

REPORT OF THE BOARD OF TRUSTEES

B of T Report 2-I-19

Subject: Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings
(Resolution 202-I-18)

Presented by: Jesse M. Ehrenfeld, MD, MPH, Chair

Referred to: Reference Committee B
(, MD, Chair)

1 INTRODUCTION

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3 At the 2018 Interim Meeting, the House of Delegates referred Resolution 202-I-18, “Enabling
4 Methadone Treatment of Opioid Use Disorder in Primary Care Settings,” introduced by the
5 Pennsylvania Delegation, which asked:

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7 That our American Medical Association study the implications of removing those
8 administrative and/or legal barriers that hamper the ability of primary care physician practices
9 to dispense methadone, as part of medication assisted treatment;

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11 That our AMA study the implications of working with other Federation stakeholders to
12 identify the appropriate educational tools that would support primary care practices in
13 dispensing ongoing methadone for appropriate patients as part of medication-assisted
14 treatment.

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16 Testimony on Resolution 202 was generally supportive of having the AMA study the implications
17 of removing barriers that hamper the ability of physician practices to dispense methadone, one of
18 the three main drug classes commonly referred to as medication-assisted treatment (MAT). There
19 also was testimony that the AMA does not need to study working with state and specialty societies
20 regarding the issues raised in Resolution 202 but instead should work directly with the Federation
21 on supporting greater access to methadone treatment for opioid use disorder, including removing
22 stigma. There was some confusion about what educational resources may exist to further these
23 goals—one of the areas which this report seeks to resolve.

24 25 DISCUSSION

26 27 *Background*

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29 As outlined in Board of Trustees Report 5-I-18, “Exclusive State Control of Methadone Clinics,”
30 the AMA has been a strong supporter of methadone maintenance treatment (MMT) as an evidence-
31 based option to help treat patients with an opioid use disorder. MMT has been used for more than
32 40 years to help patients, having been approved in 1972 by the U.S. Food and Drug Administration
33 (FDA) for treatment of heroin addiction. The health and safety of methadone has been studied
34 extensively and ample evidence exists supporting its use to aid in mortality and crime reduction.¹

1 There are 1,685 certified opioid treatment programs (OTPs) offering methadone in the United
 2 States.² According to the Substance Abuse and Mental Health Services Administration
 3 (SAMHSA), the number of persons receiving methadone increased by 34 percent from 2006
 4 (258,752) to 2016 (345,443).³ With respect to opioid-related mortality, deaths attributed to
 5 methadone increased rapidly from 1999 (784 deaths) to their peak in 2007 (5,518) and have
 6 steadily declined since. In the past five years, for example, methadone-related mortality has
 7 decreased from 3,493 (2015) to 3,078 (2019), according to the Centers for Disease Control and
 8 Prevention.⁴ It is beyond the scope of this report, however, to detail whether the methadone use in
 9 these deaths was for the treatment of pain, for opioid use disorder, related to illicit use or was a
 10 complicating polypharmacy factor. It is further beyond the scope of this report to try and ascertain
 11 how many of those persons were under the care of a physician or being treated in an OTP.

12 *Administrative/legal requirements for dispensing methadone*

13 SAMHSA has broad regulatory authority concerning MMT and OTPs. This includes the authority
 14 to certify an OTP, which is defined as “a program or practitioner engaged in opioid treatment of
 15 individuals with an opioid agonist treatment medication registered under 21 USC 823(g)(1).”⁵

16 Regulations governing OTPs are generally contained in 42 CFR Part 8, which provides that the
 17 definition of “dispense” means “to deliver a controlled substance to an ultimate user by, or
 18 pursuant to, the lawful order of, a practitioner, including the prescribing and administering of a
 19 controlled substance.” Any medication dispensed at an OTP must be dispensed by a health care
 20 professional licensed to do so under state law as well as registered under applicable state and/or
 21 federal law.⁶ In most cases, methadone is dispensed on a daily basis to the patient at the OTP, and
 22 OTP staff must observe the patient taking the medication. Take-home use is permitted under
 23 federal regulations in certain situations—subject to considerable additional oversight,
 24 documentation and monitoring for appropriate use and preventing diversion.

25 Federal rules also provide that “methadone shall be administered or dispensed only in oral form
 26 and shall be formulated in such a way as to reduce its potential for parenteral abuse.”
 27 42 CFR Part 8 also requires that for each new patient enrolled in a program, the initial dose of
 28 methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed
 29 40 milligrams, unless the program physician documents, in the patient's record, that 40 milligrams
 30 did not suppress opioid abstinence symptoms.

31 A study of primary care practices outside of an OTP providing MMT has been conducted.⁷ For the
 32 study to take place, prior approval from state and county officials and the Drug Enforcement
 33 Administration (DEA) and extensive additional documentation was required. In addition,
 34 significant controls were required, including a highly motivated group of physicians, patients who
 35 were stable for at least one year on MMT and multiple administrative requirements including
 36 regular and random toxicology screens, patient assessments, close affiliation with a cooperative
 37 OTP, close relationships with pharmacists, counselors and other staff as necessary. Notably, the
 38 primary care practice was required to have an ongoing relationship with the community OTP.

39 Patient selection and care coordination were two additional keys to the program's positive
 40 outcomes. Of the 684 patients in the community OTP, 30 qualified and agreed to the primary care
 41 provider program managing their ongoing care. Of these, 445 of 449 urinalysis tests were negative,
 42 and all random callback urinalysis tests were positive for methadone and negative for other drugs
 43 of abuse. For at least this one study and primary care practice, adding 30 patients with complex
 44 medical needs may not cause undue strain on the practice—and even likely adds many benefits. In

other words, experimental primary care models to provide MMT are possible, but whether this study can be a model for other practices is not clear.

