

OPIOID TREATMENT PROGRAM SURVEY

SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collection

a. Overview

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting OMB approval to conduct the 2011 Opioid Treatment Program (OTP) survey (Attachment A). SAMHSA's Center for Behavioral Health Statistics and Quality (CBHSQ)¹, in conjunction with the Center for Substance Abuse Treatment (CSAT), will conduct a facility-level census survey of approximately 1,200 certified opioid treatment programs in the United States.

Certified opioid treatment programs² may provide medication-assisted therapy to treat addiction to opiates such as heroin, oxycodone, and hydrocodone. Currently, methadone and buprenorphine are the only opioid medications approved for treating opioid addiction.

SAMHSA's annual census of substance abuse treatment facilities, the National Survey of Substance Abuse Treatment Services (N-SSATS, OMB No. 0930-0106) collects basic, but limited, information about OTPs, including whether the program administers methadone or buprenorphine, the number of patients receiving these medications, and whether the program offers maintenance services and/or detoxification services. However, SAMHSA currently has no source of detailed information on the specific treatment services and practices and operating procedures at OTPs. In 2005, SAMHSA published a Treatment Improvement Protocol (TIP) that provides best-practice guidelines for medication-assisted treatment for opioid addiction.³ As summarized in the TIP, research indicates that opioid addiction can be

¹ The Office of Applied Studies at SAMHSA recently changed its name to the Center for Behavioral Health Statistics and Quality.

² SAMHSA/CSAT rules define the term Opioid Treatment Program and SAMHSA/CSAT is the only entity that can certify OTPs under those rules. A facility must have SAMHSA certification in order to be recognized as an OTP and to dispense methadone and buprenorphine. SAMHSA certifies OTPs for up to three years; provisional programs with accreditation or compliance issues are certified less than three years. A clinic that moves will not lose certification, but it must complete paperwork to ensure SAMHSA is aware of the move and receive SAMHSA approval.

³ Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. DHHS Publication No. (SMA) 05-4048. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.

treated effectively with medications, particularly when these pharmacological treatments are combined with other supportive services such as medical services for co-occurring health conditions, treatment for co-occurring mental health disorders, psychosocial counseling, and vocational rehabilitation. The 2011 OTP survey will collect information consistent with this comprehensive approach to treating opioid addiction. In addition, the HITECH Act of 2009 is expected to dramatically increase the use of electronic health records and other information technology. In response, the 2011 OTP survey will collect information about programs' access to broadband technologies as well as their use of information technology for reporting purposes.

In order to realize efficiencies in cost and data analysis, the 2011 OTP survey will be conducted in conjunction with the 2011 N-SSATS. The OTP survey will use the same point prevalence date as the N-SSATS to minimize respondent burden involved with extracting data from patient records. Similar to the N-SSATS, the OTP survey will offer three completion modes (paper questionnaire, online via the Internet, and telephone interview).

The OTP survey is a periodic survey; it is anticipated that the next iteration will take place in approximately three years, pending funding availability. In this submission, SAMSHA is seeking OMB approval for the 2011 administration of the OTP survey—the questionnaire and all related respondent materials and correspondence.

b. Legal Authority

Under Section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823; Federal Regulation 42, Part 8), the Secretary of Health and Human Services has established standards to determine whether a practitioner is qualified to dispense opioid drugs in the treatment of opioid addiction. SAMHSA is responsible for determining whether a practitioner can meet and comply with those standards. Practitioners determined to be eligible are certified by SAMHSA. This certification is dependent upon the practitioner obtaining accreditation from an accreditation body that has been approved by SAMHSA.

As part of the OTP certification process, SAMHSA maintains documentation about each OTPs accreditation status, organizational structure, contact information, funding sources, and a statement regarding how accreditation regulations will be met. Under 42 CFR Part B.8.11, SAMHSA is permitted to conduct inspections and surveys to collect additional information. In addition, Section 505 of the Public Health Service Act (42 U.S.C. 290aa-4) requires SAMHSA to collect and report specific information on public and private substance abuse treatment providers and the patients served in those facilities.

