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OUTPATIENT METHADONE TREATMENT MANUAL

EXECUTIVE OFFICE OF THE PRESIDENT
SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION

PREFACE

This is one of a series of Monographs developed by the Special Action Office for Drug Abuse Prevention to help present ideas regarding efficient and effective ways of providing drug abuse treatment services. This "how to" manual is intended for guidance only and in no way implies that this is the *only* way of providing quality care. We hope you will consider this information in light of your individual program and modify it accordingly.

This Monograph is to serve as a model for the program administrator in both the early planning stages and the actual implementation phase of an Outpatient Methadone program. It is assumed that the clinic exists as an independent unit and is not part of a larger program. Each component discussed is essential for a smoothly-functioning operation, and each meets the Food and Drug Administration regulations, the CODAP client management minimum standards, and the Federal Funding Criteria for Treatment Services.

We hope you find this Outpatient Methadone Monograph helpful and are able to tailor it to meet your specific drug treatment needs.

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EXHIBITS

I. INTRODUCTION

This manual is meant to serve as a guide to the program administrator in both the early planning stages and the actual implementation phase of an outpatient methadone program.

Essentially, the manual describes a model outpatient methadone clinic. For the purposes of this document, it is assumed that the clinic exists as an independent unit and is not part of a larger program. Each component discussed is necessary for a smoothly-functioning operation, and each meets requirements contained in the Food and Drug Administration regulations (See Exhibit 1), the CODAP client management minimum standards (See Exhibit 2), and the Federal Funding Criteria (See Exhibit 3).

Prior to discussing the factors that comprise an outpatient methadone clinic, it is helpful to remember what a methadone clinic is not. It is not a magic cure for addiction. Rather it is one approach to narcotics rehabilitation which may prove useful to a community in its attempts to provide meaningful treatment to certain segments of its addict population. As with any other community service, its effectiveness depends on careful planning, efficient management, concerned staff and citizen support.

When a community decides to offer outpatient methadone treatment as part of its drug abuse prevention effort, it confronts problems on several levels. Ideological opposition, cost, and citizen responsiveness all figure prominently in the initial decision and may affect subsequent progress and/or success. Once authorization has been obtained and the go-ahead is given, however, responsible officals are then faced with what may prove to be an even more complicated question, namely: how do we implement this kind of program?

A. What is Outpatient Methadone Treatment?

Outpatient methadone treatment is a concept pioneered by Doctors Vincent P. Dole and Marie Nyswander and since modified to meet the needs of heroin addicts primarily in urban settings.

Addicts meeting certain eligibility criteria (addressed in Section A.2) are given daily dosages of methadone which relieve the "drug craving." Once they are stabilized, cross tolerance, or "blocking," develops which prevents the patient from feeling the effects of any heroin which he might inject and renders his appearance virtually indistinguishable from that of the non-addict. It is these two effects, then, which define methadone's role in the treatment of heroin addiction.

Because methadone is administered orally and has no debilitating effects when handled appropriately, it lends itself to an outpatient setting. Methadone outpatient treatment programs offer two basic services: methadone maintenance and methadone detoxification.

1. *History*

Methadone was first developed by the Germans in World War II as a substitute for morphine. Its analgesic qualities were recognized in this country shortly thereafter, and it was distributed under many trade names, the best known being Dolophine. In the 1950's, it was used extensively for heroin detoxification, and in 1964, Doctors Dole and Nyswander recognized its stabilizing effects on heroin addicts and began their experimental project at Rockefeller University which led to the now famous program at the Morris J. Bernstein Institute of the Beth Israel Medical Center. What occurred at Beth Israel is the basis for the outpatient methadone clinic as it is conceived today.

2. *Methadone Maintenance*

According to FDA regulations, methadone maintenance is the treatment classification for *all* clients who receive methadone for more than 21 consecutive days. Therefore, anyone receiving a regular dose of methadone at the same dose level, increasing dose levels, or decreasing dose levels for a period lasting more than 21 days is to be considered a methadone maintenance client.

The following are minimum eligibility criteria for methadone maintenance candidates:

a. The client volunteers for methadone maintenance;
b. The client has been dependent on opiates for at least two years;
c. The client is at least eighteen years old;
d. The client has not met requirement "c", but is at least 16 years old, has a documented history of two or more years' dependence on opiates prior to treatment application, has made two documented attempts to detoxify, and has the Federal methadone consent form signed by a parent, legal guardian, or responsible adult designated by the State Authority.

The voluntary nature of methadone maintenance should be continually reenforced with staff so that the client does not feel compelled to enter treatment without a strong personal commitment. At the same time, staff should be careful to explain fully the implications of treatment. Although this will be discussed thoroughly in the intake and orientation sections of this manual, administrators should be aware of the importance of this stance from the outset.

The client opting for the maintenance category should be urged to continue in treatment until his life situation has been stabilized for at least six months to a year. Likewise, staff have a responsibility to remind the client that he may need methadone maintenance for an indefinite period of time. This information should not be presented in a threatening manner; rather, staff should explain that premature discontinuation of treatment is often associated with a return to heroin use and the criminal behavior which the habit often necessitates.

Again, early in the treatment process, the client often expresses feelings of discouragement or frustration with the medication routine. At this point, staff will begin receiving requests for immediate detoxification; and it is important that such requests should be handled sympathetically but firmly. The ramifications of methadone treatment should be reiterated with staff pointing out that while there is no "sure" way to tell who is ready for abstinence, past experience has shown that impulsive detoxification after a few weeks on methadone is extremely risky.

3. *Methadone Detoxification*

Methadone detoxification is the treatment classification for any client receiving decreasing dosages of methadone for a period not exceeding 21 days.(The addict who applies for methadone prescriptions but does not meet the requirements for maintenance may be detoxified providing he is over 16 years old and has the proper consent forms signed.)

Anyone who detoxifies from methadone maintenance should be urged to stay in treatment until he is detoxified, and after he has achieved abstinence, for a period of approximately three months. During this time, urine testing and counseling should continue. If there are signs of renewed drug hunger, evidenced by a client's preoccupation with heroin (often exhibited in extended conversations about his need for the drug), or if there are signs of renewed drug use revealed by urine surveillance, staff should explain alternative types of treatment available to the client. Such options include therapeutic communities, inpatient programs, and methadone maintenance programs. Should methadone maintenance be selected, staff should reenforce the idea that the client is not a failure because he needs this treatment modality. The physician and counselor must play major roles in any such discussion.

B. What are the Goals of Outpatient Methadone Treatment?

For the purposes of this manual, the goals of outpatient methadone treatment are:

1. Elimination of Illegal Drug Use

Although not every client receiving metahdone treatment will be able to eliminate drugs from his life, one goal of treatment should be the discontinuation of all illegal drugs. Although this definition clearly applies to heroin, cocaine, and non-prescribed amphetamines and barbiturates, alcohol should be regarded

in this category as well. Because the client has not been able to manage mood altering drugs in the past, alcohol often poses a particularly difficult problem for him. Although staff may feel hypocritical in advising abstention from alcohol, they should be aware of its potential danger for methadone maintenance clients. This problem will be more fully discussed in the section on alcohol.

2. Adoption of Productive and Self-Fulfilling Life Style

This goal poses the greatest challenge for both client and staff. In order to help staff deal positively with this area, development of client self-esteem, employment, and behavioral patterns which conform to society's standards should be vigorously pursued as first steps. Once this degree of stability has been achieved, counselor and client together can begin work on defining a series of more abstract, long-range goals geared to the client's particular needs.

3. Elimination of Criminal Behavior

In many ways, of course, this goal is integral to goal number 2. Nevertheless, since criminal activity frequently occurs as part of the addict's effort to maintain his heroin habit, it deserves special attention. The methadone program bears a responsibility for redirecting the client from criminal behavior. Of course, the benefits from this change in life style accrue to the client and the community at large.

The three goals described here, of course, are general in nature and applicable to all outpatient methadone treatment programs. In essence, they represent a consensus drawn from other programs' experience to date.

Administrators should understand that goals are useful to programs both in setting expectations and gauging client progress. For this reason, it is crucial to a program's operation that they are clearly understood by both staff and the client and that these goals are measurable.

C. Approach to Treatment

Historically, methadone maintenance treatment was first based on a medical model. Doctors Dole and Nyswander viewed the addict as a person afflicted with a metabolic problem or disease. Simply stated, methadone maintenance was the treatment prescribed to relieve the symptoms of this chronic problem.

In the early stages of development, the methadone clinic emphasized the physician/client relationship and cast the physician in the primary decision-making role. Counseling, at that time, was viewed as a support service not necessarily needed by every client. Basically, medication itself was considered the primary treatment, with the understanding of its properties and actions deemed to be of utmost importance to staff and the client. In that model, methadone was compared to the use of insulin for diabetics and so perceived as a lifesaving treatment.

As the use of methadone gained popularity, the medical model was modified in various ways, one of the most common being a comprehensive model which accepted methadone as a treatment tool which could be effectively used in combination with both psychological and sociological counseling.

Indeed, current FDA regulations and the Federal Funding Criteria have standardized the approach used in outpatient methadone maintenance programs by requiring therapy, vocational and educational counseling, legal services, and adjunctive medical services.

