Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction - 42 CFR Part 8

Supporting Statement

A. Justification

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration is requesting a revision of OMB approval of information collection requirements for opioid treatment programs (OTPs) in regulations contained in Title 42 of the Code of Federal Regulations (CFR) Part 8 and three forms used to implement the regulations (OMB No. 0930-0206). The regulations were promulgated under authority of Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P. L. 91-513) and Section 303(g) of the Controlled Substances Act (CSA) (21 U.S.C. 823(g)(1)), as amended by the Narcotic Addict Treatment Act (NATA) (P. L. 93-281). SAMHSA has statutory authority for this program under Sections 501(d)(5) and (7) of the Public Health Service Act (42 U.S.C. 290aa).

The regulations establish a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). They became effective on May 18, 2001, and require OTPs to be certified. Certification is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body and must comply with any other conditions for certification established by SAMHSA. The regulations also provide standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes.

The regulations affect reporting requirements in two major areas. First, OTPs must keep certain records and conform to CSAT application and reporting requirements. Related to reporting requirements, OTPs sometimes need to make adjustments to existing protocols or treatment plans in order to meet emerging client needs, such as providing medication during business travel or take-home medication in response to a transportation hardship or a temporary disabling condition. Second, entities that are interested in becoming accreditation bodies under the regulations must apply to and obtain approval from SAMHSA. Accreditation bodies must develop and submit accreditation elements that are reviewed and accepted by SAMHSA. In addition, approved accreditation bodies must keep certain records of accreditation surveys and submit them periodically to SAMHSA. For example, on January 15 and July 15 of each year, accreditation bodies must send SAMHSA/CSAT a list of all programs that have been surveyed with an explanation of the outcomes of the surveys and each surveyed program's current accreditation status.

In addition, the regulation was amended with an Interim Final Rule, 42 CFR Part 8, which was issued on May 22, 2003, to permit opioid treatment programs (OTPs) to treat patients using buprenorphine and a buprenorphine combination product. The Food and Drug Administration (FDA) approved these drugs for the treatment of opioid addiction on October 8, 2002. The Interim final rule was effective on May 22, 2003. This interim final rule was presented for public comments, and the written comment period ended on July 21, 2003. On December 7, 2012, the Department issued a final rule that modified the dispensing limitations for buprenorphine products. This change, effective January 7, 2013, is expected to result in a modest decrease in the reporting burden to OTPs under this approval.

Approval is requested for the following information collection requirements in 42 CFR Part 8:

Reporting Requirements for Accreditation Bodies

42 CFR 8.3(b)(1-2)	Requires that accreditation bodies submit an initial and periodic application (Form SMA-163) for approval as an accreditation body. The accreditation body must provide: Name, address, and phone number of the official responsible for the accreditation body, evidence of nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the body is not a State agency, and a statement that it will comply with all accreditation body responsibilities set forth under 42 CFR § 8.4.
42 CFR 8.3(b)(3)	Requires that accreditation bodies develop the accreditation elements to be imposed on opioid treatment programs pursuant to 42 CFR § 8.12, and submit these elements for SAMHSA approval.
42 CFR 8.3(b)(4)	Requires that accreditation bodies develop and submit detailed procedures of the decision making process used in the accreditation process including those for performing on-site inspections of programs pursuant to 42 CFR § 8.4(a).
42 CFR 8.3(b)(5)	Requires that each accreditation body submit procedures established to avoid any conflict of interest by any of its representatives.
42 CFR 8.3(b)(6)	Requires that accreditation bodies submit descriptions of education and training requirements for the professional staff and accreditation survey team pursuant to § 8.4(h).
42 CFR 8.3(b)(7)	Requires that accreditation bodies submit a description of training policies.
42 CFR 8.3(b)(8)	Requires that accreditation bodies submit fee schedules with supporting cost data pursuant to 42 CFR § 8.4(i).
42 CFR 8.3(b)(9)	Requires that accreditation bodies submit a contingency plan for

investigating complaints pursuant to 42 CFR § 8.4(e).

42 CFR 8.3(b)(10) Requires that accreditation bodies submit policies and procedures to protect confidential information pursuant to 42 CFR Part 2.

42 CFR 8.3(b)(11) Requires that accreditation bodies submit any other information SAMHSA may require.

42 CFR 8.3(c) Requires an accreditation body that intends to continue to serve beyond its current term apply to SAMHSA for renewal or notify SAMHSA of its intention not to apply for renewal.

42 CFR 8.3(e) Requires that an accreditation body notify SAMHSA if it is relinquishing approval as an accreditation body.

42 CFR 8.3(f)(2) Requires that an accreditation body notify OTPs and transfer copies of records to SAMHSA if it is relinquishing approval as an accreditation body.

42 CFR 8.4(b)(1)(ii) Requires an accreditation body to notify SAMHSA of seriously noncompliant programs.

42 CFR 8.4(b)(1)(iii) Requires the accreditation body to notify an OTP in writing if the OTP is in noncompliance with one or more accreditation elements.

42 CFR 8.4(d)(1) Requires accreditation bodies to submit any documents or information requested by SAMHSA within 5 days of receipt of the request.

42 CFR 8.4(d)(2) Requires that accreditation bodies make available to SAMHSA a summary of the results of each accreditation survey upon request. The summary must be in sufficient detail to justify the accreditation action taken.

42 CFR 8.4(d)(3) Requires that accreditation bodies provide to SAMHSA a list of each program surveyed and the identity of all individuals involved in the conduct and reporting of survey results, upon request.