2. Purpose and Use of Information

The data collected in the OTP survey will be used to establish a database of information about the services provided at OTPs across the country. The data will be used to develop national-, regional- and state-level aggregate reports describing operating procedures at OTPs as well as the full spectrum of services offered to opiate-addicted patients. Currently there is no up-to-date detailed information on services and treatments available, staffing credentials or patient characteristics.

The survey contains two main sections that will collect information about the following topics:

- **OTP Services and Characteristics:** This section collects information about the accessibility of services, provision of medication-assisted and other forms of treatment, continuity of care and referral plans, the use of information technology, and staff credentials.
- **OTP Patient Characteristics:** This section collects information about the number of patients admitted during the prior year, the number in treatment on March 31, 2011, (the point prevalence date) and their demographic characteristics, as well as information about the pharmacological efficacy with which medications to treat opioid addiction are administered.

Dissemination of these data to policymakers, program directors and other stakeholders should heighten awareness of the OTP system with respect to program organization, services, treatment, staffing credentials and patient characteristics. This heightened awareness is expected to lead to advancements in the types of programs offered as well as improved procedures for delivering services to those who need treatment.

Participation in the OTP survey will not affect the licensing or accreditation of individual facilities and is voluntary. Because facility identifiers will not be released, there will be no consequences to facilities for providing certain responses.

Each N-SSATS facility has been assigned a unique seven-digit ID number by the N-SSATS contractor, Mathematica. This number is referred to as the "MPRID" number. Although OTP directors either know or have access to their OTP number assigned by SAMHSA as part of the OTP certification process, none are given their "MPRID" number. The MPRID number is in the N-SSATS database, but access to that database is limited to Mathematica project staff who need that information in order to monitor progress on the study. All Mathematica staff have signed a security pledge that precludes their disclosing information from any of the surveys being conducted at Mathematica. Finally, SAMHSA project staff has the "MPRID" numbers on file, but, again, access to that information is restricted. Other than a limited

number of Mathematica and SAMHSA project staff, no one else has access to the “MPRID” number information.

The N-SSATS has not added questions on health information technology (HIT). There is considerable variation in the types of facilities in the N-SSATS which limits the inclusion of questions on HIT that would be applicable to the majority of the respondents. The use of HIT by OTPs, however, is of special interest, because the adoption of HIT is an increasingly important element in the delivery of healthcare services. OTPs have certain requirements in the provision of pharmacologic therapy that would greatly benefit from HIT (e.g., FDA Adverse Event Reporting, adherence to CDC infection precautions, quality improvement requirements, medication monitoring, etc.).

Providers are continually encouraged to adopt and utilize HIT through a number of efforts, including reimbursement incentives, grants, and other mechanisms. While establishing an interoperable system of electronic health information is critical to encourage greater care coordination among mental health, primary and other health care providers, there is no information on a national level regarding the adoption or use of HIT by OTP facilities. Substance abuse and specialty addiction providers have not been targeted in many of the efforts to adopt HIT, and the information collected in this survey will provide some initial information to help identify the types and uses of electronic resources by OTPs. Such information may be particularly useful for pinpointing OTP technology needs as addiction services are increasingly integrated with primary care services and provider information systems.

The OTP supplement will collect data on patient demographics, including race. These data are not collected by the N-SSATS. The Treatment Episode Data Set (TEDS) collects demographic information on patients receiving substance abuse treatment, primarily from those facilities that receive public funds. This provides basic demographic information for the majority of substance abuse treatment patients nationally, and this suffices for most purposes. However, since TEDS collects information from primarily those facilities that receive public funds, many of the OTPs that are privately funded do not report TEDS. N-SSATS patient counts indicate that approximately 25 percent of all substance abuse treatment patients are in OTPs, however only about 6 percent of TEDS records indicate OTP involvement (based on planned use of methadone). Therefore, the patient demographics for OTP admissions in TEDS may not be representative of the total OTP patient population. In order to determine the demographic characteristics (including race) of OTP patients, it is necessary to ask it in this survey. These data are not available elsewhere. It is important to know where specific groups (such as those most in need or underserved) are finding treatment in order to ensure that access and availability to treatment is available to all who need it.