For the purposes of this manual, a "team" approach will be described. This approach has been selected because it is flexible and meets all FDA requirements and Federal Funding Criteria. In the team approach, both medical and psychosocial factors are considered elements of addiction; medical and counseling efforts, therefore, are viewed as equal components of the program. Most decisions, then, are made jointly, based on input from both.

In this approach, the counselor serves as the primary therapist and the person to whom the client voices his needs. For example, requests for a change in medication doses, transfers to a different modality, and referrals for vocational rehabilitation are all made through the counselor. The counselor consults with the other members of the team, a joint decision is reached, and the results are then communicated back to the client through the counselor. An important aspect of this approach is that it

makes the client the focal point at all times. It is the client's needs which define the program's scope and, in many ways, this greatly simplifies decision making.

The team approach also allows for wide latitude in staff selection, and this may have particular impact on programs with limited funds. Because counselors and medical staff work together, paraprofessionals may be used extensively in the counseling area since their case management is scrutinized regularly and decisions are made jointly. By its very nature, the team approach ensures information exchange and sharing of techniques. In effect, it offers built-in, on-the-job training for all employees. It has another advantage, as well. It eliminates the professional/paraprofessional split found in many programs by requiring input from each team member. Healthy staff morale usually results from this approach. In addition, the client enjoys greater flexibility since he can relate to counselors and/or medical staff. The option to choose is helpful because some clients are more comfortable with certain staff.

In the team approach, program objectives may be brought to the client's attention as soon as there is a perceptable relief of medical symptoms (craving for heroin) and improvement of the client's psychological and social adjustment.

II. ADMINISTRATOR'S GUIDE TO PLANNING

Once the responsible local officials have decided that an outpatient methadone clinic is needed, a project chief should be designated to head the next planning phase. For the purposes of this manual, this individual will be called the administrator. The outline which follows is intended as a guide for the administrator in organizing the planning process.

A. Program Planning Document

The administrator will find that a planning document gives him a program overview in developing a budget, hiring staff, and explaining the program, itself, to interested government and community groups. For this reason, it is recommended that such a plan be developed as a first step.

Many of the elements discussed in this manual can be incorporated into the plan, but the administrator must determine for himself such issues as the number of clients who will receive services, the range of services that can be provided in-house, and whether the program will be available to the community's addicts in general or geared to a specific population. Although the program plan may change for a variety of reasons once the program is functioning, it is important that it be well thought out and complete.[1]

B. Fiscal Review

The administrator should familiarize himself with the anticipated costs involved in the program so that the budget is both reasonable and meaningful to him. Administrators should be aware that a cost range exists, based on the program size. As of January, 1974, a minimal service clinic (one offering no job development or placement, education, client training or administrative services) for 300 clients costs approximately $1,300 per client year. A similar clinic treating 100 clients costs about $2,100 per client year. The small clinic has a higher cost per patient/year because of higher prices for services (e.g., urinalyses). Detailed budgets are attached which clarify and break out costs item by item (See Exhibit 4). It is useful for administrators to remember, though, that while personnel costs constitute the single largest budget item (approximately 80% of the budget), minimum staff requirements are contained in the FDA regulations and must be observed (See Exhibit 6 for sample organizational charts). However, while flexibility is limited in this area, play can be found in other line items. Usually the amount of flexibility will be determined by regional costs for lab fees, rent, etc.

One major cost that administrators must anticipate is for urinalysis. FDA requires that methadone maintenance clients undergo urine testing at least weekly for morphine and monthly for methadone, barbiturates, amphetamines, and other drugs if indicated. The Federal Funding Criteria call for urine testing on a weekly basis for morphine, methadone, cocaine, codeine, amphetamines, barbiturates, and other drugs, as indicated. Most programs will probably find it more efficient to contract out for this service. Laboratories used for this purpose must be approved by FDA and the State. Furthermore, if the program should change labs, this too must be approved. Because testing is so costly, administrators should be cautious in their choice of laboratories and hold them to the agreed upon contract specifications.

[1] Once an outpatient methadone maintenance program is functioning, a policy manual should be written to formalize all clinic operations. The manual is for internal staff use and assigns specific responsibility for both administrative and clinical duties. For example, FDA has regulated take-home medication in the broad sense, but it would be wise for the clinic to assign responsibility for carrying out this regulation to specific staff members. Counselors and medical staff would then understand the clinic's procedures for extending take-home privileges and could refer to a written document to clarify the steps to be followed in this case. Likewise, procedures for handling violence in the clinic, client alcoholism, et al., should be recorded in the manual. In addition to clinical issues, policies regarding staff promotions, vacations, sick leave, chain of command, etc., should be included. The policy manual should be a product of the weekly staff meetings. Essentially, the policy manual is a reference for staff which clarifies the program's daily operations in terms of staff roles and responsibilities.

C. Facility Planning

1. *Site Selection*

Once the administrator understands his budget and has received approval to implement his program, the first step is to locate a facility. Client accessibility and proximity to the drug neighborhood should be primary considerations. The facility should be convenient to public transportation and, if possible, contain space for parking. Past experience has demonstrated that methadone outpatient clinics arouse the least community controversy when located in a commercially zoned area. Empty supermarkets, warehouses, or business establishments are good prospects since they can be rapidly and inexpensively converted into functional clinics. If the program is one facility within a large agency, it should be located in a community which has no provision for drug treatment (as opposed to being in the same vicinity as another outpatient clinic).

2. *Space Needs*

If possible, the major operations of the program should exist on one floor (i.e., medical unit, counseling offices, and administrator's office) to facilitate smooth client flow and easier management. If necessary, clerical offices may be located on different levels.

Adequate footage for 250 clients and 20 staff is approximately 5,000 square feet.

When designing the clinic's layout, the internal traffic pattern should be kept in mind. An ideal arrangement is to locate the counselors' offices close to the entrance so that client activities can be observed by them. This helps to prevent the client from receiving medication without keeping appointments with his counselor. Sufficient space should be allocated to the counseling component to provide at least one office for every two counselors, ensure adequate privacy, and provide a *small* reception area for the client waiting to see his counselor. (Large waiting rooms are unadvisable since they encourage loitering, illegal transactions, etc.)

The medical unit should be located near the rear of the facility and should be large enough to accommodate several desks, a safe, and file cabinets. Medication should be dispensed through a small window or Dutch door, with a separate exit available for staff. Since methadone accountability is so important, only medical staff should have access to this unit. Discrepancies may then be easily attributed to a small group.

The physician's offfice should be separate from the medical unit and accessible through a separate entrance so that the client does not have to pass through the medical unit in order to see the doctor.

A large common room is necessary for group therapy, treatment team sessions, and staff meetings. It should be fairly isolated so that these activities do not intrude on individual counseling sessions or the orderly dispensing of medication.

While separate exits are often required by fire laws, there are both pros and cons involved in their use. On the one hand, client flow seems more reasonable if there are separate entrances and exits. On the other hand, exits often become entrances, providing clients with an unauthorized means of entering the clinic. Where fire laws permit, a one-way extrance/exit should be used.

Adequate toilets and sinks should be provided for staff and clients keeping in mind the number of urine specimens per day and the need for monitored urines.

Because of differing budgets, time deadlines, and site choices, administrators may be compelled to select a facility that cannot provide the kind of space discussed above. But, regardless of the physical limitations, administrators can create an atmosphere conducive to professional and dignified treatment. Sufficient lighting, the use of bright colors, and, most importantly, reasonable janitorial services can make the clinic comfortable for both clients and staff. Crowded and dirty facilities generally breed chaos. However, when a clinic is well-maintained and orderly, clients respond accordingly; their behavior within the clinic reflects the treatment they are given there.

3. *Hours of Operation*

The facility's hours of operation should be geared to clients' needs rather than staff's. This is necessary because FDA regulations require that clients attend the clinic a minimum of six times per week during the first three months of treatment. Unless hours are reasonable, clients may become frustrated and drop out. (Administrators should note that the Federal Funding Criteria require outpatient methadone clinics to operate seven days a week.) Consideration should be given to those clients who are employed and consequently must be able to visit the clinic outside of working hours. Clients who are not employed or involved in school or training programs should be expected to schedule other activities around clinic hours.

For the most part, the traditional 9:00 a.m. to 5:00 p.m. workday regimen is not acceptable for outpatient methadone treatment. In clinics with large client populations, twelve-hour clinic operations may prove necessary. This kind of operation requires a very large staff. In most instances, however, an eight hour day will suffice as long as there are at least two hours which are not part of the normal working day (e.g., noon to 8:00 p.m. or 6:00 a.m. to 2:00 p.m.). Weekend hours usually can be shortened to four hours, depending on the number of clients to be served.

One of the clinic's implicit goals is to instill a sense of responsibility into its clients. One method for achieving this end is to impose routine. The clinic, therefore, should set the example by opening and closing promptly. Haphazard hours are frustrating for clients and negatively affect the structuring of their daily schedule.

4. *Security*

Security is a complex issue for staff, clients, and the community because of the community's fear of addicts, the addict s mistrust of the police, etc.

Before opening the clinic, state authorization and FDA approval of the program's protocol must be obtained (See Exhibit 1 for the regulations and steps necessary to gain approval). In addition, the Drug Enforcement Administration (DEA) must approve the physical setup of the medical unit to ensure that the medication is adequately safeguarded (See Exhibit 5). It has also been found helpful to ask local health and law enforcement officials to review all plans for security. Not only do good suggestions emerge from this double review, but it provides an excellent opportunity for the administrator to initiate rapport with these agencies. One cautionary note should be interjected here. Although it is desirable to have the clinic under routine police surveillance during the night, frequent patrols should be discouraged while the clinic is open. Police presence will often keep clients away or cause them to distrust the program.

