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Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Service Administration

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[Docket No. 98N–0617]

RIN 0910–AA52

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction;

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services and the Substance Abuse and Mental Health Services Administration (SAMHSA) are issuing final regulations for the use of narcotic drugs in maintenance and detoxification treatment of opioid addiction. This final rule repeals the existing narcotic treatment regulations enforced by the Food and Drug Administration (FDA), and creates a new regulatory system based on an accreditation model. In addition, this final rule shifts administrative responsibility and oversight from FDA to SAMHSA. This rulemaking initiative follows a study by the Institute of Medicine (IOM) and reflects recommendations by the IOM and several other entities to improve opioid addiction treatment by allowing for increased medical judgment in treatment.

DATES: This final rule will become effective on March 19, 2001.

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 22, 1999, (64 FR 39810, July 22, 1999, hereinafter referred to as the July 22, 1999, notice or July 22, 1999, proposal) SAMHSA, FDA, and the Secretary, Health and Human Services (HHS), jointly published a Notice of Proposed Rulemaking (NPRM) to revise the conditions for the use of narcotic drugs in maintenance and detoxification treatment of opioid addiction. The agencies also proposed the repeal of the existing narcotic treatment regulations enforced by the FDA, the creation of a new regulatory system based on an accreditation model under new 42 CFR part 8, and a shift in administrative responsibility and oversight from FDA to SAMHSA.

The July 22, 1999, notice traced the history of Federal regulatory oversight of Opioid Treatment Programs (''OTPs,'' also known as narcotic treatment programs, or, methadone programs), focusing on Federal regulations enforced by FDA since 1972. The July 22, 1999, notice summarized the periodic reviews, studies, and reports on the Federal oversight system, culminating with the 1995 Institute of Medicine (IOM) Report entitled, *Federal Regulation of Methadone Treatment* (Ref. 1). As noted in the July 22, 1999, proposal, the IOM report recommended that the existing FDA process-oriented regulations should be reduced in scope to allow more clinical judgment in treatment and greater reliance on guidelines. The IOM report also recommended designing a single inspection format, having multiple elements, that would (1) provide for consolidated, comprehensive inspections conducted by one agency (under a delegation of Federal authority, if necessary), which serves all agencies (Federal, State, local) and (2) improve the efficiency of the provision of methadone services by reducing the number of inspections and consolidating their purposes.

To address these recommendations, SAMHSA proposed a ''certification'' system, with certification based on accreditation. Under the system, as set forth in the July 22, 1999, proposal, a practitioner who intends to dispense opioid agonist medications in the treatment of opiate addiction must first obtain from SAMHSA, a certification that the practitioner is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from a private nonprofit entity, or from a State agency, that has been approved by SAMHSA to accredit OTPs. Accreditation bodies would base accreditation decisions on a review of an application for accreditation and on surveys (on site inspections) conducted every three years by addiction treatment experts. In addition, accreditation bodies will apply specific opioid treatment accreditation elements that reflect ''state-of-the-art'' opioid treatment guidelines. Moreover, accreditation standards will require that OTPs have quality assurance systems that consider patient outcomes.

As noted in the July 22, 1999, proposal, this new system would replace the existing FDA regulatory system. The existing system provides for FDA ''approval'' of programs, with direct government inspection in accordance with more detailed process-oriented regulations. These process-oriented regulations are less flexible and prescribe many aspects of treatment. The existing regulations do not require that programs have quality assurance systems. Finally, under the existing system, programs are not subject to periodic certification and there is no set schedule for inspections.

Proposed Subpart A addressed accreditation and included steps that accreditation bodies will follow to achieve approval to accredit OTPs under the new system. It also set forth the accreditation bodies' responsibilities, including the use of accreditation elements during accreditation surveys. Proposed Subpart B established the sequence and requirements for obtaining certification. This section addressed how and when programs must apply for initial certification and renewal of their certification. Finally, Subpart C of proposed part 8 established the procedures for review of the withdrawal of approval of the accreditation body or the suspension and proposed revocation of an OTP certification.

In addition to proposing an entirely new oversight system, the July 22, 1999, proposal included several other new provisions. For example, the Federal opioid treatment standards were significantly reduced in scope to allow more flexibility and greater medical judgment in treatment. Certain restrictions on dosage forms were eliminated so that OTPs may now use solid dosage forms. Under the previous rules, OTPs were limited to the use of liquid dosage forms. Several reporting requirements and reporting forms were eliminated, including the requirements for physician notifications (FDA Reporting Form 2633) and the requirement that programs obtain FDA approval prior to dosing a patient above 100 milligrams. The proposal included a more flexible schedule for medications dispensed to patients for unsupervised use, including provisions that permit up to a 31-day supply. Under the current regulations, patients are limited to a maximum 6-day supply of medication. Many of these regulatory requirements had been in place essentially unchanged for almost 30 years.

SAMHSA distributed the July 22, 1999, notice to each OTP listed in the current FDA inventory, each State Methadone Authority, and to other interested parties. Interested parties were given 120 days, until November 19, 1999, to comment on the July 22,

1999, proposal. In addition, on November 1, 1999, SAMHSA, FDA, the Office of National Drug Control Policy (ONDCP), the Drug Enforcement Administration (DEA), and other Federal agencies convened a Public Hearing on the proposal. The Public Hearing was announced in the **Federal Register** published October 19, 1999, (64 FR 59624, October 19, 1999), and was held in Rockville, MD. On January 31 and May 10, 2000, the SAMHSA/CSAT National Advisory Council Subcommittee on Accreditation met to assist SAMHSA/CSAT in its review of data and information from SAMHSA/CSAT's ongoing accreditation project. The SAMHSA/CSAT National Advisory Council convened to discuss the opioid accreditation project on May 12, 2000. The May 12, 2000, Council meeting provided an opportunity for comments from the public (65 FR 25352, May 1, 2000).

II. Comments and Agency Response

In response to the July 22, 1999, proposal, SAMHSA received almost 200 submissions, each containing one or more comments. The comments were from government, industry, industry trade associations, academia, health professionals, professional organizations, patient advocacy organizations, and individual patients.

A. General Comments

1. Many comments agreed in principle that the shift to an accreditation-based system will encourage OTPs to use individualized, clinically determined treatment plans that are guided by current, best-practice medical and clinical guidelines and to evaluate clinical outcomes. Other comments noted that the accreditation proposal recognizes that opiate addiction is a medical condition. Several comments affirmed that a major segment of the healthcare system in the United States is being reviewed through accreditation systems. As such, these comments stated that applying accreditation requirements to OTPs provides the potential for mainstream medicine to embrace opioid treatment.

While not opposing the proposal, some comments stated there should be no Federal regulations in this area. Other comments expressed concerns about additional costs to OTPs and, ultimately patients, for accreditation and duplicative assessments, noting that some States will continue to enforce process-oriented regulations, supported by considerable licensing fees. Based upon these ''uncertainties,'' these comments suggest that SAMHSA wait for the results of further study before implementing new regulations.

The Secretary agrees that the SAMHSA-administered accreditation-based regulatory system will encourage the use of best-practice clinical guidelines and require quality improvement standards with outcome assessments. As set forth below, the Secretary does not agree that comments on the uncertainty about accreditation costs or State regulatory activities warrant additional study before implementing these new rules.

2. Several comments addressed the costs associated with accreditation and challenged the estimates provided in the July 22, 1999, proposed rule. One comment included the results from a survey of OTPs with accreditation experience to indicate the indirect costs of accreditation will be considerable. According to the comment, these OTPs have had to spend considerable sums to hire consultants and additional staff, upgrade computers, develop infection control manuals, and make physical plant improvements. In some cases these costs were reported to approach $50,000. Some of these comments suggested that SAMHSA await the completion of the ''accreditation impact study'' to obtain additional information on costs, before proceeding. Other comments stated that accreditation can lead to increased treatment capacity, but only if additional funds are provided. One comment suggested that SAMHSA create a capital improvement fund, while another suggested that SAMHSA allow block grant funds to be used to pay for accreditation.

The Secretary believes that the estimated costs as set forth in the July 22, 1999, notice remain reasonably accurate. As discussed in greater detail below, information on accreditation developed under the accreditation impact study, together with other ongoing SAMHSA technical assistance programs, indicates that the accreditation system will not produce an excessive burden to programs to warrant delaying the implementation of this final rule.

There are many components to SAMHSA's accreditation project that have been proceeding concurrently with this rulemaking. In April 1999, SAMSHA's Center for Substance Abuse Treatment (CSAT) issued ''Guidelines for the Accreditation of Opioid Treatment Programs.'' These guidelines are up-to-date best-practice guidelines that are based upon the Federal opioid treatment standards set forth under proposed section 8.12 as well as SAMHSA/CSAT's Treatment Improvement Protocols (TIPs) that address opiate addiction treatment. Two accreditation bodies, the Commission for the Accreditation of Rehabilitation Facilities (CARF) and the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), under contract to SAMHSA/CSAT, used these guidelines to develop ''state-of-the-art'' accreditation elements. These two accreditation bodies have surveyed dozens of programs with these new accreditation standards.

The July 22, 1999, proposal described an ongoing accreditation impact study. Under the accreditation impact study, CARF and JCAHO trained over 170 participating OTPs. In addition, more than 50 OTPs have been accredited under this system with technical assistance provided through a contract funded by SAMHSA/CSAT. None of the accredited programs have had to incur the kind of ''physical plant'' and other costly expenses predicted by some of the comments previously discussed. This direct and up-to-date information indicates that the cost estimates in the July 22, 1999, notice are up-to-date and reasonable. On the other hand, the survey discussed above that was submitted with one comment reflected accreditation surveys performed over 10 years ago. And, in some cases, the accreditation experiences discussed in these comments reflect accreditation of psychiatric hospitals, not OTPs.

The accreditation-based system which is the subject of this rule includes safeguards to reduce the risk of unnecessary and overly burdensome accreditation activities relating to OTPs. For example, SAMHSA will approve each accreditation body after reviewing its accreditation elements, accreditation procedures, and other pertinent information. SAMHSA will convene periodically an accreditation subcommittee, as part of the SAMHSA/CSAT National Advisory Council. The subcommittee will review accreditation activities and accreditation outcomes and make recommendations to the full SAMHSA/CSAT Council, and ultimately to SAMHSA on accreditation activities and guidelines. Finally, SAMHSA/CSAT has been providing technical assistance to OTPs in the accreditation impact study that has helped programs in achieving accreditation. SAMHSA/CSAT intends to continue providing technical assistance on accreditation during the 3–5 year transition period and possibly longer.

The Secretary does not agree that it is necessary to establish a special fund to help programs pay for accreditation fees and indirect ''physical plant'' improvements in order for OTPs to be

able to achieve accreditation. As noted above, the Secretary believes that the estimates in the July 22, 1999, proposal for the cost of accreditation are reasonably accurate (approximately $4–5 million per year, $5400 per OTP per year, $39 per patient per year). Nonetheless, the Secretary has taken steps to minimize the potential effects of this burden to OTPs, especially to OTPs that are small businesses or that operate in under-served communities. First, the Secretary has determined that States could use funds provided by SAMHSA under their Substance Abuse Prevention and Treatment (SAPT) Block Grants to offset costs of accreditation for programs qualified to receive assistance under the State's SAPT block grant. Second, SAMSHA has included in its budget, a plan to continue funding accreditation. Finally, SAMHSA will continue to provide technical assistance which will aid those programs that need help in achieving accreditation.

3. One OTP that is participating in the accreditation impact study, while commending the accreditation experience and accreditation in general, commented that the proposed change is premature. Some comments suggested that SAMHSA postpone implementation for an indefinite period to allow for an unspecified number of CARF and JCAHO accreditation results. Another comment stated that the first series of surveys will determine the utility of the first generation of standards, noting that the process can be focused and modified in response to results from the impact study. A few comments questioned whether all providers can make the transition.

On the other hand, many comments stated that the field has been subject to regulatory neglect long enough, and that SAMHSA should minimize the delay in finalizing rules. One comment submitted the results of a survey that suggested that as many as 155 OTPs currently need technical assistance in order to provide treatment in accordance with standards and regulations.

The Secretary does not believe that these final regulations should be delayed until the completion of the accreditation impact study. As stated in the July 22, 1999, proposal, the Department of Health and Human Services (HHS) has determined that accreditation is a valid and reliable system for providing external monitoring of the quality of health care—including substance abuse and methadone treatment. The SAMHSA/CSAT study is designed to provide additional information on the processes, barriers, administrative outcomes, and costs associated with an accreditation-based system. In addition, the study is expected to provide important information to allow SAMHSA to keep its guidelines, and its accreditation program, as responsive and up-to-date as possible. Among other things, the study will allow HHS to continuously monitor the monetary costs of accreditation, to ensure that successful OTPs are not precluded from operating by the costs of accreditation, and that patients are not denied treatment based on costs. The full study, which compares a representative sample of OTPs 6 months following accreditation to their baseline status across several variables, will require a few years to complete. Regulations can be modified at any time. If SAMHSA believes that the results of the study merit changes in the regulations, then such changes will be the subject of a future rulemaking.

The Secretary has reviewed preliminary results from the accreditation study by two accreditation bodies, CARF and JCAHO, of almost 10 percent (approximately 80 OTPs) of the entire inventory of approved outpatient OTPs. Well over 90 percent of the OTPs surveyed achieved accreditation under the ''methadone specific'' accreditation standards. Only a very few programs required a follow-up survey to achieve accreditation. And, to date, only one OTP failed to achieve accreditation. These accreditation outcome results are comparable to the historical compliance rate under the previous FDA process-oriented regulatory system. In addition, these rates correspond to the assumed accreditation resurvey rate stated in the July 22, 1999, proposal for estimating the indirect costs of accreditation.

