DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 291

Public Health Service

42 CFR Part 8

[Docket No. 98N–0617]

RIN 0910–AA52

Narcotic Drugs in Maintenance and Detoxification Treatment of Narcotic Dependence; Repeal of Current Regulations and Proposal to Adopt New Regulations

AGENCIES: Food and Drug Administration and Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Secretary of the Department of Health and Human Services (the Secretary) (DHHS) is proposing to revise the conditions for the use of narcotic drugs in maintenance and detoxification treatment of opioid addiction. The proposal includes the repeal of the existing narcotic treatment regulations enforced by the Food and Drug Administration (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 the Substance Abuse and Mental Health Services Administration (SAMHSA). This proposal follows a study by the Institute of Medicine (IOM) and reflects recommendations by the IOM and several other entities to improve narcotic addict treatment by allowing for increased clinical judgment in treatment. The proposal is also part of DHHS's Reinvention of Government review (Ref. 1).

DATES: Submit written comments on this proposal by November 19, 1999. Submit written comments on the information collection provisions by August 23, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Desk Officer for SAMHSA.

FOR FURTHER INFORMATION CONTACT:

Primary Contact: Nicholas Reuter, Center for Substance Abuse Treatment (CSAT), SAMHSA, Rockwall II, 5515 Security Lane, Rockville, MD 20857, 301–443–0457, or

Ellsworth Dory, Center for Drug Evaluation and Research (HFD–342), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7264.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Background
III. Summary of Proposed Rule
IV. Federal Opioid Treatment Standards
V. Legal Authority
VI. Proposed Implementation Plan
VII. Environmental Impact
VIII. Analysis of Impacts
IX. Paperwork Reduction Act of 1995
X. Request for Comments
XI. References

I. Introduction

The use of therapeutic narcotic drugs in the treatment of narcotic addiction has been the subject of a unique system of Federal regulation for nearly 30 years. As described as follows, one component of that system has been the enforcement by FDA of ''process oriented regulations'' governing the operation of ''narcotic treatment programs.'' These regulations reflect the fact that narcotic addiction is an illness with medical and societal origins, the treatment of which must include careful professional oversight and the availability of specialized support services. The regulatory system enforced by FDA also reflects the risks of abuse and diversion that are endemic to opioid agonist therapy (Ref. 2).

The current regulations and the system for enforcing those regulations emerged at a time when narcotic maintenance treatment experience was limited and abuses among practitioners providing narcotic drug products, including methadone, to narcotic addicts were not uncommon. In addition, there was considerable diversion of methadone. Thus, the intent of the current system was to help ensure quality treatment and reduce the risks of diversion while permitting further study of the relatively unfamiliar methadone maintenance treatment modality.

Additional study and experience has demonstrated the value of narcotic maintenance therapy in reducing drug abuse, criminal behavior, and infectious disease transmission. However, the narcotic addict patient population, and the health-care system in general, have changed dramatically since the inception of the current regulations. Despite several retrospective reviews and prospective evaluations, the system has remained essentially unchanged.

For example, compliance with the current system still depends upon inspections conducted by either FDA or State inspectors, rather than by expert accrediting teams (as is typical in many other areas of health care). Second, the regulations themselves have been criticized for imposing detailed requirements on program physicians and support personnel in a manner that has been said to stifle clinical judgment, to the detriment of the patient population. Several aspects of the current regulations also appear to reflect scientific views on opioid addiction that may be considered outdated. For example, the current regulations do not address phases of treatment, with more intense and focused treatment provided to patients at earlier stages. In addition, the current regulations emphasize the suppression of abstinence symptoms in determining appropriate dosing but do not integrate newer concepts such as ''blockade'' in determining adequate dosing.

Third, the current regulations have been criticized as being overly ''process oriented'' in that they establish administrative requirements for programs but ignore the need for ''effectiveness standards'' (Ref. 3). It has been said that under the current system, process takes precedence over performance and that a reemphasis on clinical outcomes and controls would greatly improve the effectiveness of treatment (Ref. 4).

This proposal would repeal the existing regulatory system and substitute in its place an accreditation-based system that allows for greater administrative flexibility, fewer constraints on clinical judgment, and even more focus on the needs of patients. Among other things, the new system would increase significantly the direct participation of the medical community in the oversight of addiction treatment. Moreover, individual programs will have increased flexibility to design treatments for specific patients and communities. This is expected to increase patient compliance and adherence to therapeutic regimens which, in turn, will increase the likelihood of successful outcomes.

Part and parcel with the proposed new regulatory approach will be a shift in administrative and oversight responsibilities. FDA will refocus its efforts on assuring the safety and effectiveness of new treatment modalities and will relinquish day-to-

day oversight of the treatment programs. SAMHSA will take full responsibility for carrying out the new system on behalf of the Secretary. The transfer of authority to SAMHSA, whose mission includes the goal of improving access to high quality programs for the treatment of addictive and mental disorders, reflects in part the evolution of methadone treatment from an emerging new drug therapy to a widely accepted and well understood treatment modality.

II. Background

A. Statutory and Regulatory Developments

The current system by which FDA regulates and monitors the use of narcotic drugs in the treatment of narcotic addiction began in 1970 with passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (the CDAPCA) (Pub. L. 91–513). Prior to the CDAPCA, FDA's control over therapeutic narcotic drugs such as methadone, in the treatment of addiction, was based on FDA's regulation of new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355).

Section 4 of Title I of the CDAPCA directed the Secretary to determine, after consultation with the Attorney General and national organizations, the appropriate methods of professional practice in the medical treatment of narcotic addiction of various classes of narcotic addicts (see 42 U.S.C. 257a). The primary intent of the legislation was to reduce ''uncertainty as to the extent to which [physicians] may prescribe narcotic drugs for addiction patients'' (Ref. 5). The legislation also consolidated existing Federal drug control statutes into the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act.

In 1972, FDA issued its narcotic treatment regulations based in part on the new drug provisions of the act and the CDAPCA. These regulations provided for a closed distribution system for the treatment of narcotic addiction, detailed procedures for approval of treatment programs, medical treatment standards, and procedures for revoking approval for failure to comply with the standards.

In 1974, Congress enacted the Narcotic Addict Treatment Act (the NATA) (Pub. L. 93–281) to establish the basis for increased control of narcotic addict treatment programs by the Attorney General and the Secretary. The NATA ensured that only confirmed narcotic addicts would be admitted to maintenance or detoxification treatment, that they would receive quality care, and that illicit diversions would be limited. Under the NATA, which amended the CSA (21 U.S.C. 801 *et seq.*), practitioners who dispense narcotic drugs in the treatment of narcotic-dependent persons must obtain an annual registration from the Attorney General. This authority has been delegated to the Drug Enforcement Administration (DEA). To be registered, practitioners must comply with the requirements established by DEA for secure drug storage, recordkeeping, and unsupervised use; practitioners must be qualified under the treatment standards established by the Secretary; and practitioners must comply with standards established by the Secretary regarding quantities of narcotic drugs for unsupervised ''take-home'' use by persons undergoing treatment (21 U.S.C. 823(g)).

In 1980, FDA and the National Institute on Drug Abuse (NIDA) jointly issued a final rule (45 FR 62694, September 19, 1980) amending FDA's narcotic treatment regulations to make them consistent with the requirements of the CSA, as amended by the NATA, and with implementing regulations issued by DEA. The amended regulations, codified at § 291.505 (21 CFR 291.505), have provided the Secretary's regulatory standards for the use of narcotic drugs in treating narcotic addiction.

The requirements of § 291.505 have represented the minimum standards for the appropriate methods of professional practice in the medical treatment of narcotic addiction with narcotic drugs such as methadone. Under the regulations, FDA approves new programs, periodically inspects existing programs, and may revoke approval of a program's application if the program fails to abide by all of the requirements set forth in § 291.505, or fails to monitor the activities of those employed in the program.

New legislation enacted in 1992 restructured much of DHHS's drug abuse services and research responsibilities. Under the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) Reorganization Act (Pub. L. 102–321), ADAMHA was restructured to transfer its substance abuse and mental health research institutes, including NIDA, to the National Institutes of Health (NIH), with SAMHSA established to support and administer programs relating to substance abuse and mental health prevention and treatment services. Part of SAMHSA's mission is to improve the provision of substance abuse treatment and ''coordinate Federal policy with respect to the provision of treatment services for substance abuse utilizing anti-addiction medications, including methadone'' (42 U.S.C. 290aa(d)(7)). Within SAMHSA, the Center for Substance Abuse Treatment (CSAT) has developed and issued comprehensive Treatment Improvement Protocols (TIPS) and Technical Assistance Publications (TAPS), including the publication entitled ''Approval and Monitoring of Narcotic Treatment Programs: A Guide on the Roles of Federal and State Agencies and State Methadone Treatment Guidelines.'' CSAT has also developed guidelines on phases of treatment and guidelines on the dosing of Levo-*Alpha*-Acetyl-Methadol (LAAM), another approved opioid agonist treatment medication.

In 1993, FDA and SAMHSA revised the methadone regulations to set forth conditions for authorizing ''interim methadone maintenance.'' The change, which implemented provisions of the ADAMHA Reorganization Act, authorizes public and nonprofit private narcotic treatment programs to provide interim maintenance treatment to patients awaiting placement in comprehensive maintenance treatment. In addition, the 1993 rule required all narcotic treatment programs to provide counseling on preventing exposure to, and preventing the transmission of, human immunodeficiency virus (HIV) disease (58 FR 495, January 6, 1993). Finally, the regulations were revised again in 1993 to establish standards for the use of LAAM in the maintenance treatment of narcotic addicts (58 FR 38704, July 20, 1993).

B. Current Oversight

FDA has enforced the existing narcotic treatment regulations (part 291 (21 CFR part 291)) by approving programs, monitoring programs through periodic inspections, and pursuing various means of obtaining compliance, including enforcement actions and proposals to revoke program approval. Approximately 900 treatment programs are approved under the regulations. The number of approved programs has not changed significantly over the years.

Periodic compliance inspections are carried out by FDA personnel, who generally have no specialized expertise in drug abuse treatment, or by State officials under contract with FDA. These inspections are primarily documentation audits, with an emphasis on appropriate recordkeeping and control of take-home doses. FDA inspectors typically focus their review on a sample of patient records to determine whether the program has

complied with the regulations. If an inspection results in observations of possible violations, FDA has several options for bringing the program into compliance, ranging from informal meetings with the program to warning letters to proposals to revoke the program's operating approval.

The frequency with which FDA conducts routine inspections has been steadily decreasing as FDA continues to focus on its other core priorities.

C. Evaluations of the Current System

While both the patient population and the health risks associated with illicit narcotic drug abuse have changed substantially over the last 30 years, the Federal regulatory framework governing the treatment of narcotic addiction has remained relatively unchanged. Coordination among several Federal agencies through the Interagency Narcotic Treatment Policy Review Board (Ref. 6) (INTPRB) has brought about modest changes to the existing regulations. The INTPRB helped coordinate the introduction of interim methadone maintenance and led several changes that allowed increased flexibility with regard to issues such as counselor-to-patient ratios and certain reporting requirements (Ref. 7). Nevertheless, the system that remains in place today largely remains unchanged from the original regulatory system.

The existing system, for example, has been roundly criticized for its rigidity and for the constraints it imposes on clinical judgment. As an expert agency-based panel noted:

> Some regulations, although intended to foster quality care, are based on the premise that a patient's behavior can be adequately controlled through rules. This idea often conflicts with the clinician's need to establish a therapeutic alliance and conflicts with most treatment professionals' understanding that one person is fundamentally powerless to control the drug use of another (Ref. 8).

Many in the field have also expressed concern about the future of methadone maintenance treatment under managed care (Ref. 9). Since the inception of the existing regulations, the health-care system has been evolving to a managed care environment that relies on quality assurance assessments and outcome measurements, with careful matching of patient needs to particular treatment. In such an environment, the enforcement of process oriented regulations has been criticized as having ''inhibited the development of patient-matching strategies [and] diverted attention from more clinically focused approaches, such as matching strategies and treatment guidelines'' (Ref. 10).

Others have criticized the current enforcement process to the extent that ''[m]onitoring compliance by a regulatory agency is by definition adversarial,'' and that inspectors are trained to find violations and not to ''provide technical assistance'' (Ref. 11). Even the very need for the current regulations has been questioned, with one commentator noting:

> The authorities provided to DEA by the NATA and the 1984 CSA amendments [which provided DEA with ''public interest'' revocation authority] themselves are sufficient to prevent the excesses, which occurred during the late 1960's, of an unregulated narcotic addiction treatment system. Thus, program registration by both the FDA and the DEA is duplicative, costly, and unnecessary (Ref. 12).

These types of concerns prompted several noteworthy assessments of the existing system, including reports by the General Accounting Office (GAO) and the IOM, and a thorough assessment of these reports and other relevant data by an interagency-work group.

1. The 1990 GAO Report

In 1990, the GAO issued a lengthy report, based on its review of 24 narcotic treatment programs, analyzing the effectiveness of the existing narcotic treatment regulations. The report focused on: (1) The extent of drug use by patients in methadone maintenance treatment programs; (2) the goals, objectives, and approaches of the treatment programs; and (3) the types of services available to patients in treatment.

The report noted a wide disparity in the quality of treatment provided among the 24 narcotic treatment programs reviewed. The GAO found that:

> * * * policies, goals, and practices varied greatly among the 24 methadone maintenance treatment programs. None of the 24 programs evaluated the effectiveness of their treatment. There are no federal treatment effectiveness standards for treatment programs. Instead, federal regulations are process oriented in that they establish administrative requirements for programs. Even with regard to these requirements, federal oversight of methadone maintenance treatment programs has been very limited since 1982 (Ref. 13).

Based on these findings, the GAO recommended that the Secretary direct FDA or NIDA, as appropriate, to: (1) Develop result-oriented performance standards for methadone maintenance treatment programs, (2) provide guidance to treatment programs regarding the type of data that must be collected to permit assessment of programs' performance, and (3) assure increased program oversight oriented toward performance standards.

In response to the GAO report, NIDA initiated the methadone treatment quality assurance system (MTQAS). The goal of the MTQAS was to develop outcome measures to compare the performance of methadone maintenance treatment programs. In 1993, NIDA developed a survey form with outcome variables adjusted for variations in case mix. For example, NIDA used retention in treatment and patient drug abuse as outcome variables for comparing the performance of individual treatment programs. Initial results from pilot tests of this system showed that performance measures, such as retention in treatment and decreased drug abuse, could in fact differentiate the quality and effectiveness of treatment.

The GAO report and the new information from MTQAS prompted the Public Health Service (PHS) to fund a comprehensive study on the Federal regulation of methadone treatment by the IOM.

2. The 1993 IOM Study

In 1993, NIDA, SAMHSA, and the Office of the Assistant Secretary for Health funded a 2-year IOM study of the current regulations, including enforcement issues, quality of treatment, and diversion.

In a report issued in 1995, the IOM concluded that the current regulations have little effect on the quality of treatment provided in clinics (Ref. 14). In particular, the report emphasized the need to balance process oriented regulations with clinical practice guidelines and quality assurance systems. The IOM found that ''enforceable federal standards'' are needed, not for medical reasons, but to prevent substandard or unethical practices, and to maintain community support. It recommended, therefore, that the regulations be reduced in scope to be less intrusive and to allow more clinical judgment in treatment. Clinical practice guidelines, according to the IOM, would ensure that clinical discretion is exercised in a ''sound manner.''

The IOM report also addressed the current system of enforcing the regulations, noting costly overlap among multiple Federal, State, and sometimes local inspections. As a result, the IOM recommended ''reducing the scope of administrative control by FDA and other DHHS agencies'' (Ref. 15). This reduction in scope of administrative control would follow the IOM's recommendation that:

> FDA, with SAMHSA and NIDA, conduct an extensive review of methadone enforcement policies, procedures, and practices by all health agencies of

government - federal, state, and local - for the purpose of designing a single inspection format, having multiple elements, that would provide for (1) consolidated, comprehensive inspections conducted by one agency (under a delegation of federal authority, if necessary), which serves all agencies and (2) improve the efficiency of the provision of methadone services by reducing the number of inspections and consolidating their purposes (Ref. 16).

Moreover, the IOM recommended that ''DHHS conduct a review of its priorities in substance abuse treatment, including methadone treatment, in a way that integrates changes in regulations and the development of practice guidelines with decisions about treatment financing.'' Finally, the IOM recommended that policy leadership on drug abuse treatment should be elevated to the Office of the Assistant Secretary for Health (Ref. 17).

3. The Interagency Narcotic Treatment Policy Review Board

In response to these recommendations, the Assistant Secretary for Health requested that the Interagency Narcotic Treatment Policy Review Board (INTPRB), which had been formed in the early 1970's to coordinate Federal policy regarding the use of methadone, evaluate the IOM's findings and recommendations. Membership on the INTPRB included representatives from FDA, NIDA, SAMHSA (including CSAT), the Office of the Secretary, the DEA, the Department of Veterans Affairs (VA), and the Office of National Drug Control Policy (ONDCP). Representatives from two other DHHS agencies, the Agency for Health Care Policy and Research and the Health Care Financing Administration (HCFA), were also included at various times.

After careful consideration of the IOM's work and all that preceded, the INTPRB concluded that a regulatory system centered around a core set of Federal treatment standards, in conjunction with monitoring of treatment programs through private accreditation, would be both feasible and preferable to the existing system.

First, the INTPRB reasoned that an accreditation-based system would be more consistent with the oversight approach in most other health-care fields. For example, HCFA relies on accreditation to certify approximately 7,000 hospitals that provide services to Medicare patients. In addition, under the Clinical Laboratory Improvement Act of 1988 (CLIA), private accreditation is now used as the primary basis for certifying human clinical laboratories.

Moreover, a number of narcotic treatment programs are already subject to accreditation standards and inspections. As noted in the IOM report, approximately 5 percent of the methadone maintenance patients in the United States are treated in facilities under the VA medical system (Ref. 18), all of which are subject to outside accreditation.

In addition, the INTPRB found that interest in accreditation is increasing steadily, due at least in part to its emphasis on self assessment and improvement, and on the integration of quality assurance and performance elements developed by expert accreditation organizations. The expanded use of accreditation, particularly in the substance abuse field, is reflected in the number of national accreditation bodies with standards for substance abuse treatment. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and two other national accreditation bodies, the Commission on Accreditation of Rehabilitation Facilities (CARF) and the Council on Accreditation of Services for Families and Children, Inc. (COA), have significant experience in accrediting substance abuse treatment programs. CARF conducts approximately 1,000 surveys each year (Ref. 19) and more than 100 entities, including the Federal government, have accepted accreditation by CARF. COA accredits approximately 1,000 behavioral health-care programs and 3,000 social service programs annually (Ref. 20). CARF, COA, and JCAHO all have developed or expressed an interest in developing methadone treatment accreditation standards.

The INTPRB also concluded that an accreditation-based system would improve the quality of treatment by increasing the participation of the treatment community in establishing measures for determining the effectiveness and overall success of treatment programs. Some have attributed problems in the methadone treatment area to the absence of the medical profession's participation in determining the standards of care in this area (Ref. 21). Professional accreditation bodies are expected to be able to focus closely on those aspects of treatment that, if maintained at appropriate levels, will show a measurable improvement in treatment outcomes and a measurable improvement in the overall quality of the medical care. Also, because of its widespread use in health care, an accreditation-based regulatory system may also help to mainstream the medical treatment of narcotic dependence.