D. Community Planning

Community planning is a two-way process and continues as long as the clinic provides treatment.

The pressures on the administrator are extreme during this period, and it is critical that composure be maintained and that each criticism be answered rationally without threats. Because outpatient methadone clinics are usually located in commercial areas, opposition often comes from neighboring businesses. A tested method for meeting business opposition is to point out the declining crime rates in areas where treatment has been made available and to call on such groups as the Board of Trade, Jaycees, Kiwanis, Rotarians, et al., for their support in winning over this sector of the community. Although the process is a lengthy one, the results can be surprising. Once the reality of the clinic is finally accepted, neighboring businesses often donate supplies and equipment and, more significantly, may become a source for jobs. A useful stance for the administrator is to solicit cooperation and place the burden for rejection on the community. This effectively removes the administrator from the position of alienating anyone. Developing a community advisory board may help alleviate some resistance.

Once the administrator has achieved the neighbors' acceptance, the next step is to let the community-at-large know about the clinic's existence. If there is a demand for treatment, clients will come. They will hear of it through the "grapevine". But the administrator should not rely on this alone. In the beginning stages, the administrator should embark on a vigorous campaign directed towards the courts,

social services agencies, schools, and churches to establish channels for client referral. Meetings with judges and parole and probation officers involving an explanation of the clinic's goals and objectives and a tour of the proposed facilities serve a dual purpose; they involve these people in the program and lay the groundwork for referral.

In the same way, discussions with health and welfare personnel communicate the message of methadone treatment to agencies which are, in many cases, already in contact with addicts and which may assist the clinic in establishing inroads to those health and welfare services.

When a clinic is fully functioning, additional steps can be taken to reenforce the networks established in the community. Joint counselor training sessions with welfare caseworkers and probation officers can be arranged so counselors from each program gain a better understanding of their clients' needs and problems from several perspectives.

School guidance counselors can meet with treatment personnel to share their understanding concerning the younger addict. Combined support from both the school and the rehabilitation agency is often very helpful in dealing with the adolescent addict.

A community resource specialist can be designated at the clinic and promoted as the contact person for interested outside agencies.

The purpose of these suggestions is to emphasize the necessity of enlisting community support from the outset by involving those individuals who influence community attitudes. Methadone maintenance outpatient clinics cannot remain separate from the mainstream of community resources. Rather, they must announce their dependence on these services and their willingness to cooperate in the local referral network.

E. Staff

Staff selection for drug treatment programs is a critical area and requires careful planning and recruiting. The planning aspect principally involves thorough and clear descriptions of each position, the responsibilities which accompany it, and the design of a meaningful table of organization. In addition, recruiting strategies must be developed, qualifications must be considered, training needs must be continuously assessed and reassessed, and roles of individual staff units (administrative, medical, and counseling) must be defined. These areas are covered in the following discussion.

1. *Staffing Patterns*

The principal considerations in designing a staffing pattern are:

a. the total number of ***direct, in-house*** services offered;
b. the number of staff responsible for each of these services; and
c. the number of individuals directly reporting to the administrator.

Program components or units are developed in view of these considerations. Usually, the medical and counseling units constitute the two major components, and all other services fall under one of these two categories. However, if an exceptionally large variety of services are provided in-house, the administrator may choose to establish additional units. For example, if a clinic employed three vocational rehabilitation specialists, four social workers, and two public assistance aides, the administrator might organize a social services unit and designate a supervisor.

A sample organizational chart and explanation is attached (See Exhibit 6). In the sample chart, a counselor/client ratio of 1-30 is illustrated. It is recommended that clinics maintain this ratio where possible, although differences may occur depending on the number of stable clients.

Once the administrator has decided on an organizational structure and staffing pattern, he should immediately begin the recruitment process.

2. *Recruitment and Staff Qualifications*

Recruitment efforts should be undertaken with a firm deadline set in advance. Supervisory staff should be hired first so that they can then participate in the selection of their subordinates.

Choosing staff for outpatient methadone programs is not an easy task. The greatest danger for the administrator lies in the impulse to hire because of paper qualifications. Although there is no sure-fire method for hiring, extensive interviews are very helpful because they give an indication of a person's ability to relate well to others. Whenever possible, group interviews should be given to each job candidate in addition to private interviews since they often expose qualities which might otherwise go unnoticed.

Administrators should be aware of problems that recur among professional staff regarding functional responsibilities. The professional often brings a superior attitude to his job, based on his educational background. This can become particularly troublesome when the professional is asked to work under the supervision of, or with, a paraprofessional on a peer level. Necessary clinic duties such as urine surveillance may be unacceptable to professional staff members and lead to their refusal to perform them. This situation may pose a problem for the administrator and discourage him from hiring professionals. However, these reactions can be minimized if the duties and responsibilities of each position are fully explored during the interview and the professional/paraprofessional issue is presented and clarified for the potential employee. Job candidates often disqualify themselves from future consideration once the personnel policy is enunciated. Those accepting the positions are then aware of the full range of their responsibilities (i.e., urine surveillance, providing urine specimens).

Hiring medical staff may also pose a problem. Many medical professionals are not accustomed to working with non-medical staff. Again, a clear explanation of the job and the philosophy of the program is critical if misunderstandings are to be avoided.

Many programs feel compelled to hire ex-addicts into counselor positions and often accept the first street-wise ex-addict interviewed. Unfortunately, programs who have hired ex-addicts impulsively have had serious personnel problems as a result. For this reason, the administrator should approach the hiring of an ex-addict with the same objectivity as the recruitment of non-addict staff.

It is helpful to ignore the ex-addict's background in the beginning and focus on the candidate's ability to do the job in question. Once over that hurdle, the administrator should ask himself certain questions. Has the candidate demonstrated responsible behavior in previous volunteer or paid jobs? How long has the candidate been drug-free or maintained on methadone? Does there appear to be a problem with alcohol? Has the candidate any training in group or individual counseling? If he has been institutionalized, does he have a negative attitude about working with professionals? If he is totally drug-free (not on methadone), does he have a bias against those who need methadone? Usually, ex-addicts are fairly glib and can handle a verbal interview skillfully. However, effective counseling requires good record keeping skills, as well, so the administrator should request a written sample progress note and ensure that the report is, in fact, written by the candidate.

Once the decision has been made to employ ex-addicts, the administrator should then meet with the ex-addict's supervisor in order to discuss problems encountered in the supervision of ex-addicts. In the beginning, the ex-addict employee may be frustrated by the newness of the job experience, and sometimes he will return to drug abuse, although the drug may not be heroin. These frustrations may be reflected in changes in pattern and/or behavior and the supervisor should be alert to them (e.g., reporting late to work, taking days off, etc.). Counseling by the supervisor can be very helpful to the employee at this point; however, if no improvement occurs, disciplinary action should be taken just as it would be with any other employee.

The administrator should expect some personnel failures, but this realization should not stop him from moving ahead in this area. Likewise, the administrator should not be afraid of terminating staff. In an outpatient methadone program, good staff are absolutely critical.

In order to assist administrators in recruitment and hiring, position descriptions pertaining to the medical and counseling units are included in Exhibit 7. These specifically detail the responsibilities involvec in each job as well as their relative position in the clinic. The following is a brief overview of each unit's duties to give the administrator some idea of how each functions. Hopefully, this will assist him in recruitment and review of candidates' qualifications.

a. *Medical Unit*

The duties of the medical staff consist of prescribing medication and schedules (doctor), preparing and dispensing medication (nurses), preparing a daily "miss list" (nurses) from which the counselor can note his clients' attendance, and observing patients for any medically-related problems (entire unit). In the latter case, the counselor should be immediately informed. Improved client services, as well as better staff morale and understanding, exist if the medical staff carries a reduced caseload. The doctor is available to handle any medical problems requiring his attention, and the nurses may be responsible for medically-related training of the other staff (side effects of methadone, etc.). The doctor should perform all physical examinations, read and initial all physical examination reports from the intake examination, and make the appropriate referrals. He is responsible for ensuring that clients' medical needs are periodically reviewed and that clients receive adequate medical treatment for any illness. If clients receive any prescription medicine (other than methadone), as part of treatment, they must be seen by the physician at least once every four weeks. In accordance with the revised FDA regulations, the doctor must review the status of all methadone maintenance clients after two years on maintenance treatment and justify whether continuance of maintenance treatment is indicated at that time. This decision must be reviewed periodically.

b. *Counseling Unit*

The counselor should be under the continuous technical and training supervision of the supervisory counselor. The latter should recognize counseling weaknesses and correct them as quickly and effectively as possible. The administrator and supervisory counselor should evaluate the needs of all counselors, whether it be for increased supervision, additional training, or termination of employment. The supervisory counselor should arrange on-going training for staff performing counseling roles, participate in hiring counselors and evaluating those on his staff, document performance deficiencies and notify counselors of these deficiencies (verbally and in writing), and monitor the record keeping practices of all counselors. It is the supervisory counselor's responsibility to ensure that clients are receiving appropriate medical, social, vocational, and other services. Scheduled case conferences should occur frequently between the counselor and his supervisor in which caseloads are reviewed. In addition the Federal Funding Criteria require that five hours per week of professional mental health consultation per 100 clients be provided in order to assist with client management and referrals for psychiatric services.