These accreditation outcome results have been analyzed and presented to SAMHSA/CSAT's National Advisory Council's Accreditation Subcommittee (NACAS). As discussed in the July 22, 1999, proposal, SAMHSA/CSAT augmented NACAS with consultants representing OTPs (both large and small programs), medical and other substance abuse professionals, patients, and State officials. The subcommittee has met twice, on January 31 and May 10, 2000, and the public was provided an opportunity to participate in this advisory process. On May 12, 2000, the SAMHSA/CSAT National Advisory Council urged SAMHSA/CSAT to move expeditiously to finalize the July 22, 1999, proposal.

The Secretary believes that the interim results from the accreditation impact study confirm that the accreditation guidelines, along with the accreditation process itself, are a valid and reliable method for monitoring the quality of care provided by OTPs. The results indicate that most OTPs can achieve accreditation and that treatment capacity has not declined as a result. While SAMHSA intends to continue the study to fulfill its objectives, the Secretary does not believe that it is appropriate or necessary to delay implementation of these new rules until the full study is complete.

4. Many comments, especially from current and past OTP patients, questioned the impact of revised Federal regulations in light of State regulations. These comments contend that State regulations are much more restrictive on medical and clinical practices than Federal regulations, and that State regulatory authorities have expressed little or no interest in changing their regulations or the way State regulations are enforced. Comments from OTP sponsors stated that accreditation costs would add to State licensing fees, which, in some States, exceed several thousand dollars annually.

The Secretary shares the concerns expressed in these comments about State regulations and licensing requirements. Indeed, the July 22, 1999, proposal discussed State licensure and regulatory issues. The proposal also noted that there was considerable variation in the nature and extent of oversight at the State level. Some States have regulations and enforcement programs that exceed Federal regulations. Others have relied exclusively upon FDA and DEA regulatory oversight. An increasing number of States rely on accreditation, by nationally recognized accreditation bodies, for all or part of their healthcare licensing functions.

The Secretary believes that SAMHSA's ongoing coordination activities with States will minimize the impact of Federal-State regulatory disparities upon OTPs. One objective of these activities is to increase State authorities' acceptance of the new accreditation-based system. First, SAMHSA/CSAT's OTP accreditation guidelines were developed by a consensus process that included representation from State Methadone Authorities. In addition, some State officials have accompanied CARF and JCAHO accreditation survey teams to observe site visits. Finally, SAMHSA/CSAT has distributed information on accreditation to each State. This information includes the SAMHSA/CSAT OTP accreditation guidelines, the CARF OTP accreditation standards and the JCAHO OTP accreditation standards. SAMHSA/CSAT convened three national meetings of State officials

between 1997 and 2000 and intends to continue coordinating activities with State authorities and national organizations such as the National Association of State Alcohol and Drug Abuse Directors (NASADAD).

This final rule includes provisions that would permit any State to apply for approval as an accreditation body and, if approved, accredit OTPs under the new Federal opioid treatment standards. Based on the above, the Secretary expects that many states will consider OTP accreditation and Federal certification requirements as sufficient to fulfill all or a substantial part of their licensing requirements. Taken together, the Secretary believes that these measures will minimize significantly the existing disparity between Federal and State regulation of OTPs.

5. Office-Based Treatment. The July 22, 1999, proposal discussed the concept of ''office-based opioid treatment'' and specifically solicited comments on how the Federal opioid treatment standards might be modified to accommodate office-based treatment and on whether a separate set of Federal opioid treatment standards should be included in this rule for office-based treatment.

The Secretary received many diverse comments on the office-based treatment issue. Several comments from patients and individual physicians believed that office-based treatment provided an excellent opportunity to expand opioid agonist treatment. These comments reference opioid treatment delivery systems in other countries and suggest that the U.S. should adopt similar systems. A few comments recommended that community pharmacies be encouraged to dispense methadone and LAAM as ''medication units'' as a way to make treatment more convenient for patients.

While many comments suggested separate standards for office-based treatment, others feared that different standards would result in a two-tiered system of treatment. Overall many comments stated that existing and proposed rules do not facilitate the development of the office-based practice model. As such, accreditation and certification would be prohibitively expensive for individual physicians.

On the other hand, many comments expressed concerns with the concept of ''office-based'' treatment and prescribing methadone and LAAM. Many of these comments reflected concern about the lack of trained and experienced practitioners. One comment referenced literature reports that described experiences in Australia and the United Kingdom with deaths from iatrogenic methadone toxicity associated with patients early in treatment. The experiences in these two countries were associated with an accelerated rate of patient admissions and the involvement of new, inexperienced practitioners. One comment cited research on methadone medical maintenance that indicated that approximately 15 percent of the patients treated in physicians offices were referred back to OTPs after ''relapsing'' to illicit opiate use.

Generally, most comments on this issue stated that there was not enough information on office-based practice. These comments suggest that based on the available information, office-based treatment warrants a gradual, step-wise approach, along with more use of medication units. This approach would serve to ''diffuse opioid agonist maintenance treatment into traditional settings.''

After carefully considering the diverse comments, as well as other legal and regulatory factors, the Secretary is not including in this rule specific standards that would permit physicians to prescribe methadone and LAAM in office-based settings without an affiliation with an OTP. Instead, until additional information is generated, the Secretary is announcing administrative measures to facilitate the treatment of patients under a ''medical maintenance'' model.

Current regulations enforced by DEA do not permit registrants to prescribe narcotic drugs, including opioid agonist medications such as methadone and LAAM for the treatment of narcotic addiction (see 21 CFR 1306.07(a)). In addition, the Secretary agrees that, at the present time, there should be some linkage between OTPs and physicians who treat stable patients with methadone and LAAM in their offices to address patients' psychosocial needs in the event of relapse. The Secretary agrees with the comments about the lack of trained and experienced practitioners to diagnose, admit, and treat opiate addicts who are not sufficiently stabilized, without the support of an OTP.

The Secretary has taken steps to facilitate ''medical maintenance,'' that will result in more patients receiving treatment with methadone and LAAM in an office-based setting. Medical maintenance refers to the treatment of stabilized patients with increased amounts of take-home medication for unsupervised use and fewer clinic visits for counseling or other services. First, the ''take home'' provisions in these rules have been revised from the previous regulations under 21 CFR § 291.505 to permit stabilized patients up to a one-month supply of treatment medication. In addition, SAMHSA/CSAT has developed treatment guidelines and training curricula for practitioners to increase the information and education for practitioners in this area. Finally, SAMHSA/CSAT has issued announcements to the field explaining how patients and treatment programs can obtain authorizations for medical maintenance. These authorizations were developed to address program-wide exemptions under 21 CFR 291.505; however, SAMHSA/CSAT envisions a similar approach will be used under the program-wide exemption provisions of 42 CFR 8.11(h).

Under the medical maintenance model, office-based physicians maintain formal arrangements with established OTPs. Typically, patients who have been determined by a physician to be stabilized in treatment may be referred to office-based physicians. It has been estimated that over 12,000 current patients would be eligible for medical maintenance treatment. The Secretary believes that this is a reasonable approach that will expand treatment capacity gradually while additional information and experience is developed to evaluate and refine office-based treatment models.

B. Comments on Subpart A—Definitions and Accreditation

Proposed subpart A sets forth definitions as well as procedures, criteria, responsibilities and requirements relating to accreditation.

1. A comment from a State authority suggested that the treatment plan definition under § 8.2 should be modified to require a reference to the services determined necessary to meet the goals identified in the plan. The Secretary agrees with this suggestion and has revised the treatment plan definition accordingly.

2. One comment suggested that the proposed definition of detoxification treatment specifies agonist and therefore precludes the use of mixed agonist or agonists in combination with other drugs. The Secretary has announced plans to develop new rules specifically for partial agonist medications for the treatment of opiate addiction (See 65 FR 25894, May 4, 2000). Therefore, use of the term ''agonist'' is appropriate in this context.

The use of ''other drugs'' (interpreted to mean non-narcotic substances) in combination with methadone and LAAM are not subject to the regulatory requirements of this rule.

3. Several comments were submitted on the proposed definition of opiate addiction. Some comments suggested that the definition should be revised to remove behavior-oriented concepts and rely on medical constructs only. One comment suggested substituting the definition of opiate addiction contained in the recent NIH consensus panel report. The Secretary concurs, and has revised the definition of opiate addiction to be more consistent with the recent NIH Consensus panel's recommendations.

4. A few comments were concerned that there would be only two accreditation bodies, CARF and JCAHO. In addition, these comments reflect concern that accreditation would be an additional requirement on top of existing FDA regulations.

As proposed in the July 22, 1999, notice (section 8.3(a)) any private nonprofit organization, State governmental entity, or political subdivision thereof, capable of meeting the requirements of subpart A is eligible to apply to become an accreditation body under the new rules. As discussed elsewhere in this final rule, some State authorities have contacted SAMHSA and expressed interest in becoming an accreditation body under subpart A. In addition, a number of non-governmental entities have expressed similar interest. Accordingly, the Secretary believes that there will be more than two accreditation bodies that seek and obtain approval to become an accreditation body under these rules.

The requirements for accreditation and SAMSHA certification under this final rule will replace the requirements for FDA approval of OTPs under previous regulations. The previous regulations in place under 21 CFR 291.505 will be rescinded on March 19, 2001.

5. The Secretary received a considerable number of diverse comments from State authorities, OTPs, and patients on the provision proposed under section 8.3(a) that would permit States to serve as accreditation bodies under the new rules. The preamble to the July 22, 1999, notice emphasized the need for States to consider serving as accreditation bodies. This emphasis was based upon the recommendation in the IOM Report that strongly suggested that the Federal Government design a consolidated inspection system that reduces the burden on OTPs from multiple (Federal, State, local) inspections.

State authorities provided a mixed response in their comments on this issue. As discussed below, several States expressed an interest in becoming accrediting bodies under the new rules but believed that they were ineligible because they could not accredit 50 OTPs a year under proposed section 8.3. On the other hand, many States indicated that they were not interested in becoming accreditation bodies, while several indicated that they were undecided and would await additional information.

Comments from OTPs, for the most part, reflect a longstanding cooperative relationship with State regulatory authorities. OTPs, in general, did not appear to oppose the concept of State authorities serving as accreditation bodies under the proposed new system. Indeed, some OTPs, located within States that assess extensive licensing fees, commented that it would be imperative that States take on the role of accreditation bodies under the new system in order to eliminate the financial impact of licensing and accreditation fees.

Comments from patients on this issue suggested caution. Many patients sensed that State regulators would retain strict, ''process-oriented'' regulations or philosophies. These comments urged that if SAMHSA permitted States to serve as accreditation bodies then the agency should carefully monitor accreditation standards and practices to assure that they conform with the Federal opioid treatment standards.

After considering the comments on this issue, the Secretary is retaining the provision that allows States to serve as accreditation bodies under the new rules. The Secretary acknowledges that many States will choose not to participate as accreditation bodies. Some of these States already accept accreditation by recognized accreditation bodies for licensing purposes. It is expected that more States, especially States with relatively few OTPs, will also choose to accept accreditation as meeting State licensure requirements in time. Indeed, legislation enacted recently in New Hampshire to allow methadone maintenance treatment incorporated a requirement for CARF accreditation (Ref. 2). Finally, some States will apply accreditation reviews and findings to complement their licensing activities. The Secretary recognizes that the States' role in adapting to the new system will change over time as additional information on accreditation is developed.

The Secretary believes that there are adequate safeguards to address patient concerns about overly restrictive State regulations and oversight. Under section 8.3(b)(3), SAMHSA will review each applicant accreditation body's proposed accreditation standards. As part of this review, SAMHSA will determine the extent to which the accreditation standards are consistent with the Federal opioid treatment standards. In addition, under section 8.5, SAMHSA will evaluate periodically the performance of accreditation bodies by inspecting a selected sample of the OTPs accredited by the accreditation body. As part of this effort SAMHSA may also consider follow-up inspections in cases where accreditation activities identify public health, public safety, and patient care issues.

The Secretary continues to believe, as outlined in the July 22 proposal, that there are benefits to States serving as accreditation bodies under this rule. This feature provides the potential to reduce the overall number of OTP inspections. It also permits the use and application of the vast expertise available within many State oversight agencies.

6. A number of State authorities and an accreditation body questioned the restriction under proposed section 8.3(b)(3) that would require accreditation bodies to be able to survey no less than 50 OTPs annually. Some comments contend that this would unfairly and inappropriately exclude smaller States or States with fewer OTPs from participating. These comments suggested that other requirements should be considered and applied or a waiver provision added. One accreditation body commented that accreditation bodies recognized by the Health Care Financing Administration are not subject to such arbitrary limitations. Other comments suggested that the 50 survey per year minimum was not necessary to achieve its stated purpose—to ensure the quality of accreditation services and minimize the variability of accreditation standards.

The Secretary concurs with these comments. The provisions of section 8.3(b)(3) (submission and review of proposed accreditation standards) and section 8.5 (periodic evaluation of accreditation bodies) are adequate to enable SAMHSA to ensure the quality of accreditation services and minimize the potential variability in accreditation standards. Accordingly, section 8.3(b) has been modified to remove this requirement.

7. A few comments suggested that State authorities and patient advocates should be permitted to participate in the approval of accreditation bodies under the new rules and in the accreditation process in general. These comments believe that they can make substantial contributions to the process.