42 CFR 8.4(d)(4) In instances when an accreditation body acts to confer conditional accreditation or to deny, suspend or revoke accreditation for any OTP, this section requires the accreditation body to submit the name of the opioid treatment program and the basis for the action to SAMHSA within 48 hours of the action.

42 CFR 8.4(d)(5) Requires that accreditation bodies submit to SAMHSA semi-annually a report consisting of a summary of the results of each accreditation

survey conducted. The summary must be in sufficient detail to justify each accreditation action taken.

42 CFR 8.4(e) Requires that accreditation bodies notify SAMHSA about complaints.

42 CFR 8.6(a)(2) and (b)(3) Requires that an accreditation body notify OTPs when the accreditation body's approval has been revoked.

42 CFR 8.6(b) When SAMHSA identifies minor deficiencies in accreditation operations, this section requires the accreditation body submit to SAMHSA a plan for corrective actions and a schedule for their implementation.

42 CFR 8.6(b)(1) Requires that an accreditation body notify OTPs when SAMHSA places the accreditation body in probationary status.

Record-Keeping Requirements for Accreditation Bodies

42 CFR 8.4(c)(1) Requires that accreditation bodies maintain records of their accreditation activities for 5 years and in sufficient detail to support each accreditation decision.

Disclosure Requirements for Accreditation Bodies

42 CFR 8.4(i)(1) Requires that accreditation bodies make public their fee structure, including factors contributing to variations in fees for different OTPs.

42 CFR 8.4(i)(2) Requires that accreditation organizations provide to SAMHSA financial records or other materials to assist in assessing reasonableness of fees.

Reporting Requirements for Opioid Treatment Programs

42 CFR 8.11(b) Requires submission of an application for certification (Form SMA-162) which must include a description of the organizational structure of the program, names of responsible persons, address of the primary dispensing unit and of any medication unit or other facility, sources of funding, the accreditation status of the program, and assurances that the program will comply with all opioid treatment standards set forth in 42 CFR § 8.12.

42 CFR8.11(d) Required submission of SMA-162 application for transitional certification. The submission deadline was August 17, 2001. All existing OTPs have been transitioned to the accreditation based system. This reporting

requirement is no longer applicable.

42 CFR 8.11(e)(1) Requires submission of SMA-162 application for provisional certification.

42 CFR 8.11(e)(2) Requires submission of documentation to request an extension of provisional certification.

42 CFR 8.11(f)(5) Requires OTP to notify SAMSHA of sponsor or medical director change.

42 CFR 8.11(g)(2) Requires submission of documentation to SAMHSA before interim maintenance approval.

42 CFR 8.11(h) Requires submission of any request for an exemption from any of the regulatory requirements set forth under 42 CFR § 8.11 or 8.12. The SMA-168 is a form on which the various patient exception requests may be documented and approved, under the exemption provisions of 42 CFR § 8.11(h).

42 CFR 8.11(i)(1) Requires submission of Form SMA-162 to request to establish a medication unit.

42 CFR 8.12(j)(2) Requires programs to notify the State health officer when a patient begins interim maintenance treatment, leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program.

42 CFR 8.24 Requires submission of appellant's request for review of suspension.

42 CFR 8.25(a) Requires appellant's submission of written request for informal review.

42 CFR 8.26(a) Requires submission of appellant's review file and written statement.

42 CFR 8.28(a) Requires appellant's submission of written request for expedited review.

42 CFR 8.28(c) Requires submission of appellant's review file and written statement.

Record-keeping Requirements for Opioid Treatment Programs

42 CFR 8.12(f)(4) Requires that each patient be assessed initially and periodically by qualified personnel to determine the most appropriate combination of

services and treatment. The assessment must include a treatment plan that must be reviewed and updated periodically.

42 CFR 8.12(g)(1) Requires programs to establish and maintain a record-keeping system that is adequate to document and monitor patient care and complies with all applicable confidentiality requirements.

42 CFR 8.12(g)(2) Requires programs to document that patients are not enrolled in other programs. Requires documentation at both programs when, under exceptional circumstances, a patient is granted permission to seek treatment at another program.

42 CFR 8.12(h)(3)(ii) Requires the program physician to document in the patient record instances in which more than 40 milligrams of medication are administered to the patient on the first day of treatment enrollment because a smaller dose of medication did not suppress opiate abstinence symptoms.

42 CFR 8.12(h)(4) Requires programs to maintain current, adequate procedures to ensure that medication is administered and dispensed in accordance with its approved product labeling. Any deviation from the approved labeling must be justified in the patient record.

42 CFR 8.12(i)(3) Requires documentation in the patient record for patients to receive take home doses of medication. The medical director must consider specific criteria prior to permitting take home doses. The number of take home doses allowed for take home use must follow specific criteria.

42 CFR 8.12(j)(2) Requires documentation of notification of State Health Officer when a patient begins interim maintenance treatment, leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program.

Disclosure Requirements for Opioid Treatment Programs

42 CFR 8.12(e)(1) Requires the program physician to ensure that all relevant facts concerning use of the opioid drug are clearly and adequately explained to the patient and that each patient provides informed written consent to treatment.

A revision for approval is being requested for the following three forms that SAMHSA has used in order to manage information collection requirements under 42 CFR Part 8, the SMA-162, SMA-163, and SMA-168. The forms have also been prepared for posting on a web site to permit electronic submission following approval. Copies of these “web pages” have been included in this package. (See Attachments A, B, and C). There are no changes to these forms. There are changes in the number of

respondents and the time required to respond, which decreases the burden hours.