3. *Training*

Training is an on-going need in outpatient methadone programs and is essential if quality care is to be provided. Training may be conceptualized in two ways: a) as fundamental training; and b) as specific skills training.

a. *Fundamental Training*

Fundamental training is the key to effective clinic operations. It focuses on how to train the employee to fit into an efficient therapeutic setting. Although this may appear unsophisticated, administrators should note that technical skill is meaningless without it. Clinics have found that fundamental training is best communicated through preliminary job orientation followed up by continuing on-the-job training.

Orientation has a didactic purpose in that it involves the presentation of clear information about addict behavior, methadone, and clinic procedures and how each relates to the addicts' needs. Much of this can be conveyed through lectures and the assignment of reading material. However, this information will more likely be remembered and utilized if it is reenforced through role-playing and sample situations. Examples of some useful training aids are found in Exhibit 8.

On-the-job training can be accomplished in several ways, but a useful and cost-effective medium for doing so is the weekly case review or treatment team meeting. This occurs within the clinic and should

involve the entire staff. Simply stated, the case review is a forum for exchanging information on specific client cases. What happens during this process is that each member learns from both the successes and failures of others. The case review offers an ideal setting to explain new concepts because the case itself affords an opportunity to realistically understand them and then apply them. Again, the case review demonstrates the proper and improper use of certain techniques and provides the kind of informal discussion necessary to ensure that all staff members grasp the point being made. Case review sessions can be divided up, as well, so that a specified length of time is available for internal teaching. Here one staff member may explore the current literature to gain some new insights into problems or issues confronting the clinic; for example, the phenomenon of the methadone maintained client who becomes seriously involved with alcohol, or the pregnant methadone client, etc. The designated staff member would be responsible for preparing a presentation on the subject and then would lead the entire staff in a discussion.

At this point, a clear distinction should be drawn between case reviews and staff meetings. Staff meetings should focus on administrative matters: hours, staff rotations, pay increases, need for supplies, etc. Given the attention required in a well-run case review session, the administrator should probably schedule staff meetings and case reviews on separate days.

Case reviews are very helpful to staff since both medical and behavioral issues are discussed in the context of client care. This promotes learning and understanding, and contributes to the cooperative spirit which should exist in the clinic.

Finally, regardless of how effective case reviews may be for training, they cannot replace good daily supervision.

b. *Specific Skill Training*

Once the clinic is established and operating smoothly, specific skill weaknesses of staff members may be detected or, because of changing client needs, new techniques should be introduced. A number of resources may be tapped for this training.

Often, local communities have mental health skills centers or clinics with access to private institutions which teach such subjects as group dynamics, encounter, etc. Clinic administrators might want to take advantage of these opportunities for their staffs. Again, conferences or seminars might offer new perspectives which would be useful to the clinic so the administrator might want to budget accordingly. Other resources available for training are state and federally-funded training conferences and centers. Here, again, the administrator may find subjects of value to his staff.

Outside the drug abuse/mental health area per se, numerous educational resources exist which the administrator might want to consider. Courses in effective writing or management techniques are possibilities. Although few programs have the financial resources available to pay for them, the administrator or supervisor might want to encourage employees to enter on their own, explaining the benefits in terms of personal growth and opportunities for promotion.

F. Recording Requirements for Staff Units

To ensure accountability, formal reporting requirements should be levied on unit supervisors in line with Federal, State, and local requirements. In general, they should include: caseload data and a population census; intake and termination data; numbers of dosages distributed, numbers of urines collected and tested and a synopsis of results, and numbers and status of outside agency referrals; and methadone accounting reports.

Because of the FDA requirements and the CODAP minimum standards, record keeping has emerged as a major clinic function. In the past, the need for records has elicited responses ranging from adamant refusal to paralysis. But, if the process is viewed objectively, it is possible to set up efficient procedures which do not unduly burden staff, yet meet the requirements and, most importantly, contribute to quality care.

In this manual, recording requirements are described only for those units which are common to all outpatient programs: administrative/clerical, medical, and counseling. (See Exhibits 10 and 11 for sample records.)

In this section, an overview will be provided. In sections dedicated to individual units, the how-to aspect will be explained and more detail will be presented regarding the record's content.

1. *Administrative/Clerical*

The administrative assistant and/or clerical staff have the primary responsibility for the program's written correspondence, maintenance of administrative files, and preparation of requisitions and Federal and State reports (e.g., FDA annual report, FDA notification of replacement of Program Sponsor or Medical Director, CODAP national management forms, etc.). In addition, their involvement in treatment may include setting up and maintaining a central records system for the program in which all client records are filed. (It is not recommended that staff have progress notes typed and filed for them. Maintenance of a central records system entails establishment of separate files for active and inactive clients, assurance that all folders have accurate identifying information and meet the confidentiality standards, provision of appropriate information to outside requestors, etc. Counselors should assume the responsibility for recording and filing all progress notes themselves.) Clerical staff may assist in staff training sessions if recording skills are found to be lacking in certain staff members. Additionally, clerical staff may be involved in assisting the nurse in preparing various lists and charts for the medical unit as well as assisting counselors in the record keeping and management of their clients.

2. *Medical*

Complete and orderly medical records serve both as a log of all medical services extended to clients and as useful treatment tools. The nurses observations and interactions with a client will be helpful to the physician and the client's counselor in developing a treatment plan. The use of weekly case review meetings will encourage an exchange of information between the physician, counselor, and nurse so that the data recorded by all may be as complete as possible.

The basic medical record for each client in treatment must contain: (See Exhibit 11 for specific samples.)

a. A completed physical examination form
b. Medical progress notes (which should be utilized by both the nurse and the physician) presenting in detail a view of the client's problems, care, and progress. The following areas should be covered in the notes:

    1) Initial medical unit contact with the client. This should include the client's name, sex, race, length of primary addiction, prior treatment attempts, and present methadone dose. If any problems are apparent in the history or by observation, these should also be noted.
    2) Requests for dosage change. Any medical problems encountered as the result of physical examinations or client's complaints should be noted by the nurse. An appointment should be made for the client with the physician and recorded.
    3) Any physician contact with a client. The reason for the contact, results of examination and/or interview, and any plans made must be included. If a client is referred elsewhere for any service, the results of this referral should be obtained and recorded.
    4) Observations made by the nurse of a client's behavior and action taken concerning this behavior.
    5) Client failure to report on a scheduled medication pickup day.
    6) Any adverse reactions to any medication. Adverse reactions to methadone should be documented, followed up, and reported to the FDA on form FD-1639, "Drug Experience Report" (See Exhibit 1).

c. A physician's order sheet, which is a standardized form used for recording all medications or treatments prescribed, as well as referrals for treatment. Medical orders may be written only by members of the medical staff (nurse or physician in accordance with State law). In an

emergency situation, only the physician may give telephone or verbal orders. These must be accepted and recorded by a licensed nurse and must be signed by the physician within 24 hours. The Physician's Order Sheet should be organized in the following way:

    1. For medication the physician notes correct date, the medication needed, its strength directions for use, amount to be dispensed, and duration, and then signs the order. For verbal or telephone orders, the nurse follows the above procedures, but signs the order as follows: V.O./Dr. M. Welby/C. Ivory, R.N. The clinic nurse should review all orders and initial them.
    2. Justification for any change in pickup schedule must be recorded and signed by the physician.
    3. A record must be kept of all annual physicals. When they are scheduled, the nurse notes it in the progress notes. The physician then records results of the check-up.

d. A signed "Consent to Methadone Treatment" form (See Exhibit 1). Other forms should be placed in the chart as the need arises.

3. *Counseling*

Certain kinds of information should be collected by counselors on persons entering and undergoing treatment in methadone maintenance programs. In all cases, this information should be the basis for continuing or modifying the treatment plan. For example, when the treatment plan is initially developed during the intake process, short- and long-term client goals are described and type and frequency of counseling and supportive services are detailed. However, as the client continues in treatment, the validity of the original plan is tested and the plan may then be modified based on what the information portrays in terms of progress. This information falls into five separate categories and includes:

a. Counseling and Supportive Services
b. Medical Services
c. Chemotherapy
d. Urinalysis
e. Client Progress

Explanations of the meaning of each of these categories follow:

a. *Counseling and Supportive Services*

The data to be recorded under this category generally include: the type of services scheduled (e.g., individual or group therapy, educational counseling, vocational rehabilitation referral), the type of services *actually* provided, and the amount of services provided (one-time contact, seven session, etc.).

b. *Medical Services*

These data, considered together, indicate if the medical service is provided in-house or out-of-house, give a summary of the client's medical problems identified during the intake physical and the follow-up indicated, specify the client's current medical problems, and describe the medication prescribed, dosages, directions, and limitations. These may be adequately recorded in the medical records and need not be duplicated in the counselor's notes.

c. *Chemotherapy*

These data include medication (i.e., methadone or antagonists) scheduled and dispensed for each day of the month, pick-up method, and medication reactions, if any. Again, this information need not be recorded specifically by the counselor.

d. *Urinalysis*

These data include the date the tests were scheduled, the date the tests were administered (i.e., specimen taken), and the results of the testing.

e. *Client Progress*

Client response to treatment should be reviewed at least monthly. That review is to include such things as drug problems, employment, behavioral problems, psychiatric/psychological problems, and program assignment changes.

