



Michael D. Maves, MD, MBA, Executive Vice President, CEO

September 29, 2010

Rear Admiral Eric B. Broderick, DDS, MPH
Deputy Administrator
Substance Abuse and Mental Health
Services Administration
1 Choke Cherry Road
Rockville, MD 20857

Dear Dr. Broderick:

Currently, approximately 200,000 individuals are receiving methadone in Opioid Treatment Programs (OTPs) to help manage addiction to heroin or certain other opioids. Approximately 1,200 certified OTPs are operative. As you know, OTPs must be certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) before they may dispense opioid drugs in the treatment of opioid addiction. To become certified, an OTP must: (1) meet the standards contained in 42 CFR § 8.12 (Federal Opioid Treatment Standards); (2) have a current, valid accreditation status from a SAMHSA-approved accreditation body; and (3) comply with any other conditions for certification established by SAMHSA.

Under the current regulatory framework governing confidentiality of drug abuse patient records, state-based prescription monitoring programs (PMPs) are currently prohibited from having access to patient records, including the dispensing of methadone to patients enrolled in OTPs. PMPs monitor electronically transmitted prescribing and dispensing data submitted by pharmacies and other dispensers. The data are used to support states' efforts in education, research, enforcement and drug abuse prevention. Currently, physician directors of OTPs could query the PMP to determine if their patient has a prescription for other controlled substances, but a primary care physician who has the same individual as a patient could not determine if he or she was using methadone unless that information was volunteered.

Given the rising tide of unintentional poisoning and deaths attributable to methadone use, it is reasonable to ask whether methadone dispensed to patients in OTPs should be reported to PMPs. PMP data is protected by statute, policies, and technology; it is generally not subject to subpoena or discovery in civil proceedings, but may be accessed by legal authorities pursuant to a criminal investigation. We appreciate that privacy and confidentiality issues remain a concern with PMPs, and methadone maintenance patients are confronted with serious issues related to stigma. Nevertheless, some states (e.g., West Virginia) have proposed requiring methadone treatment facilities to report take-home doses prescribed to their patients.

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SAMHSA conducted a reassessment of methadone mortality in 2007 and initiated another reassessment in July 2010. Although methadone deaths were not linked specifically with OTPs, they also were not linked exclusively with treatment for pain. The 2007 reassessment suggested that a more effective approach might be to focus on the site of treatment, drawing distinctions between office-based treatment for pain management and OTPs. Accordingly, the report identified a series of action steps to address methadone-associated deaths, one of which was to require OTPs to report dispensing data to state PMPs. This latter point also was emphasized during recent discussions surrounding the 2010 reassessment.

Therefore, the American Medical Association believes it is prudent to evaluate whether the necessary changes in federal regulation should be undertaken in order to permit reporting of methadone dispensed from OTPs to be part of state PMP databases. We believe that such a change ultimately would serve to protect patients.

Thank you for your consideration of this request.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA

cc: H. Westley Clark, MD, JD, MPH