SMA-162: Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR § 8.11

As a part of the record-keeping, application and reporting activities required by the regulation, OTPs use the SMA-162 form (Attachment A) to request four different types of approval from SAMHSA: (a) provisional certification, (b) renewal of certification, (c) permission to relocate an OTP, or (d) permission to establish a new medication unit. In addition, 42 CFR § 8.11(f)(5) requires OTPs to notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director, and OTPs may use this form to notify SAMHSA of these changes.

OTPs initially used an earlier version of the SMA-162 as an application to receive transitional certification. Transitional certification was designed to allow a limited period of time for OTPs to achieve accreditation and fulfill other requirements before SAMHSA evaluated an OTP's SMA-162 application for full certification. The deadline for applying for transitional certification" was August 17, 2001, and transitional certification was removed as type of certification from the form SMA-162 in 2002, because of the time limit placed on it by the regulation. OTPs granted transitional certification were required to achieve accreditation and full certification by May 19, 2003. However, one-year extensions of transitional certification were granted in extraordinary circumstances pursuant to 42 CFR § 8.11(d). Therefore, all OTPs that received extensions and were required to become accredited and fully certified by May 19, 2004, when the transitional certification period ended. Those that failed to do so were subject to suspension or revocation of certification pursuant to 42 CFR § 8.14 and following procedures set forth in 42 CFR Subpart C.

Newly established OTPs that have not previously received SAMHSA certification, but have applied for accreditation with a SAMHSA-approved accreditation body, must use the form to apply for provisional certification, which may be granted for up to one year. Once an OTP achieves accreditation it must use the form to apply for renewal of certification for a period up to three years, depending on the OTP's accreditation status.

The form is also used to request SAMHSA approval before an OTP relocates its dispensing location or before establishing a medication unit. A medication unit is a facility established as part of, but geographically separated from, an opioid treatment program from which opioid agonist treatment medications are dispensed.

The form collects data on the following items: Name of program; OTP number (same as Food and Drug Administration (FDA) identification number); Drug Enforcement Administration (DEA) registration number; address, telephone number and fax number of primary dispensing location; name, address, telephone number and fax number of the person who is the program sponsor; purpose of application; approximate program census on the date of application submission; and program funding sources. The form also requires the applicant to submit a description of the organizational structure of the program, names of responsible persons, addresses of any medication unit or other facility under the administrative control of the OTP, the accreditation status of the program, a description of the manner

in which adequate services will be provided, and the names and addresses of other referral facilities used to provide necessary medical and rehabilitative services. The program sponsor must sign the form, assuring that the OTP will comply with all opioid treatment standards set forth in 42 CFR § 8.12.

SMA-163: Application for Approval as Accreditation Body under 42 CFR § 8.3(b)

Section 8.3(b) of 42 CFR provides details of the procedures and requirements necessary for an entity to become a SAMHSA-approved accreditation body. The SMA-163 form (Attachment B) must be completed and submitted to SAMHSA along with required documents for an applicant to be approved as an accreditation body. The responsible official must sign the form, assuring that the organization will comply with all accreditation body responsibilities set forth under 42 CFR § 8.4 and with Federal confidentiality regulations regarding the records of alcohol and drug patients, as found in 42 CFR Part 2.

The form collects data on the following items: name, address, and telephone number of the applicant; the name of the official responsible for the accreditation body; and evidence of nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization if the applicant is not a State agency). The SMA-163 also requires the applicant to submit a set of accreditation elements along with a detailed discussion of how the elements will ensure that each OTP surveyed will meet Federal opioid treatment standards. Other required attachments include a detailed description of the accreditation body's decision-making process, applications, fee schedules, policies and procedures, and other materials usually and customarily included in accreditation manuals.

SMA-168 Exception Request and Record of Justification under 42 CFR § 8.12

Section 8.12 of the regulation sets forth the Federal Opioid Treatment standards. These standards establish procedures for the administration and management of opioid treatment under the regulations. Occasionally, there is a need to make a change in the usual treatment regimen or protocol. These are called "patient exceptions" and occur when the physician must make a treatment decision that varies from the requirements of the regulation pertaining to patient treatment. Physicians in OTPs have requested these patient exceptions to the regulations on an individual basis since the Food and Drug Administration began oversight of opioid (methadone) treatment in the early 1970's under 24 CFR Part 291.505, and this practice has continued under provisions of 42 CFR Part 8.

The SMA-168 (Attachment C) was developed in 2002 and approved in response to an informal dialogue between SAMHSA, FDA, OTPs, States and other stakeholders around the nation. It was also developed based on SAMHSA's experience with processing patient exception requests submitted in manifold formats. This simplified, standardized form was designed to facilitate the documentation, request and approval process for exceptions, and to prepare for paperless processing of exceptions.

Patient exception requests are reviewed for SAMHSA approval under the exemption provisions detailed in 42 CFR § 8.11(h). For example, certain changes in patient care that involve adjustments to medication dosage levels or medication take-home privileges may require SAMHSA approval. Or, a treatment program may need to admit a patient for an additional detoxification treatment regimen. In

many instances, the State Opioid Treatment Authority (SOTA, formerly, State Methadone Authority, or, SMA) may be required to review and approve patient exceptions involving the regulations of that particular State. States occasionally request SAMHSA approval or interpretation of the regulations before State officials will make a decision on an exception request. OTPs may choose to notify SAMHSA/CSAT, seek approval, or request regulatory guidance even when Federal approval is not mandatory.