The Secretary agrees that patients and State authorities can contribute

substantially to the successful operation of the new system. State authorities and patients have participated in the committees that have developed SAMHSA/CSAT's Accreditation Guidelines. In addition, representatives from both these groups have served on the Accreditation Subcommittee of the SAMHSA/CSAT National Advisory Council. Accreditation standards include several provisions designed to solicit and consider individual patient views regarding treatment planning and other areas. Some, though not all, accreditation bodies also have patient hotlines that allow patients to convey concerns directly to accreditation bodies. Finally, SAMHSA and State authorities will continue to consult and interact under the new rules. The Secretary believes that these measures are adequate to assure the appropriate level of State authority and patient input into the accreditation process.

8. Several comments addressed proposed section 8.3(b)(6), pertaining to the qualifications of accreditation body personnel and proposed section 8.4(h) on accreditation teams. One State authority objected that the requirement that there be a licensed physician on the accreditation body staff was an unnecessary expense to accreditation bodies. Another comment recommended that accreditation teams should include a physician certified for dispensing opioids. Some patients advocated that the accreditation team should include a current patient.

The Secretary believes the requirements for accreditation personnel and accreditation teams as set forth in the July 22, 1999, proposal are sufficient. It is not clear that every OTP would benefit from having a physician or opioid agonist patient on the accreditation team. The Secretary has reviewed the results of accreditation surveys under the SAMHSA/CSAT methadone accreditation project. Based on these reviews, the requirements set forth under section 8.4(h) are adequate to assure that accreditation bodies carefully consider the qualifications of accreditation surveyors and accreditation teams.

9. A considerable number of comments were submitted, mostly by State authorities, concerning the absence of a definition for State authority. These comments suggested that adding a definition for state authority could reduce confusion in States that serve as accreditation bodies. In addition, these comments reflect a belief that this change would help clarify the Federal-State consultation process set forth in the proposed rule. The Secretary agrees with these comments and has added a definition of State Authority. This definition tracks closely with the definition contained in the previous regulations under section 21 CFR 291.505.

C. Subpart B—Certification

Subpart B establishes the criteria and procedures for the certification of OTPs. This section also addresses the conditions for certification and the interaction between the Federal Government and State authorities under the new rules.

1. Many comments from State regulators noted that there was no reference to a requirement that OTPs obtain a license or permit from States before receiving certification from the Federal Government. These comments reflect a concern that SAMHSA may certify a program in a State where no methadone authority exists, or without the knowledge of the State authority. Other comments urged Federal certification to pre-empt State licensing, noting that ''initial State approval will remain a de facto requirement.''

The Secretary believes that the conditions for certification as set forth in the July 22, 1999, proposal, including the provisions relating to State licensure, are adequate and appropriate to fulfill the objectives of this rule. The Secretary's role in the oversight of narcotic treatment is to set standards for the appropriate use of narcotic drugs in the treatment of addiction, and then to ensure compliance with those standards. The States, on the other hand, have a broader set of responsibilities, including regional and local considerations such as the number and distribution of treatment facilities, the structural safety of each facility, and issues relating to the types of treatment services that should be available. Nothing in this part is intended to restrict State governments from regulating the use of opioid drugs in the treatment of opioid addiction. The Secretary notes that many States exercise this authority by choosing not to authorize methadone treatment at all.

The Secretary does not believe that OTPs will open and begin treating patients without State notification, review, and approval. The Secretary has been careful to state throughout this rule that OTPs (including medication units) must comply with all pertinent State and local laws as a condition of Federal certification. As such, OTPs will also be responsible for assuring that they have the necessary approvals and licensure at the State. Moreover, OTPs must obtain DEA registration prior to accepting opioid addiction treatment drugs for the treatment of opiate addiction. DEA registration is explicitly contingent upon State authority approval. Importantly, as noted below, there will be extensive consultation, coordination, and cooperation between SAMHSA and relevant State authorities.

2. One State regulator requested that the regulation be modified at section 8.11(c)(1) to add a requirement that SAMSHA notify the State upon receipt of applications for certification as well as approval and withdrawal. This comment was based upon a concern that provisionally certified programs could operate without a State's knowledge.

The Secretary agrees that it is imperative for States to be notified of significant certification activities, including new program applications, program suspensions and withdrawals. SAMHSA intends to notify States of all such developments under the provisions of section 8.11(c)(1). The Secretary believes that the rules are sufficiently clear on this point.

3. Some State authorities suggested revising proposed section 8.11(h), which states that SAMHSA ''may'' consult with State authorities prior to granting exemptions from a requirement under sections 8.11 or 8.12.

Section 8.11(h) permits OTPs to request exemptions from the requirements set forth under the regulation. This represents a continuation of a long-standing provision from the previous regulation under 21 CFR 291.505. The Secretary anticipates that most exemption requests under the new rule will be to permit variations from the treatment standards, including program-wide exemptions for medical maintenance. The Secretary agrees that it is appropriate and necessary to consult with State authorities on requests for variations from existing standards. Accordingly, section 8.11(h) is revised to require consultation with the State authority prior to granting an exemption.

4. Several comments from patients suggested that Federal regulations should prevent States from imposing additional regulatory requirements beyond the Federal regulations. Many of these comments contend that State regulations prevent treatment expansion, hinder accountability for quality treatment, limit patient access, and lead to patient abuses.

As noted above, the Secretary acknowledges the authority within State government to regulate the practice of medicine. This rule does not pre-empt States from enacting regulations necessary to carry out these important responsibilities.

Many State regulations closely resemble the previous Federal regulations under 21 CFR 291.505. In addition, many States are currently reevaluating their regulations to determine if modifications are necessary to reflect the changes in Federal rules. The Secretary encourages States to consider the new information on changes in the opioid addiction treatment field, including phases of treatment, measuring accountability for improving the quality of patient care, and modern medication dosing practices, as States proceed in revising their regulations.

The Secretary also invites States to continue to enhance their partnership with Federal authorities in this area. As noted above, the final rule includes a new feature—the opportunity for States to serve as accreditation bodies. This new activity adds to existing partnership opportunities, such as the participation in the SAPT Block Grant program and its related technical assistance program. The Secretary hopes that these actions collectively will continue the regulatory reform started with the July 22, 1999, proposal.

5. A few comments expressed concern about proposed section 8.11(e), which permits provisional certification for one year, while a program obtains accreditation. These comments believe that one year was ''too long for a program to go without accreditation.''

The Secretary believes that the maximum 1-year term (not including the 90-day extension allowed under section 8.11(e)(2)) for provisional certification is reasonable and customary with accreditation in other areas of healthcare. The purpose of this provision is to permit new OTPs to initiate operations and generate patient records to aid in the accreditation application, survey, and review process. It should be noted that OTPs will be subject to SAMHSA, DEA, and State oversight during the tenure of provisional accreditation. These OTPs must comply with Federal opioid treatment regulations and are subject to compliance actions at any time.

6. Section 8.11(i)(2) proposed that certification as an OTP would not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than addiction. One comment noted that, as written, patients admitted to hospitals for cocaine or alcohol addiction would not be eligible for treatment under this provision. The comment suggested that adding the word ''opioid'' before ''addiction'' would help to clarify this issue. The Secretary concurs and the section 8.11(i)(2) has been changed to reflect this change.

D. Subpart B—Treatment Standards

1. A number of comments were submitted on proposed section 8.12 in general. These comments stated that the Federal Opioid Treatment standards are vague and lack specificity. As such, these comments contend that the standards are unenforceable as regulations. One comment suggested that the SAMHSA/CSAT Accreditation Guidelines be incorporated as regulations.

The Secretary believes that the Federal Opioid Treatment Standards are enforceable, and do not need to be modified to accomplish their purpose under the new rules. The July 22, 1999, proposal noted that in the past, HHS has attempted to write all facets of treatment, including required services, into regulation. In addition, the proposal acknowledged that it is now accepted that (a) different patients, at different times, may need vastly different services, and (b) the state of the clinical art has changed, to reflect scientific developments and clinical experience, and is likely to continue to change and evolve as our understanding of more effective treatment methods increases. Accordingly, the Secretary proposed a more flexible approach with a greater emphasis on performance and outcome measurement. With guidance from SAMHSA, the accreditation bodies will develop the elements needed to determine whether a given OTP is meeting patient needs for required services. SAMHSA will review these elements as part of the accreditation body's initial and renewal applications to ensure that accreditation bodies have incorporated the Federal opioid treatment standards into their accreditation elements. SAMHSA will also review accreditation body elements to ensure that the elements do not exceed Federal expectations in terms of opioid agonist treatment. Incorporating accreditation guidelines into regulations would subvert this approach.

As noted in the July 22, 1999, proposal, the Secretary believes that the standards are ''enforceable regulatory requirements that treatment programs must follow as a condition of certification (64 FR 39810, July 22, 1999).'' While the new regulations increase the flexibility and clinical judgement in the way OTPs meet the regulatory requirements, they are set forth under section 8.12 as the services, assessments, procedures, etc., that OTPs ''must'' and ''shall'' provide. As such, the new standards are as enforceable as the previous regulations under 21 CFR 291.505. OTPs that do not substantially conform with the Federal Opioid Treatment standards set forth under section 8.12 will risk losing SAMHSA certification.

2. One comment recommended that proposed section 8.12(b) should be modified to require a standard that OTPs should have adequate facilities. The comment stated that this provision existed in the previous regulation. The Secretary agrees and has added a requirement that OTP's must maintain adequate facilities. The Secretary notes, however, that SAMHSA/CSAT accreditation guidelines and accreditation standards used in the SAMHSA accreditation impact study, address the adequacy of the OTP's facility. These accreditation standards, in conjunction with treatment outcomes, will help determine whether facilities are adequate under the new rules.

3. One comment addressed proposed section 8.12(b), stating that rules should expressly require compliance with civil rights laws, not just ''pertinent'' Federal laws. As such, the comment suggests that the standards should require detailed patient grievance procedures, including appeals to neutral parties. The Secretary believes that it is not necessary to modify the rule to reflect civil rights laws specifically. These laws are included under the requirement as written. In addition, SAMHSA/CSAT Accreditation Guidelines, as well as the accreditation standards developed from them include provisions for accepting and acting upon patient grievances.

4. A number of respondents commented on proposed section 8.12(d) which addresses OTP staff credentials. Under the July 22, 1999, proposal, the Secretary proposed that each person engaged in the treatment of opiate addiction must have sufficient education, training, or experience or any combination thereof, to enable that person to perform the assigned functions. Further, all licensed professional care providers must comply with the credentialing requirements of their professions. The proposal encouraged, but did not require, that treatment programs retain credentialed staff.

Some comments requested that this standard be clarified to require American Society of Addiction Medicine (ASAM)-certified medical professionals. Another comment questioned whether personnel had to be licensed in the State where the treatment program is located. Another comment from a State Authority, recommended that the regulations

specify the license, training, experience, as well as the number of licensed counselors in a program, including a minimum counselor-to-patient ratio. On the other hand, an OTP medical director commented that none of the cited credentials ''conferred competence in dealing with opioid dependent patients, per se.'' According to this comment, SAMHSA/CSAT should instead develop curricula for medical directors and other care givers.

Except for the requirements of section 8.12(h), which relate to the qualifications for practitioners who administer or order medications, the Secretary does not believe that it is appropriate to further prescribe the qualifications for health professionals in this regulation. Under sections 8.12(b), (d), (e), (f) services must be provided by professionals qualified by education and training. The Secretary does not believe that one credentialing organization should be specified as a requirement for qualifications. Instead, the Secretary intends to rely on guidelines and accreditation standards together with patient outcome assessments to determine the adequacy of training and education level of professionals in OTPs. SAMHSA/CSAT is actively developing model training curricula in this area.

5. A few comments suggested that the regulations specify the outcome measures for quality assessment plans under section 8.12(c)(1). Similarly, some comments suggested that diversion control plans, which OTPs are required to develop under section 8.12(c)(2), should also be spelled out in regulations.

The Secretary believes that the regulation as proposed provides sufficient detail on outcome measures and diversion control plans. In keeping with the intent of the regulation reform, these general requirements are elaborated in best-practice guidelines and in ''state-of-the-art'' accreditation standards. Indeed, following a review of the accreditation standards that are based upon SAMHSA/CSAT's opioid treatment accreditation guidelines, the Secretary has determined that they are adequate to ensure that OTPs will be able to develop meaningful outcome assessment and diversion control plans. In addition, these SAMHSA/CSAT accreditation guidelines and accreditation standards reflect the latest research findings in this area. Unlike the Federal regulations, these guidelines and standards will be updated periodically to reflect new research and clinical experience.

6. The Secretary received a considerable number of comments on the proposed definition and the standards for short-and long-term detoxification treatment. Most of these comments suggested that the word ''detoxification'' is a pejorative non-medical term and does not constitute treatment, because few, if any, patients can be stabilized in such a short period of time. These comments suggested that all references to detoxification should be deleted from the regulations, or at least renamed.

These comments fail to recognize the distinction between opiate dependence, for which detoxification treatment is appropriate, and opiate addiction, for which maintenance treatment is appropriate. The Narcotic Addiction Treatment Act of 1974 (NATA) and regulations have long recognized these distinctions. While a majority of the available treatment research, including recent studies, concludes that maintenance treatment is much more effective than detoxification regimens, the Secretary believes that it is still necessary to retain distinct standards for maintenance and detoxification treatment (Ref. 3).

7. Several comments were submitted in response to the Secretary's specific request for comments on proposed section 8.12(e)(4) which set forth minimum requirements for detoxification treatment. The July 22, 1999, proposal retained the requirement from the existing regulation that ''a patient is required to wait no less than 7 days between concluding one detoxification episode before beginning another.'' Essentially, while sympathetic to the need for limits on detoxification treatment, all the comments on this item opposed continuing any waiting period between detoxification episodes. These respondents believe that seven days is ''artificial * * * or more time than is needed.'' In addition, these comments indicate that OTPs often request and are granted exemptions from the waiting period requirement under the existing regulation, creating an unnecessary paperwork burden for OTPs, as well as State and Federal regulators. Instead, the comments suggested a limit on the number of unsuccessful detoxification episodes in one year before the patient is assessed for opioid agonist maintenance or other treatment. In addition, these comments recommended that an unsuccessful detoxification attempt be defined to include any relapse to abuse.