A counselor usually records client information through the use of running progress notes. Unfortunately, though, these notes are often haphazard and uneven in quality. The thrust of more efficient standards of documentation is to force a more thorough approach to recording client information. The key to this is understanding the relationship among those five categories of information mentioned earlier. The first four of these categories must be the basis upon which the assessments of client progress are made. This means that the kinds of data specified by those first four categories must appear in the client's record and must bear a clear and consistent relationship to the judgments of category five. For example, if a client has shown four dirty urines during the course of a month, has missed a number of counseling sessions and has missed his medication for several days, there should not be an entry stating that the client is being given take-home privileges. Rather, the counselor's notes should reflect an appropriate action clearly consistent with the client's performance.

Not only should client progress assessments be made consistent with the recorded data, but the rationale for other activities such as referrals should be documented. The treatment plan, itself, is an example of this. If that plan includes referrals to vocational rehabilitation services or for legal help, then the reasons for including these elements in the plan ought to be clearly spelled out. If this is not done, reasons for changing such a plan are going to appear vague or arbitrary. Furthermore, such referrals must be followed up by the counselor. There is nothing wrong with a drug counselor keeping closely in touch with a vocational rehabilitation counselor to whom the former has referred his client. In fact, this should be encouraged and contacts between them should be recorded.

The following is a list of information that must be included in a counseling record: (See Exhibit 10 for specific samples.)

- A record must be made of the initial client-counselor interview. The client's name, age, race, and sex should be the first information obtained, followed by the length of primary drug abuse, attempts at prior treatment, and reason for seeking treatment at this time. Next, the counselor should record the treatment modality to which the client has been assigned and comment on the client's understanding of this modality. Finally, the client's problems should be addressed (e.g., does he have housing, does he have legal problems, etc?). If problems are discovered which necessitate referral to another person or agency, this should be done and recorded. In the event of a readmission, some assessment must be recorded regarding the circumstances of prior discharge(s), attitude changes, and motivation. All notes must be signed.
- A treatment plan must be developed as part of the intake process and should be thoroughly explained to the client. The plan should include both short- and long-term client goals, the assignment of a primary counselor, a description of the type and frequency of counseling services to be provided, a description of those additional supportive services required by the client, how many days a week medication must be picked up, and the number of urine specimens which must be given. This plan must be reviewed every 90 days.
- A note should be written after each meaningful client/counselor contact and should include the counselor's observations, problem(s) presented, resolutions proposed, and the approximate length of time spent with the client.
- Copies of referral forms should be included in the client's folder. Specific reasons for referrals and information regarding the results of referrals should be obtained and documented.

- The results of counseling performed by any other person in the clinic should be noted on the client's chart, either by the client's counselor or the staff member involved.
- A client's progress should be reviewed at least monthly and summarized. The treatment plan should be reconsidered in view of the progress and either altered or continued. The summary must include the client's legal status (both criminal and civil), employment status, current drug use including alcohol, and any other current problems and their severity. The monthly summary should reflect a composite picture of the client's progress and not merely repeat entries made during the month.
- The date urine specimens are scheduled to be given, *are* given, and the *results* must appear in the counselor's record. Any change in methadone dosage and reasons prompting the counselor to recommend these changes should be noted.
- If a client fails to keep a scheduled appointment (e.g., medication pick-up, group counseling, individual counseling, referral service appointment, etc.), it must be documented.

It is suggested that a copy of the intake form be reviewed by the counselor prior to the initial client interview. (See Exhibit 14 for sample intake form.) This form provides much of the information required in the admission note and eliminates duplicate processing.

G. Treatment Regimen

The following is a detailed description of each phase of the treatment process incorporating all required FDA and CODAP standards and the Federal Funding Criteria. Essentially, this section of the manual traces the client from entry into treatment until completion or termination. For the purposes of this manual, it will be assumed that the outpatient clinic is totally independent and, therefore, will provide its own intake and detoxification from methadone.

1. *Intake*

Administrators should understand that intake is the client's introduction to the program, and while the importance of a thorough procedure cannot be overemphasized, it is equally important to conduct the intake process as rapidly as possible so that clients are *not* discouraged from pursuing treatment. An intake process not exceeding three days is optimum.

Individuals seeking admission to outpatient methadone treatment must be required to present staff with adequate identification. This should include name, age, and a picture of the individual. If the applicant is subsequently accepted for treatment, this information should be used to contact other treatment programs in the area to determine whether the individual is in treatment elsewhere. In many areas, the existence of a central registry makes this unnecessary.

Applicants for treatment should be interviewed to determine eligibility and obtain a social history. (Because clients usually have not developed a sense of trust in the staff and program at the time of intake, *completion* of a social history form may not be accomplished until later in treatment. Efforts should be made, however, to complete the form as soon as possible since this information may have substantial impact on the treatment plan.) In order to be placed on methadone maintenance, the applicant must have at least a two-year history of opiate addiction. This can be verified by the applicant's family, arrest records, prior treatment records, or by clients in treatment who personally know the applicant. Verfication of the applicant's age must be obtained, since FDA regulations require that an indivudal be at least 18 years of age to qualify for methadone maintenance treatment. An exception can be made for individuals between the ages of 16 and 18 who can document a two-year history of opiate addiction as well as two prior attempts at detoxification. In addition, the parent or legal guardian of these applicants (between 16 and 18) must complete and sign the FDA "Consent to Methadone Treatment" form (See Exhibit 1).

Applicants not desiring methadone maintenance but meeting the same criteria may be detoxified. This detoxification procedure may not exceed three weeks, and a repeat episode may not be initiated until four weeks after completion of the previous detoxification.

d. *Urinalysis*

These data include the date the tests were scheduled, the date the tests were administered (i.e., specimen taken), and the results of the testing.

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- The date urine specimens are scheduled to be given, *are* given, and the *results* must appear in the counselor's record. Any change in methadone dosage and reasons prompting the counselor to recommend these changes should be noted.
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Applicants not desiring methadone maintenance but meeting the same criteria may be detoxified. This detoxification procedure may not exceed three weeks, and a repeat episode may not be initiated until four weeks after completion of the previous detoxification.

After eligibility has been determined via the applicant's social and drug history, a urine specimen should be obtained to assist in documenting present opiate use. An in-depth interview with the physician will then be scheduled so that the physical symptoms of past and present addiction (e.g., needle marks) can be observed and documented and a physical examination completed. Physical signs of withdrawal such as runny nose, runny eyes, and pupillary reactions, in conjunction with the urine specimen results, can be used to document present dependence on opiates. For individuals to be placed on methadone maintenance, symptoms of past dependence such as old needle marks and tracks must be documented.

There is one exception to the requirement that individuals be presently dependent on opiates to qualify for methadone maintenance. This involves the individual who has been released no longer than one week from a penal or chronic care institution in which he stayed one month or longer. This individual must have a history of at least two years of opiate addiction prior to admission to the institution, and this must be documented as for any other methadone candidate.

After completion of the physical examination, the initial methadone dose will be determined by the physician on the basis of the individual's length of addiction, present drug use and present physical symptoms. Clients should not receive an initial dose in excess of 40 milligrams. For most clients, doses under 40 milligrams will suffice. In those areas of the country where the quality of heroin is poor, doses under 20 milligrams may be sufficient. In these cases, clinical judgment should prevail. If the client remains under observation and withdrawal symptoms persist, additional 10 milligram doses may be given.

Prior to dispensing the initial dose, the nature and implications of methadone treatment must be explained and the FDA "Consent for Methadone Treatment" form signed. This form should be signed only after the staff member explaining the treatment is assured that the applicant comprehends what he has been told. A Spanish translation of this form is available from FDA.

An initial treatment plan will then be developed on the basis of the client's needs, as determined by the social history, program guidelines, CODAP standards, and the Federal Funding Criteria. Included in this plan should be short- and long-term client goals, the assignment of a primary counselor, the number of days per week a client must report for medication, the number of urine specimens that must be given per week, a description of the type and frequency of counseling services to be provided, and description of those additional supportive services required by the client. The treatment plan should be discussed with the client and his agreement obtained.

(For complete information about intake costs, staffing requirements, and operations, please refer to the Central Intake Unit Manual available from the National Institute on Drug Abuse.)

At this point, the intake process, per se, is complete. However, for the purposes of accountability, and in the interest of smooth program operations, the client should be given some means of identifying himself for treatment. In large programs, a combination picture/signature is desirable. For small programs, facsimile signatures will serve the same purpose.

2. *Orientation*

The first four to twelve weeks after admission to treatment should be considered an induction phase. Within one week after admission, a formal orientation group should be held for all new clients. The purpose of this group will be to inform clients of all program policies, to clarify any misconceptions regarding treatment, and to answer any questions that clients have raised. Much of this information will have been shared during the admission procedure but it needs to be repeated after the anxiety surrounding admission has receded. There are certain areas that should be discussed in the orientation session which are specified below.