Other studies also found that patients stable on long-term MMT have benefited from having their care provided in a primary care setting outside of an OTP.⁸ These studies also found that, in addition to low relapse and successful provision of additional primary care services (e.g., tobacco cessation, treatment for hypertension), there were increased services provided for treatment of infectious disease. Studies also found patient and physician satisfaction levels increased during the course of the study. In addition, physician education increased and there was a reduction in stigma.

Thus, while federal law has strict controls that methadone only be dispensed from an OTP, there have been experimental programs—subject to prior federal approval—that have demonstrated benefits of having MMT provided in a primary care setting outside of a traditional OTP. These experimental programs, however, are highly structured and still must comply with state and federal rules (including who can dispense, take-home rules for stable patients, patient monitoring, strict record-keeping, etc.) governing the provision of MMT.

Educational resources to support the provision of MMT

The AMA has broadly supported efforts to enhance physicians' education with respect to many aspects of the nation's opioid epidemic, including broad support for all forms of MAT. The AMA has broadly supported legislative and regulatory efforts at the state and federal levels to expand access to MAT. AMA model state legislation calls for all payers to make all forms of MAT available without prior authorization and placed on a formulary's lowest cost-sharing tier. AMA advocacy has led to more than one dozen states removing prior authorization for MAT, including methadone, in the commercial and/or Medicaid markets in 2019.

At the same time, a review of educational resources focused on methadone shows that the AMA opioid microsite (accessible here: www.end-opioid-epidemic.org) only has three titles focused on methadone education in its library of more than 400 resources.⁹ There are, however, several physician-led organizations that have considerable education and training resources on a wide variety of areas related to methadone, including induction, ongoing maintenance, stigma and more. This includes the Providers Clinical Support System (PCSS), which is led by the American Academy of Addiction Psychiatry (and of which the AMA is a steering committee member), American Society of Addiction Medicine, the *Journal of the American Medical Association* and other trusted organizations and resources.

While it is speculative to know whether the identification and promotion of these resources would lead to increased numbers of primary care physicians either determining to open their own OTP, providing services in an OTP or even pursuing office-based opioid treatment options that do not include MMT, the Board strongly supports additional educational efforts to, at the very least, reduce the stigma of MMT and increase general knowledge about MMT.

AMA POLICY

AMA policy supports MMT as an evidence-based treatment for opioid use disorder and supports having stable patients treated in a traditional office-based setting (Policy H-95.957, "Methadone Maintenance in Private Practice"). AMA policy also supports the types of investigational studies described above to further efforts to enable office-based physicians to use MMT "to treat opiate withdrawal and opiate dependence in accordance with documented clinical indications and consistent with sound medical practice guidelines and protocols" (Policy H-95.957, "Methadone

Maintenance in Private Practice”). AMA policy also calls for broad support to expand MMT services (Policy D-95.999, “Reduction of Medical and Public Health Consequences of Drug Abuse: Update”). This includes broad support of OTPs (Policy H-95.921, “Exclusive State Control of Methadone Clinics”). With respect to physician dispensing, the AMA “supports the physician’s right to dispense drugs and devices when it is in the best interest of the patient and consistent with AMA’s ethical guidelines” (Policy H-120.990, “Physician Dispensing”).

RECOMMENDATIONS

The Board recommends that the following recommendations be adopted in lieu of Resolution 202-I-18, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support further research into how primary care practices can implement MAT into their practices and disseminate such research in coordination with primary care specialties; (New HOD Policy)
2. That our AMA support efforts to expand primary care services to patients receiving methadone maintenance therapy (MMT) for patients receiving care in an Opioid Treatment Program or via office-based therapy; (New HOD Policy)
3. That the AMA Opioid Task Force increase its evidence-based educational resources focused on MMT and publicize those resources to the Federation. (Directive to Take Action)

Fiscal Note: \$2,500

REFERENCES

- ¹ See, for example, Kleber HD. Methadone Maintenance 4 Decades Later. JAMA. 2008;300(19):2303–2305. doi:10.1001/jama.2008.648. Available at <https://jamanetwork.com/journals/jama/fullarticle/182898>
- ² Opioid Treatment Program Directory. Substance Abuse and Mental Health Services Association. Available at <https://dpt2.samhsa.gov/treatment/directory.aspx> <https://dpt2.samhsa.gov/treatment/directory.aspx>; last reviewed July 17, 2019.
- ³ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N-SSATS): 2016 Data on Substance Abuse Treatment Facilities. Available at https://www.samhsa.gov/data/sites/default/files/2016_NSSATS.pdf
- ⁴ <https://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-type-of-opioid/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>The data points are from the predicted January 12-month total as reported by the National Vital Statistics System. Available at <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#dashboard>
- ⁵ 42 CFR Part 8, available at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=3&SID=7282616ac574225f795d5849935efc45&ty=HTML&h=L&n=pt42.1.8&r=PART#se42.1.8_12
- ⁶ 42 CFR Part 8.12(h)
- ⁷ See, for example Joseph O Merrill, MD, MPH, et al, “Methadone Medical Maintenance in Primary Care, An Implementation Evaluation.” J Gen Intern Med. 2005 Apr; 20(4): 344–349.
- ⁸ See, for example, Fiellin DA, O'Connor PG, Chawarski M, Pakes JP, Pantalon MV, Schottenfeld RS. Methadone Maintenance in Primary Care: A Randomized Controlled Trial. JAMA. 2001;286(14):1724–1731. doi:10.1001/jama.286.14.1724
- ⁹ The resources that include “methadone” in the title on the microsite are from the American Society of Addiction Medicine and Providers Clinical Support System.