Medications for the Treatment of Opioid Use Disorder
Final Rule, 42 CFR Part 8

Supporting Statement

Check off which applies:
☐ New
☒ Revision
☐ Reinstatement with Change
☐ Reinstatement without Change
☐ Extension
☐ Emergency
☐ Existing

A. Justification

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting a revision from the Office of Management and Budget (OMB) for the approval of three forms used to implement the regulations (OMB No. 0930-0206). Title 42 of the Code of Federal Regulations (CFR) Part 8 was promulgated under the 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 in 2001 and revised in 2024 require that opioid treatment programs (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 (HHS). 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.

A revision for approval is being requested for the following three forms that SAMHSA has used to manage information collection requirements under 42 CFR Part 8:

- SMA-162: Application for Certification to Use Opioid Medications in a Treatment Program;
- SMA-163: Application for Approval as Accreditation Body; and
- SMA-168: Exception Request and Record of Justification.

There are minor changes to these forms to improve data collection and remove unnecessary questions.

SMA-162: *Application for Certification to Use Medications for the Treatment of Opioid Use Disorder 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 to request four different types of approval from SAMHSA: (1) provisional certification, (2) renewal of certification, (3) permission to relocate an OTP, or (4) permission to establish a new medication unit. In addition, 42 CFR § 8.11(f)(5) requires OTPs to notify SAMHSA within three 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.

Newly established OTPs that have not previously received SAMHSA certification but have applied for accreditation with a SAMHSA-approved accrediting 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 OTP from which opioid treatment medications are dispensed.

The form collects data on the following items: Name of program; SAMHSA OTP number (a unique identification number); Drug Enforcement Administration (DEA) registration number; address, telephone number of primary dispensing location; name, address, telephone number of the person who is the program sponsor and medical director; 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 person(s), 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 must be completed and submitted to SAMHSA along with required documents for an applicant to be approved. 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, telephone number, email address 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 form 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 must 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 (FDA) 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 was developed 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 decide 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 SOTAs to request additional information as necessary to approve or deny the request and provide an explanation for the action taken.

The detailed information from this form is requested so that SAMHSA personnel (and personnel who administer State opioid regulations) may determine 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 will be 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.

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 OTPs are qualified under standards established by the Secretary of the Department of 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 HHS 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 OTPs in the following ways: 1) Before provisional certification of new programs, SAMHSA reviews form SMA-162 submitted by program sponsors; and 2) For existing programs, it reviews certification renewal requests via form SMA-162, reports of accreditation site visits conducted by SAMHSA-approved accreditation bodies, and other information before granting certification. SAMHSA consults with the SOTA and the DEA 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-centered 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 publicly available online on SAMHSA Website

[https://dpt2.samhsa.gov/sma162/; https://dpt2.samhsa.gov/sma163/; and https://otp-extranet.samhsa.gov]. The forms have been prepared for electronic completion. 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 forms SMA-162 and SMA-163 by way of the publicly accessible Division of Pharmacologic Therapies (DPT) website. Users will be able to upload and attach required electronic files to be submitted along with an online SMA-162 and SMA-163 forms. 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 forms. After the SMA-162 or SMA-163 form 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 either an online SMA-162 or SMA-163 form 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 Website at which the submitted SMA-162 and SMA-163 forms and any attachments can be viewed, printed, or downloaded by SAMHSA personnel only.

Users of the SMA-168 form are provided a unique username and password to access the SAMHSA OTP Extranet website (https://otp-extranet.samhsa.gov). As an added security precaution, when an SMA-168 form is submitted, a confirmation e-mail is sent to the authorized user. SAMHSA and the relevant SOTA personnel will receive an e-mail notifying them that a SMA-168 has been submitted. They both must log onto the site to 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 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 OTPs using opioid medications 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 CSAT provides technical assistance to programs to aid in their transition to the accreditation-based oversight system.

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 forms 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 CSA (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

The notice required in 5 CFR 1320.8(d) was published in the Federal Register on June 4, 2024 (89 FR 47973). No comments were received in response to this notice.

SAMHSA pursued a consensus panel approach in developing the 2015 OTP guidelines which incorporate the opioid treatment standards set forth under 42 CFR § 8.12. SAMHSA received almost 200 submissions, each containing one or more comments. The comments and information presented were from government, industry trade associations, academia, health professionals, professional organizations, accreditation bodies, and individual patients. The Secretary of HHS considered these comments in formulating the finalization of rules under 42 CFR Part 8.

In addition, SAMHSA/CSAT consulted with FDA officials, former government employees and SOTAs in formulating the SMA-168 form. 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 a support contract regarding the format of the SMA-162, SMA-163, and SMA-168 forms. The contractor contributed to the content of the forms, formatting, instructions for their completion, and prepared electronic versions of the forms as well as electronic programming for processing the forms.

9. Remuneration of Respondents

No remuneration will be provided.