Until fairly recently, little change occurred in the field of opioid treatment. However, in the last few years we have been aware of modest growth in the number of patients served, but also some changes such as an increase in the percentage of for-profit opioid treatment programs (OTPs). Now, there is uncertainty as to how and to what extent Health Care Reform and, closely tied to it, HIT/EHR requirements, will further impact the 'demographics' of OTPs, as a substantial number may lack the resources to deal with these new challenges; and these are often the programs serving many vulnerable patients who might otherwise not receive needed treatment. This last speaks to the agency's interest in ensuring access to treatment. In addition, SAMHSA monitors and regulates OTPs toward supporting quality of opioid treatment and therefore has interest in OTPs' use of tools both to support better and more efficient treatment and better reporting of data. For these reasons, data from responses to the items added to assess OTPs' "IT readiness," both now as baseline, and into the future, will be critical in helping SAMHSA to track OTPs' progress in dealing with these challenges, and will inform the agency's efforts to make policy, and provide information and support.

3. Use of Information Technology

The 2011 OTP data collection will use the latest technology to process multiple data collection applications in order to minimize respondent burden and improve the quality of the data collected. These applications are summarized below.

A centralized database will store and organize facility information, manage and monitor survey progress, and field multiple data collection modes simultaneously. This application was developed several years ago specifically for the N-SSATS. It will be enhanced to include additional data fields that will allow monitoring the OTPs separately or in conjunction with the 2011 N-SSATS. Completed questionnaires from every mode are assigned a final status and updated in the database on a real-time basis to assure that questionnaires cannot be completed in more than one mode. The application also tracks each completed mail questionnaire from the time it is received, anticipating the date when each questionnaire should (1) receive a final status; (2) be sent to quality assurance; (3) be resolved for inconsistencies; (4) be batched for data entry; and (5) be data entered. A delay in any of these processes will generate an alert that the questionnaire should be reviewed.

Data entry will be performed with specialized data entry software called Viking which runs on Unix. Completed paper questionnaires will be data entered and then re-entered in a 100 percent verification process.

The survey will be offered in multiple modes, including a web version that respondents can log onto using a unique user ID and password assigned to their program. To encourage programs to respond via the web, for the first month of data collection, this will be the only mode available. Based on N-SSATS experience, it is expected that approximately 60 percent of all respondents will choose to complete the survey online. The web survey has a number of programmed data quality checks including range checks, data validations as well as programmed skip logic. Web respondents will be able to move back and forth in the survey and edit their responses, as well as suspend the survey and come back to the same point in the questionnaire later. The OTP survey will share a site with the 2011 N-SSATS. When logging onto the website, respondents will be asked if they choose to complete the OTP survey or the N-SSATS. After choosing and completing one of the surveys, respondents will be prompted to indicate if they would like to continue with the other survey. If they do not wish to continue, they can return at a later time and will only be given the option of accessing the uncompleted survey. Screen shots for the OTP web survey can be found in Attachment L.

The 2011 OTP survey will also include an informational website for facilities to access a sample questionnaire, definitional and instructional material, links to related SAMHSA sites, and a description of the study and its goals. Terms in the definitional material will be hyperlinked in the web survey allowing respondents to move back and forth smoothly from the questionnaire to relevant definitions.

In order to improve agency efficiency and public access to the data, reports from this survey and a de-identified public use data set will be available on the Internet.

4. Efforts to Identify Duplication

The information in the 2011 OTP questionnaire has not been collected previously. The data are not being collected by any other Federally-sponsored survey and complement, rather than duplicate, information collected by the N-SSATS.

5. Involvement of Small Entities

Many treatment facilities that will participate in the OTP survey are small businesses. The following methods will be used to minimize reporting burden for all respondents, including small entities:

- The survey is designed to collect the minimum amount of information required for the intended use of the data.
- The use of Internet technologies will increase the options available to the respondents to complete the survey and will decrease the

time between data collection and error resolution (for example, the Internet version will automatically check each response).

