Table 1 contains public comments received in addition to SAMHSA's response.
Table 2 contains comments received in support of the OTP Mortality Reporting Form.

Table 1.

Respondent's Name/Questions and Comments Received.	SAMHSA's Response
Robert G. Newman, MD Director International Center for Advancement of Addiction Treatment,Baron Edmond de Rothschild Chemical Dependency Institute of Beth Israel Medical Center Continuum Health Partners, Inc. 555 West 57th Street, 18th Floor New York, NY 10019 PH: 212-523-8390 Fax: 212-523-8433 1. to your knowledge, is anything comparable being considered by FDA, which as you note has authority over methadone prescribing for pain? It's been consistently reported by SAMHSA, CDC, national panels of experts and others that the majority of methadone-related deaths do not, in fact, involve patients, providers or medication associated with OTPs. While recognizing and respecting different responsibilities and lines of authority, one would certainly expect that two parts of the same Federal Department would very closely coordinate their efforts in this important matter. Is that happening? (The same question applies to patients receiving buprenorphine for addiction treatment from non-OTP sources - apparently the vast majority of the total buprenorphine-for-addiction recipients - and those receiving it for analgesia). 2. your "estimated annual reporting requirement burden" indicates two "responses per facility," and shows nationwide a total of 1150 such facilities. Do I correctly infer that SAMHSA/CSAT anticipates approximately 2300 deaths yearly of patients enrolled in OTP methadone	Thank you for responding to the Federal Register Notice. Responses to each of your comments are provided below. 1) FDA does not have authority over any practice of medicine to include prescribing methadone to treat pain. Through a passive surveillance system, MEDWATCH, 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 potential need to change drug label, labeling, packaging or reconsider the safety of a drug to remain on the market. Current labeling of methadone by the FDA defers to SAMHSA the use of methadone for treating 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. 2) At this time, no federal agency, to include FDA, 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 OTP programs, 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. Many deaths may be related to other conditions that may be a focus for treatment by other providers, or conditions commonly associated with addiction but are independently associated with a risk for death. Core to this voluntary reporting of all deaths is the opportunity for SAMHSA to gain information on number of deaths from any cause in order to better assist the field in the risk management of patients in treatment for opioid addiction, with an overall goal to reduce the number of deaths that might be prevented among patients who initially present daily into an OTP for medication treatment. 3) The draft form reflects core data elements that would be

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facilities? If so, I imagine you must be seeking reports on every death, regardless of cause – e.g., patients known to have had AIDS unresponsive to treatment, terminal cancer, victims of homicide, etc. Is that the case? Not criticizing – just seeking clarification. 3. It is difficult to comment on the proposed reporting system without seeing even a draft form that reflects the data elements to be captured and analyzed. Can you provide such a draft form? 4. The relevance of data is to a large extent determined by their timeliness. Have you considered the system for collecting and analyzing the information submitted, and do you have estimates of how much time - for instance - between the end of a calendar year and the public release of the findings? 5. Finally, given the importance of this effort (even though it is directed at patients and providers clearly identified as NOT being the primary contributors to the marked increase in reported methadone-deaths), why is SAMHSA proposing to make this reporting system voluntary? The data are deemed important, and the reporting process is estimated by you to involve a "burden" of no more than a half hour per mortality. So why leave it up to each OTP to decide whether or not to report? Government – at all levels – has shown very little reluctance over the course of the past 40 years to demand, as a prerequisite of continued license to operate, compliance with myriad rules and regulations. Thank you for considering these questions. I hope the answers will permit comments that will be helpful as you move ahead. ***(I am taking the liberty of also sharing these questions with readers of our website - www.opiateaddictionrx.info;***	aggregated. Please refer to the attachment for a copy of the proposed reporting form. We are not collecting information on this form for another 6 months. This form has to be approved by OMB before SAMHSA is allowed to collect any data. 4) Data would be analyzed as it comes in relative to the certified programs submitting. Feedback would initially be with the programs submitting to engage in immediate discussion and qualitatively ascertain with the program any preventive or risk management actions that might be useful. Depending on protocols established within a reporting program, feedback may also involve the accreditation body or state authority. In aggregate, SAMHSA also anticipates a year end report that would be published on its website and presented at relevant professional meetings attended by OTP personnel. 5) Given concerns expressed in this comment about reporting burden, the decision to make initial reporting voluntary allows SAMHSA to better establish true barriers and time required for reporting patient deaths. It is also possible that the information request might be more easily generated through software programs currently in use by many OTPs. Understanding barriers and time required to report will allow SAMHSA to streamline the reporting process to truly minimize reporting burden to all programs. SAMHSA will make the assumption that under voluntary reporting conditions, bias might be towards the higher quality treatment programs most interested in becoming aware of this type of data for internal risk management purposes. It is also understood that this bias may not allow aggregate findings to be generalized across all programs certified by SAMHSA. Next actions, to include a possible reporting requirement that would also be published for comment in the Federal Register, however, the overall goal is to enhance the provision of safe and competent medical care to any patient who might seek treatment within a SAMHSA certified OTP. At this time, with the known increase in drug overdose deaths, an initial prudent first step is to better understand causes of death among patients currently in treatment for opioid addiction.