The SMA-168 is a flexible, multi-purpose form on which these various requests may be documented. There are sections of the form set aside for SAMHSA and SMAs to request additional information as necessary to approve or deny the request and provide an explanation for the action taken. The form may be used in a variety of ways depending on State and Federal regulations and policy. An OTP's internal policies may also influence the manner in which the form is to be used. For example, an OTP medical director may require State or Federal approval before approving a treatment regime involving legal liability issues. In some instances, the form may require only Federal approval, and the State approval section will be left uncompleted. In other instances, the State Opioid Treatment Authority (SOTA) may review SAMHSA's response to the form before making a decision. Usually, OTPs become aware of the regulations and policies requiring SOTA approval for a particular type of patient exception, through the experience of reading the regulation and attempting to comply with it. In the same manner, OTPs learn which exceptions require Federal approval and which require both Federal and SOTA approval.

Use of the SMA-168 form is voluntary. OTPs are permitted to submit requests for patient exceptions using other formats, such as forms devised by a State or a program, memoranda or narrative requests. The detailed information from this form is requested so that SAMHSA personnel (and personnel who administer State opioid regulations) may make a determination whether to grant requested patient exceptions to the regulation. The decision is then communicated back to the requesting OTP and the State Opioid Treatment Authority, using space at the bottom of the form for a reply, which includes space to enter an explanation of the rationale for the decision. Providing a detailed written rationale assists OTPs in learning to interpret fine points of the regulation and helps CSAT to fulfill its mandate to improve treatment.

The information collected is also entered into a database and used to help monitor program operations. Data collected from Form SMA-168 will be used for management analysis and decision-making to ensure that the average turnaround time for processing these exceptions improves over time.

Using a standardized form as a guide to collect program information will ensure consistency of data provided. It also lessens the burden on requesters because they may check off items most frequently requested and respond to specific information requests, rather than write narratives. Procedures have been developed for completing and submitting the forms electronically, through a dedicated Web page that SAMHSA established for this purpose. The form may also be submitted by fax and by U.S. mail.

2. Purpose and Use of Information

The regulation, 42 CFR Part 8, requires that certain information be collected from the regulated

entities so that SAMHSA may: 1) oversee the accreditation process conducted by SAMHSA-approved accreditation bodies, 2) certify that opioid treatment programs (OTPs) are qualified (under standards established by the Secretary of the Department of Health and Human Services (HHS)) to treat patients enrolled in OTPs, and 3) fulfill its responsibilities to enforce the regulations and ensure that opioid treatment programs comply with the regulations. The overall purpose of the regulations is to ensure that opioid treatment is administered in a safe and effective manner that does not endanger public health and safety.

The statutory authority underlying 42 CFR Part 8 resides in section 303(g) of the Controlled Substances Act (CSA) (21 U.S.C. 823(g)(1)), which provides for a separate controlled substances registration for practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment of narcotic addiction. This separate registration is conditioned on the Secretary of HHS determining that the applicant is a practitioner who is qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought. Section 303(g) was added to the CSA by the Narcotic Addict Treatment Act (NATA) (P. L. 93-281), which was enacted by Congress as a means to ensure that only bona fide patients addicted to narcotics are admitted to maintenance or detoxification treatment, that they receive quality care, and that illicit diversion is limited. The standards referred to in Section 303(g) were first issued under authority of Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P. L. 91-513), which requires that the Secretary determine the appropriate methods of professional practice for medical treatment of various classes of narcotic addicts.

Thus, under 42 CFR Part 8, SAMHSA is responsible for oversight of accreditation bodies and for certification of OTPs in order to fulfill the requirements of Section 303(g) of the CSA. The Secretary of Health and Human Services delegated these responsibilities to the Administrator of SAMHSA on October 30, 2000.

In order to carry out its responsibilities, SAMHSA reviews the applications of accreditation bodies (Form SMA-163) before approving them, based on qualification requirements outlined in 42 CFR § 8.3. Only SAMHSA-approved accreditation bodies are permitted to conduct accreditation site visits for purposes of reviewing OTPs' compliance with the Federal opioid treatment standards contained in 42 CFR § 8.12. The on-site inspections/site visits are conducted by an accreditation team of qualified professionals who serve as employees of the SAMHSA-approved accreditation bodies. Accreditation bodies' responsibilities are outlined in 42 CFR § 8.4; SAMHSA periodically evaluates their performance pursuant to § 8.5; accreditation bodies may relinquish approval under § 8.3(e); and approval of accreditation bodies may be withdrawn under provisions of § 8.6 and § 8.13.

Under section 303(g) of the CSA, HHS (and by delegation, SAMHSA) has responsibilities in four areas toward OTPs. First, the Secretary establishes qualification standards for practitioners who dispense narcotic drugs to individuals in maintenance or detoxification treatment for narcotic addiction. These standards are established in 42 CFR § 8.12, and require that the practitioner obtain accreditation from a SAMHSA-approved accreditation body, as discussed in the paragraph above. Second, the Secretary certifies to DEA that applicants/practitioners are qualified under the standards and that these practitioners will comply with the standards respecting quantities of narcotic drugs that

may be provided for unsupervised use by individuals in such treatment. Third, HHS is responsible for enforcement of and ensuring compliance with the standards. Fourth, under the statutory authority of the Public Health Service Act (42 USC 290aa), SAMHSA is responsible for supporting activities that will improve treatment for substance abuse and for coordinating Federal policy with respect to anti-addiction medications.

SAMHSA determines the qualifications of practitioners (or OTPs) in the following ways: (1) Before provisional certification of new programs it reviews applications (form SMA-162) submitted by sponsors/practitioners; and (2) For existing programs, it reviews certification applications (form SMA-162), reports of accreditation site visits conducted by SAMHSA-approved accreditation bodies, and other information before granting certification. SAMHSA consults with the State Opioid Treatment Authority and the Drug Enforcement Administration as a part of the application review process and gives final approval for a treatment program once it has received notification of approval by the State authority and verification by DEA that its requirements have been met. Both DEA and the respective State authority are notified of certification decisions.