- On the paper questionnaire, the facility name and address information will be included on the cover of the questionnaire. Rather than having to provide this information on a blank questionnaire, the facility will be asked to correct and update the information directly on the cover. On the web version, the name and address information will be pre-filled on the first screen of the survey and electronic updates will be accepted.
- The facility is requested to report only on components that it operates directly and not on services that it purchases from other facilities through contracts or agreements.
- Instructions for each question are included with the question rather than in a separate instruction packet. This saves the respondent the time and effort of turning pages between the questionnaire and an accompanying instructional packet.
- An informational website will be developed that includes instructions and definitions of key terms. This will be accessible to all facilities, and those responding on the Internet can have the survey and the definitions open simultaneously in their web browser.
- Key terms in the web survey will be hyperlinked so that respondents can click on the term and be taken directly to that term on the informational website definitions page and move seamlessly back to the survey.
- Contractor staff will be available, via a toll-free telephone line, to answer any questions that respondents may have regarding the 2011 OTP survey.

6. Consequences If Information Collected Less Frequently

This is the first cycle of a survey that SAMHSA expects to conduct every three years, depending on the availability of funding. Because the purpose of the survey is to monitor changes in treatment practices and procedures at OTPs, the 3-year periodicity will allow the capture of trend data. The treatment of opioid addiction is constantly evolving. If data were collected less frequently, stakeholders would lack up-to-date information needed to make informed decisions about opioid treatment policies.

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

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

8. Consultation Outside the Agency

A Federal Register Notice published on Friday, October 1, 2010 (Volume 75, No. 190 page 60758) solicited comments on the proposed data collection. No comments were received.

Early in the questionnaire design phase, SAMHSA consulted with OTP directors representing a range of programs that varied in size and the type of services they provided. OTP directors provided advice on the concepts that should be covered in the questionnaire as well as information about the accessibility of administrative records that could inform responses to the survey. Consultants included:

1) Ms. Connie Juntanen

Alexandria Community Services Board
Substance Abuse Services
2355-A Mill Road
Alexandria, VA 22314
Standalone
Total Admissions 1,413

2) Ms. Lyn Tomlinson

Fairfax-Falls Church Community Services Board
Alcohol and Drug Services
3900 Jermantown Road
Fairfax, VA 22030
Parent (18 sites in organization)
Total Admissions 4,982

3) Mr. Michael Webster

Fairfax Methadone Treatment Center
7008 Little River Turnpike
Suite G
Annandale, VA 22003
Parent (6 sites in organization)
Total Admissions 158

4) Mr. Roger Cantoni

New Horizon Treatment Services Inc
132 Perry Street
Trenton, NJ 08618
Standalone
Total Admissions 1,545

9. Payments to Respondents

No payment or gifts will be provided to respondents to participate.

10. Assurance of Confidentiality

The OTP survey will collect only facility-level information. For data reports, the facility data will be de-identified such that it will not be possible to identify specific facilities. Data will not be released in a form that would allow the identification of individual OTPs or their patients. Reports, tables, and public use files based on the data will be made available to the public via SAMHSA's web site. The public use data file for the OTP survey will mask the identity of individual facilities.

On the OTP questionnaire SAMHSA will include the following pledge that describes the level of protections provided to the respondents:

The information you provide will be protected to the fullest extent allowable under the Public Health Service Act, 42 USC Sec 501(n). This law permits the public release of identifiable information about an establishment only with the consent of that establishment and limits the use of the information to the purposes for which it was supplied. Facility data will be de-identified such that identifying individual treatment facilities from the published data will not be possible.

Like the N-SSATS survey, the OTP survey will contain a unique identifier assigned to each facility. This number is used to facilitate tracking, monitor response rates, ensure adequate quality control, and assess analytic consistency from survey to survey. It is not released to the public.

11. Questions of a Sensitive Nature

The 2011 OTP survey does not include questions of a sensitive nature. The survey does not involve asking questions directly of patients nor is information collected about identifiable individuals. The survey will collect information about the characteristics of OTP facilities and patients served.

