee on Health and Human Services

The Department of Health and Human Services

Submitted: December 2015

Introduction

On June 30, 2015, the Maine State Legislature passed Public Law 2015, Chapter 267, Part SS, Section 1. The law requires the Department of Health and Human Services (the Department) to assemble a stakeholder group with the purpose of assisting in reviewing and making recommendations related to methadone treatment. To develop effective reforms that incorporate appropriate viewpoints, the Department requested the attendance of a diverse array of stakeholders within the methadone treatment community including individuals in recovery, methadone treatment providers, physicians, and substance abuse experts. The law specifically tasked the Methadone Treatment Stakeholder Group (the Group) to consider appropriate criteria for treatment, consider the adequacy of existing prior authorization criteria, and assesses opportunities to improve treatment services to focus on progress, recovery, and reintegration. Following the convening of the Group, Public Law 2015, Chapter 267, Part SS, Section 2 requires the Group to submit a report to the Joint Standing Committee on Health and Human Services with its findings and any recommendations for changes.

During the months of October and November, the Group convened twice at the Department of Health and Human Services, 221 State Street Augusta, Maine 04330 (see *Appendix A* for full attendance list). The meetings were facilitated by Dr. Christopher Pezzullo, Chief Health Officer of the Department, who led the Group through a review of Public Law 2015, Chapter 267, Part SS and discussed a list of focused questions that guided the dialogue (see *Appendix B* for complete question list). The Group's engagements resulted in the following recommendations and conclusions.

Stakeholder Group- Key Themes

Addressing the Underlying Issues Related to Substance Use Disorder: Throughout the stakeholder meetings, the Group made it clear that methadone treatment is evidence-based and supports individuals to manage or recover from their substance abuse disorder. However, the most effective treatment also incorporates sufficient counseling, which is not adequate for some patients at present. In addition, many individuals with a substance use disorder are furthermore faced with historical trauma and other contributing mental and behavioral health needs. As a result, the group felt that most often the genesis of addiction is trauma coupled with genetics or a pain history, and that it is imperative that methadone treatment facilities provide the correct quantity and type of behavioral health interventions to allow for the ultimate resolution of substance use disorder and recovery from methadone treatment. The Group's conversation was in line with the Federal Substance Abuse and Mental Health Services Administration (SAMHSA), which notes,

Research supports the perspective that opioid addiction is a medical disorder that can be treated effectively with medications when they are administered under conditions consistent with their pharmacological efficacy and when treatment includes necessary supportive services such as psychosocial counseling, treatment for co-occurring disorders, medical services, and vocational rehabilitation.¹

It is essential that Methadone be utilized in conjunction with the appropriate behavioral health interventions to address the health of the whole person and tackle the roots of addiction. Furthermore, the Group suggested that moving from the current state regulation of dispensing 7 days per week to the federal regulation of dispensing 6 days per week, and to conform to federal regulations regarding take-home doses of methadone. Such conformity may ease barriers to treatment and may free additional clinical resources that could be utilized to supplement behavioral health care treatment in the clinic.

- ❖ The underlying causes of addiction must be recognized and treated appropriately, especially stressing the need for the right behavioral health services at the right time. Methadone utilization alone, without appropriate behavioral health treatment, is not adequate.

¹ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Abuse Treatment, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005, p. xvii.

Prior Authorization Should Focus on the Whole Person: As indicated by SAMHSA, “Because some patients require assistance in many functional areas, treatment plans should address measurable, achievable goals relevant to the patient’s current situation.”² Some Group members believe that the current MaineCare Prior Authorization (PA) form at 24 months of treatment is inappropriate and may be seen as an arbitrary time period for review of accountability measures evidencing recovery. The American Society of Addiction Medicine (ASAM) criteria, used as a basis for the present 24 month P.A., is a one-size fits all methodology that does not adequately reflect evidence of progress and improvement in family, home, community, education and employment. Progress toward recovery must be clearly documented and frequently assessed. The Department will review the current PA for improvement and inclusion of more meaningful criteria.

