

Opioid Treatment Program (OTP) Mortality Reporting Form

Supporting Statement

A. Justification

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), is requesting OMB approval for the Opioid Treatment Program (OTP) Mortality Reporting Form. The OTP Mortality Reporting Form allows OTPs to voluntarily report mortality data on patients who at the time of death, were on a medication-assisted treatment (methadone or buprenorphine) in a SAMHSA-certified OTP.

Under the statutory authority of The Public Health Service Act (Title 42 U.S.C. 201), SAMHSA is responsible for supporting activities that will treatment for substance abuse and coordinating Federal policy with respect medication-assisted treatment. The proposed information gathering relating to mortality is ultimately in adherence to this legislative mandate.

The rate of methadone-associated deaths has continued to increase despite steps taken since the 2003 SAMHSA National Assessment of methadone-associated mortality. SAMHSA has regulatory responsibility to certify OTPs to use methadone specifically in the treatment of patients with opioid addiction; thus it is the responsibility of SAMHSA to monitor all deaths related to methadone and buprenorphine treatment of patients receiving care at an OTP. Currently, there is no standardized data collection process that would provide routine reports of patients who have died while under the medical care of an OTP.

At this time, no federal agency, including the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), or SAMHSA has knowledge of the number of deaths occurring among patients receiving addiction treatment through OTPs that are certified to operate by SAMHSA. Based upon an educated estimate from work that has been done in one state, and by expert consensus, the numbers of deaths related to methadone appear to be largely from its increasing use in the treatment of pain. From some OTPs, in informal discussion, it has also been estimated that perhaps 1% to 4% of patients in treatment within a given year may die but there is no solid knowledge about the related cause of death outside a very specific one state study. Some deaths in OTPs may be preventable if predisposing and precipitating factors are identified during the time a patient is being treated for addiction.

2. Purpose and Use of Information

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.

The represents a structured minimal amount of information that would be needed to better understand causes of mortality among patients in treatment; with the potential to identify preventable causes of deaths and take appropriate action through the current accreditation and certification process to minimize the numbers of preventable deaths.

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 deaths, it is necessary to examine all deaths related to opioid analgesics at a national level using a standardized format.

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.

The OTP Mortality Reporting form specifically gathers information on the following: patient demographic information, medical, medication and drug test history, cause of death (if known), description of factors relating to patient's death and the Medical Examiner's/Coroner's contact information.

3. Use of Information Technology

The OTP Mortality Reporting Form will be placed on SAMHSA's Opioid Treatment Program (OTP) Extranet Web site (<http://otp-extranet.samhsa.gov>) for electronic submission to SAMHSA. The OTP Extranet is a password-protected portal site already in use by OTP personnel to submit another form to SAMHSA, the SMA-168 Patient Exception Request form (OMB No. 0930-0206). Thus, placing the Mortality Report Form on the OTP Extranet will not require OTP personnel to become familiar with or obtain credentials for a new Web site.

OTP personnel will login to the site with their existing authentication credentials and select a 'Submit OTP Mortality Report' link to generate a new. The electronic form will be pre-populated with the identification number of the OTP for which the user has logged in to the site. All input fields on the form will include validation code to ensure that data can only be submitted in the correct format (e.g., numeric) and within valid ranges (e.g., valid dates). These measures will decrease burden, contribute to paperwork reduction, and ensure the submission of valid data. The Mortality Report Form will be compliant.

[with the accessibility requirements for federal Web sites specified in Section 508 of the Rehabilitation Act.](#)

4. Efforts to Identify Duplication

Currently, there are four different entities that may receive mortality data from OTPs: SAMHSA, States, FDA, and SAMHSA-approved accreditation bodies. However, none have a standardized reporting requirement or form, nor are there any requirements for these organizations to report to SAMHSA. At present, there is high variance in reporting such that currently, only anecdotal data are available for analysis. Whenever possible, SAMHSA would work with any organization listed above to request and capture data only once.

Although the majority of States collect mortality information from OTPs located within their state, the information collected varies significantly from state to state. With increasing patient safety and public health concerns related to preventable unintentional drug overdose deaths, SAMHSA has proposed uniform and voluntary collection of data related to deaths of patients who are in treatment within those programs certified to operate by SAMHSA. In fulfilling its duty to certify programs, SAMHSA must work closely with each state that certifies and allows through state laws and regulation, opioid treatment programs to operate. In many cases, SAMHSA acknowledges that both SAMHSA and the individual state will have a similar interest to collect data related to patient deaths. However, although states may collect data related to the patient deaths, state-specific forms and terminology have not been standardized and SAMHSA has no desire to interfere with individual state initiatives in this critically important area. At the national level, SAMHSA proposes standardized terminology to be used nationally for reporting into SAMHSA's proposed system. This will contribute to a more systematic analysis of potentially preventable patient deaths and causes of deaths among patients in treatment within the nation's opioid treatment programs. SAMHSA currently has an electronic data system for patient exception requests using standardized terminology in use at the national level and will leverage this system to permit any state or SAMHSA-certified opioid treatment program to transmit electronically data to SAMHSA using HL7 standard messaging.

