

## Memorandum

To: Advisory to AATOD Members

From: Mark W. Parrino, MPA  
President

Date: March 1, 2010

RE: Voluntary Reporting of Deaths While Patients Are in OTPs

As you know, there has been a great deal of discussion about “methadone-associated mortality” in the United States during the past eight years. Four national reports have been published to date, beginning with the SAMHSA/CSAT report on this topic during 2004, its subsequent reassessment of July 2007, the Department of Justice Drug Intelligence Center report of November 2007, and the General Accounting Office’s (GAO) report of March 2009.

All of these published reports agreed on one general conclusion. The increase in methadone-associated mortality in the US is directly related to the increasing use of methadone in the treatment of chronic pain and not to its use in treating chronic opioid addiction in the network of the nation’s opioid treatment programs (OTPs). It is important to point out that we are not trying to disavow a relationship between these reports of methadone mortality and deaths that occur in OTPs during induction, or during the patients’ ongoing course of care.

There has also been a great deal of discussion about flawed methadone mortality data that is due to a lack of standards for coroners and medical examiners not having to determine when methadone toxicity has truly been involved in causing a death. The first published report of SAMHSA/CSAT (2004) made a clear recommendation that “...it would be helpful to develop uniform medical examiner/coroner case definitions and reporting methods, as well as a data collection system sufficiently comprehensive and flexible to handle new problems as they arrive.” It is our understanding that the SAMHSA/CSAT group of medical examiners, coroners, and experts are completing its work in this area.

SAMHSA/CSAT has instituted a voluntary reporting form for OTPs to submit to CSAT when patients die during the course of their treatment, whether death is related to natural causes, accident or induction-related overdose. As some long-tenured administrators/medical directors may recall, this reporting was routine (through 1987) when the Food and Drug Administration (FDA) had direct regulatory oversight of the system from 1972 until 2001 prior to the transition of regulatory oversight to SAMHSA/CSAT.

The AATOD Board of Directors has discussed this matter extensively over the course of the past year and we are recommending that all OTPs in the United States voluntarily report all patient deaths during the course of their treatment to CSAT using the CSAT form (see attached). This includes deaths due to natural causes such as heart disease, as well as those associated with the ingestion of prescription and illicit drugs. The OTP Mortality Report may be faxed or electronically submitted to SAMHSA's Opioid Treatment Program (OTP) Extranet Web site (<http://otp-extranet.samhsa.gov>). The OTP Extranet is a password-protected portal site already in use by OTP personnel to submit the SMA-168 Patient Exception Request form to SAMHSA. Online submissions will reduce reporting burden and ensure the submission of valid data.

In our collective judgment, it makes sense for OTPs to submit such data to CSAT, especially since a significant number of programs already report deaths to their state authorities. While this may add some burden in terms of double reporting, we believe that it is important to have a central repository of such data as a means of further demonstrating that the clear majority of deaths due to the use of methadone lie outside of our treatment system.

It is our hope that your OTPs will report such deaths during the course of treatment voluntarily, as a means of further demonstrating that methadone is used safely in our treatment environment.

Encl:

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