The INTPRB also reasoned that accreditation could significantly improve program performance, especially at poorly functioning programs, by providing much-needed advisory services that generally have been lacking under the existing system.

Importantly, the INTPRB noted that an accreditation-based system provides an opportunity to reduce the layers of inspections from Federal, State, and local regulatory entities. State authorities may choose to apply to act as accreditation bodies for programs in their jurisdiction and, if approved, would consolidate inspections and minimize burdens. Alternatively, State authorities could adopt accreditation body findings. At least one State, Ohio, accepts as documentation of a program's compliance with State standards a program's accreditation by any of the leading private accreditation bodies (Ref. 22).

Overall, the INTPRB concluded that fewer resources would be expended at the Federal level. While there would be costs to the government in monitoring accreditation bodies, assuring that accreditation body elements are appropriate, and reviewing and approving guidelines, the overall cost should be less than that of the present system. Treatment programs would be expected to absorb modest accreditation fees, but treatment quality would be greatly improved by being more closely matched to patient needs.

In addition, accreditation holds out the prospect for more efficient treatment which, in time, would allow for more treatment at a lower cost to payers. Indeed, with its similarity to HCFA's oversight of Medicare and Medicaid programs, the accreditation-based regulatory system provides the potential for a model system that unifies ''financing, treatment, and the regulation of services'' as envisioned by the IOM and others:

Service providers have demanded that accrediting and regulatory bodies conduct their reviews jointly and/or at least accept all or part of each other's standards, reviews and reports as equivalent. It is a hopeful sign that in at least 23 states, the surveys of the JCAHO and of state health departments are being conducted jointly, and 17 others are considering such arrangements. These collaborations have been commended by the General Accounting Office of the U.S. Congress, as cost-containing efforts that successfully reduce some of the duplication of preparation and the overuse of scarce resources, which could better be used toward the improvement of quality of care (Ref. 70).

The INTPRB in April 1995 forwarded its recommendations to the Assistant Secretary for Health who, thereafter, solicited views from all Federal agencies with a substantial interest in therapeutic and controlled substances. After

receiving and evaluating endorsements from other agencies, the Assistant Secretary for Health concluded that DHHS should take all necessary steps to phase out the existing regulatory approach and adopt in its place an accreditation-based system centered around a limited set of core Federal treatment standards.

In September 1995, the Assistant Secretary for Health assigned to SAMHSA responsibility for developing the new regulatory approach. Subsequently, an interagency workgroup of the INTPRB, with representatives from DHHS (including SAMHSA, FDA, and NIDA), DEA, VA, and ONDCP, was formed to develop the new system, including the development of this proposed rule.

4. NIH Consensus Development Conference

On November 17 to 19, 1997, NIDA, the NIH Office of Medical Applications Research, and the NIH Office of Research on Women's Health sponsored a consensus development conference on the effective medical treatment of heroin addiction. NIH convened this conference to present the available data on opioid agonist treatment for heroin addiction in order to address the most important and controversial issues surrounding narcotic maintenance treatment. The independent panel concluded that opioid addiction is a medical disorder and that pharmacologic agents, such as methadone and LAAM, are effective in its treatment. The panel also addressed barriers to such treatment, including the existing regulations:

> However well-intentioned the FDA's treatment regulations when written in 1972, they are no longer necessary. We recommend that these regulations be eliminated. Alternative means, such as accreditation, for improving the quality of [opioid treatment] should be instituted (Ref. 23).

5. State Licensure and Accreditation Activities

Many States have adopted requirements that are more rigorous than the FDA standards alone. These requirements most often are imposed through licensure or funding authorities. Licensure in these States often involves a costly annual inspection program. However, the degree of oversight varies enormously across and within States. For example, many States require at least annual State licensure reviews. Of these, only one State has regulations that do not include more stringent compliance requirements than the FDA standards alone. Other States, beyond initial opening requirements, rely almost exclusively on FDA and DEA oversight of methadone programs for assuring continued compliance with those standards and regulations.

FDA's model allows for more intense oversight by States, but does not require it. Thus, many of the same problems that have been identified at the Federal level have not necessarily been corrected at the State level unless specifically addressed by a given State. To raise the standard of care consistently throughout the country, standards issued and/or required at the Federal level will have to rise. Standards on which accreditation is based are generally viewed as the highest standards of care.

At least one State, Michigan, has both a licensing and an accreditation requirement. Michigan requires opioid treatment programs (OTP's) to be accredited as a condition of receiving Medicaid and block grant funds. DHHS understands that a number of private payers in Michigan also require methadone programs to be accredited in order to receive payment for services. Payers in Michigan appear to have decided that opioid treatment should be held to the standards to which health-care providers are held, and payers in Michigan generally require hospitals and clinics to be accredited as a condition of participation. In fact, a large number of private payers throughout the nation as a whole require accreditation as a means to insure that the health care meets standards of quality and appropriateness. Based on discussion with officials in Michigan, the move to accreditation for substance abuse programs has raised standards of care. Almost all OTP's in Michigan have been accredited under this system, and it has been noted that almost all of these OTP's increased the number of patients in treatment after receiving accreditation.

6. Conclusion

This notice of proposed rulemaking (NPRM) addresses the problems and potential of opioid agonist treatment which so far in the United States has been limited to methadone and LAAM treatment. The NPRM is consistent with national policy and direction regarding the role of methadone and LAAM and other opioid agonist treatments in reducing opiate addiction. Indeed, the Office of National Drug Control Policy (ONDCP), in its ''Policy Paper—Opioid Agonist Treatment,'' highlights this proposed accreditation-based regulatory system as a key element in improving the quality of methadone treatment and expanding treatment capacity (see appendix 1). The ONDCP Policy Paper notes that in addition to a shortfall in treatment capacity, problems in the opioid agonist treatment system have long existed at two levels: (1) OTP's have not functioned with uniform high quality; and (2) Federal oversight, grounded in process-focused regulations, has not served to improve or maintain the quality of OTP's. To reduce the use of heroin and illicit opioid drugs, both of these problems must be addressed.

Methadone, the most effective treatment for chronic opioid addiction, has been used for the treatment of heroin addiction since the 1960's. It is an effective, long-acting, synthetic opioid agonist that is taken orally. Methadone blocks the craving and produces tolerance to its own analgesic effects and psychoactive effects. When used properly, at adequate doses, it also produces a physiological cross-tolerance to other opioids, rendering the patient unable to experience pharmacologic pleasure from the administration of practical doses of other opioids. Treatment with methadone requires daily dosing; LAAM blocks the effects of injected heroin for up to 3 days.

This NPRM introduces a model accreditation system for OTP's, with transfer of regulatory oversight from FDA to SAMHSA. The current, process-oriented regulatory approach, with routine inspections by HHS (FDA) staff, will be replaced by a clinically-based accreditation system, with additional oversight from SAMHSA.

D. Long Term Goals and Interim Steps

The long-term goals of this initiative are to make Federal oversight more effective, reduce the variability in the quality of opioid treatment services, and reform the treatment system to provide for expanded treatment capacity. This requires a comprehensive set of reforms including, but not limited to, the changes proposed in this document.

By incorporating accreditation into the oversight model as proposed, DHHS will be better able to identify and assist poorly functioning programs. Accreditation reviews will be conducted every 3 years by experts in the field of substance abuse treatment. Oversight will be more effective because medical experts, including addiction treatment specialists, will be conducting the onsite reviews. In addition, the onsite reviews will include a focus on treatment outcomes rather than simply measuring adherence to process-oriented standards. Importantly, the shift to an accreditation model will result in a treatment system more responsive and accountable to the

public's desire to see improvement in outcomes of addiction care.

Elsewhere in this proposed rule, DHHS describes a transition plan that sets forth a timetable for moving from the existing purely regulatory system to the accreditation-based system. In addition, DHHS has taken several key steps to ensure that the eventual implementation of an accreditation-based system will be accomplished in the least disruptive manner possible. CSAT has awarded a contract to CARF in 1997 and JCAHO in 1998 for development of accreditation guidelines and to conduct accreditation surveys of a cohort of treatment programs. Technical assistance will be provided to assist programs in preparing for and working with these accreditation guidelines.

The impact of accreditation on these programs will be studied over time and the findings used to help improve the accreditation approach. SAMHSA's CSAT has developed a project to study the impacts of accreditation using both existing standards and newly developed, methadone/LAAM specific standards, in a cohort of OTP's. This assessment will also help familiarize existing treatment programs with the accreditation process as it becomes the new standard. Finally, the study will allow for the phasing in of accreditation by providing administrative feedback that can be used to adjust the implementation of accreditation in such a manner as to minimize any potential disruptive effects. The Secretary believes that this study will demonstrate that programs will be able to achieve accreditation with minimal disruption to treatment capacity.

III. Summary of Proposed Rule

The Secretary is proposing to add new part 8 under title 42 of the Code of Federal Regulations to codify the new accreditation-based system. The proposal also includes the repeal of the existing FDA-enforced narcotic treatment regulations at 21 CFR part 291, which would go into effect when the new regulations are finalized and effective. The Secretary will delegate to SAMHSA the authority to oversee the new program proposed under 42 CFR part 8.

The proposed regulations establish the procedures by which the Secretary will determine whether a practitioner is qualified under section 303(g) of the CSA (21 U.S.C. 823(g)(1)) to dispense certain therapeutic narcotic drugs in the treatment of individuals suffering from narcotic addiction. These regulations also establish the Secretary's standards regarding the appropriate quantities of narcotic drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(3)). (See also 42 U.S.C. 257a.)

Under the proposed regulations, a practitioner who intends to dispense narcotic drugs in the treatment of addiction must first obtain from the Secretary or her delegated authority, 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 narcotic treatment programs.

The proposed new regulations are divided into three parts, subpart A, subpart B, and subpart C. Subpart A addresses accreditation that includes, at proposed § 8.3, the sequence of events that accreditation bodies will follow to achieve approval to accredit OTP's under the new system. It also establishes in proposed § 8.4 the accreditation bodies' responsibilities, including the use of accreditation elements during accreditation surveys. Subpart B of part 8 sets forth the sequence and requirement for obtaining certification. This section addresses how and when programs must apply for initial certification and renewal of their certification. DHHS's opioid treatment standards are included in this section and are segregated for a separate detailed discussion because of their importance. Subpart C of part 8 establishes the procedures for review of either withdrawal of approval of the accreditation body or the suspension or proposed revocation of an OTP certification. This section addresses procedural and informational requirements in the event of a challenge to a SAMHSA determination.

A. Subpart A—Accreditation

Subpart A of part 8 would establish the procedures whereby an entity can apply to SAMHSA to become an approved accreditation body. This part also establishes ''accreditation body responsibilities'' and general standards for accreditation bodies to ensure that practitioners are consistently evaluated for compliance with the Secretary's standards for opioid treatment.

1. Definitions and Related Requirements

Section 8.2 in subpart A defines a number of key terms for purposes of applying 42 CFR part 8. Most of these proposed definitions are identical or similar to those set forth under the existing regulations at § 291.505(a). Several, however, are unique to the new accreditation-based system and require brief mention.

For example, the Secretary is proposing to define the term ''accreditation body'' to mean a body that has been approved by SAMHSA under proposed § 8.3 to accredit OTP's. Under proposed § 8.3(a), private nonprofit organizations as well as State governmental entities, including a political subdivision of a State (such as a county) may apply to serve as an accreditation body. The Secretary believes that allowing States to serve as accreditation bodies may also help expedite the transition of previously approved programs to the new system.

It should be noted, however, that the Secretary is proposing in § 8.3 to limit eligibility to those applicants (including States and political subdivisions of a State) who demonstrate that they will be able to accredit at least 50 OTP's per year. The Secretary believes that this requirement is needed to ensure the quality of the accreditation services performed by accreditation bodies and to minimize the variability in the standards used by accrediting organizations. The Secretary is interested in comments on this restriction and may revisit this requirement after the first 3 years.

Under the proposal, prospective accreditation bodies will be required to develop and submit as part of an application for approval, ''accreditation elements''. These elements, which are defined in proposed § 8.2, are the elements that the accreditation body will apply during ''accreditation surveys'' as the basis or benchmark for determining whether a treatment program should receive accreditation. The accreditation elements are expected at a minimum to incorporate the ''Federal opioid treatment standards'' issued by the Secretary in proposed § 8.12, albeit with much greater detail. One focus of SAMHSA's oversight of the accreditation system will be the development and publication of up-to-date treatment guidelines to assist accreditation bodies in developing accreditation elements. It is also expected that an essential part of the accreditation elements will be clinical outcome and performance measures. Again, SAMHSA expects to issue detailed guidance on the development of such measures.

As mentioned previously, accreditation bodies will base their accreditation decisions on experience gained during onsite ''surveys,'' as defined in proposed § 8.2. The accreditation body's policies and procedures for conducting surveys will

be a major focus of the application process under proposed § 8.3. The Secretary expects these accreditation body surveys to, in large measure, take the place of onsite inspections by DHHS investigators as the primary means of monitoring the operations of OTP's. Nevertheless, it is important to note that the Secretary has retained the right to conduct inspections of programs, including ''for-cause inspections,'' as defined in proposed § 8.2. A ''certified opioid treatment program,'' as defined in proposed § 8.2(i), is an organization that administers or dispenses ''opioid agonist treatment medications'' (see proposed § 8.2(t)) for maintenance or detoxification treatment of opioid addiction, and that is the subject of a current certification issued by SAMHSA under proposed § 8.11. As discussed below, to obtain certification from SAMHSA, under proposed § 8.11, a treatment program must, at a minimum, ''be the subject of a current, valid accreditation by an accreditation body approved by SAMHSA * * *.'' Certification will be granted for a period not to exceed 3 years and will serve as the final determination by the Secretary that the program is ''qualified,'' as that term is used under section 303(g) of the CSA (21 U.S.C. 823(g)).

It is important to note that the proposed definition of a ''certified opioid treatment program'' includes individual practitioners, such as private physicians. Although the term ''practitioners'' was used in the NATA, historically there have been few individual practitioners who have applied to dispense methadone or LAAM under the existing regulations. The Secretary is aware, however, that there is considerable interest in the issue of physicians in private or group practices providing opioid treatment outside the traditional OTP setting.

The intent of this proposal is to develop a process for certifying qualified providers to dispense opioid drugs in the treatment of opioid addiction. Ideally, the proposed process would be sufficiently flexible to allow individual practitioners themselves to provide such services. Admittedly, the proposed Federal opioid treatment standards in some instances may not be well suited to office-based treatment. The Secretary therefore is specifically seeking comment 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 proposal also retains the concept of ''medication units,'' as defined in proposed § 8.2(s). A ''medication unit'' is a facility established as part of, but geographically dispersed from, the central location of an OTP. Licensed private practitioners and community pharmacists are permitted to administer and dispense opioid drugs from medication units without seeking a separate accreditation or a separate certification from SAMHSA. (Medication units, however, may require separate registration from DEA under section 303(g) of the CSA and 21 CFR part 1300.) These units are also authorized to collect samples for drug testing or analysis for narcotic drugs. Medication units can serve to decrease the burden of patients who must travel considerable distances to obtain medication. SAMHSA must be notified before a medication unit can begin to provide opioid treatment medications to patients.

Finally, the Secretary has proposed as a definition of the term ''opioid addiction,'' in proposed § 8.2(u), a condition in which an individual exhibits a compulsive craving for, or compulsively uses, opioid drugs despite being harmed or causing harm as a result of such craving or use. This definition reflects the idea that an individual suffering from opioid addiction may not exhibit concurrent physical dependence on opioids, as evidenced by the onset of signs of withdrawal upon administration of an opioid antagonist or following the last dose of an opioid drug.

2. Accreditation Body Approval and Related Requirements

Proposed § 8.3 outlines the process for applying to SAMHSA to become an approved accreditation body. The initial accreditation application shall include the name, address, and telephone number of the applicant and a responsible official for the application signed by the responsible official. The application also requires evidence of the nonprofit status of the applicant if the applicant is not a State governmental entity or political subdivision. The application must also include evidence that the applicant will be able to survey no less than 50 OTP's annually.

This section also requires that the application include a set of accreditation elements and a detailed discussion showing how the elements 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 proposed § 8.12. An accreditation body must also include a detailed description of its decisionmaking process. The process shall include procedures for initiating and performing onsite accreditation surveys of OTP's and the procedures for assessing OTP personnel qualifications.

The accreditation body must submit copies of the application used for accreditation, along with guidelines, instructions, and other materials to be sent to OTP's during the accreditation process. This includes a request for a complete history of prior accreditation activities and a statement that all information and data submitted in the application for accreditation are true and accurate, and that no material fact has been omitted. Applicant accreditation bodies must also submit the policies and procedures for notifying OTP's and SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTP's and policies and procedures for suspending or revoking an OTP's accreditation. The application shall include the policies and procedures that ensure processing of applications for accreditation and applications for renewal of accreditation within a timeframe approved by SAMHSA. Accreditation bodies must submit a description of the applicant's appeals process to allow OTP's to contest adverse accreditation decisions.

The application also must include a description of the 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. In addition, the applicant must submit a description of the education, experience, and training requirements of the applicant's professional staff, accreditation survey team membership and the identification of at least one licensed physician on the applicant's staff and a description of the applicant's training policies. The application must include fee schedules, with supporting cost data. Applicant accreditation bodies must provide satisfactory assurances that the body will comply with the requirements of proposed § 8.4, including a contingency plan for investigating complaints under proposed § 8.4(e). Finally the application must include policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body and any other information SAMHSA may require.

Proposed § 8.4 sets forth accreditation body responsibilities. Accreditation bodies will be responsible for conducting accreditation surveys and to take actions based upon the results of

these surveys. In addition, the accreditation body will have to keep certain records and submit periodic reports. Under proposed § 8.5, SAMHSA will periodically evaluate the performance of accreditation bodies by inspecting a sample of OTP's that have been surveyed by the accreditation body and determining whether there are deficiencies that would warrant the withdrawal of the approval of the accreditation body under proposed § 8.6. Proposed § 8.6 establishes the actions and procedures that SAMSHA will take if it determines that an accreditation body is not complying with the requirements in this rule. This section describes contingencies for major and minor accreditation body deficiencies, including probationary status and reinstatement. Finally, proposed § 8.6, provides an opportunity for accreditation bodies to challenge an adverse finding by requesting a hearing. Proposed §§ 8.7 through 8.10 are reserved.