Through a passive surveillance system, MEDWATCH, the Food and Drug Administration (FDA) collects information related to adverse events perceived to be connected with any drug to include methadone. FDA may then use that information in its post-marketing surveillance to reassess the potential need to change drug label, labeling, packaging or reconsider the safety of a drug to remain on the market. FDA does not have regulatory authority over any practice of medicine

to include prescribing methadone to treat pain. SAMHSA's, however, does have regulatory authority over the practice of medicine in the treatment of addiction. This involves dispensing methadone from OTP programs and engaging in a risk management process that should be focused on providing safe and competent care to the patient being treated for addiction. Federal regulations addressing this process are defined only under Title 42 Code of Federal Regulations Part 8, for which SAMHSA is the lead federal agency responsible to monitor compliance.

CARF-accredited OTPs are mandated to report sentinel events (sentinel events are defined as an unexpected occurrence involving death or serious physical or psychological injury or risk thereof) while other Accreditation Organizations do not require this information from the OTPs they accredit. Therefore, there is no process for these Organizations to uniformly report patient deaths to SAMHSA. Generally, standards developed by the Accreditation Organizations are intended for use of the programs who desire certification by those Organizations for continuous process improvement with the goal to improve treatment outcomes.

SAMHSA has no knowledge of trends and causes of deaths that may be occurring among patients currently in treatment because of a lack of national standards in reporting deaths. Such knowledge would help OTPs define and prioritize the range of services needed by a patient addicted to opioids that otherwise would not have been identified at the national or local level.

SAMHSA is ready to work with any specific state or accreditation organization to create a 'one-write' electronic system so that only a single report would be needed to meet different federal, state and accreditation organization reporting requirements.

5. Involvement of Small Entities

SAMHSA acknowledges the fact that small facilities might be more concerned about reporting deaths, perceiving this to be a burden. However, the number of deaths should be correspondently smaller and reports are not asking for more information than a small program should have available when expected to see patients frequently for treatment. The data collection involves OTPs of varied sizes in respect to both numbers of patients and business revenue. The same mortality form will be available for all OTPs. The information being requested from OTPs should be readily available to any OTP that has met accreditation standards. The OTP should not find any need to otherwise analyze or synthesize new data in order to complete this form. Also, the ability to complete the form by either online means or by hard copy further enhances respondents' ability to participate without disruption of daily work activities. Lastly, participation to report data

is voluntary at this time, and accordingly there is no imposition of any mandatory burden requirement.

6. Consequences if Information Collected Less Frequently

Finding trends in new deaths using national data can take many years and are not granular enough when the concern directly relates to patient safety in programs operating under SAMHSA certification. SAMHSA needs to have a more sensitive and ‘real time’ system to detect deaths quickly and intervene when patient safety might be a concern. SAMHSA intends to collect information on the occurrence of death on an ongoing basis, with the goal to improve treatment outcomes and patient safety via continuous process improvement rather than to conduct research using a representative sample periodically. In light of the increase in methadone related deaths, the collection of data surrounding a patient’s death will also allow SAMHSA to better quantify the degree to which OTP practices, e.g., induction may contribute to methadone deaths. Collection of all deaths will also allow SAMHSA to gain a broader understanding of the co-occurring disease states contributing to patient deaths, as well as to work with other health services agencies at the national and state level to provide the range of services patients might need beyond the direct treatment of opioid addiction.

7. Consistency With the Guidelines in 5 CFR 1320.5(d)(2)

This information collection fully complies with 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

The notice required in 5 CFR 1320.5(d)(2) was published in the Federal Register on January 2, 2008 (Volume 73, page 200). See Attachment A, Table 1 for a copy of comments received in addition to SAMHSA’s response and Table 2 for a copy of comments received in support of the OTP Mortality Reporting Form.

SAMHSA/CSAT consulted with the following FDA, CDC and Drug Enforcement Agency (DEA) officials, as well as State Methadone Authorities and OTPs in reviewing the Mortality Reporting Form.

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9. Payments to Respondents

No payment or other remuneration will be provided to respondents.

