INTRODUCTION

At the 2017 Interim Meeting, the House of Delegates referred Resolution 211-I-17, “Exclusive State Control of Methadone Clinics,” introduced by the Indiana Delegation, which asked:

That our American Medical Association support complete state control of all aspects of methadone clinic approval and operations; and, if deemed necessary, this control could be granted on a state by state basis.

Reference committee testimony generally was mixed and noted that there is likely both a state and federal role as it relates to methadone clinic approval and operations. Delegates encouraged further study, including discussion about methadone clinic reporting to state prescription drug monitoring programs (PDMP). This report reviews existing information, provides background and presents recommendations.

DISCUSSION

Your Board strongly agrees with the authors of Resolution 211-I-17 that methadone clinics provide a valuable service to patients with an opioid use disorder. Methadone maintenance therapy (MMT) for the treatment of opioid use disorder has been used for more than 40 years to help patients, having been approved in 1972 by the U.S. Food and Drug Administration (FDA) for treatment of heroin addiction. The health and safety of methadone has been studied extensively and ample evidence exists supporting its use to aid in mortality and crime reduction.1

There are more than 1,600 certified opioid treatment programs (OTPs) offering methadone in the U.S.2 According to the Substance Abuse and Mental Health Services Administration (SAMHSA), the number of persons receiving methadone increased by 34 percent from 2006 (258,752) to 2016 (345,443).3 With respect to opioid-related mortality, deaths attributed to methadone increased rapidly from 1999 (784 deaths) to their peak in 2007 (5,518) and have steadily declined since with 3,373 methadone-related deaths in 2016, according to the Centers for Disease Control and Prevention.4 It is beyond the scope of this report to detail whether the methadone use in these deaths was for the treatment of pain, for opioid use disorder, related to illicit use or was a complicating polypharmacy factor.

The FDA, U.S. Drug Enforcement Administration (DEA), U.S. Department of Health and Human Services (HHS) and states each have a role to play in the oversight and administration of MMT.
**FDA Regulatory Authority**

Within the broad scope of FDA’s regulatory authority is the review and approval of drugs, both brand name and generic. A general overview of the FDA process can be found online: [https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm#FDA](https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm#FDA). With respect to methadone, the FDA approved a New Drug Application for methadone in 1947. There were intervening actions, but for the purposes of this report, the FDA issued regulations for methadone Investigational New Drugs in 1971; proposed new regulations in April 1972; and issued final regulations in December 1972.  

**DEA Regulatory Authority**

DEA authority with respect to methadone focuses on the medication’s classification as a Schedule II controlled substance. Included within DEA’s responsibilities is the “enforcement of the provisions of the Controlled Substances Act as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances.” As a controlled substance, methadone falls within this scope.

**HHS Regulatory Authority**

The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), a division within HHS, has broad regulatory authority concerning MMT and opioid treatment programs (OTP). This includes the authority to certify OTPs, which is defined as “a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 USC 823(g)(1).”

Regulations concerning OTPs, where patients receive MMT (and other medications and treatments), provide guidance for numerous issues. These issues include accreditation of opioid treatment programs, certification and treatment standards for OTPs, procedures for review of suspension or proposed revocation of OTP certification, and of adverse action regarding withdrawal of approval of an accreditation body, and more.

Specifically related to methadone, 42 CFR Part 8 provides that “methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.” It also provides that:

For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient’s record that 40 milligrams did not suppress opioid abstinence symptoms.

There also are requirements for frequency of patients receiving toxicology tests, treatment of pregnant patients, requirements for take-home doses of methadone, and more.

**State Authority**

There are numerous areas where state regulatory authority and linkages with federal oversight exist regarding OTPs. One prominent area concerns who shall serve as the medical director of the OTP. Federal regulations require that the medical director must be “a physician licensed to practice medicine in the jurisdiction in which the [OTP] is located.” State licensure is squarely within the exclusive control of state licensing boards. Federal regulations also require that there are adequate
staffing requirements, employment qualifications and other personnel-related issues. These are
within the control of the state. And while it is complicated and beyond the scope of this report,
states also have a certain amount of leeway in determining zoning requirements for where an OTP
would be located. Notably, your Board strongly supports OTPs being treated no differently than
any other medical clinic that may seek to provide care in a community.10

SAMHSA also has recognized the clear need for OTPs to work with leaders in the community to
ensure comprehensive support services. That is, to support/encourage collaborative, multiagency
surveillance efforts to obtain timely and comprehensive data to target interventions and inform
prevention and response efforts. This includes working with the community to help determine
where an OTP is most needed; how an OTP can be integrated into the community with the least
impact on neighborhoods and traffic, for example; how to help educate the community on the
benefits of treatment for opioid use disorder so as to reduce stigma; and other areas.11