These provisions were developed after consulting other Federal agencies, including the VA and the HCFA, and after reviewing existing accreditation systems. DHHS has also carefully reviewed existing certification-accreditation oversight systems, including FDA's mammography regulatory system. As such, DHHS believes that these provisions are reasonable and reflect what has become a standard approach for ensuring the quality of health-care practices. Similarly, it is customary for oversight agencies to validate the performance of accreditation bodies through periodic direct inspections of establishments that have or have not received full accreditation. DHHS believes that validation inspections are a reasonable and efficient mechanism for ensuring that approved accreditation bodies are carrying out their responsibilities.

a. Patient confidentiality. The patient records maintained by OTP's are subject to the confidentiality protections of State and Federal laws. With respect to patient confidentiality, section 543 of the PHS Act (42 U.S.C. 290dd–1) and its implementing regulations, 42 CFR part 2, are fully applicable to OTP's. OTP's are ''programs'' as defined by 42 CFR 2.11 and are ''federally-assisted'' as defined by 42 CFR 2.12(b)(2). Under these regulations, the treatment programs are prohibited from disclosing patient identifying information except in certain prescribed circumstances such as under patient consent, for purposes of research, audit or evaluation, or under a court order consistent with subpart E of 42 CFR part 2.

The regulations at 42 CFR part 2 would permit programs to disclose patient records to accreditation bodies under the audit and evaluation exception at 42 CFR 2.53. To the extent that the accreditation body needs to copy records containing patient identifying information, it must agree in writing to: (1) Maintain the patient identifying information in accordance with the security requirements provided in 42 CFR 2.16 of the regulations, (2) destroy all patient identifying information upon completion of the audit or evaluation, and (3) comply with the limitations on redisclosure of 42 CFR 2.53(d).

b. Prevention of conflicts of interest. With respect to conflicts of interest, the Secretary is proposing that accreditation bodies must submit to SAMHSA, as part of an application for approval under proposed § 8.3(b)(6), the policies and procedures maintained by the accreditation body to ensure that the body remains impartial and free of commercial, financial, and other pressures that might present an actual or apparent conflict. Although it is not possible to state categorically all of the criteria for assessing whether an accreditation body will be free of conflicts, the most common condition that would indicate a potential conflict would be one in which any member of the accreditation team (or an immediate family relative) has a financial interest of any type, direct or indirect, in the treatment program to which the team is assigned. Likewise, it may be appropriate that anyone employed by the accreditation body who is involved in any respect in the accreditation decision for a particular program must be free of a financial interest in the program. DHHS seeks comments on the types of financial conflicts that should be prohibited, or on the amount of financial interest that may be considered *de minimus* such that it would not rise to a conflict of interest. Fees charged to programs must in no way be made contingent, in whole or in part, on a particular accreditation decision or outcome.

B. Subpart B—Certification and Treatment Standards

Subpart B of part 8 proposes the process by which OTP's may obtain certification from SAMHSA, the conditions necessary for remaining certified, and the process by which SAMHSA may suspend or revoke certification. In addition, subpart B of part 8 proposes the Secretary's Federal opioid treatment standards.

1. OTP Certification

Under proposed § 8.11, treatment programs must obtain certification from SAMHSA for the program to be considered ''qualified'' by the Secretary under 21 U.S.C. 823(g). Certification will be for a term not to exceed 3 years but may be extended as necessary, with permission from SAMHSA, to accommodate accreditation cycles.

A program must obtain a current, valid accreditation from a SAMHSA approved accreditation body in order to be considered eligible for certification. Although SAMHSA expects that most programs that obtain accreditation will, as a matter of course, obtain certification, there are circumstances in which SAMHSA could deny certification to an accredited program. Under proposed § 8.11(c)(2), SAMHSA may deny certification if a program's application for certification (see proposed § 8.11(b)) is deficient in any respect; if SAMHSA independently determines that the program will not be operated in accordance with the Federal opioid treatment standards; if the program has improperly denied access to the facilities or to its records; or if it is determined that the program has in any respect made misrepresentations or omitted material facts in the course of obtaining accreditation or applying for certification. Although it is expected that a denial of certification for a program that has obtained accreditation would be a rare occurrence, the Secretary nevertheless has retained the authority to deny certification. Likewise, the Secretary has retained the authority to independently certify a program that has not obtained accreditation. Again, this authority would be used only in rare circumstances.

Proposed § 8.11(d) provides for ''transitional certification'' during the period when the former regulations at part 291 will have been repealed and the new accreditation based regulations, under 42 CFR part 8, are just beginning to be implemented. The intent of these provisions is to allow programs that were approved under the old regulations to remain in operation for a reasonable period of time so that there is sufficient time for: (1) SAMHSA to approve one or more accreditation bodies, (2) programs to apply for and obtain accreditation from one of the approved accreditation bodies, and (3) SAMHSA to make certification decisions based on the outcome of the accreditation process.

First, OTP's that have not obtained certification from SAMHSA, but are the subject of a current approval by FDA

under part 291 as of the effective date of the regulation will be granted ''transitional certification'' for a period of 90 days after the effective date of the final rule. Under the proposal, programs that are granted transitional certification must apply to SAMHSA during this 90-day period to extend their transitional certification for up to 2 years from the effective date of the regulation. To extend transitional certification, an OTP must submit the information that would be required in a new application for certification (proposed § 8.11(b)). In addition, the program must include a statement certifying that the OTP will apply for accreditation from a SAMHSA approved accrediting body within 90 days from the date SAMHSA approves the first accreditation body under proposed § 8.3. SAMHSA intends to announce the approval of accreditation bodies in the **Federal Register** and through other media. In addition, if a program has applied for accreditation but the accreditation body is unable to complete its survey prior to 2 years from the effective date of this regulation, SAMHSA may extend a program's transitional certification for up to 1-additional year.

It should be noted that the Secretary is proposing that treatment programs will be subject to the requirements of these rules upon the effective date. SAMHSA will be overseeing the regulations and will be monitoring programs during the 90-day application period as well as subsequently in accordance with the regulations. It is expected that 3 years will be sufficient time for all OTP's to become accredited, although the Secretary would expect that most programs will be accredited within 2 years.

Proposed § 8.11 also provides a mechanism to allow for ''provisional certification'' when a program is diligently pursuing accreditation. Under § 8.11(e), OTP's that have not previously obtained 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 for up to 1 year, an OTP must submit the information set out in § 8.11(b) 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.

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 must submit to SAMHSA a statement explaining the program's efforts to obtain accreditation and a schedule for obtaining accreditation as expeditiously as possible.

Proposed § 8.11 also addresses the use of opioid treatment medications in patients hospitalized or admitted to long-term care facilities for treatment of a medical condition other than opioid addiction. Under proposed § 8.11(a)(4), the Secretary will not require such facilities to seek certification in order to provide maintenance or detoxification treatment to a patient who has been admitted for medical conditions other than addiction or if the patient is already enrolled in a certified OTP and such enrollment has been verified. The terms ''hospital'' and ''long-term care facility'' are determined according to the law of the State in which the facility is located. This provision is not intended to relieve hospitals and long-term care facilities from their obligations for registration under section 303(g) of the CSA and under regulations issued by DEA (see 21 CFR 1306.07(c)).

Under DEA's regulations, DEA requires (and will continue to require) registration of such facilities if approved controlled substances are dispensed or administered from a location, such as a long-term care facility, even though the controlled substances are not stored overnight. Further, if an OTP patient is admitted to a hospital for anything other than addiction, the hospital can administer or dispense a narcotic drug to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment during the term of the stay in the hospital. However, because long-term care facilities are not considered hospitals by DEA, patients in long-term care facilities cannot currently receive methadone as an adjunct to medical or surgical treatment of conditions other than addiction unless the facility is registered with the DEA. However, if the individual was formerly a patient in an OTP, the OTP may transfer the opioid medication (i.e., methadone or LAAM) to the long-term care facility under a delivery protocol which complies with State and Federal regulations.

Section 8.11(f) proposes the general conditions of certification. First, under the proposal, OTP's must agree to comply with all applicable State laws and regulations. The Secretary, however, will not require State approval of a program as a condition precedent to obtaining certification under proposed § 8.11(c). DEA regulations will continue to require State approval before issuing a DEA registration.

As provided in the CSA, 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 that should be available. For example, under the ADAMHA Reorganization Act of 1992, the Chief Public Health Officer within a State must certify that interim methadone maintenance will not ''reduce the capacity of comprehensive programs'' within the State. In addition, some States consider the proximity of other treatment programs in deciding whether to approve a treatment program, or the number of treatment programs currently operating in the State (Refs. 25 and 26). And, at least one State limits methadone treatment to nonprofit programs (Ref. 27).

Nothing in this part is intended to restrict State governments from regulating the use of opioid drugs in the treatment of opioid addiction. Importantly, there will still be extensive cooperation between SAMHSA and relevant State authorities. However, in determining whether an OTP that is applying for certification satisfies the requirements of section 303(g) of the CSA (21 U.S.C. 823(g)), the Secretary will not require that the program first obtain approval from a relevant State authority.

Second, treatment programs must agree to allow SAMHSA, DEA officials, relevant State officials, and authorized accreditation bodies access to conduct surveys and inspections (including unannounced inspections), and full access to patient records. Failure to allow such access will be grounds for denial of certification or, in the case of a certified facility, suspension or revocation of certification under proposed § 8.14(a)(4). Note also that SAMHSA will continue to conduct inspections of OTP's to validate the performance of accreditation bodies, in instances where accreditation is determined to be inadequate and otherwise as needed to ensure that all treatment programs are operating in a

manner consistent with the Federal opioid treatment standards.

Third, the proposal retains under § 8.11(g) the provisions and requirements for authorizing interim methadone maintenance program approval. These provisions were mandated by the ADAMHA Reorganization Act of 1992 and remain in effect. Under proposed § 8.12(e), SAMHSA will process requests for interim maintenance approval.

The proposal retains, under § 8.11(h), a provision that allows an OTP to request from SAMHSA an exemption from the regulatory requirements set forth under proposed §§ 8.11 and 8.12. An example of a case in which an exemption might be granted would be for a private practitioner seeking to treat a limited number of patients in an area with few physicians and no geographically accessible rehabilitative services. In such an instance, SAMHSA would consider a request for an exemption from certain of the staff credential or required services standards, as well as an exemption from the requirement to be accredited. Another example would be an exemption that might be granted to a State sponsored pilot program which uses innovative dose schedules or dispensing practices for an already approved opioid agonist treatment medication.

Finally, the proposal requires as a condition of continued certification that programs must notify SAMHSA within 3 weeks regarding any change in the status of the program sponsor, such as a corporate reorganization, or a change in the status of the medical director, such as the retirement or termination of the individual in that role.

2. Federal Opioid Treatment Standards

Proposed § 8.12 proposes the Secretary's ''Federal opioid treatment standards'' as enforceable regulatory requirements that treatment programs must follow as a condition of certification. The requirements, which are discussed in greater detail as follows, address the opioid drug products approved for use in certified OTP's, dosage form limitations, the requirements necessary to assure that medications dispensed for unsupervised or ''take-home'' use do not present inappropriate risks for diversion, the minimum program staffing requirements and staff responsibilities, admission and enrollment requirements, and required services. These standards will form the outline for, and will inform the development of, each accreditation body's approved accreditation elements.

Proposed §§ 8.13 and 8.14 address the process that SAMHSA will follow in suspending or revoking certification under these regulations. The proposal includes timeframes for notifying DEA when a treatment program's registration should be suspended or revoked. In addition, these sections address the contingencies when an accreditation body itself revokes a program's accreditation, or when an accreditation body's approval to perform accreditations is revoked.

Proposed § 8.14(b) provides the circumstances under which SAMHSA will suspend a treatment program's certification. If SAMHSA finds substantial evidence of an imminent hazard to health, SAMHSA will suspend certification and notify DEA to suspend registration under 21 U.S.C. 824(d). Substantial evidence of imminent hazard could include evidence that treatment program practices are leading to unacceptable levels of diversion or other practices that create an unacceptable level of risk to the safety of patients or the community.

The procedures set forth in this proposal for revoking or suspending certification of treatment programs are similar to the existing procedures for withdrawing approval under § 291.505(h). Notice and an opportunity for an informal review and hearing will be provided prior to revocation, in accordance with proposed subpart C (discussed as follows). An expedited process is also included for seeking review of decisions to immediately suspend certification.

It should be noted that DEA also has a process for review when a registration is revoked or suspended consistent with the requirements of 21 U.S.C. 824(c). (See part 1301 (21 CFR part 1301).) Although the procedures for review of a suspension or revocation set forth in this notice are being proposed at this time, DHHS intends to work with DEA to ensure that only a single hearing occurs when a program's certification is suspended or revoked under the DHHS regulations, so as not to duplicate effort. Specifically, it may be decided, as part of the final rule, that DEA should have the lead in conducting the hearing, in which case the regulations at part 1301 would apply rather than the hearing process in subpart C of part 8 of the proposed rule. Alternatively, it may be decided that the hearing process in subpart C of part 8 will be retained in the final rule, but that SAMHSA would request the DEA hearing official to defer to the decision of the Secretary with respect to determinations made under 21 U.S.C. 823(g)(1) and (g)(3). At this time, however, the Secretary is proposing a separate hearing process and is seeking comment on the proposed process.

The final provision in subpart B (proposed 42 CFR 8.15) proposes two new application forms: SMA–162, Application for Certification for Use of Opioid Drugs in a Treatment Program; and SMA–163, Application for Becoming an Accreditation Body under proposed 42 CFR 8.3. SAMHSA is in the process of obtaining OMB review for these new forms.

SMA–162, Application for Certification to Use Opioid Drugs in a Treatment Program, will closely track the existing application form for FDA approved treatment programs. The applicant will have to provide the name of the program (or primary dispensing location), the address of the primary dispensing location, the name and address of the program sponsor, along with appropriate telephone numbers. In addition, the form requires the submitter to provide estimates of the number of patients to be treated and the program funding source, along with descriptions of the organizational structure of the program. The new form will retain the language on establishing a patient record system, and maintaining patient records for at least 3 years. The proposed SAMHSA form would require information on the program's accreditation status as required by proposed § 8.11(a)(2).

Under the existing regulation, a treatment program is required to complete and submit a new form when there is a change in location of the treatment program, or a change in program sponsor. SAMHSA is retaining this reporting requirement. In addition, a treatment program must submit a new form before establishing a medication unit.

Under the proposal, Form FDA–2635, Consent to Treatment with an Approved Narcotic Drug, would be eliminated. Current regulations require that the person responsible for the program must ensure that the patient has voluntarily chosen to participate in treatment; that all relevant facts concerning the use of the opioid drug are clearly and adequately explained; and that the patient, with full knowledge and understanding of its contents, signs the consent form. A specific consent to treatment form was considered necessary when methadone maintenance treatment was a relatively unfamiliar treatment modality in the early 1970's. Indeed, Form FDA–2635 reflected the idea that methadone is a drug that FDA had identified under 21 CFR 310.303 as one for which

additional long-term studies were needed. FDA, however, has removed that designation for methadone (61 FR 29476, June 11, 1996). While patients should continue to be counseled on the risks of opioid agonist maintenance therapy and provide written consent to treatment, and accreditation bodies should include elements to assure such counseling, the Secretary has tentatively concluded that a Federally mandated consent-to-treatment form is no longer necessary.

Form FDA–2633, Medical Responsibility Statement for Use of Narcotic Drugs in a Treatment Program, would also be discontinued. This form predates the NATA, and was first announced in the initial 1972 regulation (Ref. 28). According to a Paperwork Reduction Act analysis published in 1998 (Ref. 29), FDA estimated that 275 of these forms are submitted annually, requiring a total of 70 hours to complete. The form must be signed by all program physicians who, in turn, agree to assume responsibility for dispensing and administering opioid substances and agree to abide by the standards set forth in the regulations. In addition, program physicians agree to adhere to the patient confidentiality requirements of 42 CFR part 2. Finally, the form requires that those program physicians who are also medical directors will assume responsibility for administering medical services and for ensuring compliance with all applicable Federal, State, and local laws. While the Secretary is proposing to retain these requirements for program physicians and medical directors, as part of the Federal opioid treatment standards and as a condition for continued certification, the requirement that a form be submitted is no longer considered necessary in order to ensure compliance.

The Secretary is also proposing to eliminate the requirement for separate forms for maintenance treatment and detoxification treatment (see FDA–2636 Hospital Request for Methadone Detoxification Treatment). Under the proposed rule, entities providing either maintenance or detoxification treatment must conform to the same core Federal opioid treatment standards. One qualification, however, is that a hospital-based detoxification program would not be required to obtain a separate accreditation if the hospital itself is accredited by a SAMHSA approved accreditation body and certified by SAMHSA.

C. Subpart C—Procedures for Review of Denial, Suspension, or Revocation of Certification

Subpart C of proposed part 8 sets forth procedures for programs to seek review of denials, suspensions, or revocations of certification. The subpart C procedures are also available to accreditation bodies who are denied approval or whose approval has been revoked by SAMHSA.

The proposed procedures will ensure that programs will be given adequate notice of adverse actions, ample opportunity to submit written information, and an opportunity to request an oral hearing. The procedural framework follows the procedures applied by SAMHSA's Division of Workplace Programs under the ''Mandatory Guidelines for Federal Workplace Drug Testing Programs'' (59 FR 29908, June 9, 1994).

IV. Federal Opioid Treatment Standards

A. General

Proposed § 8.12 sets forth the Secretary's Federal opioid treatment standards. These standards represent the Secretary's core requirements for the medical treatment of opioid addiction with opioid agonist treatment medications. Taken together, the Secretary's standards outline the essential framework of a state-of-the-art addiction treatment program, with additional details to be supplied through Federal guidelines under development by SAMHSA and by accreditation elements to be developed by expert accreditation bodies.

The Secretary's proposed standards also reflect the minimal requirements necessary to reduce the risk of diversion of opioid treatment drugs. Among other things, the Secretary has set forth specific quantities of opioid drugs to be used for unsupervised ''take home'' use and certain other constraints on take-home use.

On the whole, these standards carefully balance the need for enforceable requirements, including clear standards to minimize the risk of diversion, against the pressing need to increase the clinical discretion and judgment in opioid addiction treatment. In addition, these standards reflect many of the elements that the IOM identified as necessary to prevent ''substandard treatment.''

B. Administrative and Organizational Structure

Section 8.12(b) proposes to require that an OTP's organizational structure must be adequate to ensure patient care. At a minimum, there must be a program sponsor who agrees to adhere to regulatory requirements. In addition, the Secretary believes it is essential, as with other medical treatments, that physicians oversee the medical aspects of treatment. Therefore, all OTP's must have a designated medical director.

C. Continuous Quality Improvement

Proposed § 8.12(c) requires that OTP's have a quality assurance plan and pursue continuous quality improvement activities. Importantly, treatment programs must continuously assess patient outcomes. Consistent with the findings from the GAO report, programs will be required to assess and improve the quality of the treatment they provide. In addition, as discussed elsewhere in this document, considerable advancements have been made in the field of methadone treatment outcome assessment. (*See* section II.C. of this document, discussion of MTQAS.) Examples of possible outcomes include: Reducing or eliminating illicit drug use, reducing or eliminating associated criminal activities, reducing behaviors contributing to the spread of infectious diseases, and improving quality of life by restoration of physical and mental health status.

The Secretary also proposes, under § 8.12(c)(2), that treatment programs include a ''Diversion Control Plan'' as part of the quality assurance plan. As noted elsewhere in this proposal, the IOM devoted an entire chapter to the issue of the diversion of treatment medications, an issue that remains a serious concern. While existing regulations require programs to monitor patients with drug abuse tests, and to include contingencies for positive results, the Secretary believes that program specific diversion control plans will help to reduce the scope and significance of diversion. Such plans would describe, among other things, a comprehensive diversion monitoring program that assigns specific responsibility to medical and administrative staff for carrying out diversion control measures and functions.