The goal of most methadone treatment programs is to encourage a change in the client's life style such that, ultimately, abstinence is attained. While this is a laudable aim, it may not conform to the goals a client sets for himself. Not every client will be interested in employment, job training, additional education, or any other vehicle to change life-style and may want nothing more from treatment than sufficient methadone to allow them to cease using illegal drugs. He may be interested in some of these services but reject others. For this reason, the client should be informed that his goals will be considered in determining a treatment plan and in subsequent revisions of that plan. He must be made to understand the program's goals, and he should be counseled to eventually adopt these goals as his own.

Client expectations when entering treatment must also be explored and discussed with him in relation to program policies and the treatment plan. If a client plans to use the program to obtain methadone but accepts no counseling, then he must be made to understand that this can result in termination from treatment. Counselors must explain that the treatment plan is a contract between the client and his counselor which may be renegotiated over time. However, violation of the contract may result in disciplinary action or termination. The client who is unaware of this policy may justifiably complain when disciplinary action is taken.

One of the major concerns of the client new to treatment is his medication. He may fear that his dose will be insufficient to prevent withdrawal symptoms and he must be reassured that, while the initial dose may indeed be insufficient to render him physically comfortable, his dosage will be increased until he is. However, it must be emphasized to the client that the methadone dosage will not be increased to a level where it will mask symptoms of physical or emotional problems as heroin may have done.

Some programs do not disclose individual doses to the client. This is in an effort to prevent manipulation centered around dosage level. Others, however, feel it is beneficial to the client to know that certain elements of trust are established through client-counselor relationships. Regardless of which position is assumed, it is imperative that staff, as a group, support that position and understand the principle upon which it is based.

There are side effects of methadone that may cause the client distress. The most common and persistant of these is constipation. However, mild laxatives are effective in alleviating the condition if it does continue after the client has been stabilized. Another common side effect is a decrease in male libido, but this subsides as the client becomes more adjusted to the medication. If problems with decreased sexual drive continue, however, a reduction in dose may be indicated.

Careful and thorough medical histories obtained at intake should support (or disprove) a female client's claim of regular menses prior to methadone treatment. It is highly unusual for methadone to cause irregular menstruation, and physical complaints along this line often suggest more covert stress situations. Counseling and the physician's evaluation of symptoms, therefore, should always precede a dosage adjustment.

3. *Induction*

Since methadone dose is a major concern for the client in the induction phase, the client and counselor must work closely with the physician and nurses to achieve stabilization as early as possible. Both the counselor and nurses usually have more contact with the client than does the physician, and their input regarding the need for dosage changes should be available to him. If side effects persist, the physician should be available to determine that they are a result of methadone treatment and not a manifestation of some physical problem. A client who has been abusing opiates may complain of physical problems after admission to methadone treatment which they relate to their methadone dose. Often, these are symptoms of existing medical problems which were masked by the opiate abuse. This client should be referred to the physician so that a diagnosis can be made and appropriate treatment or referral instituted. It then becomes the duty of the counselor and nurses to encourage the client to follow the treatment prescribed. If this involves referral to an outside agency, a member of the team must be assigned to contact the agency to determine if the client was treated there and the results of that treatment.

During the admission process, a treatment plan, as discussed earlier, is developed by the counselor. It is especially necessary that during the induction phase the client be made aware of his responsibility to adhere to this plan. All missed appointments (for medication, counseling, or referral services), must be brought to the client's attention as a violation of his contract and cause for possible disciplinary action. If urine results demonstrate the continued use of illegal opiates, the counselor should intensify his counseling effort with the client to determine if a specific problem or problems is prompting abuse. Experience has demonstrated that this is usually the case. In some instances, continued abuse may indicate the need for an increase in the client's methadone dose, but this is rare and should only be responded to when the physician, nurse, and counselor jointly agree that an increase in dose is required. In the event that additional counseling and an adjustment in methadone dose do not result in cessation of drug abuse, suspension from treatment should be considered.

Many clients enter a program with acute problems other than their heroin addiction which may interfere with treatment. As part of the intake process, clients should be questioned about medical, legal, housing, and employment problems. In the event that these are discovered, appropriate steps must be taken as part of the treatment plan to resolve them (e.g., referral for public assistance if a client does not have housing). Additional problems may become apparent after a client enters treatment. This is especially true of behavioral problems which may not be detected during the intake process, but which mainfest themselves as treatment demands are made. The counselor, with input from the rest of the team, must determine what approach to use in modifying the problem behavior. This may involve setting firmer limits for the client, providing more intensive counseling, or, if the problem is severe, referral to a mental health facility.

4. *Progress in Treatment*

The goal of methadone treatment is to encourage changes in life style. Methadone by itself can alleviate the need for heroin, but effective counseling is usually necessary if the client is to make any real changes. The counselor, in individual sessions with the client, determines the client's needs and abilities and then assists him in setting or modifying goals. After goals have been set, the counselor will assist the client in achieving them by supporting and encouraging his positive efforts and by making available the services of other persons or agencies. These services will be made available as the client demonstrates progress in treatment and adherence to the treatment plan.

Group counseling should also be available, but the client and his counselor should determine if he will benefit from participating. This form of therapy provides the client with an opportunity to discuss problems and goals with his peers and to receive feedback from them regarding his progress or lack of it. Since some members of the group will have progressed further in treatment than others, they can often provide the newer client with insight into his present behavior.

(Administrators should be aware that the Federal Funding Criteria recommend that groups range in size between 5 and 15 individuals. In addition, the criteria state that a minimum of three hours per client per week of counseling shall be available. Not all clients, of course, will need this much but clinics are required to provide counseling in this amount, if indicated.)

Some clients entering treatment discover that removal of opiate abuse has uncovered serious emotional problems. These clients usually react to this discovery by requesting additional methadone to achieve the tranquillizing effect formerly provided by heroin. In these instances, the case review team must determine whether in-house counseling can provide the client with the therapy he needs. In the event it cannot, a referral for additional psychological counseling from another agency should be instituted. Other clients may require educational, occupational, family, legal, or medical counseling. Again, it must be determined whether this can be effectively provided by the program, with appropriate referrals instituted if it cannot. Follow-up on the status of all referrals must be done on a regular basis.

Counselors are obliged to keep records on the progress of each client on their caseload. Documentation of the treatment plan, meaningful counselor-client contacts or observations, referrals made and resulting follow-up, and urine specimen results provide the counselor with a useful treatment tool. A review of this documentation will indicate what progress a client has made and what behavioral patterns he has established. Only by utilizing this information can effective treatment decisions be made (e.g., if a client repeatedly fails to report for scheduled appointments, a referral for job training would not be made).

All outpatient methadone maintenance clinics should schedule a case review meeting weekly. The case review meeting will be attended by the entire staff. Each counselor will discuss selected clients on his caseload regarding their progress or lack of it. The strategy for treating clients who are presenting problems can be determined with input from the staff. This provides the counselor with assistance in planning for and dealing with clients. In addition, it provides a review of counselor performance (e.g., is the counselor aware of employment status, urine results, attendance, methadone dose?)

It is the responsibility of the supervisory counselor and the clinic administrator to ensure that appropriate cases are reviewed. Although the counselor may select "problem cases," it is equally as important that progress of other clients is reviewed. Evaluation of treatment plans may, likewise, take place during this meeting. In some instances, a counselor may deliberately not present a case for review because

he has been negligent in carrying out previous recommendations or in executing conditions of the client contract. For these reasons, complete notes should be recorded during case review meetings and filed. The notes should be reviewed by the administrator and supervisory counselor before each meeting in conjunction with the counselors' progress notes for the past week. The administrator and supervisory counselor will then come to the meeting equipped with insights into the week's events and know which counselors participate or remain uninvolved in sessions. Generally, to ensure participation and uncover potential problem areas, the administrator should require a weekly review of all new admissions until a treatment plan has been established, a review of all clients receiving detoxification treatment, and a review of all clients having special problems or involvements (e.g., pregnancy, vocational placement, requests for take-home privileges).

In addition, staff meetings should be held on a regular basis. All new information relevant to program administration should be shared here. Staff problems, questions, and suggestions will also be dealt with here. This is a mechanism to maintain open communication channels and high staff morale.

Ancillary counseling in outpatient treatment must be available since rehabilitation involves far more than methadone dispensing. Clients requiring improved academic skills must have educational counseling available to them. This is required by the FDA and the Federal Funding Criteria. Referral capabilities to general education programs should exist within the treatment program, as well. Vocational rehabilitation counselors should be available at least 20 hours per week to evaluate employment needs, client's abilities, etc. and refer the client to prospective employers. It is not necessary for the vocational counselors or educational counselors to be employed by the program itself; they may be affiliated with another agency. But, if this is the case, there should be a formal written agreement specifying that 20 hours of services will be provided. Vocational rehabilitation counselors may also assist the client in becoming involved in training programs through city agencies (e.g., Department of Vocational Rehabilitation). The FDA and Federal Funding Criteria require that programs have a formal, documented arrangement with a local hospital to ensure that clients receive necessary in- or outpatient care. The Federal Funding Criteria require that either in-house or referrals for legal services are available and formally documented. Other services which may be available on a referral basis include health and welfare liaisons, et al. All referrals should have follow-up activities documented in the client's folder.

Client response to ancillary services should have a direct relationship to program privileges. For example, take-home privileges should be extended only to the client who is employed, involved in educational or job training programs, or functioning as an active head of household.