12. Estimates of Annualized Hour Burden

The burden for completing the OTP Survey is as follows:

| Estimated Total Response Burden for the 2011 OTP Survey | | | | | | |
|---|--------------------------|-----------------|--------------------|--------------------|-----------|-----------------|
| Number of Respondents | Responses per Respondent | Total Responses | Hours per Response | Total Burden Hours | Wage Rate | Total Hour Cost |
| 1,200 | 1 | 1,200 | .83 | 996 | \$34.00 | \$33,864 |

The 50 minute burden estimate is based on the results of the pretest conducted with OTPs and the reductions made to the questionnaire following the pretest. The respondent for the OTP questionnaire is expected in most cases to be the N-SSATS respondent. These respondents are generally mid-to senior-level staff, often the facility director. Based on a recent salary survey conducted by the National Association of Addiction Treatment Providers, and taking into consideration the wide variety of facility types and sizes, it is estimated that an average salary for this level is \$34 per hour.

The pre-test report, which provides the results of the pre-test and the list of recommendations, is included as Attachment M. All but one of the recommendations to delete items to reduce burden were implemented. The one item that was not deleted was analytically important. The majority of wording changes were implemented except those that would have changed the intent of the question. The pre-test included facilities from nine different states (AZ, CA, IL, MI, NV, NY, OR, PA, and TX).

In summary, prior to recruiting OTPs for the pre-test, facilities were categorized according a number of variables including: geographic location, treatment type (outpatient, residential, hospital), size of facility, whether the facility was part of a network of multiple facilities, and metropolitan area. Facilities were selected in order to represent as many of the categories as possible. OTPs were recruited by telephone to participate in the pre-test. Each OTP represented a different state and region of the country. OTPs that agreed to participate were mailed the questionnaire to complete. Approximately two weeks after the mailing, a debriefing interview was scheduled. All OTPs that were recruited participated in the debriefing interview.

The pre-test completion times ranged from 20 minutes to three hours. Nearly half of the respondents (4), reported completion times of 60 minutes or less, two reported 90 minutes, two reported two hours and one reported three hours. Some of the longer times were rough estimates, since the respondents admitted starting and stopping due to interruptions. The wide variance among completion times was due primarily to differences in the accessibility of the needed information and the degree to which a facility's records were automated. The one facility that had estimated three hours, for example, reported that they had to "hand tabulate" the information from individual patient records for some of the questions.

Since questions are comprised of response categories, counting response categories, rather than questions, often provides a better sense of the burden involved in responding to a question. It does not, however, give a sense of the work that went into collecting the information being requested. Both aspects of burden are important. Following the pre-test, 35 response options were deleted, while 12 were added, resulting in an overall reduction of 23 response categories. However, all response categories are not equal in terms of the work entailed in providing a response. Two of the most

burdensome questions were B2 and B3, which asked facilities to report the primary opioid drug for each new OTP patient in the previous calendar year (B2) and the number of new OTP patients who had tested positive for marijuana, cocaine, and other substances (B3). (The pre-test questionnaire is in the pre-test report.) While this information was often on a patient's individual report, it was not included as part of the statistical reports that were programmed. Consequently, providing this information required examining each new OTP patient's intake record, a very time consuming task. Another question, B7, asked respondents to calculate the number of miles traveled to reach the OTP program for certain patients. After the pre-test, this was changed to a question that required only a yes/no response.

Dropping the 23 response categories reduced the number of response categories by about 14 percent. Based on the average response time per category, this would result in a 13 minute reduction in response burden. Given the time that was required to answer the most burdensome questions that were dropped from the questionnaire, it was estimated that a 20-25 minute reduction in burden was more realistic. The N-SSATS questionnaire and OTP supplement response times were compared. N-SSATS averages about 40 minutes, although the N-SSATS questionnaire is notably longer than the OTP supplement. Responding to N-SSATS has become routine for many facilities and, clearly, the OTP supplement does request some new information. However, taking into account that two of the most burdensome OTP supplement questions were deleted, it was calculated that by adding 10 minutes to the OTP supplement completion time (a 25 percent increase over N-SSATS), the time was reasonable.

The majority of OTPs indicated that demographic information is tracked in their computerized data systems, and the information is readily retrievable through a reports function. The time required to run the reports is included in the burden estimate of 50 minutes.

Less than three percent of the data was missing due to item non-response. The questions that had highest non-response rates were not included in the final version of the questionnaire. Given that only one facility per state was represented it was not possible to assess variations in data across states. Data on client counts were consistent with overall client counts obtained in the previous year's N-SSATS.