- ❖ Progress toward recovery must be proactive, closely monitored, appropriate, and measurable. Recovery and reintegration, though complex, must be the ultimate goal of the Methadone Addiction Treatment (MAT) system.

The Medical Profession and the Social Service System Needs to Become More Knowledgeable of and Comfortable with Substance Use Disorder Treatment: Education around the MAT system was a key theme, and the Group offered to be the genesis of an expert team that could provide both education as well as real-time assistance to Primary Care Physicians (PCPs) and the social service community.

The issue of confidentiality and patient connection to medical homes or other providers is complex. The federal regulation 42 CFR, section 2 rules on confidentiality are stricter than privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA), and complicate communication between an MAT and a patient’s primary physician.³ However, several MAT representatives in the Group stated that they overcome this challenge by requiring a release of information from all new patients in order to maintain communication with patient’s primary care providers.

One communication tool utilized by the healthcare system is the Prescription Monitoring Program (PMP) - an electronic database which contains information about all controlled substance prescriptions written in Maine. Maine has had a robust PMP for over 10 years. One concern, not adequately addressed by the Group, was the exclusion of outpatient methadone

² U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Abuse Treatment, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. 2005, p. 96.

³ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, ‘21 CFR Part 291, 42 CFR Part 8, Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction’, *Federal Register*, Vol. 66, No. 11, 2001, p. 4075-4102.

treatment from the PMP. This federal requirement causes a disconnect, unfortunately isolating the methadone treatment system from the greater healthcare system.

Education is needed for the medical community to better understand both the MAT system and the needs of patients in MAT. The group agreed that it could be beneficial for outpatient methadone providers to modify the current clinical structure and have primary care physicians embedded in or closely connected to these treatment facilities. The Department will review ways to educate and connect primary care providers to the MAT system.

- ❖ The healthcare system must be more responsive to, and educated about Substance Use Disorder. Confidentiality can be a double-edged sword, potentially isolating patients from the broader healthcare system.

Opioid Prescribers Need to Recognize Their Impact on Addiction: The work group recognized that heroin addiction is often the end result of opiate prescribing and implored the health system to better understand the risks and benefits of opiate prescribing. This is consistent with ASAM's *Opioid Addiction Disease 2015 Facts & Figures* that concludes (nationally), "About 75% of opioid addiction disease patients switch to heroin," (see *Appendix D* attached). Further supportive evidence for this concern can be found in the Federal CDC's Morbidity and Mortality Weekly Report on *Controlled Substances and Prescribing Patterns*, which states there are 855 distinct opiate prescriptions written for every 1,000 Maine state residents.⁴ In addition, Maine's 2015 PMP data shows that approximately 80,000,000 opioid pills are legally distributed annually throughout the state!⁵ It would follow that excessive prescriptions, resulting in the distribution of an excessive number of pills, could encourage a culture that fosters prescription drug abuse due to ease of access.

- ❖ MaineCare has successfully implemented policies to restrict the overprescribing of Opiates. We will continue to evaluate and improve these guidelines. The broader health care infrastructure needs to be aware of their role in the crisis of heroin addiction affecting Maine and take action toward similar policies

⁴S., Rasmussen, M.D., M.S., et al., 'Controlled Substance Prescribing Patterns- Prescription Behavior Surveillance System, Eight States, 2013', *MMWR Surveillance Summaries 2015*, vol. 64, no. 9, 2015, p. 5.

⁵Flanigan, K.S., M.D., *A New Approach to Pain Management: A New Utilization Pattern for Opioid Prescribing 2011-2015*, PowerPoint, 2015.