D. Staff Credentials

Proposed § 8.12(d) requires that physicians, nurses, addiction counselors, and other licensed professionals have sufficient education, training, and experience to enable them to perform assigned functions. While the standard does not require that treatment programs retain on staff individuals credentialed in the addiction treatment field, the Secretary

notes the existence of such specialties and encourages treatment programs to maintain or employ sufficient expertise in the field of addiction treatment to ensure quality treatment. In addition, licensed professional care providers, including addictions counselors, must comply with the credentialing requirements of their respective professions.

E. Patient Admission Criteria

The proposal retains most of the criteria from the existing regulation for admitting patients to maintenance and detoxification treatment. Under these criteria, patients eligible for admission to detoxification treatment (the IOM used the term ''Medically Supervised Withdrawal'') must be physiologically dependent upon opioids. In addition, qualified personnel must use accepted medical criteria, including those listed in the *Diagnostic and Statistical Manual for Mental Disorders* (DSM–IV), to determine that patients eligible for maintenance treatment are currently addicted to an opioid drug and became addicted at least 1 year before admission to treatment. The regulation retains exceptions for pregnant patients, patients released from penal institutions, and previously treated patients.

The current criteria require a 7 day waiting period between each detoxification treatment admission. The rationale for this requirement seems to have been a concern that overlapping detoxification admissions could lead to *de facto* maintenance treatment, albeit without the comprehensive treatment requirements associated with maintenance treatment. The Secretary has now tentatively concluded that 7 days is more time than is needed for this purpose, and may unnecessarily expose addicts to increased risks from HIV and other infectious diseases. The Secretary seeks comments on a shorter period, perhaps 2 days, as a waiting period between detoxification admissions.

F. Required Services

Under proposed § 8.12(f), OTP's must provide adequate medical, counseling, vocational, educational, and assessment services to patients enrolled in the OTP. These services were identified in the IOM report and elsewhere as essential standards of adequate treatment. The proposal retains the provision that these services must be available at the primary facility, unless the program sponsor has entered into a formal agreement with another entity to provide these services. Further, the proposal retains the requirement for the development and periodic evaluation of a treatment plan for each patient that reflects an assessment of the patient's current needs.

While the medication (methadone or LAAM) itself is an essential element of this modality of treatment, most patients also require a variety of other services to obtain the best and most expeditious outcomes. Since their inception, the existing regulations have reflected the need to provide services to patients in addition to the treatment medications. Indeed, the IOM report recommended that certain services should be retained as an enforceable requirement. This proposal specifies such services in the opioid treatment standards. In the past, DHHS has attempted to write all facets of these required services into regulation. It is now accepted, however, that: (1) Different patients, at different times, may need vastly different services, and (2) 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 treatment methods improve.

Through this rulemaking, DHHS is proposing a more flexible, performance-based approach. 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 application 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.

G. Recordkeeping and Patient Confidentiality

Under proposed § 8.12(g), OTP's must maintain a patient record system that is adequate to document and monitor patient care and outcomes, and comply with relevant Federal and State requirements. In addition, OTP's are required to keep patient records confidential in accordance with applicable Federal and State requirements.

Although difficult to quantify, there have been cases of patients enrolling in more than one treatment program. The Secretary, therefore, is retaining the requirement that treatment programs determine that patients upon admission are not enrolled in any other OTP.

H. Medication Administration, Dispensing, and Use

The proposal retains requirements from the existing regulations that treatment medications are dispensed by practitioners licensed under all applicable Federal and State laws to dispense such medications. In addition, the proposal retains initial and first day dose requirements for methadone which are consistent with the IOM recommendations.

Proposed § 8.12(h)(2) includes the requirement that only medications approved by FDA for the treatment of opioid dependence or addiction shall be available for use by OTP's in treating these conditions. Currently, methadone and LAAM are listed in this section. If FDA approves a new opioid medication for the treatment of opioid dependence, the Secretary would amend this regulation to address the new medication. This section is not intended to preclude the use of other types of medications in treating the patient for medical conditions other than opioid addiction. Similarly, this section is not intended to preclude the use of ancillary, approved nonnarcotic medications for the treatment of the opioid addiction to improve the effectiveness of the addiction treatment.

Moreover, approved medications must be used in accordance with current, FDA-approved labeling. Deviations from the approved labeling must be approved by the program physician and justified in the patient's medical records.

The proposed regulations do not include the specific requirements set forth in the existing regulations at § 291.505(k)(1) for the use of LAAM. These requirements include provisions on initial dosing with LAAM, LAAM dosage form, distinguishing LAAM and methadone dosage forms, and prohibiting the unsupervised (take-home) use of LAAM. In addition, the regulations prohibit the use of LAAM in patients under 18 years of age and require initial and periodic pregnancy testing for the drug to be administered to patients of childbearing potential.

The Secretary is proposing to withdraw these LAAM specific requirements from the Federal opioid treatment standards, to allow more room for clinical judgment. Some of these changes reflect the experience gained from over 4-years experience with the use of LAAM in OTP's. Requirements relating to the unsupervised use of LAAM are discussed as follows.

The Secretary notes that there are new medications under development for the treatment of opioid addiction. While still under investigation and review, it is conceivable that these new medications will present safety and effectiveness profiles that differ from the existing approved treatment

medications, methadone and LAAM. A new medication, for example, could rely on weak or partial agonist properties or on mixed agonist-antagonist properties, with pharmacokinetic and pharmacodynamic properties that would minimize the risk of deliberate abuse through injection and, in turn, would minimize the overall risk of diversion. As such, it may be appropriate to tailor the Federal opioid treatment standards to the specific characteristics of these future medications.

I. Unsupervised Use

The existing regulations establish a complex scheme to address the unsupervised use of methadone, including extensive ''time in treatment requirements.'' The program physician's rationale for prescribing take-home doses must be documented in the patient's medical records and must reflect eight subjective criteria (''take-home criteria'') specified in the regulations (§ 291.505(d)(6)(iv)(B)(*1*) through (d)(6)(iv)(B)(*8*)), to ensure that the patient will be responsible in handling the opioid drugs.

Many have criticized the emphasis and extent of these requirements, noting that methadone patients are already subject to extraordinary degrees of monitoring (Ref. 30). The regulations governing the use of take-home medications in OTP's are among the requirements that have been in existence since 1972.

As noted in the 1995 IOM report, problems associated with diverted methadone have been reduced substantially from the 1970's. The IOM, for example, examined 1992 Drug Use Forecasting (DUF) data on arrests and found that the recent use of methadone among those arrested is low relative to other drugs included in the DUF database. The IOM noted that ''while some street methadone is abused, it constitutes a relatively small part of the drug abuse problem generally * * * [and] instances of primary addiction are few'' (Ref. 31). The IOM concluded that most of the diversion associated with methadone is from patients' take-home supplies, however, ''the amount of methadone diverted to the street, by whatever means, is relatively small.'' The IOM also found a dearth of information on the degree to which methadone is implicated in drug-related crimes and on the amount of police effort devoted to the prevention of its diversion and, therefore, concluded that ''diverted methadone plays a small part in the overall drug-crime problem and receives a low priority in law enforcement efforts.''

The IOM also examined the extent to which diverted methadone contributes to death and morbidity, and the extent to which proceeds from the sale of diverted methadone are used to purchase other illicit drugs. No strong evidence surfaced to demonstrate that methadone plays a significant role in drug-related deaths or emergency hospital care, or that proceeds from the sale of diverted methadone are used to any notable extent in the purchase of illicit drugs.

DEA, on the other hand, published a ''Methadone Diversion'' (Ref. 32) report in April 1995 citing cases of armed robbery and clandestine methadone laboratories and found that, indeed, methadone is diverted and abused. In addressing some of the IOM recommendations, DEA stated that ''[t]o relax controls in clearly identified areas which contribute to the illicit trafficking would not enhance treatment, but instead would further erode public confidence in treatment and expand traffic and abuse of methadone.''

Having considered both sides of the issue, the Secretary is proposing several options for determining whether OTP's comply with standards respecting the quantities of opioid drugs which may be provided to patients for unsupervised use. The Secretary is specifically requesting comment on these approaches, as well as the optimal combination of regulatory requirements, accreditation elements, and oversight procedures to reduce the risks of diversion.

The options set forth as follows reflect two important factors. First, the Secretary has tentatively concluded that certain of the restrictions in the existing regulations are too restrictive, especially when they are applied to those patients who have been in treatment for extended periods and have demonstrated responsibility in handling opioid drugs. Such a patient, for example, could greatly benefit from having access to take-home supplies beyond 6 days, an amount which under the current regulations would require the granting of a special exemption by FDA. The options, then, reflect greater flexibility for providing take-home supplies to certain long-term patients.

Second, as noted previously, the current regulations prohibit the dispensing of LAAM for unsupervised use. This prohibition reflected the lack of experience with LAAM at the time of its approval in 1993, coupled with concerns about LAAM's lengthy induction properties. LAAM has now been available to treatment programs for several years, and the number of programs authorized to use LAAM has grown considerably. In addition, FDA and SAMHSA have received numerous inquiries expressing concern about the prohibition on the unsupervised use of LAAM, particularly with respect to those who need to travel and must abruptly switch to methadone. Such switching can be disruptive to patients stabilized on LAAM. Accordingly, the Secretary has tentatively decided to remove the prohibition on the unsupervised use of LAAM.

Options 2, 3, and 4, would allow unsupervised use of any approved opioid treatment medication. The Secretary, however, is specifically requesting comments, including data from the treatment field, that bear on the issue of whether to allow take-home use of LAAM.

1. Option 1—Retain Current System

Under the first option, the Secretary would retain the current regulatory scheme prohibiting the unsupervised use of LAAM. For methadone, the time-in-treatment requirements, maximum 6-day supply, probation, exemptions, and criteria for determining responsibility all remain as opioid treatment regulatory requirements. As in the current regulations, the program physician would be required to consider the following ''take-home criteria'' in determining whether a patient is responsible in handling opioid drugs:

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

2. Regularity of clinic attendance;

3. Absence of serious behavioral problems at the clinic;

4. Absence of known recent criminal activity, e.g., drug dealing;

5. Stability of the patient's home environment and social relationships;

6. Length of time in comprehensive maintenance treatment;

7. Assurance that take-home medication can be safely stored within the patient's home; and

8. Whether the rehabilitative benefit to the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion (§ 291.505(d)(6)(iv)(B)).

Accreditation bodies would have elements designed to ensure that treatment program quality assurance plans include sentinel events and followup actions to assure that patients are not misusing medications provided for unsupervised use. SAMHSA would determine program-wide and individual patient exemptions for take-home use beyond a 6-day supply.

2. Option 2—Follow the IOM's Recommendation

The second option tracks the IOM's recommendation. This option would retain the regulatory requirement that the medical director shall be responsible for determining whether a patient can responsibly handle opioid treatment drugs for unsupervised use. In addition, all decisions on take-home medications would be documented in the patient's medical chart. The basis for the medical director's clinical judgment must be, at a minimum, the eight criteria listed currently in § 291.505(d)(6)(iv)(B). These criteria would be a required part of the accreditation elements that will be assessed periodically by accreditation bodies and would be included in the determination of whether to accredit the treatment program.

The Federal opioid treatment standards would include the following restrictions on the use of controlled opioid medications for unsupervised use:

1. For the first month of treatment, the maximum take-home supply is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision.

2. In the second month of treatment, the maximum take-home supply is two doses after each supervised ingestion.

3. In the third month of treatment, the patient should have ingestion observed at least twice a week, with take-home permitted for other doses.

4. In the remaining months of the first year, the maximum take-home supply of methadone is three doses after each supervised ingestion.

5. After 1 year, a selected patient would become eligible for less intensive supervision of medical ingestion and may be given up to a 31-day supply of take-home medication and monthly visits. Another variation on this option would have patients receiving up to a 14 day take-home supply after 1 year, and up to a 31-day supply after 2 years. In addition, patients could be subject to monthly drug abuse tests.Under this option, SAMHSA would still consider individual, but not program-wide, exemptions for travel, medical, or other ''hardships.''

The Secretary has tentatively concluded that Option 2 contains the optimal level of control and has therefore included this option in § 8.12 of the proposed rule. Option 2 is the alternative which follows the IOM's recommendations and which involves the regulatory requirement that the medical director shall be responsible for determining whether a patient can responsibly handle unsupervised medication. Documentation of the decision regarding take-home medication would continue to be required in the patient record, and the decision would be based on the eight criteria currently listed in § 291.505(d)(6)(iv)(B). Restrictions on controlled opioid medications for unsupervised use would be: 1 take-home dose per week for the first month of treatment; 2 doses per week after each supervised ingestion in the second month of treatment; ingestion observed at least twice weekly with take-homes permitted for other doses during the third month of treatment and maximum take-home supply of 3 doses per week after each supervised ingestion for the remainder of the first year. After 1 year, a selected patient may become eligible for less intensive supervision and may have take-home doses varying from 14 to 31 days at a time. DHHS believes this take-home schedule reflects patient responsibility timeframes and adequately balances the need for clinical judgment in this treatment parameter with the risk of medication diversion. The DEA supports proposed Option 2.

3. Option 3—Maximum Amount Approach

Under the third option, the regulations would set a maximum amount, 1.5 grams of methadone or 0.8 grams of LAAM, per 2-week period. In addition, treatment programs would be required to maintain adequate records on the dispensing of opioids for unsupervised use to demonstrate compliance with conditions of accreditation. The existing regulatory criteria would become accreditation elements.

4. Option 4—Retain Existing Requirements, Subject to Continuous Review by Accreditation Bodies

The fourth and final option would retain the regulatory requirement that the medical director, or a designated program physician, is responsible for determining that a patient can responsibly handle medication for unsupervised use. All decisions on take-home medications would be documented in the patients' medical chart, using a standardized format. The basis for the medical director's clinical judgment must follow, at a minimum, the types of criteria listed in § 291.505(b)(3)(i)(D). The criteria and the methodology by which they are applied must be included in the accreditation elements, must be assessed periodically by accrediting bodies, and must be part of the determination of whether to accredit the program. The methodology shall include the OTP's quality assurance plan for regular review of all take-home decisions (initial authorization, renewals, and revocations).

At least one existing accreditation body has accreditation standards that address take-home privileges. COA's Methadone Maintenance Service Standard requires that take-home privileges are earned by the individual and are part of each individual's service plan. A team consisting of the patients's counselor, medical and other appropriate personnel, the patient, and whenever possible, his/her family are involved in deciding whether the patient is ready to receive take-home privileges. Factors that support initiation of take-home privileges include: Length of time in treatment, attainment of clinical stability, progress in rehabilitation, medical necessity, behavioral factors, and emergency circumstances. In addition, the standard includes protocols for deciding when take-home medication is contraindicated, including: Signs or symptoms of withdrawal, continued illicit drug use, the absence of laboratory evidence of methadone in toxicology samples, potential complications from concurrent disorders, ongoing criminal behavior, and an unstable home environment.

Moreover, under COA's standards, toxicology tests are to be scheduled regularly to ensure that the patient is consuming the methadone provided and remains free of illicit substance use, and other such measures to help avoid diversion must be implemented. Importantly, each patient's case or record is reviewed by a physician at least every 90 days, or more frequently if clinically indicated, and the team periodically reviews the benefits and drawbacks of continuing take-home privileges.

I. Interim Maintenance Treatment

The proposal retains standards for interim maintenance treatment. Conceptually, interim maintenance treatment allows authorized programs with documented treatment waiting lists to provide methadone treatment to eligible patients without some of the services required under the regulations. Interim maintenance treatment was mandated by the ADAMHA Reorganization Act.

With respect to the issue of unsupervised use of opioid treatment medications, the proposal retains the prohibition on unsupervised use for patients in short-term detoxification treatment and interim maintenance

treatment. Under the existing regulations, patients in long-term detoxification treatment are permitted one unsupervised dose of methadone per week. The Secretary is proposing to allow the unsupervised use of treatment medications with responsible patients in long-term detoxification treatment because long-term detoxification patients who meet the time in treatment requirements set forth for patients in maintenance treatment should be also eligible to be considered for unsupervised use of treatment medications. This proposed change is consistent with other changes in this notice (e.g., consolidated application forms) that will make the regulations less complicated.

V. Legal Authority

The Secretary's legal authority under section 303(g) of the CSA to issue treatment standards, including standards regarding the quantities of opioid drugs that may be dispensed for unsupervised use, is well established. (See generally section II.A of this document. See also 42 U.S.C. 257a.) In addition, the Secretary has specific authority, through the Administrator of SAMHSA, to coordinate Federal policy with respect to the provision of treatment services for substance abuse using medications such as methadone (21 U.S.C. 290aa(d)(7)). The Secretary is also authorized to establish conditions for allowing interim treatment of opioid addiction. (See section 1976 of the PHS Act, 42 U.S.C. 300y–11.)

Part and parcel with the Secretary's general authority to establish treatment standards, and to ensure that those standards will be met, is the authority to delegate to qualified third parties a role in helping to ensure compliance with the Secretary's standards. The Secretary has retained full responsibility for all final determinations, including all standard setting determinations, as well as the authority to reject the recommendations of an accreditation body, to independently inspect treatment programs, and to perform her own independent certifications. The proposal also includes ample measures to ensure the impartiality of the accreditation body decision makers. Under these circumstances, the Secretary believes that her reliance on accreditation bodies, as outlined in the proposal, is fully consistent with the law as it pertains to subdelegation of agency responsibilities to third parties. See, e.g., *Fleming* v. *Mohawk Wrecking and Lumber Co.*, 331 U.S. 111 (1947); *Tabor* v. *Joint Board for Enrollment of Actuaries*, 566 F.2d 705, 708 n.5 (D.C. Cir. 1977); *National Association of Psychiatric Treatment* v. *Mendez*, 857 F. Supp. 85, 91 (D.D.C. 1994); *Hall* v. *Marshall*, 476 F. Supp. 262, 272 (E.D. Pa. 1979), aff'd 622 F.2d 578 (3d Cir. 1980).

VI. Proposed Implementation Plan

There are approximately 900 OTP's (currently referred to as narcotic treatment programs or ''NTPs'') approved under the existing regulatory system. The Secretary intends to move entirely to the accreditation-based system as soon as practicable, albeit with certain accommodations to allow treatment programs sufficient time to obtain accreditation and, thereafter, certification under new 42 CFR part 8.

The Secretary is proposing that the effective date of the rule, once finalized, will be 60 days after publication of the final rule in the **Federal Register**. However, as discussed in section III.B of this document, the rule will allow for transitional certification for programs that were approved under part 291 as of the effective date of this regulation. In addition, SAMHSA will apply the provisional certification provisions under proposed § 8.11(e) to allow new programs to begin to operate while completing accreditation.

These provisions will allow a sufficient amount of time for accreditation bodies to apply for and obtain SAMHSA approval and, in turn, to begin conducting accreditation surveys.