There is always concern about burden on respondents. A way to reduce this burden as much as possible is to administer the two surveys together. This approach means that general categorizing information needs to be asked only once (in N-SSATS) and can be used for analysis with the OTP survey.

Additionally, in 2010, the Center for Mental Health Services' National Mental Health Services Survey (N-MHSS; OMB No 0930-0119) was in the field

at the same time as N-SSATS. Some facilities received both surveys and there was concern about burden effects on response rate. However, not only did the N-SSATS response rate not suffer (remaining at about 93 percent), but the N-MHSS achieved a best-ever response rate of about 91 percent. It is suspected that the strong support from facilities for the N-SSATS transferred over to the N-MHSS for those facilities that received both surveys. There is no reason to suspect a different outcome for the N-SSATS and OTP surveys.

Furthermore, there is strong support from the OTP community. Endorsements from the American Association for the Treatment of Opioid Dependence (AATOD) and the State Opioid Treatment Authorities (SOTAs) have been obtained.

13. Estimates of Annualized Cost Burden to Respondents

There are no capital, start-up, operations, or maintenance costs to respondents associated with the OTP survey.

14. Estimates of Annualized Cost to the Government

The annualized cost to the Government for the OTP survey contract is estimated to be \$390,000. This includes \$250,000 each year for implementation of all aspects of OTP survey (including the preparation of forms and mailing lists, data cleaning and entry, data analysis, and preparation of data reports, analytic files, and public use files.

The cost for monitoring the contract and carrying out related work includes the salary of one FTE, for a total of approximately \$140,000.

15. Changes in Burden

This is a new project.

16. Time Schedule, Publication and Analysis Plans

a. Time Schedule

The table below shows the time schedule for the 2011 OTP survey. Data collection is scheduled to begin April 1, 2011, to coincide with the N-SSATS data collection effort.

| TASK | COMPLETION DATE |
|--|-----------------|
| Finalize questionnaire | January 2011 |
| OTP survey data collection (Reference date March 2011) | September 2011 |
| Data report | July 2012 |
| Public use data file | July 2012 |

b. Analyses and Publications

The OTP data will be disseminated in the following manner:

2011 Opioid Treatment Program Report. This publication will present the main findings from the survey, consisting of cross-tabulations and descriptive analyses on facility services and characteristics and patient characteristics. The report will be available on the SAMHSA website (<http://www.samhsa.gov>). Currently, among the 49 states/jurisdictions that have any OTPs, there are no states that have fewer than three. In the event that only one OTP responds, the table format in which resulting data will be reported will not permit a determination as to which OTP responded. See Attachment K for examples of tables. The general format of tables in the published N-SSATS reports will be followed.

Medication-Assisted Treatment for Opioid Addiction State Profiles. This publication will present profiles for each state, and will be available on the SAMHSA website.

Public Release Data Files. Public release files of OTP survey data will be available for downloading and on-line analysis at the Substance Abuse and Mental Health Data Archive (SAMHDA) website (<http://www.icpsr.umich.edu/SAMHDA>).

No patient identifiers will be collected by the OTP supplement. Patient characteristics will be collected in summary form as counts or totals for each question's response categories. While the survey will collect facility patient totals for gender and facility patient totals for several age groups, there is no way to determine the number of female patients age 18-34, for example, for any facility because no individual-level patient records will be obtained. In the same way, no individual patient records will be collected to which individual patient identifiers could be linked.

Because no individual-level patient data will be obtained, there can be no release of individual-level data in the Public Use Files (PUFs). Because the OTP survey will collect patient counts from facilities, and will not collect individual patient data or individual records from facilities, patient data from one question, such as the number of females and number of males from the question on gender, cannot be analyzed or cross-tabulated with any other patient questions in the survey. Prior to release of the PUF, SAMHSA will employ procedures to review risk of disclosure and will address any issues identified. Disclosure review for all CBHSQ public use files is performed by the Disclosure Review Board of the Substance Abuse and Mental Health Data Archive (SAMHDA). SAMHDA is operated by the Inter-university Consortium for Political and Social Research (ICPSR) under contract with SAMHSA.