Appendix A- Stakeholder Group Attendees

- Adolphsen, Nick: DHHS- Commissioner's Office
- Black, Anna: DHHS- Substance Abuse and Mental Health Services
- Brooks, Jamie: Individual in Recovery
- Cassella, Christine: Individual in Recovery
- Coffey, Dan: Acadia Hospital
- Cohen, Jim, J.D.: Verrill Dana
- Coutu, Katherine: DHHS- Substance Abuse and Mental Health Services
- D'Agostino, Marietta: DHHS- Division of Licensing and Regulation Services
- Jorgenson, Doug, D.O.: Physician
- Kiezulas, Andrew: Individual in Recovery
- Lamensky, Tyler: DHHS- Commissioner's Office
- Leet, Thomas: DHHS- Office of MaineCare Services
- MacLean, Andy, J.D.: Maine Medical Association
- Martin, Kevin: Individual in Recovery
- Nadeau, Stefanie: DHHS- Office of MaineCare Services
- Norris, Merideth, D.O.: Physician
- Osgood, Denise: DHHS- Program Integrity
- Pezzullo, Chris, D.O.: DHHS- Center of Disease Control and Prevention
- Py, Joe, D.O.: Physician
- Ryder, Catherine: Tri-County Mental Health Services
- Senft, Samuel, J.D.: DHHS- Office of MaineCare Services
- Smyrski, Joan: DHHS- Substance Abuse and Mental Health Services
- Tompkins, Karen: Individual in Recovery

Appendix B- Discussion Questions

Treatment Criteria: Caring for the Whole Person

- ✓ What makes methadone a preferred treatment modality?
- ✓ Who is best treated with methadone and why?
- ✓ How do you ensure primary care participation?
- ✓ How do you keep MAT patients engaged in a medical home?
- ✓ Do you regularly communicate with the patients' primary care providers? If not, what are the barriers to communication that cause the Methadone Treatment system to remain separate and non-integrated with the health care system?
- ✓ How do you ensure safety for the children of patients involved in MAT?

Prior Approval: Evaluation and Expectation

- ✓ How could the ASAM criteria be used to hold providers to a measurable standard of recovery? Give examples of performance metrics utilized regarding employment rates, educational goals, family stability, etc. as they pertain to recovery from addiction. Could you give examples of a study you've done related to this?
- ✓ Define and give examples of the role of CQI/QA (Continuous Quality Improvement/Quality Assurance) as it pertains to MAT (Medication Assisted Therapy).
- ✓ What does/should counseling look like for a typical MAT patient?

Treatment Services: Opiate Addiction System

- ✓ Define recovery from drug addiction.
- ✓ What do you want us to know about addiction?
- ✓ What's the process of moving from methadone to another treatment or modality as a step-down?
- ✓ What's the process of moving from methadone to another treatment modality if methadone treatment has not been effective?
- ✓ Should all patients utilizing MAT-methadone be weaned to suboxone, vivitrol or abstinence after 24 months? If not, why not?
- ✓ What 3 things could improve the MAT (medication assisted therapy) system in Maine?
- ✓ How can we better train primary care providers to assist you in addiction treatment? How would you be willing to assist in their training?

Appendix C- ASAM Criteria

ASAM CRITERIA

ASAM's criteria, formerly known as the ASAM patient placement criteria, is the result of a collaboration that began in the 1980s to define one national set of criteria for providing outcome-oriented and results-based care in the treatment of addiction. Today the criteria have become the most widely used and comprehensive set of guidelines for placement, continued stay and transfer/discharge of patients with addiction and co-occurring conditions. ASAM's criteria are required in over 30 states.

How ASAM's Criteria Works

ASAM's treatment criteria provide separate placement criteria for adolescents and adults to create comprehensive and individualized treatment plans. Adolescent and adult treatment plans are developed through a multidimensional patient assessment over five broad levels of treatment that are based on the degree of direct medical management provided, the structure, safety and security provided and the intensity of treatment services provided.