The Secretary agrees with the recommendations that the intent of the restrictions on detoxification can be accomplished without a mandated time interval between detoxification admissions. The standards for detoxification treatment set forth under section 8.12(e)(2) and (4) have been revised to state that patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. This change is consistent with SAMHSA/CSAT accreditation guidelines which also elaborate on unsuccessful detoxification treatment attempts.

8. A considerable number of diverse comments addressed proposed section 8.12(f) relating to required services. This section of the July 22, 1999, proposal requires that ''adequate medical, counseling, vocational, educational and assessment services are fully and reasonably available to patients enrolled in an OTP.''

Two comments strongly recommended that the regulation require integrated, simultaneous treatment by specially cross-trained staff, for co-occurring opioid treatment and mental illness. These respondents believe that integrated services for persons with an addiction(s) and a psychiatric disorder are crucial. These dually-diagnosed patients represent 50–80 percent of substance dependent populations.

The Secretary agrees with the importance of providing adequate integrated services for opiate-addicted patients who also suffer from psychiatric disorders. Indeed, the SAMHSA/CSAT Accreditation Guidelines, along with the accreditation standards developed by CARF and JCAHO all address the need to evaluate patients for co-occurring illnesses, including mental illness. CARF Opioid Treatment Program Accreditation Standards state that services for co-occurring illness should be provided on site or by referral. However, the same standards note that ''coexisting conditions, especially in persons from disenfranchised populations, are most effectively treated at a single site.'' The Secretary takes note that these provisions for co-occurring disorders under these new rules will be a vast improvement over the previous regulatory system, which did not address co-occurring opiate addiction and psychiatric disorders at all. As such, under the new rules, patients' access to effective treatment for co-occurring disorders will be enhanced substantially. However, the Secretary believes that it would be prohibitively expensive to require every OTP to hire and retain specialists in the treatment of co-occurring disorders.

Other comments on this section stated that the regulations should specify a schedule for services. Some comments

recommended that the regulations require OTPs to document that patients actually receive services when they are referred to off-site providers. Other comments suggested that accreditation bodies should monitor the extent to which services are provided as part of their periodic onsite surveys. Still other comments, mostly from patients, suggested the requirement for services be eliminated, maintaining that medication is all they needed.

The Secretary believes that the requirements for services as stated in the July 22, 1999, proposal, together with the accreditation process, provide adequate assurance that patients enrolled in OTPs receive the services that they have been assessed to need. The July 22, 1999, proposal emphasized the need for these services as an essential part of treatment. However, in shifting to an accreditation approach with an emphasis on performance outcomes, the Secretary was no longer attempting to ''write all facets of these required services into regulation.'' OTPs must initially and periodically assess each patient and ensure that adequate services are available to patients determined to need them. SAMHSA/CSAT Accreditation Guidelines and accreditation standards will elaborate on the standards for services. OTPs will be accountable through the accreditation process to assure that patients receive the appropriate services they need for successful treatment outcomes; for some patients, medication services may be sufficient to produce positive outcomes.

9. A number of respondents submitted comments on proposed section 8.12(f)(2), which requires a complete medical examination within the first 30 days following admission. Some of these comments noted that this provision, as proposed, permitted patients to enter treatment while tests, some of which required several days, are completed. Others commented that the 30 days was too long to wait for a medical exam to be completed, noting that information from the exam is crucial to the first few days of treatment. Finally, some comments suggested that regulations should specify the contents of the medical exam.

The intent of proposing 30 days for the completion of the physical exam was to allow patients into treatment while OTPs wait for the results of serology and other tests that require, in some cases, several days to complete. Section 8.12(f)(2) has been revised to clarify the requirement for a physical exam upon admission, with serology and other tests results completed w/in 14 days. The Secretary does not agree that regulations should specify the contents of the medical examination. Instead, the Secretary believes that accreditation guidelines should express the state-of-the-art content for a medical exam appropriate for the treatment of opiate addiction.

10. The July 22, 1999, notice proposed that OTPs conduct at least eight random drug abuse tests per year for each patient. Many comments suggested that the Federal standards specify more frequent drug abuse tests, including weekly testing, to balance the more flexible proposed take-home schedule. Other comments suggested that Federal regulations should specify measures to prevent adulteration. On the other hand, some comments suggested that quarterly drug abuse testing is appropriate. Moreover, one comment recommended substituting an ''honor system'' because patients can corrupt the testing process and falsify results.

After considering the comments on this issue, the Secretary is retaining the requirement for a minimum of eight random drug abuse tests per year for maintenance treatment. The Secretary believes that this is an adequate and balanced standard for drug abuse testing. There is extensive discussion on drug abuse testing issues in the SAMHSA/CSAT Treatment Improvement Protocols and the SAMHSA/CSAT Accreditation Guidelines. In addition, these guidelines elaborate on measures to address the corruption and falsification of results. Finally, as the Federal standard is a minimum, OTPs can require more frequent tests if desired.

11. The Secretary received many comments on proposed section 8.12(g)(2) which requires OTPs to determine and document that patients are not enrolled in other programs. Most respondents question how such determinations could be made without a patient registry. One comment stated that multiple enrollments are attributable to inadequate medication dosing practices.

The July 22, 1999, proposal retained the provisions relating to multiple enrollments from the previous regulations under 21 CFR 291.505. In proposing to retain the requirement, the Secretary noted that there have been cases of patients enrolling in more than one treatment program; however, the extent of this practice is undetermined but not considered to be widespread. The intent of this provision is for OTPs to make a good faith effort, using available resources and mechanisms to ascertain whether or not a prospective patient was currently enrolled in another OTP. Some individual States with OTPs concentrated within a community have established a patient registry and require OTPs to report new patients and patients who have discontinued in treatment. In other jurisdictions, patient registries are developed and maintained voluntarily by OTPs. OTPs also often contact other OTPs in the vicinity to determine if the patient is currently enrolled in an OTP, or they ask the patient. If used, these mechanisms must be used in accordance with the provisions at 42 CFR 2.34, regarding disclosures to prevent multiple enrollments. The Secretary acknowledges that none of these mechanisms can determine with complete certainty whether or not a patient is enrolled in more than one OTP. Accordingly, the Secretary expects that OTPs will document in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled in any other OTP. Section 8.12(g)(2) has been revised accordingly.

12. The Secretary received many comments on proposed section 8.12(j), relating to interim methadone maintenance. Most of these comments were from patients who suggested interim maintenance as a model for long standing patients who have been stabilized in treatment. As such, these comments suggested that the term for interim methadone maintenance be extended beyond 120 days.

These comments reflect a misunderstanding of interim methadone maintenance. Interim methadone maintenance was mandated by the ADAMHA Reorganization Act of 1992 as a measure to address shortages in treatment capacity and documented waiting lists (Pub. L. 102–321, See also 58 FR 495, January 5, 1993). The legislation included several restrictions which were incorporated and retained into Federal regulations. Although very few programs have applied for authorization to provide interim methadone maintenance, the Secretary does not at this time believe it is necessary or appropriate to change the standards. Instead, as discussed elsewhere in this notice, the Secretary believes that medical maintenance provides a more reasonable approach for expanding treatment capacity.

13. The Secretary received comments on proposed section 8.11(h), which provides for exemptions from treatment standards or certification requirements. One comment suggested that the examples in the previous regulation for exemptions, be retained in the final new regulations. The comment suggests that this would encourage individual physicians, pharmacists, or both to

provide methadone treatment in rural areas where methadone treatment is scarce or unavailable. Another comment suggested that SAMHSA streamline the exemption process and do more to publicize the availability of such regulatory options. The Secretary accepts both of these suggestions, and section 8.11(h) has been revised accordingly. In addition, SAMHSA has already taken steps to streamline the exemption process and publicize the availability of certain exemptions (Ref. 4).

14. Most comments strongly supported the provisions in proposed section 8.12(h)(3)(i) which permits OTPs to use solid dosage forms. Some patients reported spoilage and decomposition problems with 14-day supplies of liquid dosage form. Other comments suggested that the use of solid medication will reduce treatment cost modestly by eliminating the need for dosage bottles for solutions. The Secretary agrees that permitting OTPs to use solid medication will reduce treatment costs and increase treatment convenience to patients.

15. The Secretary received many comments on proposed section 8.11(h)(3)(iii) that would have required the program physician to justify in the patient record all doses above 100 mg. Most comments viewed this requirement as an inappropriate ''value judgement'' that hampers clinical judgement. The Secretary agrees that the requirement to justify a dose above 100 mg, which is a modification of a requirement under the previous regulation, is not necessary to reduce the risk of medication diversion. Accordingly, this requirement has been eliminated from the final rule.

16. The Secretary specifically requested and received comments on proposed changes to the requirements under section 8.12(i) pertaining to medications dispensed for unsupervised use (hereinafter ''take-homes''). The July 22, 1999, proposal set forth four options for addressing take-homes. These options ranged from retaining the previous requirements to a scheme based on a maximum dose. Option number 2 was discussed as the option preferred by HHS and endorsed by DEA. This option resembles the requirement under the previous regulations and retains the 8-point take-home criteria. However, option number 2 permitted patients in stable treatment for one year to receive up to a 31-day supply of medication, while the previous regulation included a maximum take-home supply of 6 days.

Most comments supported proposed option 2, with modifications. In supporting option 2, current patients stated that less frequent clinic attendance will make treatment much more convenient. In addition, Option 2 will eliminate travel hardships and facilitate employment commitments, ultimately increasing retention in treatment and rehabilitation. Option 1, which encompassed the take-home schedule from the previous regulation, was viewed by many comments as too restrictive. Many comments opposed option 3, which proposed a set 2-week maximum milligram amount for take-homes, because it unfairly penalized patients receiving higher doses.

On the other hand, a form letter circulated and submitted by several treatment programs stated that no patients should be eligible for a 31-day take-home supply. According to these comments, all patients must report to clinics often so that their rehabilitation can be monitored appropriately. In addition, these comments stated that allowing any patient a 31-day take-home supply presents an unacceptable risk of diversion.

The Secretary does not agree with these comments. Indeed, there is considerable evidence that many patients can responsibly handle supplies of take-home medications beyond the 6-day maximum allowed under the previous regulations. In addition, FDA has permitted hundreds of patients to receive monthly take-home supplies of methadone through exemptions or Investigational New Drug Applications. These investigations have been analyzed and reported in scientific literature and indicate that patients successfully continue in rehabilitation (Ref. 5). Moreover, these cases indicate that rehabilitation is enhanced through these ''medical maintenance'' models. Accordingly, and in response to an increased interest in this issue, FDA and SAMHSA/CSAT issued a ''Dear Colleague'' letter on March 30, 2000, that advised the field on procedures for obtaining OTP exemptions for medical maintenance, which include a provision for up to a 31-day supply of take-home medication (Ref 4).

The Secretary notes that many comments provided suggestions on refining the basic schedule for take-home eligibility outlined in proposed option 2. For example, many comments suggested that one year of stable treatment was still too short a period of time to evaluate whether patients can responsibly handle a 31-day supply of take-home medication. These comments suggested an interim step that permits a 14-day take-home supply after one year of stable treatment before a patient is eligible for a 31-day supply.

The Secretary concurs with these comments. The 2-year time in treatment requirement is more consistent with the studies and exemptions for medical maintenance granted to date under the previous rules. In addition, this schedule is more consonant with the schedule set forth in the SAMHSA/CSAT Accreditation Guidelines and the accreditation body standards. Accordingly, section 8.12(i)(3) has been revised to reflect a 14-day take-home step after one year of stable treatment and to reflect that patients are eligible for a take-home supply up to 31 days after two years of stable treatment. The language in other parts of section 8.12(i)(3) has been modified slightly for clarity to lengthen the duration of the steps within the first year of treatment, and to remove some requirements for observed ingestion.

17. Comments overwhelmingly supported the proposal to permit take-home use of LAAM and suggest that the Secretary apply the same schedule as methadone, *e.g.* option 2. A comment from a practitioner who has treated over 500 patients, stated that patients dislike being switched from LAAM to methadone when necessary for travel purposes. Most comments suggested that diversion of LAAM is no more likely than the diversion of methadone which generally is not problematic. One comment submitted the results of a 149-patient study on LAAM take-home use. Patients were randomized into take-home and clinic only groups. As part of the study, 545 take-home doses of LAAM were distributed to patients, and patients were subject to random ''callbacks.'' There was no evidence of tampering, diversion, or interest in obtaining LAAM take-home supplies illicitly. In addition, there were no differences between the two groups in the measured outcome variables. The investigator concluded that methadone and LAAM should be subject to the same take-home requirements. The Secretary concludes that LAAM should be available for take-home use under this rule.

18. A comment submitted by a physician discussed his successful experience using LAAM for detoxification treatment, finding LAAM to be superior to methadone for detoxification with some patients. The comment suggested that the regulations should be modified to permit the use of LAAM for detoxification.

Although previous **Federal Register** notices may have suggested that LAAM was not available for use in detoxification treatment (58 FR 38704, July 20, 1993), the July 22, 1999, proposal does not prohibit the use of

methadone or LAAM for detoxification treatment. Indeed, the current FDA approved labeling for LAAM discusses and provides guidance on withdrawing patients from LAAM therapy:

> ORLAAM is indicated for the management of opiate dependence * * * There is a limited experience with detoxifying patients from ORLAAM in a systematic manner, and both gradual reduction (5 to 10% a week) and abrupt withdrawal schedules have been used successfully. The decision to discontinue ORLAAM therapy should be made as part of a comprehensive treatment plan.