Facility identifiers will not be included in the public use files and no patient-level records will be collected, therefore disclosure issues will be minimal.

17. Display of Expiration Date

The expiration date for OMB approval will be displayed.

18. Exceptions to Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act submissions.

B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The universe for the OTP survey is derived from the Inventory of Substance Abuse Treatment Services (I-SATS), an electronic master list of all organized substance abuse treatment facilities known to SAMHSA. I-SATS includes approximately 1,200 substance abuse treatment facilities with certified opioid treatment programs in the United States. The I-SATS data set is part of DASIS--the Drug and Alcohol Services Information System. DASIS is the primary source of national information on the services available for substance abuse treatment and the characteristics of individuals admitted to treatment. I-SATS is updated on a monthly basis. Since a full enumeration of these 1,200 certified OTPs is planned, no formal sampling plan is needed.

One goal of the survey is to produce state-level profiles and many states have as few as 3-5 OTPs. Under these circumstances, designing a sample that would permit state-level analysis as well as detailed analysis of the data on a national level would be problematic. Given that this is the first survey of its kind, little is known about the prevalence of OTP characteristics, making it even more difficult to calculate an adequate sample size. Furthermore, in advance of the survey, we could only guess at what some of the key stratification variables might be. Under these circumstances, surveying all known OTPs is only way to guarantee that the goals of the survey can be achieved.

2. Information Collection Procedures

The OTP survey will be conducted in conjunction with the 2011 N-SSATS survey, using the same point prevalence date (March 31, 2011). Piggybacking the OTP survey onto the N-SSATS minimizes data collection costs, simplifies the task of completing the OTP survey for the respondent and maintains data comparability with N-SSATS. To launch the 2011 OTP survey data collection effort, the contractor will first send a letter introducing the survey to OTP program directors (Attachment B). The introductory letter

will alert directors that the 2011 N-SSATS survey will include this new supplement for substance abuse treatment facilities that operate certified OTPs and will explain how data from this new survey will be used. It will also inform directors that they will receive OTP survey instructions and materials in early April. In addition to alerting program directors about the impending survey, this letter will also provide Mathematica with valuable information about facilities that have moved and for which updated address information is required.

Next, on or about March 31, the contractor will send a survey packet containing additional OTP survey informational materials. The packet will include a cover letter describing the package contents, endorsement letters from the State Opioid Treatment Authorities (SOTA) and the American Association for the Treatment of Opioid Dependence (AATOD), on-line survey access instructions, and a list of frequently asked questions and answers (FAQs). Copies of these documents are provided as Attachments D through H to this submission.

Two weeks following the initial survey packet mailing described above, the contractor will send a reminder postcard to all non-responding facilities (Attachment H). The postcard will include the web address for the survey and a toll-free number to call and obtain specific program log-in information and answers to other survey related questions. The reminder postcard is an inexpensive method of contact.

Approximately one to two weeks after the reminder postcard is sent, N-SSATS will send a reminder letter via first class mail to all non-responding facilities. For the 1,200 N-SSATS respondents who are also OTPs, the letter will encourage response to both surveys, if neither has been completed. If the N-SSATS has been completed, the reminder letter will focus on OTP survey completion (Attachment I). The contractor will also send a thank you letter to all facility directors who have completed both surveys at this time (Attachment J).

Facilities that have not completed either survey by the last week in May will be sent a final general N-SSATS survey mailing. A paper version of the OTP survey will be included in this mailing and the cover letter will be revised to encourage response to both surveys. The paper questionnaire is not included in early mailings to encourage web-based completion. Web-based responses are more cost effective for the government and result in more accurate data because of imbedded data edits. In the 2009 N-SSATS data collection, 61 percent of OTPs responded via the web. To date in the 2010 N-SSATS, 57 percent of OTPs have responded via the web suggesting that SAMHSA will meet or exceed the 2009 OTP web response rate.