AT A GLANCE: THE SIX DIMENSIONS OF MULTIDIMENSIONAL ASSESSMENT		
ASAM's criteria uses six dimensions to create a holistic, biopsychosocial assessment of an individual to be used for service planning and treatment across all services and levels of care. The six dimensions are:		
1	DIMENSION 1	Acute Intoxication and/or Withdrawal Potential Exploring an individual's past and current experiences of substance use and withdrawal
2	DIMENSION 2	Biomedical Conditions and Complications Exploring an individual's health history and current physical condition
3	DIMENSION 3	Emotional, Behavioral, or Cognitive Conditions and Complications Exploring an individual's thoughts, emotions, and mental health issues
4	DIMENSION 4	Readiness to Change Exploring an individual's readiness and interest in changing
5	DIMENSION 5	Relapse, Continued Use, or Continued Problem Potential Exploring an individual's unique relationship with relapse or continued use or problems
6	DIMENSION 6	Recovery/Living Environment Exploring an individual's recovery or living situation, and the surrounding people, places, and things

<http://www.asam.org/publications/the-asam-criteria/about>

Appendix D- ASAM Opioid Addiction Disease 2014 Facts & Figures



OPIOID ADDICTION DISEASE

2015 FACTS & FIGURES

Opioid Addiction Disease Basics

- Opioids are any of various compounds that bind to specific receptors in the central nervous system and have analgesic (pain relieving) effects including prescription medications such as oxycodone and hydrocodone and illicit substances such as heroin
- Opioid addiction is federally described as a progressive, treatable brain diseaseⁱ
- *ASAM Addiction Definition:* Chronic, relapsing brain disease characterized by compulsive drug-seeking behavior and drug use despite harmful consequenceⁱⁱ
- Any type of opioid can trigger latent chronic addiction brain disease
- 24.6 million people 12 or older (9.4% of the population) live with substance dependence or abuseⁱⁱⁱ
- 1.9 million Americans live with prescription opioid abuse or dependence, while 517,000 Americans live with heroin addiction^{iv}
- Opioid addiction disease occurs in every American State, County, socio-economic and ethnic group
- 23% of heroin users develop chronic opioid addiction disease

National Opioid Overdose Epidemic

- Over 100 Americans died from overdose deaths each day in 2013^v
- 46 Americans die each day from prescription opioid overdoses; two deaths an hour, 17,000 annually^{vi}
- While illicit opioid heroin poisonings increased by 12.4% from 1999 to 2002, the number of prescription opioid analgesic poisonings in the United States increased by 91.2% during that same time period^{viii}
- Drug overdose was the leading cause of injury death in 2013, greater than car accidents and homicide^{ix}
- About 8,200 Americans die annually from heroin overdoses^x
- About 75% of opioid addiction disease patients switch to heroin as a cheaper opioid source^{xi}
- In 2012, 259 million opioid pain medication prescriptions were written, enough for every adult in America to have a bottle of pills^{xii}

Public Health Special- Populations Impact

Adolescents (12 to 17 years old)

- Every day, 2,500 American youth abuse a prescription pain reliever for the first time^{xiii}
- Nearly 1 in 20 high school seniors has taken Vicodin, 1 in 30 has abused OxyContin^{xiv}
- Over 50% of individuals 12 years or older used pain relievers nonmedically from a friend or relative^{xv}
- Adolescent abuse of prescription drugs is frequently associated with other risky behavior, including abuse of other drugs and alcohol^{xvi}
- The number of opioids prescribed to adolescents and young adults (ages 15 to 29) nearly doubled between 1994 and 2007^{xvii}

Appendix D- Continued

Women

- Prescription opioid overdose caused five times as many women's deaths in 2010 than in 1999^{xiii}
- In 2010, more than 6,600 women died from prescription painkiller overdoses (18 each day)^{xx}
- Every three minutes, a woman goes to the emergency department for prescription painkiller misuse or abuse^{xx}