The Secretary believes that the regulations are adequately clear on this point.

19. A few respondents commented upon the proposed implementation plan and whether OTPs could be expected to comply with the timetables for achieving accreditation. Under proposed section 8.11(d), treatment programs approved under the previous regulations are deemed certified under the new rules. This ''transitional certification'' would expire on June 18, 2001 unless the OTPs certify with a written statement signed by the program sponsor that they will apply for accreditation within 90 days of the date SAMHSA approves the first accreditation body. Transitional certification, in that case, will expire on March 19, 2003. SAMHSA may extend transitional certification on a case-by-case basis for up to one year under certain conditions. The comments questioned whether SAMHSA had empirical evidence that OTPs could meet this timetable.

The Secretary believes that the timetables proposed in the July 22, 1999, notice remain reasonable. A significant number of OTPs have already had experience with accreditation. This includes programs located in Department of Veterans Affairs Medical Centers, as well as OTPs located in the several States that require accreditation of OTPs (Maryland, Indiana, North Carolina, Georgia, South Carolina, and Michigan). Moreover, as discussed previously, as part of SAMHSA/CSAT's accreditation implementation plan, two accreditation bodies conducted accreditation surveys of OTPs and accredited over 50 OTPs in just a few months. SAMHSA/CSAT has planned additional training and technical assistance to enable OTPs to understand and comply with the new regulations. In addition, the regulations have been streamlined with fewer reporting and recordkeeping requirements. OTPs have had ample opportunity to prepare for this final rule, and the SAMHSA/CSAT Accreditation Guidelines as well as the CARF and JCAHO accreditation standards have been widely available for years. Taken together, these factors provide the Secretary with reasonable confidence that OTPs can apply for and achieve accreditation within two years from the effective date of this rule.

The Secretary is sensitive to concerns about OTPs contacting accreditation bodies and scheduling accreditation reviews in a convenient manner. Therefore, while not changing the timetables for achieving accreditation under the final rule, the Secretary has modified section 8.11(d) to state that programs will agree to apply for accreditation within 90 days from the date SAMSHA announces the approval of the second accreditation body. The Secretary believes that tying this certification for OTPs to apply from the date SAMHSA announces the approval of the first accreditation body to the date SAMHSA announces approval of the second accreditation body will facilitate OTPs contacting and achieving accreditation under the final rule.

20. A few comments requested that OTPs that have been previously accredited by JCAHO and CARF should be ''grandfathered'' somehow under the new final regulations.

There are no provisions in the final rule to accept accreditation by accreditation bodies that have not been approved by SAMHSA under section 8.3(d). These accreditation bodies did not develop and apply accreditation standards that were based upon the opioid agonist treatment standards set forth under section 8.12. SAMHSA, however, will consider on a case-by-case basis, whether OTPs that achieved accreditation under the SAMHSA/CSAT implementation initiative can be exempted from re-accreditation under this final rule, pursuant to section 8.11(h).

E. Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

1. One comment recommended that subpart C should be revised to add discovery provisions. This would enable OTPs to obtain crucial information on how ''accreditation bodies conducted their investigation.'' The Secretary believes that the provisions of subpart A that require that accreditation bodies have appeals procedures in their accreditation decision-making process is adequate to assure that OTPs can obtain the information they need on accreditation activities.

2. One comment suggested that subpart C should be revised to allow applicant OTPs to appeal decisions to deny approval of an initial application. The Secretary does not agree and points out that OTPs will be able to appeal denials of accreditation by accreditation bodies under § 8.3(b)(4)(vii).

3. Response times in § 8.26(a), (b) and (c) have been lengthened, as have the oral presentation timeframes in § 8.27(d), and expedited procedures in § 8.28(a) and (d).

F. Conclusion and Delegation of Authority

After considering the comments submitted in response to the July 22, 1999, proposal, along with the information presented during the November 1, 1999, Public Hearing, the Secretary has determined that the administrative record in this proceeding supports the finalization of new rules under 42 CFR part 8.

In a notice to be published in a future issue of the **Federal Register,** the Secretary will announce the delegation of authority to the Administrator of SAMHSA, with the authority to redelegate, responsibility for the administration of 42 CFR part 8.

III. Analysis of Economic Impacts

The Secretary has examined the impact of this rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. While this rule is not a significant economic regulation, the Secretary finds that this rule is a significant regulatory action as defined by Executive Order 12866. As such, this rule has been reviewed by the Office of Management and Budget (OMB) under the provisions of that Executive Order. In addition, it has been determined that this rule is not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or

innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

A. Introduction

As noted in the July 22, 1999, proposal, approximately 900 OTPs provide opioid agonist treatment to approximately 140,000 patients in the U.S. For almost 30 years, FDA has applied process-oriented regulations with periodic inspections to approve and monitor these OTPs. This final rule establishes an accreditation-based regulatory system, administered by SAMHSA, to carry out these responsibilities. In addition, this final rule includes changes that will make the regulations more flexible, and provide the opportunity to increase treatment capacity. OTPs will incur additional costs under the new accreditation-based system, but these additional costs are modest, and the Secretary believes are offset by benefits set forth under the new rules.

The additional costs under these new rules are attributable to the costs of accreditation. FDA did not assess fees for inspections under the previous regulations. Under the new rules, private not-for-profit accreditation bodies will assess accreditation survey fees, and if necessary, reinspection fees. The July 22, 1999, proposal estimated that the direct and indirect costs of accreditation at $4.9 million per year. These annual cost equal approximately $5,400 per facility and $39 per patient. The cost estimates were based on discussions with three accreditation bodies. Overall, the net costs of the new system over the existing FDA system, factoring in SAMHSA's estimated annual oversight costs of $3.4 million, was $4.4 million. The July 22, 1999, proposal noted that additional information on accreditation costs would be derived from SAMHSA/CSAT ongoing accreditation implementation project and requested specific comments on the estimates provided.

As discussed above, although a number of comments submitted in response to the July 22, 1999, proposal predicted that accreditation costs could be higher, these predictions were based upon accreditation experiences in the past, not associated with the specific accreditation standards set forth under the new system. The results from approximately 50 accreditation surveys under the SAMHSA accreditation impact study suggest that the costs, as estimated in the July 22, 1999, proposal, are reasonably accurate.

The July 22, 1999, proposal discussed the benefits of the proposed rule in terms of the advantages of accreditation and in terms of relapse rates as a function of retention in treatment. Although difficult to quantify, the Secretary believes that the accreditation-based system will provide more frequent quality surveys of OTPs and allow greater flexibility in the delivery of opioid treatment. In addition, patients have commented that the increased flexibility of the new regulations, particularly in the standards for medications dispensed for unsupervised use, will increase patient convenience, increase patient satisfaction, and increase patient retention in treatment. Importantly, changes in the regulations will facilitate and expand medical maintenance treatment freeing resources to expand treatment capacity. As noted in the July 22, 1999, proposal, increasing retention in treatment and increasing the number of patients in treatment will lead to decreases in mortality and morbidity associated with opiate addiction, decrease health expenditures, and decrease criminal activity. These benefits are likely to be significantly greater than the costs of these new regulations.

B. Small Entity Analysis

The Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on a substantial number of small entities. SAMHSA included such an analysis in the July 22, 1999, proposal.

1. Description of Impact

The July 22, 1999, proposal provided an extensive description of the industry, and concluded that, although the regulations were streamlined under the proposal with fewer forms and reporting requirements, the proposed rule constituted a significant impact on a substantial number of small entities. This impact is attributable to the requirement that all OTPs, regardless of size, must be accredited and maintain accreditation in order to continue to treat patients. Overall, the July 22, 1999, proposal estimated that the cost per patient for a ''small'' OTP (defined as an OTP treating 50 or fewer patients) would increase slightly more than the industry average ($50 compared to $39).

2. Analysis of Alternatives

The July 22, 1999, notice included a brief discussion of alternatives to the proposed accreditation-based regulatory scheme. In the analysis set forth initially in the July 22, 1999 notice, the Department discussed but dismissed the alternative of continuing the existing direct, FDA monitored, regulatory system because of the findings and criticisms of that system identified in the Institute of Medicine Report and elsewhere. In addition, the alternative of allowing self-certification was discussed, but rejected due to concerns about diversion and insufficient enforceability.

The preamble to the proposed rule also included a brief discussion of alternatives that would minimize the economic impact of the new regulations on small businesses and other small entities. For example, the notice discussed the alternative of exempting small facilities from some requirements. It was also noted that small facilities could seek arrangements with larger facilities that could lower costs with economy-of-scale features.

The issues in this initial analysis were highlighted for specific comment, and the notice itself was sent to every OTP identified in the FDA inventory of approved programs. Except to say that small programs should not have to close under the new rules, or that small programs should be exempt from accreditation, very few comments addressed the issue specifically, or provided information on alternatives. Therefore, this initial analysis does not require changing and is adopted as the final regulatory flexibility analysis.

3. Response to Comments From Small Entities

These issues were highlighted for specific comment, and the notice itself was sent to every OTP identified in the FDA inventory of approved programs. Except to say that small programs should not have to close under the new rules, or that small programs should be exempt from accreditation, very few comments addressed the issue specifically, or provided information on alternatives.

As discussed above, SAMHSA has evaluated the results of accreditation surveys of OTPs conducted pursuant to the proposed Federal opioid treatment standards. As such, SAMHSA has a better understanding of how accreditation will work in both large and small OTPs. Moreover, SAMHSA has provided technical assistance to participating programs to help them achieve accreditation. SAMHSA expects to continue providing technical assistance to programs during and after the transition to the new system.

The accreditation-based system, the subject of these new rules, includes flexibility measures for small OTPs. The Secretary anticipates that there will be a number of approved accreditation bodies to choose from, including those

that will adjust accreditation fees on a sliding scale tied to the patient census. In addition, SAMHSA will retain the authority to certify programs without accreditation and could apply this provision, if necessary, to address burdens to OTPs with low patient censuses. SAMHSA prefers this case-by-case approach to a blanket exemption from accreditation requirements for programs below an arbitrary size. Such a blanket exemption would not be consistent with the intent of this regulatory initiative—to enhance the quality of opioid agonist treatment. The Secretary believes that, taken together, these considerations can mitigate the impact on small entities, while still meeting the objectives of this rulemaking.

C. Unfunded Mandates Reform Act of 1995

The Secretary has examined the impact of this rule under the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). This rule does not trigger the requirement for a written statement under section 202(a) of the UMRA because it does not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by State, local, and tribal governments in the aggregate, or by the private sector, in any one year.

IV. Environmental Impact

The Secretary has previously considered the environmental effects of this rule as announced in the proposed rule (64 FR 39810 at 39825). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

V. Executive Order 13132: Federalism

The Secretary has analyzed this final rule in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the Order, ''policies that have federalism implications'' refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

The Secretary is publishing this final rule to set forth treatment regulations that provide for the use of approved opioid agonist treatment medications in the treatment of opiate addiction. The Narcotic Addict Treatment Act (the NATA, Pub. L. 93–281) modified the Controlled Substances Act (CSA) to establish the basis for the Federal control of narcotic addiction treatment by the Attorney General and the Secretary. Because enforcement of these sections of the CSA is a Federal responsibility, there should be little, if any, impact from this rule on the distribution of power and responsibilities among the various levels of government. In addition, this regulation does not preempt State law. Accordingly, the Secretary has determined that this final rule does not contain policies that have federalism implications or that preempt State law.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA)(44 U.S.C. 3507(d)). The title, description and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Narcotic Drugs in Maintenance and Detoxification Treatment of Narcotic Dependence; Repeal of Current Regulations and Adoption of New Regulations.

Description: The Secretary is issuing regulations to establish an accreditation-based regulatory system to replace the current system that relies solely upon direct Federal inspection of treatment programs for compliance with process-oriented regulations.

These new rules are intended to enhance the quality of opioid treatment by allowing increased clinical judgment in treatment and by the accreditation process itself with its emphasis on continuous quality assessment. As set forth in this final rule, there will be fewer reporting requirements and fewer required forms under the new system. The total reporting requirements are estimated at 2,071 hours for treatment programs, and 341 hours for accrediting organizations as outlined in Tables 1 and 2.

The regulation requires a one-time reporting requirement for transitioning from the old system to the new system. The estimated reporting burden for ''transitional certification'' is approximately 475 hours. The proposal also requires ongoing certification on a 3-year cycle, with an estimated reporting burden of approximately 300 hours.

Description of Respondents: Business or other for-profit; Not-for-profit institutions; Federal Government; State, local or tribal government.

No comments were submitted in response to the Secretary's invitation in the July 22, 1999, proposal to comment on the information collection requirements.

TABLE 1.—ANNUAL REPORTING BURDEN FOR TREATMENT PROGRAMS

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.11(b)	New programs approval (SMA–162)	75	1	1.50	112.50
8.11(b)	Renewal of approval (SMA–162) [1]	300	1	1.00	300.00
8.11(b)	Relocation of program (SMA–162)	35	1	1.17	40.83
8.11(d)	Application for transitional certification (SMA–162) [2]	300	1	1.58	475.00
8.11(e)(1)	Application for provisional certification	75	1	.50	37.50
8.11(e)(2)	Application for extension of provisional certification	30	1	.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change	60	1	.33	20.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance.	1	1	2	2.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12.	800	3	.438	1050.00

TABLE 1.—ANNUAL REPORTING BURDEN FOR TREATMENT PROGRAMS—Continued

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units.	3	1	.25	.75
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance.	1	1	.33	.33
8.24	Contents of Appellant Request for Review of Suspension.	2	1	.25	.50
8.25(a)	Informal Review Request	2	1	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement	2	1	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review	2	1	1.00	2.00
8.28(c)	Appellant's Review File and Written Statement	2	1	5.00	10.00
Total					2,070.91

[1] Applications for renewal of certification are required every 3 years.
[2] Transitional Certification is a one-time requirement and will be included in the total annualized burden but averaged over the 3-year period of the OMB collection activity approval.