SAMHSA grants exemptions from the regulatory requirements set forth in § 8.11 and § 8.12, under exemption provisions contained in § 8.11(h). As mentioned earlier, exemptions may include OTP-wide exemptions or individual patient exceptions. SAMHSA and the programs use the SMA-168 to expedite and facilitate the approval of patient exceptions. SAMHSA currently estimates that it receives approximately 24,000 patient exception requests per year, submitted in a variety of formats. Patient exception processing is an important part of SAMHSA's regulatory responsibilities because it fulfills the goal of making the regulations increasingly flexible and patient-care focused, while preventing substandard or unethical practices and maintaining public support. In addition, this process serves to assist SAMHSA with improving the provision of opioid treatment to patients throughout the country.

Section 8.14 of the regulation provides for suspension or revocation of an OTP's certification. Subpart C of the regulation contains procedures for review of suspension or proposed revocation of OTP certification and of adverse action regarding withdrawal of approval of an accreditation body.

3. Use of Information Technology

Currently, the SMA-162, SMA-163, and SMA-168 are available on the SAMHSA/CSAT Web site in "pdf" (Adobe Acrobat) format to download for use as hard copies. The forms have also been prepared for electronic completion and posted on the World Wide Web. The "pdf" and the electronic form SMA-162 may be found at http://dpt2.samhsa.gov/sma162/; the SMA-163 is at http://dpt2.samhsa.gov/sma163/; and the SMA-168 is at http://dpt.samhsa.gov/regulations/exrequests.aspx. The electronic versions of the forms are compliant with Section 508 of the Rehabilitation Act, which requires agencies and their contractors to buy electronic and information technology that is accessible to people with disabilities.

Users will submit online SMA-162s and SMA-163s by way of the publicly accessible DPT Website.

Users will be able to upload and attach required electronic files to be submitted with an online SMA-162 and SMA-163. All attachments will be automatically scanned for viruses by the system, and quarantined if a virus is found. Users will be required to provide an email address with the online SMA-162 and SMA-163. After the SMA-162 or SMA-163 is submitted, the system will automatically send a confirmation email to the address provided by the user. The email will instruct the user to complete the submission process by replying to the confirmation email. When an online SMA-162 or SMA-163 is submitted, the system will also automatically send a notification e-mail to designated SAMHSA personnel. The notification e-mail will contain a link to a Web page at which the submitted SMA-162 and SMA-163 can be viewed and printed, and from which any attached files can be downloaded. Only SAMHSA personnel will be able to access these links.

Users of the SMA-168 are provided a unique username and password to access the SAMHSA OTP Extranet website (http://otp-extranet.samhsa.gov). At the extranet website users can submit SMA-168s, which they electronically sign by entering their assigned system password. As an added security precaution, when an SMA-168 is submitted a confirmation e-mail is sent to the address associated with the signing user name and password, so that the user will know when an SMA-168 is submitted with their credentials. SAMHSA and the relevant State Methadone Authority personnel then receive an e-mail notifying them that an SMA-168 has been submitted. They log onto the site using their unique e-mail username and password and process the form.

4. Efforts to Identify Duplication

The information collection, record-keeping, disclosure and reporting requirements mandated by 42 CFR Part 8 do not conflict with or duplicate the requirements of other regulations. They do, however, complement the Drug Enforcement Agency's (DEA) security, storage, and record-keeping regulations for narcotic (or opioid) drugs used to treat narcotic addiction (21 CFR Part 1300). They also do not duplicate regulations or data collection requirements that some States have established to provide oversight on the use of narcotic drugs for the treatment of narcotic addiction. Many State regulations are modeled on Federal regulations and in some instances are more restrictive.

These regulations are the only regulatory standards published under HHS authority that concern use of opioid drugs for maintenance or detoxification treatment. Thus, there are no other data sources available that can be used by SAMHSA.

5. Involvement of Small Entities

SAMHSA's charge to regulate opioid addiction treatment programs using opioid drugs applies to small as well as to large businesses involved in maintenance and detoxification treatment. SAMHSA believes that its duty requires the equal application of the regulations to all enterprises. While SAMHSA does not believe it can apply different standards with respect to statutory requirements, SAMHSA does provide special help to small and non-profit businesses. The Center for Substance Abuse Treatment, within SAMHSA, is providing technical assistance to programs to aid in their transition to the accreditation based oversight system.
11.

6. Consequences if Information Collected Less Frequently

Failure to collect the information required by the regulation using the SMA-162, SMA-163, and SMA-168 would be inconsistent with requirements established in Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513) and Section 303(g) of the Controlled Substances Act (21 U.S.C.(g)(1)). This, in turn, would result in SAMHSA's non-compliance with the statutes. SAMHSA plans to collect the required information as specified in 42 CFR Part 8 and no more frequently.

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

The requirements of 42 CFR Part 8 are consistent with 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

In developing the regulations and the interim final rule, SAMHSA consulted with representatives from the Interagency Narcotics Treatment Policy Review Board (INTPRB), which is a Federal board which works to coordinate Federal narcotics treatment policy among the agencies which share responsibility for it. The INTPRB membership includes the Food and Drug Administration (FDA), the National Institute on Drug Abuse (NIDA), the Center for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), the Office of National Drug Control Policy (ONDCP), and the Drug Enforcement Administration (DEA). Interagency coordination has been achieved in recent years with *ad hoc* conferences amongst the pertinent Federal agencies and without formally convening the INTPRB. For example, in 2003 and 2007, SAMHSA convened two national assessment panels on methadone associated mortality.