10. Assurance of Confidentiality

The OTP Mortality Reporting Form requests a patient identification number and admission date. This information is collected only as an aid in tracking a particular request and in aiding communication between SAMHSA and the regulated entity. The patient identification number is assigned by and known only to the treatment program. The patient's admission date is collected only to identify if the patient was dosed appropriately given the length of time in treatment. All online reports will be password protected and will only be accessible by authorized individuals. All printed reports and written information pertaining to the reports will be locked in a file.

11. Questions of Sensitive Nature

The information collection does include questions concerning sensitive information such as the patient's medications history of disease progression. However, no personal identifying information will accompany the report.

12. Estimates of Annualized Hour Burden

The annualized burden of information collection for OTPs to report mortality data on patients who, at the time of death, were enrolled in OTPs certified to operate by SAMHSA is set forth in the tables that follow.

The total number of burden hours annually for OTP respondents is approximately 1,150 hours.

Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs

Form Name	Purpose	Number of facilities (OTPs)	Responses per facility	Burden/Response (Hours)	Annual Burden (Hours)	Average hourly wage	Total cost
SAMHSA OTP Mortality Report	To report mortality data on patients who, at the time of death, were enrolled in Opioid Treatment Program (OTPs) certified to operate by SAMHSA	1,150	2 per year	0.5	1150	18.56	21,344

Estimated Costs of Reporting Burdens for OTPs

Hourly labor costs involved in reporting requirements vary greatly between programs. Employees involved in complying with reporting requirements range from counselors earning an average of \$15 an hour, licensed practical nurses and registered nurses earning an average of \$18 to \$29 per hour, administrators earning an average of \$35 per hour, and physicians earning an average of \$75 per hour. The estimated average hourly wage for program personnel to complete the Mortality is \$18.56. Multiplying the estimated average hourly wage by 1.5 to account for non-wage labor costs, an estimated hourly labor cost of \$27.84 is obtained. The estimated total annualized cost to the treatment program respondents for preparing the OTP Mortality Reporting Form using \$27.84 as the hourly cost figure, is \$40,020. These wage estimates were obtained from the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics Web site.

13. Estimates of Annualized Cost Burden to Respondents

There are neither capital or startup costs nor are there any operation and maintenance costs.

14. Estimates of Annualized Cost to Government

The total annualized cost to SAMHSA administering the OTP Mortality Reporting Form is estimated at \$130,469. This amount includes the following: The estimated annualized cost for a contract for the mortality reporting is estimated at \$100,000 and the cost of 1/3 FTE staff responsible for the CSAT data collection effort at a GS-14 range of \$30,469/year. This wage estimate was obtained from the U.S. Office of Personnel Management Web site. (<http://www.opm.gov/oca/06tables/gscalcul.asp>).

The principal additional cost to the government for this project is the cost of a contract to collect the data from the various programs, conduct analysis and generate reports from the data collected. Medical professionals deemed appropriate may need to be contacted, phone interviews with programs, and designated family members may need to be conducted. A contractor will need to work with the Government Project Officer (GPO) when preparing reports.

15. Changes in Burden

This is a new project.

16. Time Schedule, Publication and Analysis Plans

Initial collection date	As soon as OMB approval is received
Length of time needed for data collection	Ongoing
Analysis	Ongoing

Publication: Information from the OTP Mortality Reporting Forms will be entered into a database to assist with tracking and program monitoring. The Agency, via a contractor, will manage the data and generate a report annually.

Analysis Plan: The information will be collected on the forms, entered into a database, and summary reports will be prepared. As determined appropriate, programs will be interviewed to better characterize and resolve ambiguous or conflicting information received by electronic or paper reports and documents; a qualitative review of accreditation reports as well as accreditation and certification status will be conducted to identify potential risk management issues; a review of exception database will be conducted for profiling clinic exception requests and specific exceptions requested for the deceased if any. Upon completion of an investigation, reports will be generated that document the causes of deaths and provide preventable risk management guidance for a more improved coordination of care and robust referral/treatment/information network. Additionally, the collection of reports will establish a denominator for total numbers of patients and standard mortality ratios as needed and appropriate for locations and programs reporting OTP deaths.

17. Display of Expiration Date

The OMB expiration date will be displayed.

18. Exceptions to the Certification Statement

The collection of information involves no exceptions to the Certification for Paperwork Reduction Submissions.

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The respondent universe for the OTP Mortality Reporting Form is the entirety of OTP mortality cases from all active SAMHSA-certified OTPs in the United States and its Territories. At present there are approximately 1,150 active OTPs. Based on available information sources, SAMHSA estimates there are an average of 2 instances of mortality per year per active OTP. This results in an estimate of 2,300 instances of OTP-associated mortality per year.