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hopefully it will serve your goal of getting more comments and suggestions regarding your proposed reporting system - and if you wish us to post your response, we'll be happy to do that, with no editing of whatever you wish us to post)	
Richard Trotman Co-Director Mountain Area Recovery Center richard.trotman@marc-otp.com In North Carolina we already have numerous forms to fill out for the state department of mental health regarding any critical incident including death. The information SAMHSA wishes to gather is already being collected by the state why not have the 52 states report instead of 1,150 clinics ?	SAMHSA has statutory responsibility to certify and regulate opioid treatment programs. In this context, and 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.
Glen J. Cooper Executive Director This is in regard to the proposal to require reporting of all deaths occurring to persons while receiving methadone treatment. I am the administrator of programs that serve over 700 methadone treatment patients. I am also the past president of our state methadone association and past Board member of AATOD. In regard to the proposal, I would	Comments addressed in A2, A3, and A12.

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suggest that usually science moves forward by studying a representative sample rather than the entire universe of possibilities. It would be much preferable for SAMHSA to fund studies at selected service sites rather than to have each and every clinic report on each and every death into the foreseeable future. That just isn't necessary or reasonable. This is especially true in that very few deaths have any connection at all with methadone medication per se. Rather, most are from hepatitis, cancer, accidents, and so on and it is completely unreasonable for us to be required, at our own expense, to report on such deaths. I would also point out that the "reporting burden" calculation underestimates (not surprisingly) the burden of compliance. Firstly, there are going to be more than "2 responses per facility" per year. That is less than 1% of the total clinic population dying each year which seems to greatly understate the death rate from hepatitis, HIV, etc. and is not consistent with my experience. Additionally, the proposal suggests that the time required to comply is only 15 minutes per death. That is totally unrealistic and I don't see how anyone could suggest such a number (except, of course, to make the requirement seem less burdensome). This data will not accomplish any of the purported goals unless there is a significant amount of information provided (such as shown on the proposed reporting form) and none of the time to acquire/verify that data seems to be accounted for. Methadone treatment is the most studied treatment ever, with literally thousands of published articles examining every nuance. Further, regulators, accreditors, and funders of every stripe enter our clinics and look through charts for days a time.	

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Virtually every serious look at methadone treatment comments on the gross over-regulation which burdens clinics and adds to costs. It's only been a few years since SAMHSA imposed the accreditation requirement for which it provided no funding (other than for the survey itself). Surely there is a way SAMHSA can assure itself as to the realities of treatment without layering on yet another reporting requirement.	
Penny Hall gaflagal@bellsouth.net GPA Treatment, Inc. At this time, CARF accredited clinics are already required to report deaths. So why not get the information from them? Or if SAMHSA wants the information, require CARF to discontinue their request. I have never been explained why CARF is requiring this reporting anyhow. It will be difficult to accomplish this reporting because many times clinics do not know that the patient has passed away. They just don't show up any more. In this day of the huge amount of methadone available in pain management practices, it is very common for even long term patients to disappear. Also when I have had dealings with the local coroner in our area, he stated that often the cause of death is not really certain. Unless the coroner is informed by a friend/family member, then they have no clue as to what medication or if any medications were involved. It would prove to be astronomically expensive to test for all of the chemical entities currently available. Also there are incorrect causes of death reported. I had a patient in a small rural county who passed away. The coroner said that his death was	Although it is mandatory to report sentinel events (sentinel events are defined as an unexpected occurrence involving death or serious physical or psychological injury or risk thereof) to CARF, other Accreditation Organizations do not require this information from the Opioid Treatment Program (OTP) they accredit and 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's duty to certify is contingent upon an OTP achieving accreditation by an appropriate Accreditation Organization, but SAMHSA certification also relies on other factors defined in Title 42 Code of Federal Regulations part 8 (42CFR8). SAMHSA interprets 42CFR8 to mean that certification identifies to the public that the OTP is operating with the necessary skill and resources needed to assure patients receive safe and effective treatment. With increasing national concern over preventable drug overdose deaths, OTPs become an increasingly needed resource to assure patients who have become addicted can access treatment known to be effective in preventing an opioid-related death. SAMHSA acknowledges that there is no systematic and standardized coding for causes of deaths across the many medical examiner and coroner jurisdictions within each state and territory. From prior studies, SAMHSA also believes that people dying from methadone-related overdoses have mostly occurred outside OTPs. However, because of the lack of national standards in reporting of deaths, SAMHSA has no knowledge of trends and causes of deaths that may be occurring among patients currently in treatment. 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