As part of the transition from the current regulatory approach to the proposed accreditation/regulatory approach, SAMHSA's CSAT has developed a study of an initial cohort of 180 randomly selected, volunteer OTP's (Ref. 33). The study will be used by SAMHSA to develop and continually update the agency's accreditation guidelines. The study, which is not expected to be completed for several years, may also provide useful information for refining the accreditation model that is the subject of this proposed rulemaking.

The shift to an accreditation model is expected to have both administrative and clinical consequences. The CSAT study is designed to provide additional information on the processes, barriers, administrative outcomes, and costs associated with an accreditation-based system. The study will measure program accessibility, client population served, program structure, operation and costs, clinical practice, staff attitudes and behavior, methadone diversion, patient satisfaction, and treatment outcomes at a sample of treatment providers before and after they go through the accreditation process. No OTP participating in the study will be prohibited by the FDA or the DEA from operating because of failure to meet the standards for accreditation.

The focus of the study is a pretest-posttest design with a comparison or control group. This design assumes that a series of variables will be influenced by the intervention, i.e., accreditation, and that measurable information on these variables is available both prior to and following the intervention. The effect of the intervention is then measured by comparing the post-intervention values of the outcomes with the pre-intervention values. The evaluation contractor will collect pre-intervention data from participating OTP's at approximately 6 months prior to accreditation to provide sufficient lead time to measure the baseline status of these programs. It is expected that the OTP's will make program changes to meet the accreditation standards, apply for accreditation, undergo the accreditation process, deliver services post-accreditation, and collaborate in the evaluation. The evaluation contractor will collect post-intervention data from each participating OTP at approximately 6 months following the accreditation survey to provide sufficient time to measure the changes in OTP operations after the accreditation process. The evaluation contractor will collect data from the control group at approximately the same time that data will be collected from the study group.

SAMHSA's CSAT Advisory Council will assist in the evaluation of the study data. SAMHSA expects that the advisory council will establish a subcommittee that will make recommendations to the full committee which, after deliberation, will make recommendations to SAMHSA as appropriate. SAMHSA expects to bring in consultants to the subcommittee who ideally will include representation from stakeholders such as OTP's (both large and small programs), medical and other substance abuse professionals, consumers, and State officials. SAMHSA expects the first meeting of the advisory committee and subcommittee on the issues will convene within 6 months of the first group of accreditation surveys.

DHHS has determined that accreditation is a valid and reliable system for providing external monitoring of the quality of health care—including substance abuse treatment. This study, which will proceed alongside the rulemaking proceeding, is expected to provide important information to allow DHHS to keep its guidelines, and its accreditation

program, as responsive and up-to-date as possible. Among other things, the study will allow DHHS to continuously monitor the monetary costs of accreditation, to ensure that successful OTP's are not precluded from operating by the costs of accreditation, and that patients are not denied treatment based on costs.

Finally, under the project, SAMHSA will fund the accreditation of a large cohort of OTP's. As a result, a substantial subset of the universe of approved programs will have experience with accreditation. During the course of the study, CSAT will make technical assistance available to OTP's to help them meet accreditation requirements.

VII. Environmental Impact

The Secretary has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

A. Introduction

This section briefly describes the current estimates of accreditation costs likely to accrue to OTP's as a result of this proposed rule.

The Secretary has examined the impact of this proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (Pub. L. 96–354), under the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs 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). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on a substantial number of small entities. The Small Business Regulatory Enforcement Fairness Act extends the Regulatory Flexibility Act by making such analyses subject to more detailed reviews. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). A summary of the appropriate analyses follows.

B. Purpose of the Proposed Regulation

Federal, State, local, and private sponsors spend billions of dollars each year for substance abuse treatment programs (Ref. 34), of which opioid maintenance has been an important option since the early 1970's. OTP's have been subjected to regulations administered by FDA for more than 25 years. These regulations reflect the view that because such treatment programs dispense treatment drugs with abuse potential to drug abusers, they pose risks to communities from potential abuse and/or diversion of the supplied therapeutic drug (Ref. 35). In addition, DEA requires annual registration of OTP's, and enforces regulations relating to security and control of the controlled drug products (Ref. 36).

The motivation for providing opioid maintenance is rarely based on economic criteria. One study indicated that treatment expenditures may be offset by decreased direct costs of incarceration and legal supervision (Ref. 37). Another study suggested that continued methadone treatment for recovering opioid addiction resulted in significant reductions in criminal activity (Ref. 38). Reduced health care costs have also been identified as a benefit of continued treatment, particularly as treatment procedures have been revised to reduce the spread of HIV infection through needles (Ref. 39). Continued treatment has also been shown to lead to increased earnings by allowing patients to maintain regular employment (Ref. 40) and family and personal relationships and to decrease mortality (Ref. 41). A recent study has estimated that the value of avoiding morbidity associated with drug use could be as high as $160,000 per case (Ref. 42). But studies show that these benefits are obtainable only if patients continue to take active roles in their treatments.

As discussed in section II.B of this document, compliance with current regulations is assured through process oriented inspections conducted by either FDA or State inspectors. As FDA has focused on other core priorities, the annual number of OTP inspections by FDA has declined. Meanwhile, as summarized in section II.C of this document, several groups have questioned the emphasis of the current regulations. This proposal is designed to improve the quality of care by shifting oversight of OTP's from a system based on process compliance to an accreditation-based system refocused on the needs of patients.

There has long been controversy centered around the appropriate measures to use in assessing outcomes from drug abuse treatment programs (Ref. 43), although substantial progress has been made in outcome assessment over the last 20 years. One of the important areas of progress from this research has been to shift the focus of treatment outcome assessment from implicitly conceptualizing drug addiction as an acute illness from which the patient either recovers (i.e., remains abstinent) or does not (everything else) to one that is chronic and relapsing. This shift in recognition has resulted in a change in expectations for the outcomes of any one treatment episode where reduced consumption, longer abstention periods, reduced psychiatric symptoms, improved health, maintaining employment, fewer legal problems, and improved family relations demonstrate treatment efficacy. The strategy for measuring success is similar to that used with other chronic disorders such as asthma, arthritis, diabetes, heart disease, hypertension, and other psychiatric disorders. This strategy for assessing outcomes has been adopted by the FDA for measuring pharmaceutical efficacy (Ref. 44).

This change in the way drug addiction and abuse is viewed has led to the development of improved outcome measures, such as those contained in the Addiction Severity Index (Ref. 45), the Individual Assessment Profile (Ref. 46), and the Client Assessment Profile (Ref. 46). These instruments all measure changes in the severity of the problem areas that are commonly affected by addiction. These areas are: Drug use, alcohol use, medical, legal, employment, family/social, and psychiatric. Particularly notable have been studies demonstrating reductions in criminal behavior associated with participation in methadone treatment (Refs. 47, 48, and 49).

Improvements in outcomes after methadone treatment are almost always equal to or greater than improvements seen in treatments for other chronic relapsing disorders (Ref. 50). For example, studies of methadone maintenance programs routinely show reductions of 80 percent or more in heroin use after several months with even greater reductions for patients who remain in treatment for more than 1 year (Refs. 51, 52, and 53). More recently, studies have consistently shown that the risk for HIV infection is significantly reduced by opioid agonist therapy, even

in the absence of total cessation of drug use (Refs. 54, 55, and 56). These proposed regulations are designed to improve the therapeutic impact of treatment programs by assuring adequate quality of care, including adequate doses of medication to have optimal therapeutic effects.

C. Baseline Description of the Industry

FDA has approved 869 methadone treatment programs as of early 1997, including 209 programs also approved for LAAM treatment (Ref. 57). This total encompasses only outpatient maintenance programs and does not include almost 300 inpatient hospital detoxification units. This total likely overstates the actual universe of OTP's because FDA considers individual dispensing sites as separate treatment programs for inspectional purposes, although sites may be affiliated with other organizations. Another estimate of active programs includes 668 reports of active methadone services from SAMHSA's 1996 Uniform Facility Data Set (UFDS) (Ref. 58), although the definition of ''treatment unit'' was left up to the discretion of the respective States (Ref. 59). This estimate may understate the universe of approved treatment programs because not all treatment programs responded to the annual survey. For this assessment, the Secretary has assumed 900 active OTP's as the universe of affected programs.

Data from SAMHSA's UFDS Data Set (Ref. 60) can be used to estimate the number of patients in treatment. The 1996 Data Set includes a 1-day census of patients in treatment, by type of care and jurisdiction. According to the most recent report, there were 940,131 patients in substance abuse treatment facilities (private and public funded) on October 1, 1996. The 1996 report indicates that 13.2 percent or 124,098 of these patients were receiving narcotic substances (assumed to be methadone or LAAM). For the purposes of this analysis, the Secretary estimates the total census of patients in opioid treatment to be approximately 125,000.

Data from SAMHSA indicate that some OTP's may be providing treatment to over 2,085 patients, but most programs have very small patient bases (Ref. 61). Approximately 20 percent of all programs treat 50 or fewer patients (Ref. 62), and 10 percent treat 10 or fewer patients. The median OTP had a patient census of 125 patients, but the mean program size was much larger. Two studies that included methadone program cost parameters indicate a weighted average of 250 patients per OTP (Refs. 63 and 64). For this assessment, the Secretary has assumed a typical OTP can treat 140 patients, for a total industry census of 125,000 patients.

Current cost estimates of providing annual treatment have ranged from approximately $2,500 (Ref. 65) to $4,000 (Ref. 66). The lower cost estimate did not account for all fixed and variable costs associated with operating a treatment facility (e.g., rent and equipment maintenance and operating costs were not adequately accounted). For this assessment, the Secretary has estimated that it costs approximately $4,000 per year to treat one patient.

D. Costs of the Current Regulations

For purposes of this analysis, the Secretary estimates the costs of enforcing the current regulations to average approximately $3.3 million per year. These costs include inspections, support, review of applications, and all overhead. In addition, OTP's found to be violative must improve performance in order to continue operations. Typically, many inspections result in observable violations based on a failure to fully document or record activities. The Secretary has estimated that a typical facility must improve patient recordkeeping as a result of an inspection at a cost of $4.70 per patient per year (or almost $660 per OTP per year ($4.70 x 140)). This cost is estimated by assuming that 10 minutes of nurse/technician time will be required to enter and check records for each patient per year. The total average compensation for a nurse/technician in the health services sector totaled $28.07 per hour in 1996 (Ref. 67). The estimated annual cost for programs to meet requirements of current inspections and correct violations equals $0.59 million. The Secretary seeks comments and information to further assess or estimate the costs for programs to meet the requirements of the current regulations. The total annual cost of continuing the current regulations (in the absence of these proposed regulations) is estimated to equal $3.9 million, most of which is administrative costs of maintaining a regulatory system.

E. Costs of the Proposed Regulation

The proposed rule will generate regulatory costs to OTP's in two general areas. These areas are: (1) The direct costs of becoming accredited through a survey of practices and procedures, and (2) the more indirect costs of improving procedures, if necessary, to meet the quality level required to achieve and maintain accreditation, including resurvey costs. The Secretary has developed preliminary estimates of these cost elements in terms of costs per annual client. Thus, if an OTP must initiate an activity to become accredited, the costs include maintaining that activity at an acceptable level of quality.

In addition, SAMHSA will incur costs to provide oversight of accreditation bodies, review and approve applications from prospective programs, and conduct ''for-cause'' inspections. The Secretary has assumed that DEA will not incur any change in enforcement costs due to these proposed regulations.

Costs are estimated as average annual costs. A 7-percent discount rate is used to estimate the present value of future expenditures and to amortize one-time costs. A 3-year evaluation period (the length of the expected accreditation cycle) is used to analyze any one-time costs associated with compliance.

F. Accreditation of Opioid Treatment Programs

The process of professional accreditation includes external peer review of practices in order to assure an acceptable level of quality. Most accrediting organizations have criteria of what clinical procedures assure a minimum level of quality of care. Usually, a team consisting of various professional specialties will spend several days at a candidate facility during an accrediting survey. The team will examine records and observe practices that determine the facility's level of quality. After receiving accreditation, a facility must show that quality remains at an acceptable level by maintaining proper procedures. Recently, the JCAHO announced that it would develop specific performance outcome measures as accreditation criteria.

The costs of operating an accreditation program are estimated from data provided by three national accreditation bodies: JCAHO, CARF, and COA. Currently, most OTP's are not required to be routinely accredited by any national accreditation body. However, all three bodies have some experience accrediting OTP's. Approximately 36 hospital-affiliated OTP's are currently accredited by the JCAHO, and CARF has accredited some OTP's and is currently developing a specific accreditation manual. COA has drafted standards for OTP services that incorporate many of the requirements of the proposed regulation.

JCAHO would charge a mental health facility with size and operating characteristics similar to an average OTP a base of $5,655 plus $0.23 per outpatient-visit (Ref. 68). JCAHO's definition of an outpatient visit may not strictly apply to opioid treatment

because patients are typically treated as many as six times a week. For the purposes of this analysis, the Secretary has applied the $0.23 per outpatient-visit charge on a weekly basis. The estimated accreditation survey charge for JCAHO accreditation is the base charge plus $1,674 (140 patients times $0.23 times 52 weeks), or approximately $7,300.

Discussions with CARF have indicated that a facility seeking accreditation would pay an application fee of $300, purchase a survey manual for $100, and pay $950 per surveyor per day to conduct an accreditation survey. CARF expected a facility survey to require 2 days onsite, and while they estimated two-person teams, three-person teams may be likely. Thus, a CARF accreditation survey for an OTP seeking accreditation is estimated to cost approximately $5,100, including travel costs.

COA presented data that showed an average charge of about $5,500, but added an additional $1,500 for travel expenses of the accreditation survey team. In addition to the direct accreditation costs, the survey team for COA incurs opportunity costs based on the time necessary to complete a survey. Discussions with COA show that typically a survey team consists of three unpaid persons from previously accredited facilities. While JCAHO and CARF indicated that the labor costs for a survey team were included in the charges, COA did not. For the purpose of estimating the opportunity costs of these survey members, the Secretary has estimated that a typical survey team will consist of an administrator or program director, and a nurse or counselor or social worker. A typical survey is expected to take 2 days to complete. The Bureau of Labor Statistics collects average wage rates by occupation (Ref. 69). In 1996 (the latest year for which these data are published), the average hourly compensation of a nurse or technologist was $28.07, while an administrator or clinic director had total hourly compensation of approximately $33.29. Thus, the opportunity cost of the survey team for conducting an accreditation survey adds almost $1,000 for a total estimated survey cost of $8,000.

For the purposes of this analysis, the Secretary estimates the direct cost of conducting an accreditation survey as the average of these three programs, or $6,800 per treatment program. Assuming a 3-year accreditation cycle, and a 7-percent discount rate, the average annual cost to a treatment facility of conducting accreditation surveys will equal approximately $2,600. Overall, the total average annual accreditation costs for all affected programs are likely to equal $2.3 million.

G. Compliance and Quality Assurance for Opioid Treatment Programs

According to COA, approximately 30 percent of the nonvoluntary accreditation inspections result in some remedial action. CARF has reported an approximately 25 percent less-than-full accreditation rate for facilities that have been required to seek accreditation. Regardless of what the less-than-full accreditation rate is for the first accreditation cycle, subsequent accreditation cycles should have significantly lower rates of less-than-full accreditation as programs adjust to the accreditation process. In addition, CSAT will make available technical assistance to help programs meet accreditation requirements.

While it is possible that increased Federal inspection and enforcement activity (in the absence of this rule) could result in fewer violative programs, the Secretary believes the requirement of accreditation will provide a greater impetus for program-by-program improvements. Shorter accreditation cycles are believed to minimize the opportunity for programs to become noncompliant. In addition, managed health-care payers for psychiatric care often require program accreditation for reimbursement (Ref. 70) and this trend is expected to continue for opioid treatment.

The costs of remediation were estimated from variable program cost data developed for SAMHSA from nine OTP's (Ref. 71). This study presented annual operating costs per patient to maintain what is presumed to be an acceptable level of quality. The consultants collected accounting costs for 14 specific parameters that contribute to overall program quality such as initial assessment, medical examination, case management, etc. While the Secretary does not have data to show that these 14 parameters are inclusive, a weighted average of the costs for the variable cost parameters (for both methadone and LAAM patients) resulted in an average cost per activity of approximately $150 per parameter per patient.

Remedial action to achieve accreditation could require implementation of a service that is currently not available, or it could require only marginal improvements to the level of an ongoing activity. For example, an OTP that did not offer acquired immune deficiency syndrome (AIDS) counseling would be required to start doing so, while a different OTP may be required to improve the quality of such counseling.

At this time, the Secretary does not have data to indicate the minimum level of compliance that would currently allow an OTP to remain in operation. The Secretary has assumed that the complete absence of any one quality enhancing activity would result in a loss of accreditation. Assuming that 25 percent of facilities are expected to require remediation from the initial cycle of accreditation surveys, these facilities are likely to be distributed between two extremes.

The most costly compliance activities would be for OTP's that currently do not offer one of the identified services. In order to continue operations, these facilities would be required to offer these services, and incur costs of $150 per patient or $21,000.

The other extreme would be OTP's that must increase resources to one activity (e.g., improve recordkeeping). This may require increased costs of only $0.67 per patient (based on dividing $150 by 25 percent of the affected programs).

The average cost for a typical less-than-fully accredited OTP to come into compliance during this initial inspection is estimated as the average of these amounts, or approximately $75 per patient or $10,500 per noncompliant program. Having assumed that 25 percent of all OTP's (or 225 programs) would require improvements in the first accreditation cycle, the total costs to the industry are estimated to be $2.4 million.

These costs are estimated based on costs per patient per year, and are thus annual operating costs of ongoing quality assurance activities as well as implementation costs. As such, they also incorporate the cost of maintaining acceptable quality levels between accreditation cycles. These cost estimates take into account typical quality assurance programs that include development of quality assurance manuals and periodic meetings by a quality assurance staff through the evaluation period. Each OTP is likely to invest in a quality assurance program that will contain elements of authority, purpose, organization, scope, responsibility, implementation, and evaluation (Ref. 72). Future accreditation surveys may identify OTP's that do not receive full accreditation, but the noncompliant rate is expected to be low. By maintaining current expenditures and quality assurance programs as estimated in this section, no additional costs are attributable to this regulation.

A resurvey would be required for each OTP needing remedial action. Direct costs for resurveying are part of the original survey, but indirect costs must be accounted for, as measured by the opportunity costs of the survey team. This would likely be travel costs ($1,500) and opportunity costs for the survey team ($1,000) for a total of approximately $2,500 for a resurvey. With an estimated 225 resurveys, the total industry cost would equal $0.6 million. This one-time cost, when amortized for 3 years at 7-percent discount rate to account for an accreditation cycle, results in an average annual cost for the industry of $0.2 million.

H. Annual Costs to Opioid Treatment Programs of the Proposed Regulation

Total costs of this proposed regulation include average annual direct accreditation survey costs of approximately $2.3 million. The average annual costs of both coming into compliance and ensuring an acceptable level of quality is estimated to be $2.6 million. The total average annual costs to OTP's for this proposed regulation is $4.9 million, which includes maintaining an improved quality level. These annual costs equal approximately $5,400 per facility and $39 per patient, an overall average increase of approximately 1.0 percent per patient. Costs are expected to vary by facility and by patient population.

