Dear Colleague:

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), has received approval [from the Office of Management and Budget (OMB)] for the Opioid Treatment Program (OTP) Mortality Reporting Form, SMA-xxx. The report form allows OTPs to voluntarily report mortality data on patients who at the time of death, were receiving medication-assisted treatment (methadone or buprenorphine) at a SAMHSA-certified OTP.

In 2004, accidental poisoning became the second leading cause of injury death in this country, with drug poisoning deaths being responsible for the large increases seen in recent years, since 1999. While it is believed that most of this increase has been among individuals taking a prescription narcotic and not in medication assisted treatment for opioid addiction, there are no current means of estimating the number of patients dying while enrolled in Opioid Treatment Programs (OTPs) and the causes of those deaths. Under the statutory authority of The Public Health Service Act, SAMHSA is responsible for supporting activities that will improve treatment for substance abuse and coordinating Federal policy with respect methadone. The proposed information gathering relating to mortality is ultimately in adherence to this legislative mandate.

The core to this voluntary reporting of all deaths is the opportunity for SAMHSA to gain information on the number of deaths from any cause in order to better assist the field develop and conduct quality improvement and risk management activities, with an overall goal to reduce the number of preventable deaths among patients who present daily to OTPs for medication treatment.

Understanding the cause of death of patients enrolled in OTPs or other drug treatment facilities can be a challenging task for many reasons, including inconsistencies in how deaths are reported; patients' use of other drugs, including illicit, over-the-counter, and prescription products; and other aspects of the patient's physical and mental condition. Therefore, in order to truly understand the data on methadone-associated deaths, it is important to be able to have a standardized, national reporting system to examine all deaths related to the use of methadone and buprenorphine.

The standardized terminology in this report will contribute to a more precise analysis of the data received. These data will be used to increase understanding of the factors contributing to these deaths and to help improve the quality of care. The form is collecting information

that should be readily available to any OTP that has met accreditation and certification standards. The OTP should not find any need to otherwise analyze or synthesize new data in order to complete this form. In addition, information from this reporting will not be used for compliance or enforcement purposes.

The Mortality Reporting Form will be made available via the SAMHSA website shortly. Thorough instructions will be provided to guide the reporter in completing the form. The form may be completed and submitted online or it may be mailed. A designated OTP staff member should complete and submit the form to SAMHSA within 48 hours of notification of a patient death. The OTP's investigation into a patient death should follow the policies and procedures set forth by the state and program. Additional information pertinent to the cause(s) of death discovered after the initial notification should be forwarded to SAMHSA immediately. All subsequent communications should reference the initial report.

At this time, we are requesting that this information be voluntarily reported to SAMHSA. We also welcome any feedback you have regarding use of the reporting form. Given national concerns over drug poisoning deaths, and the belief that a SAMHSA certified OTP should represent safe and competent addiction treatment of patients who have become dependent on heroin or prescription opioid drugs, SAMHSA may propose new rules requiring mandatory mortality reporting. This will facilitate our ability to work with OTP programs, accreditation bodies and state regulatory authorities to improve early detection and response to serious adverse events that can arise within the course of treatment.

For additional information or questions, please contact Alina Walizada, Public Health Advisor, at (240) 276-2755 or by e-mail at Alina.Walizada@samhsa.hhs.gov.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H., CAS,

Director

FASAM

Center for Substance Abuse Treatment