Another area of state control—which raises potential conflicts with federal law—concerns whether
OTPs should be required to report methadone dispensing information to the state PDMP. This issue
is extremely controversial. In fact, while this issue was raised by the resolution that gave rise to this
report, it also was raised in Resolution 507 from the 2018 Annual Meeting. Resolution 507-A-18
was referred for further study of a more extensive range of privacy and clinical issues relating to
PDMPs and OTPs. Given that your Board is currently deliberating on Resolution 507-A-18, and
the fact that SAMHSA has not specifically resolved the many issues associated with reporting OTP
information to state PDMPs,12 your Board believes it would be prudent to delay further comment
here so as not to cause confusion with pending research and discussions. Your Board does note,
however, that our AMA continues to urge physicians to use PDMPs to help inform their clinical
decision making. There is nothing to prevent physicians and other health care professionals in an
OTP from checking the state PDMP to ensure a patient is not receiving prescriptions for controlled
substances from other providers. Whether an OTP should report to a PDMP, however, is a matter
of federal—not state—jurisdiction.

Additional areas where states can help complement the medical care provided at OTPs include
promotion of take-home naloxone (governed by state law); education that helps remove the stigma
associated with MMT and medication assisted treatment (MAT); working toward policies that
remove health insurance and pharmacy benefit management company barriers to receiving MMT
and MAT (e.g., prior authorization, network adequacy for mental health care); prompt and accurate
overdose reporting for surveillance efforts related to prevention, treatment, and response;
identification of linkages within the community to peer counseling and other support services, to
name a few.

Furthermore, to complement and assist OTPs with the federal requirement to help an OTP identify
and prevent patients from enrolling in multiple OTPs concurrently, states can develop
communications and other tools to help OTPs (and other health care providers) identify all OTPs
doing business in a state and in surrounding areas. Federal rules already require an OTP to take
reasonable measures to do this. It seems reasonable that this would be an area where the state,
working with health insurance companies and other payers, as well as with the medical community,
would be well-advised to develop such a mapping/informational tool. This would not only allow
OTPs to more easily communicate with each other, but it would help patients identify where OTPs
exist in the state.

In Indiana, for example, the federal OTP locator maintained by SAMHSA identifies 16 OTPs
operating in the state,13 but it does not allow for multiple states to be displayed simultaneously. The
SAMHSA locator also does not allow for multiple OTPs within the state to be displayed.
simultaneously. While the AMA appreciates the technical and other challenges that may be present in maintaining and keeping a current list of OTPs, creating a more robust OTP locator tool may be an area where state-based expertise and multistate partnerships can tailor solutions so that patients and physicians would be able to more easily locate and communicate with OTPs.

AMA POLICY

Relevant AMA policy provides for strong support of access to methadone. This includes MMT used in combination with behavioral and social supports, as well as support for physicians and organized medicine to provide education and training regarding treatment of substance use disorders (Policy H-95.957, “Methadone Maintenance in Private Practice;” Policy D-120.985, “Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone”). AMA policy also calls for continued funding of OTPs operating in states (Policy D-95.999, “Reduction of Medical and Public Health Consequences of Drug Abuse: Update”); and for the AMA to “advocate for legislation that eliminates barriers to, increases funding for, and requires access to all appropriate FDA-approved medications or therapies used by licensed drug treatment clinics or facilities” (Policy D-95.968, “Support the Elimination of Barriers to Medication-Assisted Treatment for Substance Use Disorder”). AMA policy also clearly supports MAT in correctional settings and in the community in conjunction with counseling (Policy H-430.987, “Opiate Replacement Therapy Programs in Correctional Facilities”).

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AMA policy also provides, in part, that “local communities or regions should exercise the responsibility for assessing their needs with respect to the type, size, scope, and location of health care facilities. State governments should ensure that needs of the underserved are being met satisfactorily without wasteful duplication” (Policy H-205.992, “Supply and Distribution of Health Care Facilities”).

RECOMMENDATIONS

The Board recommends that the following recommendation be adopted in lieu of Resolution 211-I-17, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support the right of federally certified Opioid Treatment Programs (OTPs) to be located within residential, commercial and any other areas where there is a demonstrated medical need; (New HOD Policy)

2. That our AMA encourage state governments to collaborate with health insurance companies and other payers, state medical societies, national medical specialty societies, OTPs and other health care organizations to develop and disseminate resources that identify where OTP providers operate in a state and take part in surveillance efforts to obtain timely and comprehensive data to inform treatment opportunities; and (New HOD Policy)
3. That our AMA advocate for the federal agencies responsible for approving opioid treatment programs to consider the views of state and local stakeholders when making decisions about OTP locations and policies. (New HOD Policy)

Fiscal Note: $2,500
REFERENCES

4 Opioid Overdose Deaths by Type of Opioid. Kaiser Family Foundation analysis of CDC data. Available at 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
7 42 CFR Part 8, available at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=3&SID=7282616ae574225795d5849935e6f45&ty=HTML&h=L&n=pt42.1.8&r=PART#se42.1.8_12
8 42 CFR Part 8, available at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=3&SID=7282616ae574225795d5849935e6f45&ty=HTML&h=L&n=pt42.1.8&r=PART#se42.1.8_12
9 42 CFR Part 8.12