I. Costs to SAMHSA of the Proposed Regulation

The average estimated annual cost of administering an accreditation based system of regulation, based on SAMHSA estimates, is $3.4 million.

J. Total Net Costs of the Proposed Regulations

The total cost of these proposed regulations is the combination of the industry and the government costs. The best estimate of the total average annual cost is $8.3 million. The annual cost of FDA enforcement of the current regulation of OTP's has been estimated to equal $3.9 million. The average annual net cost of this proposal equals the difference, or $4.4 million.

K. Benefits of the Proposed Regulations

Methadone maintenance (and by extension LAAM maintenance) has been identified as the most successful known treatment in avoiding relapses in addiction. Depending on definitions, approximately 80 percent of individuals seeking treatment for substance abuse (including alcohol), from all such treatments (including all alternative treatments), have been reported to have returned to substance use following treatment (Ref. 73). While individual opioid maintenance programs vary in success rates, a study of six clinics showed that the continued use of drugs ranged from only 10 percent of patients in the most effective clinic to 56 percent in the least effective (Ref. 74). Among other factors, the more effective clinics were characterized by treatment goals of ongoing maintenance, better staff-patient relationships, and higher average medication doses (Ref. 75).

A study of relapse rates reported that overall methadone maintenance programs reported a 40-percent average relapse rate (Ref. 76), compared to an 80-percent relapse rate for all substance abuse treatment. However, for patients still in treatment, the reported relapse rate was 31.7 percent, while patients out of treatment reported a 65-percent relapse rate. But, those patients who had completed a course of treatment of at least 24 months reported relapse rates one-third lower than those in treatment for fewer than 6 months (50 percent to 71.8 percent) (Ref. 77). These findings imply that continuing treatment and length of treatment decrease the probability of relapse.

The Secretary cannot with certainty predict the effect of these regulations on the expected rate of relapse. However, the following example illustrates the range of potential benefits that might be achieved if the average patient remains in treatment for 6 months longer than the current reported average duration of treatment (14.7 months to 20.7 months). In this instance, the expected average rate of relapses would decrease from 40 percent to 32.3 percent. This implies that the number of annual relapses from therapy would be reduced by 12,320 patients. In 1993, there were more than 13,000 drug related mortalities (Ref. 78), not all of which could be attributable to drugs treatable by opioid maintenance. However, it is likely that at least some of these mortalities would be avoided if greater numbers of patients avoided relapse by maintaining treatment.

In addition, other benefits such as reduced health expenditures, better personal relationships, and reduced criminal activity would be expected. Based on plausible values for such gains, even very minor improvements in patient outcomes could easily offset the net annual compliance cost of this proposed regulation.

L. Impact on Small Opioid Treatment Programs

1. Description of Impact

As discussed previously, the proposal is expected to provide more frequent quality surveys of OTP's and allow for greater flexibility in the delivery of opioid treatment.

Under definitions provided by the Small Business Administration (SBA), virtually the entire industry would be composed of small entities (Ref. 79). The SBA uses an estimate of $5.0 million in gross revenues as a definition of small entity for industry SIC 8093 (Specialty Outpatient Facilities, NEC). An OTP would need to provide treatment to 1,250 to reach that level. As stated earlier, 20 percent of the OTP's serve 50 or fewer patients. This segment of the industry may be assumed to be considered small relative to the typical OTP.

All small programs would be required to be accredited by an accreditation body approved by SAMHSA. Each OTP, regardless of size would be expected to maintain this accreditation in order to continue to treat patients. There are several important changes in these proposed regulations from current requirements, but no major changes in current recordkeeping.

2. Analysis of Alternatives

Alternative regulatory schemes were considered. The continuation of the current regulatory oversight was dismissed in light of the findings and criticisms discussed in section II of this document. The idea of providing greater levels of self-certification was deemed insufficient, primarily because of concerns over the potential diversion of the treatment medications.

SAMHSA has issued evaluation contracts to determine whether this proposal will result in unforeseen impacts on small programs. In particular, the feasibility of exempting small facilities from some requirements will be examined. Some small OTP's may find it necessary or desirable to forge arrangements with more financially secure organizations so as to provide quality treatment services to individuals in the community. SAMHSA will make every effort possible to ensure that access to quality opioid addiction treatment services is not diminished, especially in rural areas, as a consequence of this regulatory reform.

3. Assuring Small Entity Participation

It is likely that this proposed rule may have a significant economic effect on a substantial number of small entities.

Based on the cost parameters reported for the three smallest programs included in a SAMHSA analysis (Ref. 80), the average cost to maintain and service a patient for 1 year in a small, 50-patient facility was estimated to be $3,200. An average accreditation survey for a program of only 50 patients is expected to take only 1 day and cost approximately $4,000, or approximately $1,500/year (at a 7-percent discount rate). The average cost per patient of achieving and maintaining a quality-enhancing activity at a small OTP at an acceptable compliance level is assumed to be equal to the industry average of $45. A 25 percent less-than-full accreditation rate (the same as for the overall industry) was assumed and resurveys are estimated to cost $500.

Overall, the cost per patient for a program servicing 50 patients would increase by slightly more than the industry average ($50 compared to $39) under the proposed regulations. This represents a greater proportionate increase (1.6 percent as compared to 1.0 percent) than the increase expected for the average sized facility. The Secretary is in the process of collecting better data on this industry segment and solicits comments in this area.

M. Conclusions

The average annual net cost of this regulation is estimated to be $4.4 million. The costs represent a shift of costs to individual OTP's to maintain accreditation and the accompanying assurance of quality. Research has indicated that increased compliance with drug abuse treatment is correlated with beneficial and therapeutic outcomes to patients, and the Secretary believes that the use of private accreditation would improve treatment outcomes. If patient participation in therapy could be extended by an average of 6 months, relapse rates could decrease by approximately 20 percent. Even modest improvements, therefore, would bring substantial reductions in mortality and significant improvements in physical health, decreased criminal activity (including diversions), increased earnings and employment, better family and personal relationships (Ref. 81). The Secretary, including SAMHSA, continues to research this area and is specifically soliciting comments on these issues.

This proposal constitutes a significant impact on a substantial number of small entities. The Secretary solicits comments on how to address this impact.

The estimated annual cost of $4.4 million is far below the threshold defined by the Unfunded Mandates Act.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collections 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 and recordkeeping 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 Proposal to Adopt New Regulations.*

Description. The Secretary is proposing to issue 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 proposed changes 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 proposed rule, there will be fewer reporting requirements and fewer required forms under the new system. The total reporting requirements are estimated at 2,074 hours for treatment programs, and 341 hours for accrediting organizations.

A recent FDA information collection analysis (Ref. 82) estimated the annual paperwork burden for the existing regulations to be approximately 1,500 hours. The proposed 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. Deducting these two requirements (total 775 hours) from the estimate for the proposed system (2,074 hours) leaves a reporting burden of approximately 1,300 hours, which is less than the estimated burden under the existing system. This is consistent with the streamlining of requirements under the proposal, and the elimination of certain forms and reporting requirements altogether.

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

TABLE 1.—ANNUAL REPORTING BURDEN FOR TREATMENT PROGRAMS

42 CFR Citation and Purpose	No. of Respondents	Responses per Respondent	Minutes per Response	Total Hours
8.11(b)—New program approval SMA–162	75	1	90	112.5
8.11(b)—Renewal of approval[1] SMA–162	300	1	60	300
8.11(b)(3)—Relocation SMA–162	35	1	70	40.83
8.11(d)—Application for transitional certification[2] SMA–162	300	1	95	475
8.11(e)(1)—Application for provisional certification	75	1	30	37.5
8.11(e)(2)—Application for extension of provisional certification	30	1	15	7.5
8.11(f)(5)—Notification of sponsor or medical director change	60	1	20	20
8.11(g)(2)—Documentation to SAMHSA for interim maintenance	1	1	120	2
8.11(h)—Request to SAMHSA for exemption from 8.11 and 8.12	800	3	26.25	1050
8.11(i)(1)—Notification to SAMHSA before establishing medication units	3	1	15	.75
8.12(j)(2)—Notification to State Health Officer when patient begins interim maintenance	1	1	20	3.33
8.24—Contents of appellant request for review of suspension	2	1	15	.5
8.25(a)—Informal review request	2	1	60	2
8.26(a)—Appellant's review file and written statement	2	1	300	10
8.28(a)—Appellant's's request for expedited review	2	1	60	2

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

42 CFR Citation and Purpose	No. of Respondents	Responses per Respondent	Minutes per Response	Total Hours
8.28(c)—Appellant review file and written statement	2	1	300	10
Totals				2,073.91

[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 proposal does not increase the estimated annualized burden. Certain reporting requirements have been proposed for elimination, 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 proposal 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 proposed for elimination, 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 proposal, accreditation bodies, under contract to SAMSHA, will be accrediting existing OTP's as part of an initiative to gain more information on the accreditation of OTP's. SAMHSA has 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[1]

42 CFR Citation and Purpose	No. of Respondents	Responses per Respondents	Hours per Response	Total Hours
8.3(b)—Initial approval SMA–163	10	1	3	30
8.3(c)—Renewal of approval SMA–163	3	1	1	3
8.3(e)—Relinquishment notification	1	1	0.5	0.5
8.3(f)—Nonrenewal notification to accredited OTP's	1	90	0.1	9
8.4(b)(1)(ii)—Notification to SAMHSA for serious noncompliant programs	2	2	1	4
8.4(b)(1)(iii)—Notification to noncompliant programs	2	2	1	4
8.4(d)(1)—General documents and information to SAMHSA upon request	10	2	0.5	10
8.4(d)(2)—Accreditation survey to SAMHSA upon request	10	6	0.2	12
8.4(d)(3)—List of surveys, surveyors to SAMHSA upon request	10	6	0.2	12
8.4(d)(4)—Less than full accreditation report to SAMHSA	10	7.5	0.5	37.5
8.4(d)(5)—Summaries of inspections	10	30	0.5	150
8.4(e)—Notification complaints	10	1	0.5	5
8.6(a)(2) and (b)(3)—Revocation Notification to accredited OTP's	1	90	0.3	27
8.6(b)—Submission of 90-day corrective plan to SAMHSA	1	1	10	10
8.6(b)(1)—Notification to accredited OTP's of probationary status	1	90	0.3	27
Totals				341

[1] 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 OTP's set forth in proposed § 8.12 include maintenance of the following: A patient's medical evaluation and other assessments when admitted to treatment, and periodically throughout treatment § 8.12(f)(4)); the provision of needed services, including any prenatal support provided the patient (§ 8.12(g)(1)and (g)(2)); justification of exceptional initial doses; changes in a patient's dose and dosage schedule; justification of exceptional daily doses (§ 8.12(h)(3)(iii)); justification for variations from the approved product labeling for LAAM and future medications (§ 8.12(h)(4)); and the rationale for decreasing a patient's clinic attendance (§ 8.12(i)(3)).

In addition, proposed § 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 OTP's 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 proposal retains requirements that OTP's and accreditation organizations disclose information. For example, proposed § 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 proposal requires under § 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.

As required by section 3507(d) of the PRA, the Secretary has submitted a copy of this proposed rule to OMB for its review. Comments on the information collection requirements are specifically solicited in order to: (1) Evaluate

whether the proposed collection of information is necessary for the proper performance of DHHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of DHHS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

OMB is required to make a decision concerning the collection of information contained in these proposed regulations between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to DHHS on the proposed regulations.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, (address above).

X. Request for Comments

Interested persons may, on or before November 19, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Unified Agenda of Federal Regulatory and Deregulatory Actions, 61 FR 62003 to 62502, November 29, 1996.
2. Glass, R. M., Methadone Maintenance New Research on Controversial Treatment, *Journal of the American Medical Association*, vol. 269, no. 15, p. 1995, 1993.
3. U.S. General Accounting Office, *Methadone Maintenance: Some Treatment Programs Are Not Effective, Greater Federal Oversight is Needed*, GAO/HRD–90–104, 1990.
4. U.S. Institutes of Medicine, *Federal Regulation of Methadone Treatment*, National Academy Press, 1995.
5. U.S. Code Congressional and Administrative News, 91st Cong., 2d sess., vol. 3, p. 4580, 1970.
6. METHADONE HEW/FDA Proposes Conditions for Use, 41 FR 17922, April 29, 1976.
7. Nightingale, S. L., Methadone Treatment Programs, Quarterly Bulletin of the Association of Food and Drug Officials of the United States, vol. 38, no. 2, pp. 99–101, 1974.
8. Center for Substance Abuse Treatment, ''State Methadone Treatment Guidelines: Treatment Improvement Protocol (TIP) Series 1,'' 1993.
9. Molinari, S. P., J. R. Cooper, D. J. Czechowicz, ''Federal Regulation of Clinical Practice in Narcotic Addiction Treatment: Purpose, Status, and Alternatives,'' *The Journal of Law, Medicine and Ethics*, vol. 22, no. 3, 1994.
10. Center for Substance Abuse Treatment, ''Matching Treatment to Patient Needs in Opioid Substitution Therapy: Treatment Improvement Protocol (TIP), Series No. 20,'' p. 6, 1995.
11. Molinari, S. P., J. R. Cooper, D. J. Czechowicz, ''Federal Regulation of Clinical Practice in Narcotic Addiction Treatment: Purpose, Status, and Alternatives,'' *The Journal of Law, Medicine and Ethics*, vol. 22, no. 3, 1994.
12. Molinari, S. P., J. R. Cooper, D. J. Czechowicz, ''Federal Regulation of Clinical Practice in Narcotic Addiction Treatment: Purpose, Status, and Alternatives,'' *The Journal of Law, Medicine and Ethics*, vol. 22, no. 3, 1994.
13. United States General Accounting Office, ''Methadone Maintenance: Some Treatment Programs Are Not Effective; Greater Federal Oversight Needed,'' GAO HRD–90–104, 1990.
14. Institute of Medicine, Federal Regulation of Methadone Treatment, National Academy Press, 1995.
15. IOM Report, p. 213.
16. IOM Report, p. 221.
17. IOM Report, p. 236.
18. IOM Report, p. 166.
19. *The 1996 CARF Accreditation Sourcebook*, Commission on Accreditation of Rehabilitation Facilities, 1996.
20. A Voice for Quality: The Newsletter of the Council on Accreditation of Services for Families and Children., COA, 1996.
21. Dole, V. P., ''Hazards of Process Regulations,'' *Journal of the American Medical Association*, vol. 267, p. 2234, April 1992.
22. Annotated Code, State of Ohio, Ohio Annotated Code, p. 3793, 2–1–01, 1996.
23. ''Effective Medical Treatment of Heroin Addiction,'' NIH Consensus Statement 1997, vol. 15, no. 6, p. 10, November 17 to 19, 1997.
24. ''Narcotic Analgesics,'' in *The Pharmaceutical Basis of Therapeutics*, edited by Louis Goodman and Alfred Gilman, 14th ed., p. 237, 1971.
25. ''THIRD METHADONE CLINIC PROPOSED,'' Tammie Smith, *The Tennessean*, January 18, 1997.
26. ''Marrero to Get Methadone Clinic,'' Copyright 1997 The Times-Picayune Publishing Co., *The Times-Picayune*, February 28, 1997.
27. Annotated Code, State of Ohio, Ohio Annotated Code, p. 3793, 2–1–01, 1996.
28. METHADONE: Listing as New Drug With Special Requirements and Opportunity for Hearing, 37 FR 26791, December 15, 1972.
29. Agency Information Collection Activities; Submission for OMB Review; Request for Comments, Docket No. 97N–0456, Food and Drug Administration, ''Conditions for the Use of Narcotic Drugs for Treatment of Narcotic Addiction Reporting and Recordkeeping Requirements,'' OMB Control Number 0910–0140—Reinstatement, 63 FR 14468, March 25, 1998.
30. *New York Times*, February 2, 1997, Sunday, Late Edition—Final: Section 1; p. 12; Column 1; National Desk, ''Ex-Addicts Find Methadone More Elusive Than Heroin,'' Christopher S. Wren.
31. IOM Report, pp. 92–118.
32. Methadone Diversion, DEA, April 1995.
33. Substance Abuse and Mental Health Services Administration, ''Request for Proposal (RFP) No. 270–97–7003: 'Development and Implementation of Opioid Treatment Program Accreditation','' April 15, 1997.
34. U.S. General Accounting Office, *Billions Spent Annually for Treatment and Prevention Activities*, GAO/HEHS–97–12; October 8, 1996.
35. Glass, R. M., ''Methadone Maintenance: New Research on Controversial Treatment,'' *Journal of the American Medical Association*, vol. 269, no. 15, 1995.
36. U.S. Drug Enforcement Administration, *Methadone Diversion: 1995*, Office of Diversion Control, April 1995.
37. Rice, D., S. P. Kelman et al., *The Economic Costs of Alcohol and Drug Abuse and Mental Illness, 1985*, San Francisco, University of California, Institute for Health and Aging, 1990.
38. Anglin, M. D., G. Speckart et al., ''Consequences and Costs of Shutting Off Methadone,'' *Addictive Behaviors*, vol. 14, pp. 307–326, 1989.
39. Dennis, M., J. Fairbanks et al., ''Enhanced Counselor's Manual,'' NIDA Grant No. 1–R18DA7262–01, Research Triangle Institute, 1991.
40. Bradley, C. J., M. T. French et al., ''Financing and Cost of Standard and Enhanced Methadone Treatment,'' *Journal of Substance Abuse Treatment*, vol. 11, no. 5, pp. 433–442, 1994.
41. Ralston, G. E., and P. Watson, ''Methadone Programmes: The Costs and Benefits to Society and the Individual,'' *PharmacoEconomics*, vol. 10, no. 4, pp. 321–326, 1996.
42. French M. T., J. A. Mauskoph et al., ''Estimating the Dollar Value of Health Outcomes from Drug Abuse Interventions,'' *Medical Care*, vol. 34, pp. 890–910, 1996.
43. Goldschmidt, P. G., ''A Cost-Effectiveness Model for Evaluating Health Care Programs: Application to Drug Abuse Treatment,'' *Inquiry*, vol. 13, no. 3, pp. 29–47, 1976.

44. U.S. Food and Drug Administration, *Guidelines for Medications Development for Substance Abuse Disorders*, 1996.

45. McLellan, A. T., H. Kushner et al., ''The Fifth Edition of the Addiction Severity Index,'' *Journal of Substance Abuse Treatment*, vol. 9, pp. 199–213, 1992.

46. Horton, A. M., ''Future Directions in the Development of Addiction Assessment Instruments,'' in *Diagnostic Source Book on Drug Abuse Research and Treatment* (NIDA Research Monograph No. xx) Rounsaville, B. J., F. M. Tims, A. M. Horton, and B. J. Sowder, (Eds), U.S. Department of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse, Washington, D.C.: U.S. Government Printing Office, 1993.

47. Anglin, M. D., G. Speckart et al., ''Consequences and Costs of Shutting Off Methadone,'' Addictive Behaviors, vol. 14, pp. 307–326, 1989.