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due to pneumonia complicated by methadone (?). He had had his yearly physical two days prior to his death and had no symptoms at all. But his drug screen did have benzodiazepines in it. So that combination was more probable to have been the cause. Wouldn't it make more sense to restrict the reporting to only deaths that involved methadone (no matter which agency ends up being reported to)? I have many patients that are in their mid to late 50's. So why would I be required (as I currently am) to report their deaths from liver failure, emphysema, etc.? And lastly, once again something is being added that will make us look like we are a problem! The deaths from methadone are significantly less than the deaths from aspirin!	the national or local level. We acknowledge that the OTP may not be aware of the occurrence of a death or the contributing cause of death for all specific patients in treatment who may die. However, to meet state and federal certification requirements, OTP patients are expected to be followed very closely, sometimes on a daily basis, and that the death of a patient in treatment should be relatively easy to discover. If and when any information related to the death of a patient in OTP treatment is discovered, this information should be reported to SAMHSA, and to whomever else requiring that information that may include the accreditation body and the State. 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. The standardized terminology to be used nationally for reporting in SAMHSA's proposed system, will contribute to a more systematic analysis of individual cases and national trends. An analysis of the coroner's/medical examiner's report, as well as any information provided by the OTP, will allow SAMHSA to examine all factors contributing to the death of a patient and ultimately minimize risks for patients enrolled in OTPs, as well as potentially identify variance in cause of death reporting by medical examiners and coroners. The intent of this reporting system is to improve patient safety and the quality of care provided in OTPs, not to diminish the need of methadone maintenance treatment. 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.

Table 2.

Respondent's Name/Questions and Comments Received.	SAMHSA's Response
Rebecca Clayton, EdS MLAP Executive Director The Treatment Centers Inc 256-549-9011 treatmentcenters@bellsouth.net	

Respondent's Name/Questions and Comments Received.	SAMHSA's Response
Gadsden Treatment and Shoals Treatment, both located in Alabama, will be glad to provide data when the form is available for use. If it is available on the web site now and you would like us to start collecting data, please let me know. This information could prove to be valuable in the increasing negative perspective some government and local officials have toward methadone clinics while seeming to have a more positive outlook on methadone from pain clinics. In our area of Alabama, it seems the methadone "on the streets" is that in pill form available from the pain management doctors and not from the methadone clincis as we only use the liquid form of methadone in both of our clinics.	
Susan E Templar Executive Assistant Cleveland Treatment Center mailto:ctc1127@attglobal.net The Cleveland Treatment Center received a fax in regards to a new project regarding the mortality of patients while enrolled in an OTP. The Cleveland Treatment Center would like to comply with this request, however we can not find the form to report a death. Would it be possible for you to forward one to us at the above e-mail address? Your assistance is appreciated.	
John Brooklyn, MD Medical Director Chittenden Center 1 So Prospect St Burlington, Vermont 05401 802 656 3708 I received a request to respond to the proposed reporting requirements for OTPs regarding untimely deaths related to methadone and/or buprenorphine. I understand the purpose and believe it is very useful to look at the proportion of deaths occurring in the induction, maintenance, or post treatment phases and what role the actual drug may have played in the deaths occurring. I would not have a problem reporting this information. I would like to know if the information is for collection only or if specifics are involved and how detailed those specifics would be, i.e. urine or blood toxicology reports, autopsy or police reports, hospital records and if the burden would be placed on us in the initial stages of reporting	Thank you for responding to the Federal Register Notice. Please note that the reporting would not be limited to "untimely deaths related to methadone or buprenorphine". We are asking that all deaths of patients in OTPs be reported to us. We acknowledge that the OTP may not be aware immediately of the occurrence of a death or the contributing cause of death for patients in treatment who have died. However, to meet federal OTP certification requirements, OTP's are expected to monitor patient outcomes. If and when any information related to the death of a patient in OTP treatment is discovered, this information should be reported to SAMHSA, and to State or accreditation organizations as appropriate. SAMHSA will review each report in order to gather as much information about the nature of the death. This reporting initiative is a