The final rule does not increase the estimated annualized burden. Certain reporting requirements have been eliminated, such as submissions for authorizations to use LAAM, the requirement to submit a physician responsibility statement (FDA Form 2633), and elimination of the requirement to obtain Federal approval for take-home doses of methadone in excess of 100 mg that exceed a 6-day supply. The new rule adds a one-time requirement for existing programs to apply for transitional certification, and a requirement to apply for certification renewal every third year. The annualized burdens associated with these new reporting requirements offset the burdens eliminated, resulting in no estimated net change.

Accreditation bodies will also require treatment programs to submit information as part of the standard operating procedures for accreditation. As mentioned earlier in this notice, accreditation bodies, under contract to SAMHSA, have accredited existing OTPs as part of an initiative to gain more information on the accreditation of OTPs. SAMHSA prepared a separate OMB Paperwork Reduction notice and analysis for that information collection activity (63 FR 10030, February 27, 1998, OMB approval number 0930–0194).

TABLE 2.—ANNUAL REPORTING BURDEN FOR ACCREDITATION ORGANIZATIONS

42 CFR citation	Purpose	No. of respondents	Responses/ respondent	Hours/ response	Total hours
8.3 (b) (1–11)	Initial approval (SMA–163)	10	1	3.0	30.0
8.3 (c)	Renewal of approval (SMA-163)	3	1	1.0	3.0
8.3 (e)	Relinguishment notification	1	1	0.5	0.5
8.3 (f) (2)	Non-renewal notification to accredited OTP's	1	90	0.1	9.0
8.4 (b) (1) (ii)	Notification to SAMHSA for serious noncompliant programs.	2	2	1.0	4.0
8.4 (b) (1) (iii)	Notification to OTP for serious noncompliance	2	2	1.0	4.0
8.4 (d) (1)	General document and information to SAMHSA upon request.	10	2	0.5	10.0
8.4 (d) (2)	Accrediation survey to SAMHSA upon request	10	6	0.2	12.0
8.4 (d) (3)	List of surveys, surveyors to SAMHSA upon request.	10	6	0.2	12.0
8.4 (d) (4)	Less than full accrediation report to SAMHSA	10	7.5	0.5	37.5
8.4 (d) (5)	Summaries of Inspections	10	30	0.5	150.0
8.4 (e)	Notifications of Compliants	10	1	0.5	5.0
8.6 (a) (2) and (b) (3)	Revocation notification to Accredited OTP's	1	90	0.3	27.0
8.6 (b)	Submission of 90-day Corrective plan to SAMHSA	1	1	10	10.0
8.6 (b) (1)	Notification to accredited OTP's of Probationary Status.	1	90	0.3	27.0
Total		82			341

Note: Because some of the numbers underlying these estimates have been rounded, figures in this table are approximate. There are no maintenance and operation costs nor start up and capital costs.

Recordkeeping—The recordkeeping requirements for OTPs set forth in sec. 8.12 include maintenance of the following: A patient's medical evaluation and other assessments when admitted to treatment, and periodically throughout treatment Sec. 8.12(f)(4)); the provision of needed services, including any prenatal support provided the patient (Sec. 8.12(f)(3) and (f)(4)) justification of exceptional initial doses; changes in a patient's dose and dosage schedule; justification for variations from the approved product labeling for LAAM and future medications (Sec. 8.12(h)(4)); and the rationale for decreasing a patient's clinic attendance (Sec. 8.12(i)(3)).

In addition, sec. 8.4(c)(1) will require accreditation bodies to keep and retain for 5 years certain records pertaining to their respective accreditation activities.

These recordkeeping requirements for OTPs and accreditation bodies are customary and usual practices within the medical and rehabilitative communities, and thus impose no additional response burden hours or costs.

Disclosure—This final rule retains requirements that OTPs and accreditation organizations disclose information. For example, sec. 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 new rules require under sec. 8.4(i)(1) that each accreditation organization shall make public its fee structure. The Secretary notes that the preceding section of this notice contains publicly available information on the fee structure for each of three accreditation bodies. This type of disclosure is standard business practice and is not considered a burden in this analysis.

Individuals and organizations may submit comments on these burden estimates or any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to: SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

The information collection provisions in this final rule have been approved under OMB control number 0930–0206. This approval expires 09/30/2002. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Nelba Chavez,

Administrator, Substance Abuse and Mental Health Services, Administration.

Dated: January 5, 2001.

Donna E. Shalala,

Secretary of Health and Human Services.

VII. References

The following references have been placed on display at SAMHSA/CSAT Reading Room (7–220), 5515 Security Lane, Rockville, MD 20852.

1. Institute of Medicine, Federal Regulation of Methadone Treatment, National Academy Press, 1995.

2. ''New Hampshire Legislature Allows Methadone Treatment,'' Copyright 2000, Alcoholism & Drug Abuse Weekly, Manisses Communications Group, Inc., Vol. 12, No. 23, Monday, June 5, 2000.

3. Sees, K.L., D.O., et al., ''Methadone Maintenance vs 180-Day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence, A Randomized Controlled Trial,'' Journal of the American Medical Association, Vol 283, No. 10 p1303–1310, March 8, 2000.

4. Clark, H. Westly, M.D., Lepay, David, M.D., ''Dear Colleague Letter on Medical Maintenance'', March 30, 2000.

5. Schwartz, M.D., et al., ''A 12-Year Follow-Up of a Methadone Medical Maintenance Program, Am J Addiction, Vol. 8, pp 293–299, 1999.

List of Subjects

21 CFR Part 291

Health professions, Methadone, Reporting and recordkeeping requirements.

42 CFR Part 8

Health professions, Levo-Alpha-Acetyl-Methadol (LAAM), Methadone, Reporting and recordkeeping requirements.

Therefore, under the Comprehensive Drug Abuse Prevention and Control Act of 1970, the Controlled Substances Act as amended by the Narcotic Addict Treatment Act of 1974, the Public Health Service Act, and applicable delegations of authority thereunder, titles 21 and 42 of the Code of Federal Regulations are amended as follows:

21 CFR Chapter I

PART 291—[REMOVED]

1. Under authority of sections 301(d), 543, 1976 of the Public Health Service Act (42 U.S.C. 241(d), 290dd–2, 300y–11); 38 U.S.C. 7332, 42 U.S.C. 257a; and section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)), amend title 21 of the Code of Federal Regulations by removing part 291.

42 CFR Chapter I

2. Amend 42 CFR Chapter I by adding part 8 to subchapter A to read as follows:

PART 8—CERTIFICATION OF OPIOID TREATMENT PROGRAMS

Subpart A—Accreditation

Sec.
8.1 Scope.
8.2 Definitions.
8.3 Application for approval as an accreditation body.
8.4 Accreditation body responsibilities.
8.5 Periodic evaluation of accreditation bodies.
8.6 Withdrawal of approval of accreditation bodies.

Subpart B—Certification and Treatment Standards

8.11 Opioid treatment program certification.
8.12 Federal opioid treatment standards.
8.13 Revocation of accreditation and accreditation body approval.
8.14 Suspension or revocation of certification.
8.15 Forms.

Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

8.21 Applicability.
8.22 Definitions.
8.23 Limitation on issues subject to review.
8.24 Specifying who represents the parties.
8.25 Informal review and the reviewing official's response.
8.26 Preparation of the review file and written arguments.
8.27 Opportunity for oral presentation.
8.28 Expedited procedures for review of immediate suspension.
8.29 Ex parte communications.
8.30 Transmission of written communications by reviewing official and calculation of deadlines.
8.31 Authority and responsibilities of the reviewing official.
8.32 Administrative record.
8.33 Written decision.
8.34 Court review of final administrative action; exhaustion of administrative remedies.

Authority: 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd–2, 300x–23, 300x–27(a), 300y–11.

Subpart A—Accreditation

§ 8.1 Scope.

The regulations in this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether a practitioner is qualified under section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) to dispense opioid drugs in the treatment of opioid addiction. These regulations also establish the Secretary's standards regarding the appropriate quantities of opioid drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(1)). Under these regulations, a practitioner who intends to dispense opioid drugs in the treatment of opioid addiction must first obtain from the Secretary or by delegation, from the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), a certification that the practitioner is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from an accreditation body that has been approved by SAMHSA. These regulations establish the procedures whereby an entity can apply to become an approved accreditation body. This

part also establishes requirements and general standards for accreditation bodies to ensure that practitioners are consistently evaluated for compliance with the Secretary's standards for opiate addiction treatment with an opioid agonist treatment medication.

§ 8.2 Definitions.

The following definitions apply to this part:

Accreditation means the process of review and acceptance by an accreditation body.

Accreditation body means a body that has been approved by SAMHSA under § 8.3 to accredit opioid treatment programs using opioid agonist treatment medications.

Accreditation body application means the application filed with SAMHSA for purposes of obtaining approval as an accreditation body, as described in § 8.3(b).

Accreditation elements mean the elements or standards that are developed and adopted by an accreditation body and approved by SAMHSA.

Accreditation survey means an onsite review and evaluation of an opioid treatment program by an accreditation body for the purpose of determining compliance with the Federal opioid treatment standards described in § 8.12.

Accredited opioid treatment program means an opioid treatment program that is the subject of a current, valid accreditation from an accreditation body approved by SAMHSA under § 8.3(d).

Certification means the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the Federal opioid treatment standards.

Certification application means the application filed by an opioid treatment program for purposes of obtaining certification from SAMHSA, as described in § 8.11(b).

Certified opioid treatment program means an opioid treatment program that is the subject of a current, valid certification under § 8.11.

Comprehensive maintenance treatment is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

Detoxification treatment means the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within such period.

Federal opioid treatment standards means the standards established by the Secretary in § 8.12 that are used to determine whether an opioid treatment program is qualified to engage in opioid treatment. The Federal opioid treatment standards established in § 8.12 also include the standards established by the Secretary regarding the quantities of opioid drugs which may be provided for unsupervised use.

For-cause inspection means an inspection of an opioid treatment program by the Secretary, or by an accreditation body, that may be operating in violation of Federal opioid treatment standards, may be providing substandard treatment, or may be serving as a possible source of diverted medications.

Interim maintenance treatment means maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

Long-term detoxification treatment means detoxification treatment for a period more than 30 days but not in excess of 180 days.

Maintenance treatment means the dispensing of an opioid agonist treatment medication at stable dosage levels for a period in excess of 21 days in the treatment of an individual for opioid addiction.

Medical director means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

Medical and rehabilitative services means services such as medical evaluations, counseling, and rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement), that are intended to help patients in opioid treatment programs become and/or remain productive members of society.

Medication unit means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

Opiate addiction is defined as a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

Opioid agonist treatment medication means any opioid agonist drug that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opiate addiction.

Opioid drug means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

Opioid treatment means the dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to opiate addiction. This term encompasses detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.

Opioid treatment program or ''OTP'' means a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication.

Patient means any individual who undergoes treatment in an opioid treatment program.

Program sponsor means the person named in the application for certification described in § 8.11(b) as responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Registered opioid treatment program means an opioid treatment program that is registered under 21 U.S.C. 823(g).

Short-term detoxification treatment means detoxification treatment for a period not in excess of 30 days.

State Authority is the agency designated by the Governor or other appropriate official designated by the

Governor to exercise the responsibility and authority within the State or Territory for governing the treatment of opiate addiction with an opioid drug.

Treatment plan means a plan that outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and which specifies the services to be provided and the frequency and schedule for their provision.

§ 8.3 Application for approval as an accreditation body.

(a) *Eligibility.* Private nonprofit organizations or State governmental entities, or political subdivisions thereof, capable of meeting the requirements of this part may apply for approval as an accreditation body.

(b) *Application for initial approval.* Three copies of an accreditation body application form [SMA–163] shall be submitted to SAMHSA at rm. 12–105, 5600 Fishers Lane, Rockville, MD 20857, and marked ATTENTION: OTP Certification Program. SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. Accreditation body applications shall include the following information and supporting documentation:

(1) Name, address, and telephone number of the applicant and a responsible official for the accreditation body. The application shall be signed by the responsible official;

(2) Evidence of the nonprofit status of the applicant (*i.e.,* of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a State governmental entity or political subdivision;

(3) A set of the accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the Federal opioid treatment standards set forth in § 8.12;

(4) A detailed description of the applicant's decisionmaking process, including:

(i) Procedures for initiating and performing onsite accreditation surveys of OTPs;

(ii) Procedures for assessing OTP personnel qualifications;

(iii) Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process, including a request for a complete history of prior accreditation activities and a statement that all information and data submitted in the application for accreditation is true and accurate, and that no material fact has been omitted;

(iv) Policies and procedures for notifying OTPs and SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTPs;

(v) Policies and procedures for suspending or revoking an OTP's accreditation;

(vi) Policies and procedures that will ensure processing of applications for accreditation and applications for renewal of accreditation within a timeframe approved by SAMHSA; and

(vii) A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions.

(5) Policies and procedures established by the accreditation body to avoid conflicts of interest, or the appearance of conflicts of interest, by the applicant's board members, commissioners, professional personnel, consultants, administrative personnel, and other representatives;

(6) A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician on the applicant's staff;

(7) A description of the applicant's training policies;

(8) Fee schedules, with supporting cost data;

(9) Satisfactory assurances that the body will comply with the requirements of § 8.4, including a contingency plan for investigating complaints under § 8.4(e);

(10) Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body; and

(11) Any other information SAMHSA may require.