48. Ball, G. A., A. Ross, *The Effectiveness of Methadone Treatment*, Springer Verlag, New York, 1991.

49. Gerstein, D. R., R. A. Johnson et al., *Evaluating Recovery Services: The California Drug and Alcohol Treatment Assessment (CALDATA)*, Sacramento, CA, California Department of Alcohol and Drug Programs, 1994.

50. McLellan, A. T., D. S. Metzger et al., ''Worth It? Public Health Expectations, Policy-Based Comparisons,'' *Millbank Quarterly*, 1995.

51. Ball, G. A., A. Ross, *The Effectiveness of Methadone Treatment*, Springer Verlag, New York, 1991.

52. Gerstein, D. R., R. A. Johnson et al, *Evaluating Recovery Services: The California Drug and Alcohol Treatment Assessment (CALDATA)*, Sacramento, CA, California Department of Alcohol and Drug Programs, 1994.

53. Hubbard, R. L., M. E. Marsden et al., *Drug Abuse Treatment: A National Study of Effectiveness*, Chapel Hill, NC, University of North Carolina Press, 1989.

54. Des Jarlais, D. C., S. R. Friedman et al., ''HIV 1 Infection among Intravenous Drug Users in Manhattan, New York City: 1977 to 1987'' *Journal of the American Medical Association*, vol. 261, pp. 1008–1012, 1989.

55. Metzger, D. S., G. E. Woody et al., ''HIV Conversion Among In and Out-of-Treatment Intravenous Drug Users in Philadelphia,'' *Journal of AIDS*, vol. 6, pp. 1049–1056, 1993.

56. U.S. National Institutes for Health, *NIH Consensus Panel on Prevention and Treatment of Substance Use Disorders for HIV Risk Reduction*, Bethesda, MD, 1997.

57. U.S. Food and Drug Administration, Narcotic Treatment Programs Directory, February 20, 1997.

58. U.S. Substance Abuse and Mental Health Services Administration, Uniform Facility Data Set (UFDS): Data for 1996 and 1980–1996, Office of Applied Studies, December 1997.

59. U.S. Substance Abuse and Mental Health Services Administration, National Drug and Alcohol Treatment Unit Survey, 1993a.

60. U.S. Substance Abuse and Mental Health Services Administration, Uniform Facility Data Set (UFDS): Data for 1996 and 1980–1996, Office of Applied Studies, December 1997.

61. U.S. Substance Abuse and Mental Health Services Administration, 1997.

62. U.S. Substance Abuse and Mental Health Services Administration, Uniform Facility Data Set (UFDS): Data for 1996 and 1980–1996, Office of Applied Studies, December 1997.

63. Capital Consulting Corporation and the Lewin Group ''Methadone and LAAM: An Analysis of the Cost of Treatment Using Alternative Medications for Opiate Addiction,'' Contract No. SAMHSA 270–91–8327, October 31, 1996.

64. Bradley, C. J., M. T. French et al., ''Financing and Cost of Standard and Enhanced Methadone Treatment,'' *Journal of Substance Abuse Treatment*, vol. 11, no. 5, pp. 433–442, 1994.

65. Capital Consulting Corporation and the Lewin Group, ''Methadone and LAAM: An Analysis of the Cost of Treatment Using Alternative Medications for Opiate Addiction,'' Contract No. SAMHSA 270–91–8327, October 31, 1996.

66. Bradley, C. J., M. T. French et al., ''Financing and Cost of Standard and Enhanced Methadone Treatment,'' *Journal of Substance Abuse Treatment*, vol. 11, no. 5, pp. 433–442, 1994.

67. U.S. Bureau of Labor Statistics, Compensation and Working Conditions, vol. 2, no. 4, p. 88, 1997.

68. Joint Commission on Accreditation of Healthcare Organizations, *1996 Survey Fees*, 1996.

69. U.S. Bureau of Labor Statistics, Employment and Earnings, 1995.

70. Bonn, E. M., ''Accreditation and Regulation of Psychiatric Facilities,'' in *Psychiatric Administration*, edited by J. A. Talbott and S. R. Kaplan, Grune and Stratton, pp. 299–310, 1983.

71. Capital Consulting Corporation and the Lewin Group ''Methadone and LAAM: An Analysis of the Cost of Treatment Using Alternative Medications for Opiate Addiction,'' Contract No. SAMHSA 270–91–8327, October 31, 1996.

72. Conklin, T. J., ''Quality Assurance,'' in *Psychiatric Administration*, edited by J. A. Talbott and S. R. Kaplan, Grune and Stratton, pp. 273–285, 1983.

73. Marlatt, G. A., J. R. Gordon, *Relapse Prevention*, Guilford Press, New York, 1985.

74. Ball, G. A., A. Ross, *The Effectiveness of Methadone Treatment*, Springer Verlag, New York, 1991.

75. Ball, G. A., A. Ross, *The Effectiveness of Methadone Treatment*, Springer Verlag, New York, 1991.

76. Goldschmidt, P. G., ''A Cost-Effectiveness Model for Evaluating Health Care Programs: Application to Drug Abuse Treatment,'' *Inquiry*, vol. 13, no. 3, pp. 29–47, 1976.

77. Goldschmidt, P. G., ''A Cost-Effectiveness Model for Evaluating Health Care Programs: Application to Drug Abuse Treatment,'' *Inquiry*, vol. 13, no. 3, pp. 29–47, 1976.

78. U.S. National Center for Health Statistics, Monthly Vital Statistics Reports, 1993.

79. U.S. Small Business Administration, *Table of Size Standards*, March 1, 1996.

80. Capital Consulting Corporation and the Lewin Group, ''Methadone and LAAM: An Analysis of the Cost of Treatment Using Alternative Medications for Opiate Addiction,'' Contract No. SAMHSA 270–91–8327, October 31, 1996.

81. Ralston, G. E., and P. Watson, ''Methadone Programmes: The Costs and Benefits to Society and the Individual,'' PharmacoEconomics, vol. 10, no. 4, pp. 321–326, 1996.

82. Agency Information Collection Activities; Submission for OMB Review; Request for Comments, Docket No. 97N–0456, Food and Drug Administration, ''Conditions for the Use of Narcotic Drugs for Treatment of Narcotic Addiction Reporting and Recordkeeping Requirements,'' OMB Control Number 0910–0140—Reinstatement, 63 FR 14468, March 25, 1998.

List of Subjects

21 CFR Part 291

Health professions, Methadone, Reporting and recordkeeping requirements.

42 CFR Part 8

Health professionals, 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, the Federal Food, Drug, and Cosmetic Act, and applicable delegations of authority thereunder, it is proposed that titles 21 and 42 of the Code of Federal Regulations be 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; sections 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 371); 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

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 argument.
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 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)(3)). 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 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 opioid treatment.

§ 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.

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 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 approved accreditation body.

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 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.

Opioid addiction means a condition in which an individual exhibits a compulsive craving for or compulsively uses opioid drugs despite being harmed or causing harm as a result of such craving or use.

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 opioid 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 opioid 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.

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.

§ 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. 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 application. 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) Evidence demonstrating that the applicant will be able to survey no less than 50 OTP's annually;

(4) A set of the accreditation elements and a detailed discussion showing how the proposed accreditation elements 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;

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

(i) Procedures for initiating and performing onsite accreditation surveys of OTP's;

(ii) Procedures for assessing OTP personnel qualifications;

(iii) Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTP's 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 OTP's and SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTP's;

(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 OTP's to contest adverse accreditation decisions.

(6) 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;

(7) 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;

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

(9) Fee schedules, with supporting cost data;

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

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

(12) 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 subpart A of this part, 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 OTP's 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 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 review 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 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 programs with less substantial violations. Such accreditation shall not exceed 12 months. Programs 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 semi-annually, 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, 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 2 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 OTP's 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 OTP's.

(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 OTP's accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTP's 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 OTP's 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 OTP's 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) and (g)(3) of the Controlled Substances Act (21 U.S.C. 823(g)(1) and (g)(3)) to dispense opioid drugs in the treatment of opioid addiction. An OTP must be determined to be qualified under section 303(g)(1) and (g)(3) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(2), 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). 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 address 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) and (g)(3) of the Controlled Substances Act.

(d) *Transitional certification*. OTP's that on (date 60 days after date of publication of final rule in the **Federal Register**) were the subject of a current, valid approval by FDA under 21 CFR part 291, are deemed to be the subject of a current valid certification for purposes of paragraph (a)(11) of this section. Such ''transitional'' certification shall expire on (date 150 days after date of publication of final rule in the **Federal Register**), except that such transitional certification of an OTP that submits the information required by paragraph (b) of this section to SAMHSA on or before (date 150 days after date of publication of the final rule in the **Federal Register**), along with a statement certifying that the OTP will apply for accreditation from a SAMHSA approved accreditation body within 90 days from the date SAMHSA announces the approval of the first accreditation body under § 8.3, shall expire on (date 2 years and 60 days after date of publication of final rule in the **Federal Register**). SAMHSA may extend the transitional certification of an OTP for up to 1 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) OTP's 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 the program's efforts to obtain accreditation and a schedule for obtaining accreditation as expeditiously as possible.

(f) *Conditions for certification.* (1) OTP's shall comply with all pertinent State laws and regulations. Nothing in this part is intended to limit the authority of State and 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 programs operated directly by the Veterans' Administration or any other department or agency of the United States. Federal agencies operating narcotic treatment programs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal narcotic treatment programs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.

(2) OTP's 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) OTP's shall notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTP's 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) OTP's 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 §§ 8.11 and 8.12. 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 may 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 OTP's 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 SMA–162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit.

(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 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.* OTP's must provide treatment in accordance with these standards and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* An OTP's organizational structure 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 program shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the program 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 program. In addition, the medical director shall be responsible for ensuring that the program 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 attempts at short-term detoxification or drug-free treatment to be eligible for maintenance treatment. A waiting period of no less than 7 days is required between the first and the second short-term detoxification 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. At a minimum, a program physician shall determine that each patient admitted is physically dependent on opioid drugs. In addition, a patient is required to wait no less than 7 days between concluding a short-term detoxification or long-term detoxification treatment episode and beginning another.

(f) *Required services*—(1) *General.* OTP's shall provide adequate medical, counseling, vocational, educational, and assessment 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.* OTP's shall require each patient to undergo a complete, fully documented medical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, within the first 30 days following admission to the OTP.

(3) *Special services for pregnant patients.* OTP's must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services for 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 patients'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) OTP's 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 drug abusers, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTP's 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) OTP's 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.* OTP's must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient, 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) OTP's 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) OTP's shall include, as an essential part of the recordkeeping

system, documentation in each patient's record showing that the OTP made the determination, upon the admission of each patient, that the patient is not enrolled in 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) OTP's 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) OTP's 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, OTP's 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, provided the investigational use of the drug by the OTP is fully consistent with the protocol and other conditions set forth in that application. Only 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) Levo-Alpha-Acetyl-Methadol (LAAM).

(3) OTP's 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.

(iii) The administering physician shall ensure that any time a daily dose greater than 100 milligrams is provided to a patient, the justification for such a daily dose is stated in the patient's record.

(4) OTP's 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 deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are justified 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 (h)(4)(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 (h)(4)(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 month of treatment, the maximum take-home supply is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under these regulations.

(ii) In the second month of treatment, the maximum take-home supply is two doses after each supervised ingestion.

(iii) In the third month of treatment, the patient shall have observed ingestion at least twice a week, with take-home permitted for other doses.

(iv) In the remaining months of the first year, the maximum take-home supply of opioid medication is three doses after each supervised ingestion.

(v) After 1 year, a patient may be given a maximum of 31 days 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) OTP's 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 (see Poison Prevention Packaging Act, Pub. L. 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 § 8.12(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 OTP's 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, OTP's 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 42 CFR 8.3.

Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification

§ 8.21 Applicability.

These procedures apply when:

(a) SAMHSA has notified an OTP in writing that its certification under these regulations has been suspended or that SAMHSA proposes to revoke such certification; and

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

§ 8.22 Definitions.

(a) *Appellant* means the treatment program which has been notified of its suspension or proposed revocation of its certification under these regulations and has requested a review thereof.

(b) *Respondent* means the person or persons designated by the Secretary in implementing these regulations.

(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 of his or her 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, the necessary interpretations of those facts, these regulations, 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) 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 or proposed revocation, a brief statement of why the decision to suspend or propose revocation is incorrect, and the appellant's request for an oral presentation, if desired.

(b) 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 argument.

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 15 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 is incorrect (appellant's brief).

(b) *Respondent's documents and brief.* Within 15 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, 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 or proposed revocation (respondent's brief).

(c) *Reply briefs.* Within 5 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 step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

§ 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 his or her 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 30 days of the date appellant's request for review is

received or within 10 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 of his or her 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 or propose revocation 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 prehearing 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. 1505 or 1001.

(g) *Post-hearing procedures.* At his or her 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 5 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 10 to 14 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 will 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 by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested.

§ 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) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile transmission, personal service, 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) 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 reviewing official.

In addition to any other authority specified in these procedures, 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 these procedures.

§ 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 or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefor 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 his or her 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 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 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 or proposed revocation, 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.

Dated: July 14, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Nelba Chavez,

Administrator, Substance Abuse and Mental Health Services Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

Note: The following appendix will not appear in the Code of Federal Regulations:

BILLING CODE 4160–01–F

Appendix 1

OFFICE OF NATIONAL DRUG CONTROL POLICY
POLICY PAPER
OPIOID AGONIST TREATMENT

March 1999

OFFICE OF NATIONAL DRUG CONTROL POLICY (ONDCP) POLICY PAPER -- OPIOID AGONIST TREATMENT

INTRODUCTION

This paper is circulated by the Director, ONDCP, under his statutory authority [Section 704 (b) (3) of Public Law 105-2 77, the Office of National Drug Control Policy Reauthorization Act of 19981 to coordinate and oversee the implementation by the National Drug Control Program agencies of the policies, goals, objectives, and priorities established for the national drug control programs and the fulfillment of the responsibilities of such agencies under the National Drug Control Strategy.

In response to recent increases in heroin use, ONDCP has joined with the Departments of Health and Human Services (DHHS) and Justice (DOJ), to address the problems and potential of opioid agonist treatment, primarily methadone treatment. In addition to a shortfall in treatment capacity, problems have long existed at two levels: first, methadone treatment programs have not functioned with uniform high quality; and, second, Federal oversight, grounded in process-focused regulations, has not served to improve or maintain the quality of methadone treatment programs. To reduce the use of illicit drugs, both of these problems must be addressed.

1. PURPOSE: The purpose of this document is to discuss national policy and direction regarding the role of methadone, levo-alpha-acetylmethadol hydrochloride (LAAM), and other opioid agonist treatments in reducing opiate addiction.

2. OBJECTIVE: A major priority of the Office of National Drug Control Policy (ONDCP) is to allow those addicted to heroin to receive quality drug treatment, including opioid agonist treatment when it is the indicated modality, in the context of expanding overall treatment capacity for all drugs of abuse.

3. DISCUSSION:

A. The Scope of the Heroin Problem: Although a relatively small percentage of America's illegal drug users use heroin, the debilitating effects of the drug make it, along with cocaine, a major source of drug-related health, crime, and social costs. And the heroin using population has grown in recent years. Data from the National Household Survey on Drug Abuse indicate that current (i.e., past month) use of heroin in the household population, age 12 years and older, has risen dramatically, from 71,000 in 1991 to 325,000 in 1997. ONDCP estimates a population of 810,000 chronic heroin users in the United States in 1995.

(1) Trends -- High Purity: While the number of new heroin initiates is still relatively low, it is apparent that the availability of high-purity heroin has led to an increase in use, probably related to changes in the route of administration. High purity heroin can be snorted, smoked, or otherwise inhaled, and need not be injected. Heroin users

who have snorted or smoked heroin increased from 55 percent of heroin users in 1994 to 82 percent m 1996. This trend is disturbing in two aspects: first, because it expands the use of heroin to those who might be reluctant to inject drugs; and, second, because heroin can now be ingested using the same "pathway" as abused substances such as tobacco, crack, methamphetamine, and marijuana. The ability to snort or smoke heroin is likely to foster experimentation, adding to the number of users and leading to injection for many of them over time. The *Drug Abuse Warning Network* (DAWN) reports that the proportion of drug-related episodes that involve heroin/morphine increased steadily from 4 percent in 1978 to 13.8 percent in 1995, before leveling off in 1996 and the first six months of 1997. The number of heroin/morphine "mentions~~ increased each year from 1991 through 1996 (35,898 in 1991, 48,003 in 1992, 63,232 in 1993, 64,013 in 1994, 70,838 in 1995, and 73,846 in 1996). Most of these patients sought detoxification or medical treatment to deal with overdose or the chronic health effects of heroin use.

(2) Trends -- Heroin Addicts and Other Chronic, Hardcore Drug Users are Undercounted: Because of the nature of heroin abuse, many chronic users may not be captured by traditional surveys such as the *National Household Survey on Drug Abuse* (which only surveys those living in households) and *Monitoring the Future* (which only surveys youth enrolled in school and present on the day of the survey). To provide a more accurate estimate, ONDCP sponsored a pilot research study in Cook County, Illinois, to test a new methodology for estimating addicted drug users. In addition to validating the new methodology, the study found that there were three times as many hardcore addicts in Cook County than the number estimated by the Household Survey. These results suggest that the actual number of chronic heroin users in the United States may be even larger than ONDCP's estimate of 810,000.

(3) Trends -- The Population of Addicts is Aging, Even as Younger Initiates Increase: Many heroin addicts encounter serious health problems after years of use. Heroin addicts who began use in the last great heroin epidemic of the late 1960s and early 1970s now require significantly increased and costly medical care for the cumulative debilitating effects of their drug use. Since 1978 the number of emergency room mentions for heroin among those aged 35 and older has tripled. The DAWN report of drug mentions in hospital emergency departments shows that heroin/morphine mentions more than doubled from 1990 through 1996 (from 33,900 to 73,800), as did the rate per 100,000 population (from 15.3 in 1990 to 31.4 in 1996). And, although their numbers remain relatively small, increases in heroin mentions are also seen among youth ages 12 to 17 and 18 to 25. This DAWN data is consistent with the finding of the National Household Survey on Drug Abuse that the mean age of initiation for heroin dropped from 26.2 years in 1988 to 18.1 in 1996.

B. The Implications of the Problem: As with cocaine and methamphetamine users, heroin users are at risk for a plethora of negative social and health consequences.

(1) Heroin is a Toxic Substance: The danger of a fatal overdose is more immediate and likely for a heroin user today than for users of other common drugs of abuse because of the route of administration and common miscalculations regarding drug purity. Misjudging heroin purity can have fatal implications. Heroin use is involved in about 15 percent of all drug-related emergency room visits -- a number that far exceeds the proportion of heroin users in the general drug-using population.

(2) Heroin Use is Associated with Crime: Because of the addictive and tolerance properties of heroin, users find that they need heroin frequently in increasing amounts. Because the withdrawal effects of heroin are both severe and frequent, addicts typically use heroin several times a day. The need to purchase large amounts of a costly drug inevitably leads to crime. For decades some cities have estimated that over half of all property crime is attributable to heroin use. Twenty percent of all people arrested in Manhattan in 1997 tested positive for opiates. In the same year, 22 percent of all arrestees in Chicago tested positive for opiates.