No similar collection of mortality information from OTPs has previously been performed. To better define the incidence of mortality occurring while in OTP treatment SAMHSA is requesting all OTPs report all instances of mortality. Reporting by OTPs will be voluntary. As no previous collection of OTP-related mortality data has ever been conducted, no valid estimate of reporting rates can be developed at this time. For determination of maximal reporting burden, SAMHSA is assuming a reporting rate of one hundred percent. No stratification of the respondent universe will be made, and no statistical sampling techniques employed.

OTP Mortality Reporting Universe

Form Name	Approximate Number of Active OTPs	Estimated Average Annual Incidence of OTP-Associated Mortality	Estimated Total Annual OTP Mortality Reports
SAMHSA OTP Mortality Report	1,150	2 per OTP	2,300

2. Information Collection Procedures

OTP-associated mortality data will be reported to SAMHSA on the [OTP Mortality Reporting Form](#). The form will be accessible via [SAMHSA's OTP Extranet Web site \(http://otp-extranet.samhsa.gov\)](http://otp-extranet.samhsa.gov). The OTP Extranet is a password-protected portal site already in use by OTPs and State Methadone Authority personnel to submit and process other electronic forms. All active OTPs in the United States and Territories have accounts on the OTP Extranet Web site. A copy of the Web interface is included in Attachment C.

The OTP Mortality Reporting Form will not be provided in hard copy or through any means other than the OTP Extranet Web site. Providing the OTP Mortality Reporting Form only on the OTP Extranet Web site will decrease the reporting burden on OTPs and will help ensure the submission of quality data through automated data validation checks.

OTP personnel will login to the site with their existing authentication credentials and select a 'Submit OTP Mortality Report' link to generate a new. The electronic form will be pre-populated with the identification number of the OTP for which the user has logged in to the site. All input fields on the form will include validation code to ensure that data can only be submitted in the correct format (e.g., numeric) and within valid ranges (e.g., valid dates). The will be compliant with the accessibility requirements for federal Web sites specified in Section 508 of the Rehabilitation Act.

SAMHSA will inform and instruct the OTP community about the availability and use of the Mortality Report Form via a series of mail and electronic communications, described further in section B3. OTP personnel will be asked to report instances of mortality as they occur, rather than on a defined periodic basis. OTP personnel will be able to contact the SAMHSA OTP Extranet Information Center at a toll-free telephone number or via e-mail for questions about the.

3. Methods to Maximize Response Rates

SAMHSA will inform and instruct the OTP community about the availability and use of the OTP Mortality Reporting Form via a 'Dear Colleague' letter (see Attachment B). SAMHSA routinely sends 'Dear Colleague' letters to the OTP community via mail, e-mail, and fax. These communications provide information on regulatory and clinical developments of interest to the OTP community. The communications are also sent to all State Methadone Authority personnel.

Because of the potential for OTPs to be hesitant to voluntarily report instances of mortality among their clientele, SAMHSA will make clear that the use of the data is for developing a better understanding of the issue of preventable OTP-associated mortality and that no punitive action or SAMHSA follow up with individual OTPs will occur as a result of submitted mortality reports. SAMHSA's communications will additionally make clear that reported data will not be disseminated outside of the Federal government, and that there will be no reporting to the public or otherwise about instances, rates, or comparisons of mortality among or between individual OTPs or geographic regions.

SAMHSA will gauge the response rate to its initial communications about the OTP Mortality Report Form and will disseminate additional communications as necessary if response rates are significantly below expectations.

4. Test of Procedures

No pilot testing of the OTP Mortality Reporting Form or reporting procedures is planned. The report will be made available to all OTPs simultaneously via the SAMHSA OTP Extranet Web site. It is believed that OTPs will have minimal difficulty completing and submitting the form as they are already using the OTP Extranet Website to submit more complex forms to SAMHSA. OTPs will be able to contact the SAMHSA OTP Extranet Information Center for help completing the form and for questions about SAMHSA expectations for reporting. SAMHSA will evaluate the nature and quantity of support

queries to the OTP Extranet Information Center and adjust its communications to the OTP community about the Report Form if common themes indicating areas of uncertainty are identified.

5. Statistical Consultants

The SAMHSA staff member with primary responsibility for evaluating submitted OTP Mortality Reporting Forms is:

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The vendor managing the SAMHSA OTP Extranet Web site, which will house the OTP Mortality Report Form and submitted data is:

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List of Attachments:

Attachment A	Public Comments
Attachment B	Dear Colleague Letter
Attachment C	OTP Mortality Reporting Form
Attachment D	OTP Mortality Reporting Form Fax Instructions
Attachment E	OTP Mortality Reporting Form Online Instructions