(c) *Application for renewal of approval.* An accreditation body that intends to continue to serve as an accreditation body beyond its current term shall apply to SAMHSA for renewal, or notify SAMHSA of its intention not to apply for renewal, in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of an accreditation body's term of approval, the body shall inform SAMHSA in writing of its intent to seek renewal.

(2) SAMHSA will notify the applicant of the relevant information, materials, and supporting documentation required under paragraph (b) of this section that the applicant shall submit as part of the renewal procedure.

(3) At least 3 months before the date of expiration of the accreditation body's term of approval, the applicant shall furnish to SAMHSA three copies of a renewal application containing the information, materials, and supporting documentation requested by SAMHSA under paragraph (c)(2) of this section.

(4) An accreditation body that does not intend to renew its approval shall so notify SAMHSA at least 9 months before the expiration of the body's term of approval.

(d) *Rulings on applications for initial approval or renewal of approval.* (1) SAMHSA will grant an application for initial approval or an application for renewal of approval if it determines the applicant substantially meets the accreditation body requirements of this subpart.

(2) If SAMHSA determines that the applicant does not substantially meet the requirements set forth in this subpart. SAMHSA will notify the applicant of the deficiencies in the application and request that the applicant resolve such deficiencies within 90 days of receipt of the notice. If the deficiencies are resolved to the satisfaction of SAMHSA within the 90-day time period, the body will be approved as an accreditation body. If the deficiencies have not been resolved to the satisfaction of SAMHSA within the 90-day time period, the application for approval as an accreditation body will be denied.

(3) If SAMHSA does not reach a final decision on a renewal application before the expiration of an accreditation body's term of approval, the approval will be deemed extended until SAMHSA reaches a final decision, unless an accreditation body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of approval.* An accreditation body that intends to relinquish its accreditation approval before expiration of the body's term of approval shall submit a letter of such intent to SAMHSA, at the address in paragraph (b) of this section, at least 9 months before relinquishing such approval.

(f) *Notification.* An accreditation body that does not apply for renewal of approval, or is denied such approval by SAMHSA, relinquishes its accreditation approval before expiration of its term of approval, or has its approval withdrawn, shall:

(1) Transfer copies of records and other related information as required by SAMHSA to a location, including

another accreditation body, and according to a schedule approved by SAMHSA; and

(2) Notify, in a manner and time period approved by SAMHSA, all OTPs accredited or seeking accreditation by the body that the body will no longer have approval to provide accreditation services.

(g) *Term of approval.* An accreditation body's term of approval is for a period not to exceed 5 years.

(h) *State accreditation bodies.* State governmental entities, including political subdivisions thereof, may establish organizational units that may act as accreditation bodies, provided such units meet the requirements of this section, are approved by SAMHSA under this section, and have taken appropriate measures to prevent actual or apparent conflicts of interest, including cases in which State or Federal funds are used to support opioid treatment services.

§ 8.4 Accreditation body responsibilities.

(a) *Accreditation surveys and for cause inspections.* (1) Accreditation bodies shall conduct routine accreditation surveys for initial, renewal, and continued accreditation of each OTP at least every 3 years.

(2) Accreditation bodies must agree to conduct for-cause inspections upon the request of SAMHSA.

(3) Accreditation decisions shall be fully consistent with the policies and procedures submitted as part of the approved accreditation body application.

(b) *Response to noncompliant programs.* (1) If an accreditation body receives or discovers information that suggests that an OTP is not meeting Federal opioid treatment standards, or if survey of the OTP by the accreditation body otherwise demonstrates one or more deficiencies in the OTP, the accreditation body shall as appropriate either require and monitor corrective action or shall suspend or revoke accreditation of the OTP, as appropriate based on the significance of the deficiencies.

(i) Accreditation bodies shall either not accredit or shall revoke the accreditation of any OTP that substantially fails to meet the Federal opioid treatment standards.

(ii) Accreditation bodies shall notify SAMHSA as soon as possible but in no case longer than 48 hours after becoming aware of any practice or condition in an OTP that may pose a serious risk to public health or safety or patient care.

(iii) If an accreditation body determines that an OTP is substantially meeting the Federal opioid treatment standards, but is not meeting one or more accreditation elements, the accreditation body shall determine the necessary corrective measures to be taken by the OTP, establish a schedule for implementation of such measures, and notify the OTP in writing that it must implement such measures within the specified schedule in order to ensure continued accreditation. The accreditation body shall verify that the necessary steps are taken by the OTP within the schedule specified and that all accreditation elements are being substantially met or will be substantially met.

(2) Nothing in this part shall prevent accreditation bodies from granting accreditation, contingent on promised programmatic or performance changes, to OTPs with less substantial violations. Such accreditation shall not exceed 12 months. OTPs that have been granted such accreditation must have their accreditation revoked if they fail to make changes to receive unconditional accreditation upon resurvey or reinspection.

(c) *Recordkeeping.* (1) Accreditation bodies shall maintain records of their accreditation activities for at least 5 years from the creation of the record. Such records must contain sufficient detail to support each accreditation decision made by the accreditation body.

(2) Accreditation bodies shall establish procedures to protect confidential information collected or received in their role as accreditation bodies that are consistent with, and that are designed to ensure compliance with, all Federal and State laws, including 42 CFR part 2.

(i) Information collected or received for the purpose of carrying out accreditation body responsibilities shall not be used for any other purpose or disclosed, other than to SAMHSA or its duly designated representatives, unless otherwise required by law or with the consent of the OTP.

(ii) Nonpublic information that SAMHSA shares with the accreditation body concerning an OTP shall not be further disclosed except with the written permission of SAMHSA.

(d) *Reporting.* (1) Accreditation bodies shall provide to SAMHSA any documents and information requested by SAMHSA within 5 days of receipt of the request.

(2) Accreditation bodies shall make a summary of the results of each accreditation survey available to SAMHSA upon request. Such summaries shall contain sufficient detail to justify the accreditation action taken.

(3) Accreditation bodies shall provide SAMHSA upon request a list of each OTP surveyed and the identity of all individuals involved in the conduct and reporting of survey results.

(4) Accreditation bodies shall submit to SAMHSA the name of each OTP for which the accreditation body accredits conditionally, denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action.

(5) Notwithstanding any reports made to SAMHSA under paragraphs (d)(1) through (d)(4) of this section, each accreditation body shall submit to SAMHSA semiannually, on January 15 and July 15 of each calendar year, a report consisting of a summary of the results of each accreditation survey conducted in the past year. The summary shall contain sufficient detail to justify each accreditation action taken.

(6) All reporting requirements listed in this section shall be provided to SAMHSA at the address specified in § 8.3(b).

(e) *Complaint response.* Accreditation bodies shall have policies and procedures to respond to complaints from SAMHSA, patients, facility staff, and others, within a reasonable period of time but not more than 5 days of the receipt of the complaint. Accreditation bodies shall also agree to notify SAMHSA within 48 hours of receipt of a complaint and keep SAMHSA informed of all aspects of the response to the complaint.

(f) *Modifications of accreditation elements.* Accreditation bodies shall obtain SAMHSA's authorization prior to making any substantive (*i.e.,* noneditorial) change in accreditation elements.

(g) *Conflicts of interest.* The accreditation body shall maintain and apply policies and procedures that SAMHSA has approved in accordance with § 8.3 to reduce the possibility of actual conflict of interest, or the appearance of a conflict of interest, on the part of individuals who act on behalf of the accreditation body. Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision.

(h) *Accreditation teams.* (1) An accreditation body survey team shall consist of healthcare professionals with

expertise in drug abuse treatment and, in particular, opioid treatment. The accreditation body shall consider factors such as the size of the OTP, the anticipated number of problems, and the OTP's accreditation history, in determining the composition of the team. At a minimum, survey teams shall consist of at least two healthcare professionals whose combined expertise includes:

(i) The dispensing and administration of drugs subject to control under the Controlled Substances Act (21 U.S.C. 801 *et seq.*);

(ii) Medical issues relating to the dosing and administration of opioid agonist treatment medications for the treatment of opioid addiction;

(iii) Psychosocial counseling of individuals undergoing opioid treatment; and

(iv) Organizational and administrative issues associated with opioid treatment programs.

(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest.

(i) *Accreditation fees.* Fees charged to OTPs for accreditation shall be reasonable. SAMHSA generally will find fees to be reasonable if the fees are limited to recovering costs to the accreditation body, including overhead incurred. Accreditation body activities that are not related to accreditation functions are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different OTPs.

(2) At SAMHSA's request, accreditation bodies shall provide to SAMHSA financial records or other materials, in a manner specified by SAMHSA, to assist in assessing the reasonableness of accreditation body fees.

§ 8.5 Periodic evaluation of accreditation bodies.

SAMHSA will evaluate periodically the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with the Federal opioid treatment standards. The evaluation will include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under § 8.6.

§ 8.6 Withdrawal of approval of accreditation bodies.

If SAMHSA determines that an accreditation body is not in substantial compliance with this subpart, SAMHSA shall take appropriate action as follows:

(a) *Major deficiencies.* If SAMHSA determines that the accreditation body has a major deficiency, such as commission of fraud, material false statement, failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart, SAMHSA shall withdraw approval of that accreditation body.

(1) In the event of a major deficiency, SAMHSA shall notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify each OTP that has been accredited or is seeking accreditation that the accreditation body's approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by SAMHSA.

(b) *Minor deficiencies.* If SAMHSA determines that the accreditation body has minor deficiencies in the performance of an accreditation function, that are less serious or more limited than the types of deficiencies described in paragraph (a) of this section, SAMHSA will notify the body that it has 90 days to submit to SAMHSA a plan of corrective action. The plan must include a summary of corrective actions and a schedule for their implementation. SAMHSA may place the body on probationary status for a period of time determined by SAMHSA, or may withdraw approval of the body if corrective action is not taken.

(1) If SAMHSA places an accreditation body on probationary status, the body shall notify all OTPs that have been accredited, or that are seeking accreditation, of the accreditation body's probationary status within a time period and in a manner approved by SAMHSA.

(2) Probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of SAMHSA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems.

(3) If SAMHSA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, SAMHSA may withdraw approval of the accreditation body. The accreditation body shall notify all OTPs that have been accredited, or are seeking accreditation, of the accreditation body's loss of SAMHSA approval within a time period and in a manner approved by SAMHSA.

(c) *Reapplication.* (1) An accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to SAMHSA to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If SAMHSA determines that the new application demonstrates that the body satisfactorily has addressed the causes of its previous unacceptable performance, SAMHSA may reinstate approval of the accreditation body.

(3) SAMHSA may request additional information or establish additional conditions that must be met before SAMHSA approves the reapplication.

(4) SAMHSA may refuse to accept an application from a former accreditation body whose approval was withdrawn because of fraud, material false statement, or willful disregard of public health.

(d) *Hearings.* An opportunity to challenge an adverse action taken regarding withdrawal of approval of an accreditation body shall be addressed through the relevant procedures set forth in subpart C of this part, except that the procedures in § 8.28 for expedited review of an immediate suspension would not apply to an accreditation body that has been notified under paragraph (a) or (b) of this section of the withdrawal of its approval.

Subpart B—Certification and Treatment Standards

§ 8.11 Opioid treatment program certification.

(a) *General.* (1) An OTP must be the subject of a current, valid certification from SAMHSA to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) to dispense opioid drugs in the treatment of opioid addiction. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the

Attorney General to dispense opioid agonist treatment medications to individuals for treatment of opioid addiction.

(2) To obtain certification from SAMHSA, an OTP must meet the Federal opioid treatment standards in § 8.12, must be the subject of a current, valid accreditation by an accreditation body or other entity designated by SAMHSA, and must comply with any other conditions for certification established by SAMHSA.

(3) Certification shall be granted for a term not to exceed 3 years, except that certification may be extended during the third year if an application for accreditation is pending.

(b) *Application for certification.* Three copies of an application for certification must be submitted by the OTP to the address identified in § 8.3(b). SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. The application for certification shall include:

(1) A description of the current accreditation status of the OTP;

(2) A description of the organizational structure of the OTP;

(3) The names of the persons responsible for the OTP;

(4) The addresses of the OTP and of each medication unit or other facility under the control of the OTP;

(5) The sources of funding for the OTP and the name and address of each governmental entity that provides such funding; and

(6) A statement that the OTP will comply with the conditions of certification set forth in paragraph (f) of this section.

(7) The application shall be signed by the program sponsor who shall certify that the information submitted in the application is truthful and accurate.

(c) *Action on application.* (1) Following SAMHSA's receipt of an application for certification of an OTP, and after consultation with the appropriate State authority regarding the qualifications of the applicant, SAMHSA may grant the application for certification, or renew an existing certification, if SAMHSA determines that the OTP has satisfied the requirements for certification or renewal of certification.

(2) SAMHSA may deny the application if SAMHSA determines that:

(i) The application for certification is deficient in any respect;

(ii) The OTP will not be operated in accordance with the Federal opioid treatment standards established under § 8.12;

(iii) The OTP will not permit an inspection or a survey to proceed, or will not permit in a timely manner access to relevant records or information; or

(iv) The OTP has made misrepresentations in obtaining accreditation or in applying for certification.

(3) Within 5 days after it reaches a final determination that an OTP meets the requirements for certification, SAMHSA will notify the Drug Enforcement Administration (DEA) that the OTP has been determined to be qualified to provide opioid treatment under section 303(g)(1) of the Controlled Substances Act.