In addition to the minimum requirements set by the Federal regulations and the Federal Funding Criteria, client attitudes and total program participation should be evaluated. Candidates for privileges should be presented at case review meetings and the issue discussed by the entire team. Similarly, revocation of privileges is handled accordingly.

5. *Take-Home Medication*

If, after three months in treatment, the client exhibits satisfactory social adjustment such as steady employment, involvement in an education or job training program, or responsible functioning as the head of household, and is responding to treatment, the clinic may allow him the privilege of take-home medication. According to the FDA regulations, this means that the client may receive take-home three times weekly so that he has no more than a two-day take-home supply. After two years of solid progress in treatment, the client may receive medication twice weekly.

Take-home medication must be dispensed in liquid form and given to the client in child-proof packages labeled with the program's name, address, and telephone number. Depending on the attitude of local law enforcement officials, the clinic might want to prepare a brief explanation of the take-home policy for distribution to the police. This can often prevent future misunderstandings, particularly in communities sensitive to the problem of methadone diversion.

Occasionally, clients will become ill and confined to home. In this situation, the clinic may either approve extended take-home or may permit authorized staff (licensed practitioner) to deliver medication to the invalid.

Regardless of the circumstances, though, clients must be made aware of their responsibilities when take-home is given and impressed with the fact that it is a privilege and will be revoked immediately if irresponsible behavior is demonstrated.

6. *Treatment Termination*

There are two categories of clients who terminate their treatment. The first is comprised of those who complete the intake process, but fail to return to the program for treatment. The intake counselor should attempt to contact the client, then the client's counselor should report his efforts and results in writing to his supervisor. If the client does not appear within a specified time (e.g., 14 days), he will be reported as a drop-out upon intake. If he appears after the required time, he must undergo the entire intake process once again.

The second category of treatment termination involves the client whose termination occurs after treatment has begun. There are five instances in which this situation might occur:

a. *Transfer*

Transfers may occur between facilities within the same program (intra-agency) or between programs which have no administrative relationship to each other (inter-agency). In either event, the client should not be transferred because he is seen as a "problem" by the staff. A transfer is definitely not the positive way of dealing with the problem. Transfers may be indicated if the client has a change of address or job and another center is a more convenient location for him. Some programs have clinics which emphasize certain aspects of treatment given the client's need for specific care (e.g., pregnancy, detoxification). The client, therefore, in instances of various treatment needs, may be transferred. In some cases, the client is leaving town or going on an extended vacation and will require an out-of-town transfer (temporary or permanent). Whatever the situation, a transfer should be handled as smoothly as possible so that there is no serious interruption in the provision of services to the client.

The procedure for local transfer should involve the counselor, the medical staff, the administrator, and anyone else assigned the responsiblity for delivering program records. After the counselor has received the request for transfer from the client (or the indication for transfer is clear from the client's need for specific care), the administrator and medical staff must be informed. If they agree with this decision, the receiving program is contacted, and a transfer date is confirmed. (This may be a clerical function.) Treatment summaries are recorded in the medical and counseling notes which indicate reason for transfer, level of methadone dose, any specific problems—medical or otherwise—and the client's general response to treatment. The last date of treatment at the transferring center and the date treatment is expected to begin at the receiving center should be included. *All records should precede the client to the new center*. If possible, staff from the receiving center should meet the client prior to his arrival there.

For the client who desires a transfer to a new program because he is going on vacation or relocating to another city, assistance is offered at the national level from Treatment Referral, Information and Placement Services (TRIPS—202-466-2310). The procedure includes the same responsibilities as listed above, except the TRIPS Office acts as liaison between programs. In instances when a *permanent* transfer is requested, TRIPS provides the transferring program with the name, phone number, and contact person at the receiving program and encourages personal contact between programs. This minimizes misinterpreted information. In the event of a *temporary* transfer, TRIPS makes all arrangements and provides all necessary information to *both* programs. One week lead time is required in either case. The contact between the program and TRIPS should be routinely made by the same individual in an effort to maximize efficiency. This person has been identified by the TRIPS Office as an "Authorized Individual" and need not necessarily be a counselor.

b. *Detoxification*

The request for detoxification should be initiated by the client, unless it occurs as a disciplinary action. (In that event, staff may make the decision and inform the client of how much longer he can expect to be part of the program.) Ordinarily, however, the client and counselor discuss the detoxification process,

the approximate length of time the process takes, and the alternatives if detoxification is not successful. During this preparatory stage, stability indicators (e.g., employment, family relationships, general emotional level, etc.) should be of prime consideration. The request is then discussed at the treatment team meeting, followed by a discussion with the physician. At each level, a re-evaluation of the client as a "detox" candidate occurs. The discussion with the doctor should include the clients, and all the points previously made by the counselor should be reenforced. A physical examination may be appropriate at this time.

The time involved in the detox process may vary since the rate of medication decrease may be greater for some individuals than others. If the client has any specific date by which he desires the detox to have been completed, this should be considered. He should be advised, however, that the detox schedule is flexible, and if he feels that the schedule is too rapid, he should request a slower one. The client should be advised that detoxification from methadone may be a lengthy process and that he should be prepared to spend from weeks to several months in carrying this out.

Counseling sessions and contact with all agencies providing ancillary services (e.g., vocational rehabilitation) should be increased. Emphasis in the counseling sessions should be on non-drug coping mechanisms (e.g., community activities, memberships in clubs, associations, yoga, etc.). The withdrawal symptoms of methadone detox, however, should be understood, but not overemphasized, since discussion of these symptoms may help produce them.

Withdrawal symptoms include abdominal cramps, nausea, occasional vomiting, general aches and pain, anxiety, and insomnia. Symptoms attributable to withdrawal may last from several days to several months. Treatment of withdrawal symptoms is a controversial subject at best. Some physicians prescribe tranquillizers and mild hypnotics to alleviate the client's anxiety. Caution should be used, however, since the client is extremely vulnerable to drug abuse at this time. Prescriptions should not be given to the client, and ancillary medications, if used, should be dispensed only by the medical staff. (Physicians treating a client outside the clinic should recommend only non-prescription medication.) Objections are raised to the use of ancillary medications by clinic physicians because the client generally has such a high level of anxiety and such serious insomnia problems that tranquillizers and hypnotics would have to be prescribed in large doses to produce the desired effect. The effectiveness of this therapy has not been proven, however, and methadone maintenance clinics are encouraged to utilize strong counseling as their primary tool.

The only exception to this detoxification procedure occurs when the client reaches the end of his second year on maintenance treatment. At that time, the physician must review the client's status, and make a clinical judgment whether maintenance treatment should be continued or discontinued. Both the decision and the basis for it must be included in the client's medical record.

c. *Completed Medical Treatment*

A client who has successfully completed medical treatment before dropping out should be considered in this category. Programs should establish criteria for this category other than completing detoxification (e.g., four weeks clean urine), and all clients who have been detoxified should be encouraged to stay in treatment for a specified length of time. Progress as an abstinence client can then be monitored. During this period, there is a very high risk of relapse to heroin use. Therefore, phone and personal contact should be maintained on any client who does not report as scheduled. Participation in group and individual counseling should be strongly encouraged.

d. *Voluntary Drop Out*

Drop outs occur most frequently in the beginning of treatment. They are less likely to occur when the counselor-client relationship is strong because the client is more likely to feel that someone actually cares about him. Drop outs can also be reduced when immediate follow up to missed clinic visits takes place.

The counselor and supervisory counselor should work closely during the first days of treatment to create a comfortable atmosphere for the client which will be conducive to fostering a positive attitude toward treatment. If drop outs occur, both the counselor and supervisory counselor should attempt to

determine whether it was due to poor or inadequate counseling. If that was the case, increased counselor training would be indicated.

Clinics must establish criteria for dropout status (e.g., number of missed appointments over weeks). Some clinics distinguish between clients who have dropped out of treatment and must undergo the entire readmission process, and those whose medication and other services have been discontinued and must see their counselor before services are resumed. Both categories are usually based on a specific length of time established by the program and the "discontinuation" usually precedes the "dropout" status designation.

e. *Suspension*

If a counselor determines that a client should be suspended from treatment, the administrator and case review team must be informed, and they must approve the proposed action. Alternative suggestions should be offered by staff members as to techniques of behavioral change which have not been tried. The client should be given at least one month on this trial period. The staff should work with him at this time in every possible way. If no improvement is shown and the decision is made that the client is receiving no benefit from treatment, it may be in his best interest to be placed on "administrative detoxification", that is, involuntary detoxification which is accomplished rapidly but within a defined period of time (e.g., three weeks). Administrative detoxification is not a punishment and should only be used as a tool in the client's interest when he has continually manipulated the program and all other methods of changing behavior have failed. It is the goal of the clinic to maintain a consistent level of expectation toward which clients should strive. Administrative detoxification is one method of reminding them of this. If a client demonstrates a new desire to comply with clinic regulations, administrative detoxification can be stopped and the client given another chance. This should be done at the joint discretion of the counselor and administrator. Under no circumstances should administrative detoxification be initiated without the serious deliberation of the team. Administrators should assume the responsibility for completely justifying motives when administrative detox is recommended. In addition, situations under which administrative detox would be warranted should be clearly stated in the program's policy manual (e.g., violence, threats, use of weapons, drug trafficking, etc.).