ASAM FACTS & FIGURES 2015: DATA SOURCES

- ⁱ Opioid addiction is federally described as a progressive, treatable brain disease, according to the American Society of Addiction Medicine's definition of addiction.
- ⁱⁱ <http://www.asam.org/for-the-public/definition-of-addiction>
- ⁱⁱⁱ In 2013, the *National Survey on Drug Use and Health (NSDUH)* estimated that, within the past year, 24.6 million people 12 or older (9.4 percent of the population) live with substance dependence or abuse, based on *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition (DSM-IV) criteria. <http://www.samhsa.gov/data/sites/default/files/NSDUH-SR200-RecoveryMonth-2014/NSDUH-SR200-RecoveryMonth-2014.htm>
- ^{iv} In 2013, the *National Survey on Drug Use and Health (NSDUH)* estimated that 1.9 million Americans live with opioid pain reliever addiction and 517,000 are addicted to heroin. <http://www.samhsa.gov/data/sites/default/files/NSDUH-SR200-RecoveryMonth-2014/NSDUH-SR200-RecoveryMonth-2014.htm>
- ^v According to the National Institute on Drug Abuse (NIDA), about 23% of heroin users develop chronic opioid addiction disease. <http://www.drugabuse.gov/publications/drugfacts/heroin>
- ^{vi} <http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html>
- ^{vii} According to the Centers for Disease Control and Prevention (CDC), 46 Americans die every day from opioid prescription drug overdoses; that translates to almost two deaths an hour and 17,000 annually. CDC Vital Signs, July 2014 (<http://www.cdc.gov/vitalsigns/opioid-prescribing/>)
- ^{viii} Paulozzi LJ. Opioid analgesic involvement in drug abuse deaths in American metropolitan areas. *Am J Public Health* 2006;96(10):1755–1757. <http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2005.071647?journalCode=ajph>
- ^{ix} According to statistics from the Centers for Disease Control and Prevention's Web-based Injury Statistics Query and Reporting System (WISQARS) (2014), drug overdose was the leading cause of injury death in 2012, killing more than motor vehicle accidents.
- ^x According to the Centers for Disease Control and Prevention (CDC), more than 3,000 Americans die annually from heroin overdoses. <http://www.cdc.gov/nchs/data/databriefs/db190.htm>
- ^{xi} <http://archpsyc.jamanetwork.com/article.aspx?articleid=1874575>
- ^{xii} CDC Vital Signs, July 2014 (<http://www.cdc.gov/vitalsigns/opioid-prescribing/>)
- ^{xiii} Every day, 2,500 American youth abuse a prescription pain reliever for the first time, according to Foundation for a Drug-free World. <http://www.drugfreeworld.org/drugfacts/prescription/abuse-international-statistics.html>
- ^{xiv} Nearly 1 in 20 high school seniors have taken Vicodin and 1 in 30 has abused OxyContin, according to the National Institute on Drug Abuse, Monitoring the Future Study (<http://www.drugabuse.gov/trends-statistics/monitoring-future/monitoring-future-study-trends-in-prevalence-various-drugs>)
- ^{xv} Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011:2011. <http://www.samhsa.gov/data/sites/default/files/NSDUHNationalFindingsResults2010-web/2k10ResultsRev/NSDUHResultsRev2010.pdf>
- ^{xvi} Adolescent abuse of prescription drugs frequently is associated with other risky behavior, according to the National Institute on Drug Abuse.
- ^{xvii} Fortuna RJ, Robbins BW, Caiola E, et al. Prescribing of controlled medications to adolescents and young adults in the United States. *Pediatrics* 2010;126(6):1108–1116. <http://pediatrics.aappublications.org/content/126/6/1108.long>
- ^{xviii} Prescription opioid overdose caused five times as many women's deaths in 2010 than in 1999, according to the Centers for Disease Control and Prevention Vital Signs Report (<http://www.cdc.gov/vitalsigns/PrescriptionPainkillerOverdoses/index.html>)
- ^{xix} The Centers for Disease Control and Prevention in Vital Signs, July 2013, reported that, in 2010, more than 6,600 women died from prescription painkiller overdoses (18 a day). <http://www.cdc.gov/vitalsigns/PrescriptionPainkillerOverdoses/index.html>
- ^{xx} <http://www.cdc.gov/vitalsigns/prescriptionpainkilleroverdoses/infographic.html>

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U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, '21 CFR Part 291, 42 CFR Part 8, Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction', *Federal Register*, Vol. 66, No. 11, 2001, p. 4075-4102.