Reminder calls will begin in mid-June. During the initial reminder call, respondents will be encouraged to respond by mail or web, but may also respond by telephone. After every facility has received one reminder call,

then all subsequent calls will be directed toward completing the interview by telephone. The telephone follow-up effort will continue through the end of September 2011. SAMHSA anticipates that very few interviews will be conducted by telephone; therefore, the OTP survey will not be programmed as a computer-assisted telephone interview (CATI) instrument. In 2009, only nine percent of OTPs completed the survey by telephone. While the contractor anticipates that the majority of facilities will respond via the web or by telephone, some will choose to complete paper questionnaires. Questionnaires completed using the paper version will go through detailed editing procedures similar to those used for N-SSATS. That is, all paper questionnaires will be edited using POET, the Paperless Online Edit Tracking System, housed within Mathematica's Sample Management System (SMS). Once edited, a determination is made regarding the need for a call back to the respondent. After editing and necessary callbacks are completed, the questionnaire is batched for data entry. All data entry is 100 percent verified by a second data entry operator.

At the conclusion of an N-SSATS CATI interview, an alert will inform the interviewer to continue with the OTP survey if the facility is an OTP. Interviewers will access to the web version of the OTP survey and conduct the interview over the telephone thereby benefiting from all of the data checks that are built into the computerized version of the questionnaire.

3. Methods to Maximize Response Rates

The following methods will be used to maximize response rates for the OTP survey and a 90%-95% response rate is expected. These methods are modeled on those that proved to be successful in the N-SSATS data collection. They include:

- Advance letters to alert facility directors to the upcoming OTP mailing;
- Letters of support from state and national OTP organizations;
- Multiple modes for responding including an on-line response option which allows respondents to complete the survey on the Internet;
- Telephone interviews to collect the information from those who do not respond by mail or web;
- Strategically timed reminder mailings and telephone calls;
- Re-mailings on request and as needed;
- An OTP toll-free hotline with live help from 8 a.m. to 8 p.m. that facilities may call with questions about the survey;
- An OTP website that provides survey specific information such as the OTP questionnaire, question definitions, FAQs, and letters; and links to relevant sites such as SAMHSA, Mathematica, and DASIS;

- Tracking and locating efforts to determine whether a facility is still in business, has closed, or merged with another facility.
- A questionnaire limited to essential items, thereby reducing burden.

4. Tests of Procedures

The OTP questionnaire was methodically pretested with nine facility directors to assess OTP facility record keeping practices, evaluate the clarity of questions, identify possible modifications to question wording or sequence, and estimate respondent burden. Pretest participants completed the survey using a hard copy version of the questionnaire and participated in a telephone debriefing about the experience. The questionnaire version included with this submission incorporates the lessons learned from the pretest. Both versions of the questionnaire—web and paper—contain identical content. The pre-test report is found in Appendix M.

Because this was a newly developed questionnaire with content that had not yet been tested, it was expected that significant revisions would be made following the pretest. Therefore, it was not cost-effective to program the pretest questionnaire for the web. Indeed, numerous changes were made to the instrument based on the pre-test experience. The web programming for the OTP questionnaire will use the same software and formats as the programming for the N-SSATS, which have performed successfully for the past 9 years. Most of the feedback from N-SSATS web respondents has been extremely positive and it is not expected that the OTP questionnaire will pose any unusual programming challenges. Before the web questionnaire “goes live,” it will be tested thoroughly by Mathematica and SAMHSA project staff to ensure that there are no programming errors or anomalies. Early web responses to the OTP supplement will be monitored. The N-SSATS/OTP supplement helpline number is displayed on all web screens and in the materials mailed to respondents. If respondents have any problems completing the OTP questionnaire, whether related to the web mode in particular or the questionnaire content, they will receive personal assistance from the helpline staff.

5. Statistical Consultants

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List of Attachments:

Attachment A: 2011 Opioid Treatment Program (OTP) Questionnaire

Attachment B: OTP Alert Letter

Attachment C: OTP Cover Letter

Attachment D: SOTA Letter of Support

Attachment E:AATOD Letter of Support

Attachment F: On-line Survey Access Instructions

Attachment G: 2011 OTP Survey Frequently Asked Questions

Attachment H: OTP Reminder Post Card

Attachment I: OTP Reminder Letter

Attachment J: OTP Survey Thank You Letter

Attachment K: Examples of Tables

Attachment L: Web Screens

Attachment M: OTP Questionnaire Pre-Test Report