(3) Heroin Use Affects Public Health: There is a strong nexus between heroin use and many life-threatening diseases, including infections such as hepatitis B and C, HIV/AIDS, and endocarditis; as well as tuberculosis and sexually transmitted diseases. The heroin subculture -- with its sharing of needles and "cooking equipment" and associated high-risk sexual behaviors, including prostitution and trading sex for drugs -- is a major factor in the transmission of disease. The Centers for Disease Control (CDC) estimates injecting drug users (most of whom are heroin users) account for between 15 and 36 percent of the nation's new HIV infections each year. According to CDC's HIV/AIDS Surveillance Report, of 13,111 new HIV cases reported between July 1996 and June 1997, injecting drug use was an "exposure category" for over 2,200. Heroin not only undermines the health of users, but -- in the case of pregnant women -- can seriously affect the health of their children.

(4) Heroin Addiction is Difficult to Overcome: The National Institute of Drug Abuse has declared that heroin is a powerfully addicting substance producing tolerance, physical dependence, and the clinical state of addiction (defined as compulsive, often truly uncontrollable drug craving, seeking, and use). The psycho-pharmacological effects of heroin are extremely strong. Satisfaction of the self-destructive need becomes nearly a full-time occupation. Heroin addicts spend a large amount of their time searching for drugs. An ONDCP study of cocaine, crack, and heroin abuse in six cities found that the percentage of heroin users who used heroin for 30 or more consecutive days over a 90 day period was four times greater than the percentage for crack and powder cocaine users. This finding indicates that there is a high proportion of heroin addicts among the users of heroin. Cessation of heroin use is difficult: the same study found that heroin users reporting 30 or more consecutive days of abstinence in a 90 day period tended to be lower than for crack or powder cocaine users. The relatively stable number of heroin addicts over the years,

particularly in older age groups, indicates the relative shortfall in effective treatment capacity and aggressive outreach programs to get the addicts into treatment. In some cities, an entire heroin culture that spans generations has evolved, as addicts cycle through the criminal justice system and back into street addiction without any prospect of entering an effective treatment regimen.

C. Methadone -- Part of the Solution: Methadone has been used for the treatment of heroin addiction since the 1960s. It is an orally effective, long-acting, synthetic opioid agonist. In other words, methadone operates by "occupying" the brain receptor sites that are affected by heroin and blocks the craving attendant to addiction. Eventually it produces tolerance to its own analgesic effects, as well as its psychoactive effects, and also produces a physiological cross-tolerance to other opiates. Initially, methadone was used in the context of abstinence-based drug treatment to alleviate withdrawal pains for heroin addicts. Because of methadone's long duration of action before withdrawal begins (24 hours at adequate doses), it is relatively easy to maintain an addict on methadone without abrupt side effects. A more recently approved agent, levo-alpha-acetylmethadol hydrochloride (LAAM), will last even longer, up to three days.

Although much is known about the action and effectiveness of methadone, less is known about the addict population. Among the questions remaining to be answered by research and experience is how to determine with confidence which addicts should most properly be referred to therapeutic community-like residential treatment, which to methadone detoxification, which to limited term methadone-to-abstinence treatment, and which to long-term maintenance.

(1) The Rise of Methadone Treatment: Heroin addiction became a major public concern during the epidemic of the 1960s and early 1970s. The growth in heroin addiction occurred during a major shift in public health approaches, away from an (often coercive) in-patient treatment regimen to out-patient, community-based treatment. Confronted with a rising number of heroin addicts and faced with a choice between methadone treatment and other treatment regimes, which promised uncertain results at the time, many governmental agencies opted to pursue methadone treatment. The American Bar Association noted in a 1972 report that New York City had 18,072 people in methadone programs, with a waiting list of 15,000 more, and that 65 percent of all participants in New York City treatment programs were in methadone treatment. National estimates of the number of patients in methadone treatment have indicated growth, with an estimate of 81,852 in methadone treatment in 1987, nearly 95, 300 in 1991, and 117,000 in 1993. A recent survey of the states by the American Methadone Treatment Association (AMTA) indicates that over 170,000 patients are engaged in some form of methadone treatment at this time.

(2) Methadone Treatment Today: Methadone treatment is the most widely used treatment for heroin addiction today. It has been studied more than any other drug treatment modality, with uniformly positive results. Thousands of Americans are able to

lead stable lives as a result of methadone treatment. Most of the over 900 methadone treatment programs in America provide an invaluable service. Typically, methadone patients go to a treatment program each day, to receive, and be observed ingesting, an oral dose of methadone in liquid form. Many stable, compliant patients are eventually allowed to take a number of doses home, reducing the number of trips they must make to the program. Better treatment programs make provision for systematic drug testing, monitoring for compliance, counseling, provision of other needed services, and periodic assessment of the continuing appropriateness of methadone. Unfortunately, many programs do not provide such comprehensive services.

Given the less than uniform state of methadone treatment, the outcomes achieved are remarkable. The National Institute on Drug Abuse (NIDA) has conducted literally dozens of studies that show the effectiveness of methadone treatment. *The Drug Abuse Treatment Outcome Study (DATOS),* the most recent study by NIDA, found that among participants in outpatient methadone treatment, weekly heroin use decreased 69 percent, cocaine use by 48 percent (many heroin users are polydrug users), illegal activity decreased 52 percent, and full time work increased by 24 percent. Methadone treatment, at an average cost of $13 or less per day, is clearly a cost effective alternative to incarceration for many drug-dependent offenders. Yet, in spite of this proven track record, methadone treatment capacity has not experienced marked growth. Treatment capacity is insufficient to provide most of the 810,000 chronic heroin addicts with methadone treatment or any other effective form of drug abuse treatment. Methadone treatment is still not available in eight states: Idaho, Mississippi, Montana, New Hampshire, North Dakota, South Dakota, Vermont, and West Virginia.

(3) Criticisms of Methadone Treatment: The full benefits of any intervention, including methadone treatment, are only obtained within a comprehensive treatment environment, which screens and evaluates patients and assigns them to appropriate treatment regimes, based upon the nature of each patient's addiction as well as other problems (e.g., psychological, family, vocational). By itself, methadone is simply a medication, a drug. As noted by the November 1997 National Institutes of Health Consensus Development Statement, non-pharmacologic supportive services are pivotal to successful treatment. Ongoing substance abuse counseling and other psychosocial therapies, vocational rehabilitation, and needed medical and social services are essential for program retention and positive outcome. For example, a study by McLellan in 1993 showed that patients who received comprehensive services including methadone, when compared to those who received methadone only, had a strikingly higher level of improvement. Comprehensive programs evaluate continued use of methadone and assess methadone's utility for each patient at regular intervals, as well as evaluating the need for treatment of problems that often interfere with adequate rehabilitation.

Unfortunately, such discipline has not universally been the case among programs. A 1990 GAO report based on observations of 24 methadone treatment organizations found that policies, goals and practices varied greatly and that not one of the programs studied

evaluated the effectiveness of their treatment. Although many improvements have been made, the failures of the unsuccessful programs tarnished the entire idea of methadone treatment, rather than spurring significant efforts to improve the quality of services and acknowledging the effectiveness of comprehensive programs.

(4) The Future of Methadone Treatment:

a. A standardized accreditation system for opioid agonist treatment programs with transfer of regulatory oversight from the Food and Drug Administration (FDA) to the Substance Abuse and Mental Health Services Administration (SAMHSA): The current, process-oriented regulatory approach will be replaced with a system that is more akin to a clinically-based accreditation model. Providers will know with certainty what is required of them --clinically, administratively, and programmatically -- to initiate or continue an opioid agonist treatment program. Regulatory and enforcement agencies will have a clear understanding of the nature and limits of their authority.

To start this process, CSAT/SAMHSA will lead the interagency effort, in 1999, to assess the impact of the accreditation process and proposed accreditation standards on methadone program quality, capacity, and oversight. Based on the results of the evaluation, feedback from treatment experts and public officials, and public comments on the Notice of Proposed Rule Making, a final rule will be promulgated to introduce reformed treatment standards and an accreditation process. Integrating regulatory oversight for methadone into CSAT/SAMHSA responsibilities for overseeing treatment services will facilitate the much-needed expansion of methadone treatment capacity while enhancing the application of clinical standards. In the interim, programs will remain subject to FDA oversight and monitoring.

Responsibility for preventing the diversion of methadone to illicit use will remain with the Drug Enforcement Administration (DEA). For the process of reform to progress with clear expectations, DEA's role will be spelled out in detail and distinguished from that of the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAT). Specifically, DEA's anti-diversion authority will be clearly distinguished from SAMHSA/CSAT' s clinical practice authority.

b. Provision for individual physician administration of methadone treatment to stabilized, methadone-maintained patients: Methadone is a tool of proven effectiveness in treating heroin addicts. But no tool is effective in isolation. The recovering heroin addict must be integrated back into employment and into society. It is estimated that, at a minimum, seven percent of those presently receiving methadone are sufficiently stable to be transferred to a private

physician for continued maintenance. When this transfer can be accomplished, additional program capacity will be made available for those awaiting treatment.

This will not happen overnight. Most physicians are ill-equipped to practice addiction medicine. However, as physician training and certification in the administration of opioid agonist treatment is accomplished, regulations will be reformed to allow trained physicians to use all the counter-addiction modalities in the physician's preferred clinical setting supported by ancillary services.

4. THE CHALLENGE: Currently only a fraction of those addicts who can benefit from methadone treatment do so. Expansion of methadone and other heroin treatment modalities, such as residential treatment, is essential to reach the untreated majority of the opiate addicted.

A. Policy Barriers: The laws governing methadone treatment -- the Controlled Substances Act (C.S.A.) and Narcotic Addict Treatment Act (NAIA) -- date from the 1970s, and reflect the political and social climate of the day, rather than rigorous study. These laws pre-date research breakthroughs on the nature of addiction and the success of drug treatment, and they arbitrarily limit the administration of treatment programs and the expansion of treatment capacity. Furthermore, they are implemented with process-focused regulations, which do not address treatment quality.

(1) Uneven Application of Standards for Admission to Methadone Treatment: As the 1990 GAO study noted, there is a wide variance of policies among methadone treatment programs. FDA admission standards are not uniformly applied by programs in evaluating potential patients and referring them to appropriate treatment. This lack of uniformity in practice continues under state managed care systems. Not everyone will benefit from methadone treatment and the failure to apply uniform assessment standards makes it probable that some addicts will be assigned to methadone or other treatment regimes inappropriately.

(2) Variance in Oversight and Limits on Program Administration: There is considerable overlap in governmental oversight and enforcement, with Federal, state, and local agencies involved in some states with different priorities and concerns. And an attempt to accomplish, with regulations, matters that depend on medical discretion. For example, Federal regulations address limits on dosage and on take-home medication privileges, with take-home privileges based on time spent in the program, rather than on clinical criteria. Both practices should be based on sound clinical criteria for decision-making, as the former practice can lead to under-treatment and the latter to both diversion to illicit use and interference with rehabilitation.

Given the critical role of the states in the reform of methadone regulations, lead Federal agencies must maintain continuing communication with relevant state authorities, to identified state-specific issues and plan for their resolution.

(3) Lack of Enforceable Clinical Guidelines: Paradoxically, in an environment in which methadone is over-regulated, there is a dearth of enforceable clinical guidelines. In lieu of outcome-oriented measures, the Federal Government has developed over time a regime of regulatory oversight that has controlled diversion to illegal use, but does little to enhance treatment quality, and at times actually interferes with treatment. There is a substantial body of knowledge and a rare scientific consensus on both the utility of methadone treatment and its appropriateness for many addicts. This body of clinical knowledge -- rather than the current regulatory maze -- should form the basis for clinical oversight and broader employment of methadone treatment.

Bringing existing treatment programs into conformance with established science will, at a minimum, require comprehensive technical assistance. And funding assistance might well be needed for programs to be able to meet the costs of the accreditation process and meet accreditation standards.

(4) Stigmatization of Addiction and Methadone Treatment: Some critics have called methadone treatment simply a way to keep people addicted, simply the substitution of one addiction for another. But methadone treatment is not simply a substitute for heroin. As noted by scholars such as Avram Goldstein, methadone's totally different pharmacokinetics make it a very different drug. While both heroin and methadone can occupy the mu opioid receptors in the brain, the steady, stable occupancy by methadone contrasts sharply with the repeated, excessive "highs" followed by excessive "lows" with heroin. This continuous receptor occupancy is the stabilizing factor that permits addicts on methadone to normalize their behavior and to discontinue heroin use. It diminishes the craving for heroin and, by producing opioid tolerance, blocks the heroin "high." Methadone makes possible the substitution of a stable existence for one of compulsive drug seeking and taking, criminal behavior, chronic unemployment, and high risk sexual and drug use behaviors.

"Drug-free" treatment (i.e., treatment with no pharmacologic agents) is considered by many to be preferable to methadone. (And it should be noted that evaluations of residential programs, although fewer in number, yield essentially similar results.) Some who prefer drug-free treatment reject the use of methadone entirely and others would set specific time limits on it's use (e.g., six months). The problem with these strident approaches is that they fail to recognize the changes in brain structure that accompany, and might in certain cases precede, addiction. Medical technology has enabled scientists to observe the changes in the addicted brain, specifically the damage to the reward pathway that spurs compulsive use and the sick feeling that

accompanies withdrawal. And while it is clear that addiction is a disease of the brain, more research is needed to distinguish those addicts who may have had a damaged brain reward pathway from birth, thus being predisposed to addiction, from those who have damaged their brain reward pathway through drug use. Furthermore, research will be required to distinguish brain changes that can be reversed from those that appear permanent. The decision to administer methadone and the duration of its use are clinical matters that should be informed by a science-based assessment of each patient's requirements.

B. Understanding the Role of Drug Treatment: The contributions of drug treatment in general and methadone treatment in particular are not universally understood or accepted. Drug treatment is sometimes characterized as another form of welfare, as "something for nothing," when it is actually very demanding for participants and the single most cost effective policy option for reducing the consumption of drugs and the commission of drug-related crimes. Indeed, from a public policy perspective, drug treatment is not solely, or even primarily, a service for the benefit of the drug-dependent. Although addicts clearly benefit with the acceptance of personal accountability; it is public safety, public health, and the public purse that are the primary beneficiaries of drug treatment. And they suffer when treatment is withheld or poorly delivered.

The Institute of Medicine of the National Academy of Sciences found in 1995 that a reduction in existing regulations could be accomplished without negative impact on health or safety standards. A 1997 consensus development conference, convened by the National Institutes of Health (NIH), strongly recommended broader availability of methadone treatment programs for people who are addicted to heroin or other opiate drugs and assessed as likely to benefit from agonist treatment. The NIH conference called for the elimination of Federal and State regulations and other barriers that improperly impede access. And a 1998 GAO review of the science identified methadone as the most effective treatment (to date) for heroin addiction. The conclusions of these prestigious bodies join the overwhelming scientific evidence supporting the expansion of methadone treatment within the overall context of an expansion of drug abuse treatment.

5. OUTCOMES: Methadone treatment is a lynchpin of modern opiate addiction treatment. It must be more widely available to those who need it and it must be conducted in a way that ensures quality and inspires public confidence.

Effective methadone treatment is an essential contributor to the attainment of the Performance Measures of Effectiveness established for the *National Drug Control Strategy*. This is most directly the case regarding Impact Targets for Goal 3, Reduce health and social costs to the public of illegal drug use:

- Reduce the health and social costs associated with illegal drugs by 10 percent by 2002, and by 25 percent by 2007; and

- Reduce the number of chronic drug users by 20 percent by 2002, and by 50 percent by 2007.

A. DESIRED END STATE:

(1) A comprehensive system of treatment oversight and delivery, guided by continuous assessment to ensure appropriate initial placement, appropriate retention, and movement to other modalities as necessary.

(2) A national cadre of well-trained health professionals, skilled in treating and managing addiction.

(3) Adequate treatment capacity for all who need and are willing to accept drug treatment.

(4) Adequate methadone treatment capacity for all of America's opiate drug addicts for whom it is indicated by appropriate assessment.

(5) Well-run programs with sufficient capacity, and ancillary services, to accommodate:

- state-of-the-art detoxification services;
- those who need long-term maintenance;
- those who can benefit from short-term methadone treatment, while receiving appropriate rehabilitation services to increase the likelihood they can remain abstinent after detoxification.

(6) A comprehensive evaluation and accreditation system to continue to ensure the effectiveness of methadone treatment.

- programs should be held accountable for, and required to monitor, participant cessation of alcohol and other drug use, engagement in productive employment, and cessation of criminal activity.

B. INTERMEDIATE BENCHMARKS:

(1) Increased public and, especially, medical community understanding of the efficacy of methadone treatment for those for whom it is indicated by appropriate assessment.

(2) Development of rational rules governing access to methadone treatment, allowing such treatment, where clinically warranted, in the offices of trained and accredited physicians.

- Both certification by a nationally recognized professional organization, and successful completion of a specific training program on issues pertinent to opioid maintenance therapies, should be required for primary care physicians to provide office-based narcotic addiction treatment.

- Physicians in private practice who prescribe methadone for stabilized addicts should make provision for simultaneous treatment of substance abuse disorders and physical and psychiatric comorbidity, and for other community services and self-help.

- Methadone treatment programs should function as hub referral sites.

(3) Development and utilization of a field-tested and proven system for accrediting methadone treatment programs with transfer of regulatory oversight from FDA to SAMHSA.

C. IMMEDIATE ACTIONS:

(1) Testing and evaluation of newly developed accreditation standards.

- Accreditation standards should be adopted only after a demonstration of their successful application.

(2) SAMHSA and FDA provision of technical assistance to programs, and continuing communication with Federal, state, and local government authorities, to facilitate a thorough demonstration and evaluation.

(3) Active ONDCP oversight of the demonstration and evaluation process, and subsequent action plan, to be accomplished through the Interagency Narcotic Treatment Policy Review Board.

(4) Discussion of the role of both short- and long-term methadone treatment and of alternative strategies for expanding treatment capacity for opiate drug addicts in the drug treatment and medical communities.

(5) A clear delineation and distinction of the roles and authorities of SAMHSA/CSAT and DEA.

(6) Active ONDCP oversight of the development of educational standards in addictions for health professionals, to be accomplished through the Interagency Narcotic Treatment Policy Review Board.

6. CONCLUSION: Methadone treatment, in its present state, has been demonstrated to be effective. However, it is not as effective as it can and should be. With increased funding must come increased quality and accountability. Appropriate treatment needs to be based on an assessment of

each individual and development of a regimen best suited to that individual's condition. Comprehensive patient assessment should precede any decision to provide opioid-based therapy. Anti-addiction medication should be prescribed in conjunction with comprehensive treatment services, such as counseling and needed medical services to diagnose and treat infectious diseases. And periodic assessment should determine the appropriateness of continuing opioid-based therapy. To improve quality and access, continuing work is necessary regarding government oversight of programs, quality assurance in both public and private programs, and the role of private medical practitioners.

[FR Doc. 99–18562 Filed 7–21–99; 8:45 am]
BILLING CODE 4160–01–C