(d) *Transitional certification.* OTPs that before March 19, 2001 were the subject of a current, valid approval by FDA under 21 CFR, part 291 (contained in the 21 CFR Parts 200 to 299 edition, revised as of July 1, 2000), are deemed to be the subject of a current valid certification for purposes of paragraph (a)(11) of this section. Such 'transitional certification' will expire on June 18, 2001 unless the OTP submits the information required by paragraph (b) of this section to SAMHSA on or before June 18, 2001. In addition to this application, OTPs must certify with a written statement signed by the program sponsor, that they will apply for accreditation within 90 days of the date SAMHSA approves the second accreditation body. Transitional certification, in that case, will expire on March 19, 2003. SAMHSA may extend the transitional certification of an OTP for up to one additional year provided the OTP demonstrates that it has applied for accreditation, that an accreditation survey has taken place or is scheduled to take place, and that an accreditation decision is expected within a reasonable period of time (*e.g.,* within 90 days from the date of survey). Transitional certification under this section may be suspended or revoked in accordance with § 8.14.

(e) *Provisional certification.* (1) OTPs that have no current certification from SAMHSA, but have applied for accreditation with an accreditation body, are eligible to receive a provisional certification for up to 1 year. To receive a provisional certification, an OTP shall submit the information required by paragraph (b) of this section to SAMHSA along with a statement identifying the accreditation body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. A provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph, unless SAMHSA determines that patient health would be adversely affected by the granting of provisional certification.

(2) An extension of provisional certification may be granted in extraordinary circumstances or otherwise to protect public health. To apply for a 90-day extension of provisional certification, an OTP shall submit to SAMHSA a statement explaining its efforts to obtain accreditation and a schedule for obtaining accreditation as expeditiously as possible.

(f) *Conditions for certification.* (1) OTPs shall comply with all pertinent State laws and regulations. Nothing in this part is intended to limit the authority of State and, as appropriate, local governmental entities to regulate the use of opioid drugs in the treatment of opioid addiction. The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States. Federal agencies operating OTPs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal OTPs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.

(2) OTPs shall allow, in accordance with Federal controlled substances laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, by the DEA, and by authorized employees of any relevant State or Federal governmental authority.

(3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2, and every program must comply with that part. Records on the receipt, storage, and distribution of opioid agonist treatment medications are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.). Federally-sponsored treatment programs are subject to applicable Federal confidentiality statutes.

(4) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee

of SAMHSA to have access to and to copy all records on the use of opioid drugs in accordance with the provisions of 42 CFR part 2.

(5) OTPs shall notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II, and must be registered by the DEA before administering or dispensing opioid agonist treatment medications.

(7) OTPs must operate in accordance with Federal opioid treatment standards and approved accreditation elements.

(g) *Conditions for interim maintenance treatment program approval.* (1) Before a public or nonprofit private OTP may provide interim maintenance treatment, the program must receive the approval of both SAMHSA and the chief public health officer of the State in which the OTP operates.

(2) Before SAMHSA may grant such approval, the OTP must provide SAMHSA with documentation from the chief public health officer of the State in which the OTP operates demonstrating that:

(i) Such officer does not object to the providing of interim maintenance treatment in the State;

(ii) The OTP seeking to provide such treatment is unable to place patients in a public or nonprofit private comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek admission to such programs;

(iii) The authorization of the OTP to provide interim maintenance treatment will not otherwise reduce the capacity of comprehensive maintenance treatment programs in the State to admit individuals (relative to the date on which such officer so certifies); and

(iv) The State certifies that each individual enrolled in interim maintenance treatment will be transferred to a comprehensive maintenance treatment program no later than 120 days from the date on which each individual first requested treatment, as provided in section 1923 of the Public Health Service Act (21 U.S.C. 300x-23).

(3) SAMHSA will provide notice to the OTP denying or approving the request to provide interim maintenance treatment. The OTP shall not provide such treatment until it has received such notice from SAMHSA.

(h) *Exemptions.* An OTP may, at the time of application for certification or any time thereafter, request from SAMHSA exemption from the regulatory requirements set forth under this section and § 8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. SAMHSA shall consult with the appropriate State authority prior to taking action on an exemption request.

(i) *Medication units, long-term care facilities and hospitals.* (1) Certified OTPs may establish medication units that are authorized to dispense opioid agonist treatment medications for observed ingestion. Before establishing a medication unit, a certified OTP must notify SAMHSA by submitting form SMA–162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent state laws and regulations.

(2) Certification as an OTP under this part will not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than opiate addiction and who requires maintenance or detoxification treatment during the period of his or her stay in that hospital or long-term care facility. The terms ''hospital'' and ''long-term care facility'' as used in this section are to have the meaning that is assigned under the law of the State in which the treatment is being provided. Nothing in this section is intended to relieve hospitals and long-term care facilities from the obligation to obtain registration from the Attorney General, as appropriate, under section 303(g) of the Controlled Substances Act.

§ 8.12 Federal opioid treatment standards.

(a) *General.* OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid addiction which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) *Continuous quality improvement.* (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current ''Diversion Control Plan'' or ''DCP'' as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(d) *Staff credentials.* Each person engaged in the treatment of opioid addiction must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.

(e) *Patient admission criteria.*—(1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) Maintenance treatment for persons under age 18. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) Maintenance treatment admission exceptions. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

(4) Detoxification treatment. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

(f) *Required services.*—(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(3) Special services for pregnant patients. OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

(4) Initial and periodic assessment services. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

(5) Counseling services. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined by the program staff to be in need of such services.

(6) Drug abuse testing services. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

(g) *Recordkeeping and patient confidentiality.* (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid addiction. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

(h) *Medication administration, dispensing, and use.* (1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application

under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid addiction. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid addiction:

(i) Methadone; and

(ii) Levomethadyl acetate (LAAM).

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.

(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) Unsupervised or ''take-home'' use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;

(ii) Regularity of clinic attendance;

(iii) Absence of serious behavioral problems at the clinic;

(iv) Absence of known recent criminal activity, *e.g.,* drug dealing;

(v) Stability of the patient's home environment and social relationships;

(vi) Length of time in comprehensive maintenance treatment;

(vii) Assurance that take-home medication can be safely stored within the patient's home; and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the following restrictions apply:

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.

(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is two doses per week.

(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91–601 (15 U.S.C. 1471 *et seq.*)).

(j) *Interim maintenance treatment.* (1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x–27(a), and 300y–11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of § 8.11(g).

(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or ''take-home'' use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

§ 8.13 Revocation of accreditation and accreditation body approval.

(a) *SAMHSA action following revocation of accreditation.* If an accreditation body revokes an OTP's accreditation, SAMHSA may conduct an investigation into the reasons for the revocation. Following such investigation, SAMHSA may determine that the OTP's certification should no longer be in effect, at which time SAMHSA will initiate procedures to revoke the facility's certification in accordance with § 8.14. Alternatively, SAMHSA may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation body approval.* (1) If SAMHSA withdraws the approval of an accreditation body under § 8.6, the certifications of OTPs accredited by such body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the accreditation body, unless SAMHSA determines that to protect public health or safety, or because the accreditation body fraudulently accredited treatment programs, the certifications of some or all of the programs should be revoked or suspended or that a shorter time period should be established for the certifications to remain in effect. SAMHSA may extend the time in which a certification remains in effect under this paragraph on a case-by-case basis.

(2) Within 1 year from the date of withdrawal of approval of an accreditation body, or within any shorter period of time established by SAMHSA, OTPs currently accredited by the accreditation body must obtain accreditation from another accreditation body. SAMHSA may extend the time period for obtaining reaccreditation on a case-by-case basis.

§ 8.14 Suspension or revocation of certification.

(a) *Revocation.* Except as provided in paragraph (b) of this section, SAMHSA may revoke the certification of an OTP if SAMHSA finds, after providing the program sponsor with notice and an opportunity for a hearing in accordance with subpart C of this part, that the program sponsor, or any employee of the OTP:

(1) Has been found guilty of misrepresentation in obtaining the certification;

(2) Has failed to comply with the Federal opioid treatment standards in any respect;

(3) Has failed to comply with reasonable requests from SAMHSA or from an accreditation body for records, information, reports, or materials that are necessary to determine the continued eligibility of the OTP for certification or continued compliance with the Federal opioid treatment standards; or

(4) Has refused a reasonable request of a duly designated SAMHSA inspector, Drug Enforcement Administration (DEA) Inspector, State Inspector, or accreditation body representative for permission to inspect the program or the program's operations or its records.

(b) *Suspension.* Whenever SAMHSA has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, SAMHSA may immediately suspend the certification of an OTP before holding a hearing under subpart C of this part. SAMHSA may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under subpart C of this part if SAMHSA makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with the Federal opioid treatment standards presents an imminent danger to the public health or safety;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the failure to comply with the Federal opioid treatment standards was intentional or was associated with fraud.

(c) *Written notification.* In the event that SAMHSA suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, SAMHSA shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested. Such notice shall state the reasons for the action and shall state that the OTP may seek review of the action in accordance with the procedures in subpart C of this part.

(d)(1) If SAMHSA suspends certification in accordance with paragraph (b) of this section:

(i) SAMHSA will immediately notify DEA that the OTP's registration should be suspended under 21 U.S.C. 824(d); and

(ii) SAMHSA will provide an opportunity for a hearing under subpart C of this part.

(2) Suspension of certification under paragraph (b) of this section shall remain in effect until the agency determines that:

(i) The basis for the suspension cannot be substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The OTP's certification shall be revoked.

§ 8.15 Forms.

(a) SMA–162—Application for Certification to Use Opioid Agonist Treatment Medications for Opioid Treatment.

(b) SMA–163—Application for Becoming an Accreditation Body under § 8.3.

Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

§ 8.21 Applicability.

The procedures in this subpart apply when:

(a) SAMHSA has notified an OTP in writing that its certification under the regulations in subpart B of this part has been suspended or that SAMHSA proposes to revoke the certification; and

(b) The OTP has, within 30 days of the date of the notification or within 3 days of the date of the notification when seeking an expedited review of a suspension, requested in writing an opportunity for a review of the suspension or proposed revocation.

(c) SAMHSA has notified an accreditation body of an adverse action taken regarding withdrawal of approval of the accreditation body under the regulations in subpart A of this part; and

(d) The accreditation body has, within 30 days of the date of the notification, requested in writing an opportunity for a review of the adverse action.

§ 8.22 Definitions.

The following definitions apply to this subpart C.

(a) *Appellant* means:

(1) The treatment program which has been notified of its suspension or proposed revocation of its certification under the regulations of this part and has requested a review of the suspension or proposed revocation, or

(2) The accreditation body which has been notified of adverse action regarding withdrawal of approval under the regulations of this subpart and has requested a review of the adverse action.

(b) *Respondent* means SAMHSA.

(c) *Reviewing official* means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more HHS officers or employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

§ 8.23 Limitation on issues subject to review.

The scope of review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts the regulations, in the subpart, and other relevant law.

§ 8.24 Specifying who represents the parties.

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

§ 8.25 Informal review and the reviewing official's response.

(a) *Request for review.* Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension, proposed revocation, or adverse action, a brief statement of why the decision to suspend, propose revocation, or take an adverse action is incorrect, and the appellant's request for an oral presentation, if desired.

(b) *Acknowledgment.* Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

§ 8.26 Preparation of the review file and written arguments.

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's documents and brief.* Within 30 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification or to take adverse action regarding withdrawal of approval of the accreditation body is incorrect (appellant's brief).

(b) *Respondent's documents and brief.* Within 30 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification, or approval as an accreditation body, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension, proposed revocation, or adverse action (respondent's brief).

(c) *Reply briefs.* Within 10 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive documentation.* The reviewing official may take any appropriate steps to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

(f) *Discovery.* The use of interrogatories, depositions, and other forms of discovery shall not be allowed.

§ 8.27 Opportunity for oral presentation.

(a) *Electing oral presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decisionmaking process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at the presiding official's discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and place of oral presentation.* The presiding official will attempt to schedule the oral presentation within 45 days of the date appellant's request for review is received or within 15 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the oral presentation.*—(1) General. The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more HHS officers or employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral

presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) Burden of proof/standard of proof. In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend, propose revocation, or take adverse action is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is incorrect.

(3) Admission of evidence. The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the pre-hearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) Motions. The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) Transcripts. The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of justice or making of false statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1001 or 1505.

(g) *Post-hearing procedures.* At the presiding official's discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

§ 8.28 Expedited procedures for review of immediate suspension.

(a) *Applicability.* When the Secretary notifies a treatment program in writing that its certification has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 10 days of the date the OTP received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is incorrect, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing official's response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review file and briefs.* Within 10 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official in accordance with § 8.27(a), the presiding official will attempt to schedule the oral presentation within 20 to 30 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with § 8.27(c) and will conduct the oral presentation in accordance with the procedures of §§ 8.27(e), (f), and (g).

(e) *Written decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7 to 10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in § 8.33 apply.

(f) *Transmission of written communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be sent by facsimile transmission, personal service, or commercial overnight delivery service.

§ 8.29 Ex parte communications.

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

§ 8.30 Transmission of written communications by reviewing official and calculation of deadlines.

(a) *Timely review.* Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile transmission, personal service, or commercial overnight delivery service, or certified mail, return receipt requested, in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) *Due date.* In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

§ 8.31 Authority and responsibilities of the reviewing official.

In addition to any other authority specified in this subpart C, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of the procedures in this subpart.

§ 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

§ 8.33 Written decision.

(a) *Issuance of decision.* The reviewing official shall issue a written decision upholding or denying the suspension, proposed revocation, or adverse action. The decision will set forth the reasons for the decision and describe the basis for that decision in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision.* The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public notice and communications to the Drug Enforcement Administration (DEA).* (1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. SAMHSA will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**. SAMHSA will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

§ 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under § 8.28(e) or § 8.33(a), constitutes final agency action as of the date of the decision.

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