10. Assurance of Confidentiality

Data will be kept private to the extent allowed by law. No assurances of confidentiality are made to

respondents. To protect the privacy of patient records, submissions dealing with individual patients are identified by a unique number, which in most cases assigned by the treatment program. The following regulations (e.g., 42 CFR § 8.4(c)(2), 8.12(g)(1)) include several provisions for the protection of patient records in treatment programs.
The SMA-168 form requests a patient identification number and admission date. This information is collected only as an aid in tracking a 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 for Civil Rights of the Department of HHS 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 number of annual burden hours for SMA-163 respondents is approximately 394 hours. The number of annual burden hours for SMA-162 and SMA-168 respondents is approximately 2954.00 hours. The total annual burden associated with the SMA forms is estimated to be 3,348 hours.

Form	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
SMA-163	54	26.055	1,407	0.28	394
SMA-162	751.33	17.976	13,506	0.08	1,081
SMA-168	1,302.67	17.977	23,418	0.08	1,873
Subtotal	2,054	17.977	36,925	0.08	2,954
Total			38,332		3,348

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 ($7.25) clerical workers; counselors averaging $22.14 an hour; managers, licensed practical nurses and registered nurses averaging $35.36 per hour; administrators averaging $52.58 per hour; and physicians averaging $96.26 per hour. The estimated average hourly wage for program personnel involved in reporting requirements is $42.71. Multiplying the estimated average hourly wage by 1.5 to account for non-wage labor costs, an estimated hourly labor cost of $64.07 is obtained. Therefore, the estimated costs of reporting burdens for OTPs and accreditation is $64.07 x 3,348 hours = $214,506.36.

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 $42.71 per hour and an average of 1.33 site visits per facility, the total cost would be $10,225 or an annualized cost of $3,408 per facility. For approximately 1,200 affected OTPs these total annual costs are estimated to be $4,089,600. 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 cost 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 access a website 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 (PRA) activities as a result of this regulation is estimated as $137,392.65, as shown in the following table.

Annualized Cost to SAMHSA

Item (Purpose)	Responses	Hours per Response	Total Hours	Total Cost @ $53 per hour
SMA-162 (New Programs)	42	1.5	63	$3,339.00

Item (Purpose)	Responses	Hours per Response	Total Hours	Total Cost @ $53 per hour
SMA-162 (Renewal)	386	.75	289.5	$15,344.00
SMA-162 (Relocation)	35	.25	8.75	$464.00
Notification of Provisional Certification	40	.50	20	$1,060.00
Notification of Extension of Provisional Certification	15	.50	7.5	$397.50
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
Requests to SAMHSA for Exemption from § 8.11 and 8.12 (including SMA-168 form)	24,000	0.07	1680	$89,040.00
Notification to SAMHSA Before Establishing Medication Units	20	1.00	20	$1,060.00
Review of Submissions under Part C	2	2.00	4	$212.00
Accreditation Body Initial Application (SMA-163 form)	3	40	120	$6,360.00
Accreditation Body Renewal (SMA-163 form)	3	40	120	$6,360.00
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	$530.00

Item (Purpose)	Responses	Hours per Response	Total Hours	Total Cost @ $53 per hour
Accreditation Survey to SAMHSA Upon Request	383	.50	191.5	$10,149.50
Less Than Full Accreditation Report to SAMHSA	10	1.00	10	$530.00
Summaries of Inspections	12	1.00	12	$636.00
Notification of Complaints to SAMHSA	10	1.00	10	$530.00
Submission of 90-Day Corrective Plan to SAMHSA	1	4.25	4.25	$225.25
SUB TOTAL	25,0360	0	2592.30	$137,392.65

15. Changes in Burden

There are minimal changes proposed to the form SMA-162 and those changes do not impact the response burden. For this cycle, we are seeking to remove questions 1e: ISATS-ID and 1f: National Provider Identification Number on form SMA-162 as they are no longer relevant to OTP oversight codified under Final Rule 42 CFR Part 8. We are seeking to update terminology on questions 13a – change term from "treatment" to "medication" and 13b change term from "drug" to "medication". Additionally, we are seeking to add an option for tribal and carceral based program statuses on #14a on form SMA-162. This will increase our ability for data tracking. The number of respondents has also increased as the universe of OTPs and staff have increased since the last renewal of the forms. Lastly, the regulatory requirements section of the form SMA-168 has been updated to reflect changes made to Final Rule 42 CFR Part 8 § 8.12(i).

16. Time Schedule, Publication and Analysis Plans

Time Schedule: The SMA-162 form 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 form 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 form 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-168 form 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 website at (https://dpt2.samhsa.gov/treatment/) a service to the public. The directory groups OTPs by state and city; and it displays the name of the program, current address, and telephone. It may be downloaded or printed from the website. SAMHSA staff can provide hard copies of the directory 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 at https://www.samhsa.gov/medication-assisted-treatment/become-accredited-opioid-treatment-program/approved-accreditation-bodies 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 Government Performance and Results Act (GPRA) measure.

Analysis Plans: Summary reports are prepared based on the information collected on the forms (SMA-162, SMA-163 and SMA-168) and entered into a database.

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 PRA Submissions.

List of Attachments

- SMA-162, "*Application for Certification to Use Opioid Medications in a Treatment Program Under 42 CFR § 8.11*"
- SMA-163, "*Application for Approval as Accreditation Body Under 42 CFR § 8.3(b)*"
- SMA-168, "*Exception Request and Record of Justification Under 42 CFR § 8.11(h), and Instructions for Form 168*"