SAMHSA also pursued a consensus panel approach in developing accreditation guidelines which incorporate the opioid treatment standards set forth under 42 CFR § 8.12. In response to the July 22, 1999, Notice of Proposed Rulemaking SAMHSA received almost 200 submissions, each containing one or more comments. Additional information was also presented during a November 1, 1999, Public Hearing. The comments and information presented were from government, industry trade associations, academia, health professionals, professional organizations, accreditation bodies, and individual patients. The Secretary of Health and Human Services considered these comments in formulating the finalization of rules under 42 CFR Part8. Finally, SAMHSA received comments in response to the May 2003 Interim Final Rule, and the June 19, 2009, Notice of Proposed Rulemaking.

In addition, SAMHSA/CSAT consulted with FDA officials, former Government employees and State Methadone Authorities in formulating the SMA-168. The final version of the form was based on a content analysis of the information provided during the patient exception approval process. SAMHSA staff consulted with several SOTAs and OTPs in refining the form.

SAMHSA/CSAT has also consulted with American Institutes for Research (AIR) staff (through a support contract) regarding the format of the SMA-162, SMA-163, and SMA-168. AIR staff contributed to the content of the forms, formatted them (as agreed upon in discussions with CSAT

staff), prepared instructions for their completion, and prepared electronic versions of the forms as well as electronic programming to prepare for processing the forms.

The notice required in 5 CFR 1320.8(d) was published in the Federal Register on January 15, 2013, (78 FR 3015). No comments were received in response to this notice.

9. Remuneration of Respondents

No remuneration will be provided.

10. Assurance of Confidentiality

No assurances of confidentiality are made to respondents. In order to protect the privacy of patient records, submissions dealing with individual patients (e.g., summaries, accreditation reports, complaints) identify them only with a private number, in most cases assigned by the treatment program. In addition, the regulations include several provisions (e.g., 42 CFR § 8.4(c)(2), 8.12(g)(1)) for protection of patient records in treatment programs.

The SMA-168 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 the length of time a patient has been in treatment; SAMHSA requires the admission date because the patient's length of time in treatment is necessary to interpret treatment provisions of the regulation appropriately.

SAMHSA has consulted the Office of Civil Rights of the Department of Health and Human Services regarding the applicability of Title 45 of the Code of Federal Regulations § 164.512 to these information collection activities. This section is titled, "Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required," and was issued under regulations written to enact the mandate of title II, subtitle F, section 261-264 of the HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA), Public Law 104-191. Currently, it appears that § 164.512 (b) of the regulation permits SAMHSA, as a public health entity that is authorized by law, to collect information for the purpose of preventing or controlling disease, injury or disability, including the conduct of public health surveillance and investigations.

11. Questions of a Sensitive Nature

The information requirements contained in 42 CFR Part 8 do not result in the collection of sensitive information.

12. Estimates of Annualized Hour Burden

Pursuant to 42 CFR Part 8 accreditation bodies and OTPs are required to submit information to SAMHSA/CSAT. The annualized burden of information collection for OTPs and accreditation bodies

under the rule is set forth in the tables that follow.

The total number of burden hours annually for accreditation body respondents is approximately 394.20 hours. The total number of burden hours annually for OTP respondents is approximately 1,868.95 hours. The annual burden associated with this rule and the associated forms is estimated to be 2,263.15 hours.

Estimated Annual Reporting Requirement Burden for Accreditation Bodies

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.3(b)(1-11)	Initial approval (SMA-163)	1	1	1	6.0	6
8.3(c)	Renewal of approval (SMA-163)	2	1	2	1.0	2
8.3(e)	Relinquishment notification	1	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTPs	1	90	90	0.1	9
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs	2	2	4	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance	2	10	20	1.0	20
8.4(d)(1)	General documents and information to SAMHSA upon request	6	5	30	0.5	15
8.4(d)(2)	Accreditation survey to SAMHSA upon request	6	75	450	0.02	9
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request	6	6	36	0.2	7.2
8.4(d)(4)	Report of less than full	6	5	30	0.5	15

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
	accreditation to SAMHSA					
8.4(d)(5)	Summaries of Inspections	6	50	300	0.5	150
8.4(e)	Notifications of Complaints	12	6	72	0.5	36
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTPs	1	185	185	0.3	55.5
8.6(b)	Submission of 90-day corrective plan to SAMHSA	1	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTPs of Probationary Status	1	185	185	0.3	55.5
SUB TOTAL		54		1,407		394.20

Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.11(b)	Renewal of approval (SMA-162)	386	1	386	0.15	57.9
8.11(b)	Relocation of Program (SMA-162)	35	1	35	1.17	40.95
8.11(e)(1)	Application for provisional certification	42	1	42	1	42.00

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.11(e)(2)	Application for extension of provisional certification	30	1	30	0.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change (SMA-162)	60	1	60	0.1	6.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance	1	1	1	1	1.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12 (including SMA-168)	1,200	20	24,000	0.07	1,680
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA-162)	10	1	10	0.25	2.5
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance	1	20	20	0.33	6.6
8.24	Contents of Appellant Request for Review of Suspension	2	1	2	0.25	.50
8.25(a)	Informal Review Request	2	1	2	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement	2	1	2	5.00	10.00

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.28(a)	Appellant's Request for Expedited Review	2	1	2	1.00	2.00
8.28(c)	Appellant Review File and Written Statement	2	1	2	5.00	10.00
SUB TOTAL		1,775		24,594		1,868.95
TOTAL		1,829		26,001		2,263.15