Respondent's Name/Questions and Comments Received.	SAMHSA's Response
on these deaths. Often, as you can imagine, we don't know the cause of death and I would not want to be held liable for determining the cause in this phase of the data collection. Can you elaborate on this? Thank you, John Brooklyn	direct result of our concern about reports of increasing numbers of deaths associated with methadone, although not necessary involving OTP patients. Review of reported deaths will permit us to capture in better detail the medical conditions of patients who are receiving treatment in OTPs and provide information that may be useful in developing services to address health conditions. This process may require following up with the individual entities possessing information specific to the patient's treatment and death, i.e., medical examiner, police, family, etc. The purpose of collecting patient death is to promote medical practice transparency for safety assessment and treatment enhancement to any patient enrolled in a SAMHSA certified OTP.
Eric Comstock mailto:ecomstock@sbcglobal.net Today, I found a notation concerning data collection on death of patients in methadone programs. Since comments concerning the program are accepted for only a few more days, I wish to advise of my interest in participating in this effort in any way possible. I have been involved in research and treatment of drug-related issues since the 1960's, at which time my practice was limited to treatment of acute poisoning in emergency departments in the Houston area, the vast majority of which were suicidal gestures using prescription drugs. I provided such treatment for over 1,000 patients during that time. In 1969 to 1970, under contract with the Bureau of Narcotics and Dangerous Drugs, and as President of the American Academy of Clinical Toxicology, I designed and field tested a collection of data from the emergency departments, resulting in the development of the Drug Abuse Warning Network which is known at the present time as Project DAWN. That research was undertaken with the assistance of the members of the Board of Directors of the American Academy of Clinical Toxicology. I have provided medication-assisted treatment for opiate dependence since 1972 and have published numerous papers on research funded by the	

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National Institute on Drug Abuse and other organizations in which I was the principal investigator (please see pages 18-19 of my Curriculum vitae, attached which is posted on my website at: toxicologyassociates.com, under the subtitle, "medicolegal consultation). Also listed on my website are full texts of relevant publications. My most recent involvement in issues of methadone treatment was a three-hour tutorial presented by Katie O'Neill and myself at the AATOD Conference in San Diego in October, 2007, concerning medication-assisted treatment of opiate dependence. My primary topic was methadone-associated death during induction. I look forward to an opportunity to discuss your project. I will be back in my office in Houston on February 26, 2008, for the subsequent several weeks. I may be reached at (713) 541-3214. I hope that you will keep me advised of your effort to implement a vitally important data collection concerning deaths occurring among patients actively engaged in methadone-assisted treatment. I am forwarding a copy of this letter to Jeffrey Brent, M.D., member of the Board of Directors of the American College of Medical Toxicology. I am sure your project will be of interest to the Board during its upcoming meeting.	
Terry Jackson **TerryJackson@oasas.state.ny.us** The New York State Office of Alcoholism and Substance Abuse Services (OASAS) appreciates he proposed survey as proposed in the Jan 2nd Federal Register, related to deaths of patients enrolled in opioid treatment programs (OTPs). There is a need to both better understand the underlying causation for these deaths and to use this knowledge to ensure safe and effective treatment for patients with opioid dependence. OASAS believes that the following suggestions would enhance the quality, utility and clarity of the survey information that is proposed to be collected: • The report should be mandatory for all SAMHSA certified OTPs (not voluntary). • The goal is to better understand patient deaths related to pharmacology for opioid dependence treatment, SAMHSA may want to consider expanding the survey's scope to other programs (than just the OTPs). • Respondents should be asked to report policy, procedure, or service changes implemented as a result of the death, if any.	Comments addressed in A2.