Estimated Costs of Reporting Burdens for OTPs and Accreditation Bodies

Hourly labor costs involved in reporting requirements vary greatly between programs. Employees involved in complying with reporting requirements range from minimum wage clerical workers, to counselors making $11 to $16 an hour, managers, licensed practical nurses and registered nurses making $20 to $45 per hour, administrators making more than $35 per hour, and physicians making $75 or more an hour. The estimated average hourly wage for program personnel involved in reporting requirements is $28.50. Multiplying the estimated average hourly wage by 1.5 to account for non-wage labor costs, an estimated hourly labor cost of $42.75 is obtained. The cost to accreditation bodies for applying for initial and ongoing approval with Form SMA-163, as well as for complying with the reporting requirements under 42 CFR § 8.4 and 8.6 may be estimated at $16,852.05, using the $42.75 hourly cost figure. The estimated total annualized cost to the treatment program respondents for preparing the Form SMA-162 and for complying with other reporting requirements pursuant to 42 CFR § 8.11, 8.24, 8.25, 8.26, and 8.28, using $42.75 as the hourly cost figure, is $8,077.61. Similarly, the estimated total annualized cost to treatment program respondents for preparing the SMA-168, as required, is $91,271.25. These wage estimates were obtained from the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics website.

Items	Preparation Time (Hours)	Cost / Hour	Total Cost

Form SMA-163, compliance with the reporting requirements under 42 CFR § 8.4 and 8.6	394.2	$42.75	$16,852.05
Form SMA-162, compliance with other reporting requirements under 21 CFR § 8.11, 8.24, 8.25, 8.26, and 8.28	188.95	$42.75	$8,077.61
Form SMA-168, Exception Request and Record of Justification Under 42 CFR § 8.11(h)	2,135	$42.75	$91,271.25
SUB TOTAL			$116,200.91

Record Keeping

The record-keeping requirements set forth in 42 CFR § 8.4 and 8.12 include maintenance of the following: a patient's medical examination when admitted to treatment; a patient's history; a treatment plan; any prenatal support provided the patient; justification of unusually large initial doses; changes in a patient's dosage schedule; the rationale for decreasing a patient's clinic attendance; and documentation of physiologic dependence.

SAMHSA believes that the record-keeping requirements are customary and usual practices within the medical and rehabilitative communities. Accreditation bodies also maintain accreditation records for 5 or more years as a customary and usual practice. SAMHSA has neither calculated a response burden nor a cost burden for these activities.

Record Keeping for Accreditation Bodies

42 CFR Citation	Purpose
8.4(c)(1)	Requirement that accreditation bodies retain certain records pertaining to accreditation for 5 years

Record Keeping for OTPs

42 CFR Citation	Purpose
8.12(f)(4)	Patient Medical Evaluation and other assessments when admitted to treatment and periodically throughout treatment.
8.12(g)(1-2)	Record of the provision of needed services including prenatal support
8.12(h)(3)(ii)	Program physician record to document excessive dose on first day

8.12(h)(3)(iii)	Record of justification of exceptional initial and daily doses
8.12(h)(4)	Record of justification of variations from approved product labeling for levo-alpha-acetyl-methadol (LAAM) and future medications
8.12(i)(3)	Record of the rationale for decreasing patient clinic attendance
8.12(j)(2)	Record of reports to State Health Officers when enrollment status changes for patients in interim maintenance treatment

Disclosure Burdens

This rule includes requirements that OTPs and accreditation organizations disclose information. For example, § 8.12(e)(1) requires that a physician explain the facts concerning the use of opioid drug treatment to each patient. This type of disclosure is considered to be consistent with the common medical practice and is not considered an additional burden. Further, the rule requires, under § 8.4(i)(1), that accreditation organizations shall make public their fee structure. The Preamble of the Notice of Proposed Rulemaking contained publicly available information on the fee structure for three accreditation bodies. This type of disclosure is standard business practice and is not considered a burden in this analysis.

Disclosure Burden for Accreditation Bodies

42 CFR Citation	Purpose
8.4(i)(1)	Requires that the accreditation organization disclose fee structures
8.4(i)(2)	Requires that the accreditation organization provide to SAMHSA financial records or other materials to assist in assessing reasonableness of fees

Disclosure Burden for OTPs

42 CFR Citation	Purpose
8.12(e)(1)	Requirement that physician explain the facts concerning the use of opioid treatment drugs to each new patient

13. Estimate of Annualized Non-hourly Cost Burden to Respondents

There are no capital or start up costs above the normal office and laboratory equipment required for achieving regulatory compliance. It is estimated that there are some costs associated with

preparation for the accreditation site visit itself; assuming that OTP staff spend approximately 180 hours preparing for the site visit at an average cost of $28.50 per hour and an average of 1.33 site visits per facility, the total cost would be $6,822 or an annualized cost of $2,274 per facility. For the approximately 1,200 affected OTPs these total annual costs are estimated to be $2,728,800. The percentage of this total cost that is associated with record keeping and reporting only is difficult to estimate, but is estimated to be a small fraction of the total associated with accreditation.

14. Estimate of Annualized Cost to the Government

The total annualized cost to SAMHSA for administering 42 CFR Part 8 is estimated at $450,000. This estimate includes the cost of an outside contractor to develop and maintain an extensive on-line system for SAMHSA, opioid treatment programs, State Authorities, Accreditation Organizations and others to have use a protected web site for day-to-day regulatory activities. This estimate does not include what SAMHSA/CSAT spends in the form of grants to accreditation organizations to offset the direct cost of accreditation, or the funds CSAT allocates for its "look back" program, to monitor the adequacy of accreditation inspections. Of this amount, the total annualized cost to SAMHSA for Paperwork Reduction Act activities as a result of this regulation is estimated as $176.321, as shown in the following table.

Annualized Cost to SAMHSA/CSAT

Item (Purpose)	Responses	Hours per Response	Total Hours	Total Cost @ $53 per hour
SMA-162 (New Programs)	42	1.5	63	$3,339
SMA-162 (Renewal)	386	.75	289.5	$15,344
SMA-162 (Relocation)	35	.25	8.75	$464
Notification of Provisional Certification	40	.50	20	$1,060
Notification of Extension of Provisional Certification	15	.50	7.5	$397.5
Notification of Sponsor or Medical Director Change	60	0.33	19.8	$1,049.40
Documentation to SAMHSA for Interim Maintenance	1	0.50	0.5	$26.50

Item (Purpose)	Responses	Hours per Response	Total Hours	Total Cost @ $53 per hour
Requests to SAMHSA for Exemption from § 8.11 and 8.12 (including SMA-168)	24,000	0.07	1680	$89,040
Notification to SAMHSA Before Establishing Medication Units	20	1.00	20	$1,060
Review of Submissions under Part C	2	2.00	4	$212
Accreditation Body Initial Application (SMA-163)	3	40	120	$6,360
Accreditation Body Renewal (SMA-163)	3	40	120	$6,360
Relinquishment Notification	1	.50	0.5	$26.50
Notification for Serious Non-Compliant Programs	2	.50	1	$53.00
General Documents to SAMHSA Upon Request	10	1.00	10	$530
Accreditation Survey to SAMHSA Upon Request	383	.50	191.5	$10,149.5
Less Than Full Accreditation Report to SAMHSA	10	1.00	10	$530
Summaries of Inspections	12	1.00	12	$636
Notification of Complaints to SAMHSA	10	1.00	10	$530
Submission of 90-Day Corrective Plan to SAMHSA	1	4.25	4.25	$225.25
SUB TOTAL	25,036	97.15	2231.05	$137,392.65

15. Changes in Burden

Currently there are 2,718 total approved burden hours. The program is requesting 2,263.15. The decrease of 454 hours is due to the improvements and enhancements to the web-based online reporting system for forms SMA-162 and SMA-168. The forms available online include a unique online feature for both the SMA-162 and SMA-168 that pre-populates certain information within the form. This in turn reduces the program's time spent filling out the forms as well as the staff time spent on processing it.

Importantly, this modest increase in the number of regulated entities responding has been offset by the online function. Also with the approval of the new regulation on buprenorphine there have been fewer patient exceptions necessary therefore reducing burden hours. The response number and total hours requested for accreditation organizations has increased slightly. This is due to the emphasis on patient (and other) complaint monitoring and accreditation organization follows up.

The estimated burden in the tables accompanying this submission has been adjusted accordingly and indicates a decrease in the estimated information collection burden since the last submission. The net result of these re-estimations is an adjustment decrease of 454 hours from the previously approved level of 2,718 hours.

16. Time Schedule, Publication and Analysis Plans

Time Schedule: The SMA-162 application is generally required once every three years for triennial renewal of certification, but some treatment programs may submit this form more frequently if there is a change in accreditation status. The only other occasions that require submitting an SMA-162 are when programs request approval to relocate or to establish a medication unit or notify SAMHSA of a change in sponsor or medical director. Other forms of notification are accepted.

The SMA-163 application is required for initial approval and again at the end of the accreditation body's period of approval, which shall not exceed five years, as specified by 42 CFR § 8.3(g).

The regulation requires programs to submit requests for exemptions from regulatory requirements and permits programs to submit exemption requests at the time of certification application or at any time thereafter. Thus, OTPs will submit SMA-168s to request patient exceptions on an on-going basis, depending on the needs of individual patients.

Publication: At this time, the only publication of information collected from the SMA-162 is the SAMHSA/CSAT "Opioid Treatment Programs Directory." The directory is available on SAMHSA's web site at http://dpt2.samhsa.gov/regulations/smalist.aspxas a service to the public. The directory groups OTPs by State and city; and it displays the name of the program, program sponsor, current address, telephone, fax number, and e-mail address. The directory also lists hospitals and other facilities authorized to dispense narcotic drugs for detoxification treatment. It is updated monthly, and may be downloaded or printed from the web site. SAMHSA staff members provide hard copies of the directory printed from a web version of the document upon request from the public.

For SAMHSA-approved accreditation bodies, the address and telephone numbers and any other contact information collected from the Application for Approval as an Accreditation Body (SMA-163) are displayed on the SAMHSA/CSAT Web page as a service to the public.

Information from the patient exception forms (SMA-168) is entered into a database to assist with tracking and program monitoring. The average amount of time taken to process exception requests and notify requesters is a GPRA measure.

Analysis Plans: The information is collected on the forms and entered into a database, and summary reports are prepared.

17. Display of Expiration Date

Expiration dates for OMB approval will be printed on all data collection instruments (SMA-162, SMA-163, and SMA-168).

18. Exceptions to Certification Statement

This collection of information involves no exception to the Certification for Paperwork Reduction Act Submissions.

B. Statistical Methods

Not applicable.

List of Attachments

I. SMA-162, “Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR § 8.11"

II. SMA-163, Application for Approval as Accreditation Body Under 42 CFR § 8.3(b)

III. SMA-168, Exception Request and Record of Justification Under 42 CFR § 8.11(h), and Instructions for Form 168