There are other circumstances under which treatment may be interrupted, if not terminated. The most common of these are hospitalization, illness at home, and arrest. In the case of hospitalization, the client should inform his counselor of the impending hospitalization and his attending physician of the fact that he will need methadone. After the client has consented in writing for pertinent information to be made available to hospital personnel, arrangements can be made for methadone treatment during hospitalization. In the event of emergency hospitalization or police arrest, the treatment program may provide information to hospital or jail staffs without violating the Federal law, and without the client's consent. Both situations are considered medical emergencies. It is helpful for all concerned if the clinic has established procedures for emergencies, in advance, and communicated them to neighboring hospitals and the police.

Illness at home may be handled through take-home medication. This situation is explained in the section on Take-Home Medication.

III. SUMMARY

In conclusion, the administrator should remember that this manual offers guidelines and not laws, although it is consistent with the FDA regulations and the Federal Funding Criteria.

Throughout this document there has been an attempt to support the clinic administrator's decision-making role. The Federal government, likewise, acknowledges the importance of this stance. For this reason, formal procedures are available to administrators to express disagreement or request exceptions to the current regulations and criteria. When an administrator believes that it is in the best interests of his clients to seek such a change, he should send a written request to the following:

A. *For An Exception to the FDA Regulations*

Methadone Monitoring Staff
Office of Compliance
Room 10 B-4
5600 Fishers Lane
Rockville, Maryland 20852

B. *For An Exception to the Federal Funding Criteria*

Director
Division of Community Assistance
National Institute on Drug Abuse
11400 Rockville Pike, Room 700
Rockville, Maryland 20852

Exhibit 1

FDA Regulations

federal register

FRIDAY, DECEMBER 15, 1972
WASHINGTON, D.C.
Volume 37 ■ Number 242
PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

METHADONE

Listing as New Drug With Special Requirements and Opportunity for Hearing

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER C—DRUGS

PART 130—NEW DRUGS

Approved New Drugs Requiring Continuation of Long-Term Studies, Records, and Reports; Listing of Methadone With Special Requirements for Use

In the FEDERAL REGISTER of January 7, 1972 (37 F.R. 201), the Commissioner of Food and Drugs added a new section, § 130.48 *Drugs that are subjects of approved new drug applications and that require special studies, records, and reports,* to Part 130—New Drugs, Subpart A—Procedural and Interpretative Regulations. In the FEDERAL REGISTER of April 6, 1972 (37 F.R. 6940), the Commissioner proposed special requirements for use of methadone, by adding a new paragraph (b) to § 130.48, which would place methadone on the list of drugs subject to special studies, records, and reports, provide for the drug to be considered no longer exclusively investigative, establish special requirements for use of the drug, no longer approve its use as an antitussive, and revoke § 130.44 *Conditions for investigational use of methadone for maintenance programs for narcotic addicts* (21 CFR 130.44) upon the effective date of § 130.48(b).

Section 130.44 was promulgated on April 2, 1971, in concert with the promulgation of regulations by the Bureau of Narcotics and Dangerous Drugs now cited as §§ 306.04 and 306.07 under Chapter II of Title 21 of the Code of Federal Regulations. Publication of these regulations were each predicated on the investigational status of methadone in the maintenance treatment of narcotic addicts. Their effect was to require submission of an IND application to the Food and Drug Administration and submission of an application for separate registration to the Bureau of Narcotics and Dangerous Drugs for approval by each on the basis of a specific research protocol. The regulation of the Bureau of Narcotics and Dangerous Drugs required that approval be based on a concurrent review by the Food and Drug Administration for scientific merit and by the Bureau of Narcotics and Dangerous Drugs for the drug control requirements. In the interval, experience with the use of methadone in maintenance treatment programs has increased; and such programs have greatly expanded. This expansion has led in some cases to a growing problem of abuse and diversion. The promulgation of the revised § 130.44 is designed to set forth medical standards in the treatment of narcotic addiction in accordance with section 4 of title 1 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and to help reduce the likelihood of diversion by providing for a closed system of methadone distribution. The Bureau of Narcotics and Dangerous Drugs which has primary responsibility for the elimination of the diversion of narcotic drugs has been consulted in the drafting of these regulations and will continue to exercise supervision of methadone programs in this aspect. In addition, because of the broader acceptance of methadone in the treatment of narcotic addiction, legislation has been introduced into the Congress for the purpose of strengthening the authority of the Bureau of Narcotics and Dangerous Drugs to impose and enforce standards relating to the security and diversion of narcotic drugs utilized in the treatment of narcotic addiction.

In response to the April 6, 1972, publication several hundred comments were received from known authorities in the treatment of drug addiction, concerned citizens, members of Congress, municipalities and organizations currently operating methadone treatment programs, State and local governmental authorities, the medical community through the American Medical Association, the American Psychiatric Association and State and local medical societies, the Medical Committee for Human Rights, the National Association of Social Workers, the American Society of Hospital Pharmacists, the American Pharmaceutical Association, and pharmaceutical manufacturers.

1. Numerous comments stated that the proposed regulation represents an unwarranted intrusion into medical practice and the physician-patient relationship by a regulatory agency and would severely impede the ability of the serious practitioner to treat and rehabilitate the addict population. It was suggested that flexibility should be allowed in deciding what is good medical management of patients. These respondents recognized the necessity to control diversion and abuse but felt that the treatment of narcotic dependence is a medical problem the management of which should emanate from the medical profession. The Food and Drug Administration (FDA) has no intention of interfering with legitimate medical practice or the exercising of medical judgment in the treatment of narcotic addiction. Clinical judgment must ultimately determine the type and course of treatment for each patient. Because of the hazards known to exist from diversion and misuse of methadone, however, strict control over the distribution, administration, and dispensing of the drug is necessary to assure its safe use. This regulation provides sufficient latitude within which medical judgment may properly be exercised.

2. A number of physicians and pharmacists expressed concern that the regulation may limit the availability of the drug for antitussive and severe pain uses (as in cancer patients) and that this is discriminatory. The Commissioner concludes that the closed system of distribution provided for in the regulation, although unique, is necessary to protect the public health by minimizing diversion and misuse of methadone. In some instances other drugs may have to be substituted for the analgesic or detoxification uses of methadone as well as for emergency treatment of withdrawal symptoms. In almost all instances in which methadone might be the drug of choice for its analgesic use this should still be possible by utilizing the dispensing services of approved hospital pharmacies, or in remote areas without hospitals, community pharmacies which may be approved by FDA for dispensing methadone on the recommendation of the State authority and after consultation with the Bureau of Narcotics and Dangerous Drugs (BNDD). Although the Commissioner recognizes the effectiveness of methadone as an antitussive, he concludes that there are only limited indications for this use because of the ready availability of other effective agents. The benefits derived from the drug for antitussive use do not outweigh the hazards of diversion and abuse which would result from the increased availability if such use were allowed.

3. Some comments also expressed concern that outpatient or ambulatory detoxification and emergency treatment for heroin withdrawal will not be sufficiently widely available. Some persons recommended the authorization of specific physicians for the purpose of providing ambulatory withdrawal treatment and the authorization of community pharmacies as well as hospitals for administering and dispensing methadone. Private physicians who wish to use methadone for ambulatory detoxification or maintenance treatment of addicts can do so by obtaining approval for the operation of a methadone treatment program or by serving as an approved methadone treatment medication unit for an approved program. Community pharmacies will also be able to administer and dispense methadone either by being an integral part of an approved program or by serving as a methadone treatment medication unit for an approved program.

4. Several comments noted that no provision has been made for the hospitalized narcotic addict who is not enrolled in a methadone treatment program but requires other general medical or surgical care while in the hospital and requires treatment with methadone while these other conditions are being attended. Similarly, if a person enrolled in a methadone treatment program is hospitalized for other general medical or surgical care, the treatment program would have to provide the drug supply to the hospital under the proposed regulation. The regulation has been revised to include temporary treatment of narcotic addicts enrolled in methadone treatment programs while hospitalized for other medical or surgical conditions. Those addicts not enrolled in a methadone treatment program who are admitted to the hospital for other general medical or surgical care may be detoxified with methadone if their condition warrants or, if not, they may be temporarily treated with methadone during the acute phase of their care.

5. One comment suggested the use of hospitals for stocking methadone as an emergency, temporary outpatient detoxification and/or maintenance treatment facility when an approved methadone treatment program is terminated. This comment has merit, and in the event that other approved programs are not available to the addicts or cannot accommodate displaced addicts, consideration will be given to using hospitals for the purposes of detoxification and/or maintenance treatment until such time as the patients can be referred to other approved methadone treatment programs.

6. One comment called attention to the language used in the proposal to describe the storage requirements for the drug and how it differs from the BNDD regulations. This comment also noted the BNDD regulations require that records pertaining to narcotic distribution need only be retained for a period of 2 years. The Commissioner recognizes that only 2-year record retention is required under the BNDD regulations, but concludes that there is a need for additional control of this drug, as evidenced by its potential for abuse and its demand as a substitute for other addictive drugs. State laws may require even longer record retention. The storage requirements under this regulation are identical to the BNDD regulations.

7. A number of comments argued that alternative methods of control and distribution should be considered (e.g., centrally processed multiple prescription blanks and selected pharmacies). For the reason expressed in item 2 above the comments are rejected except that community pharmacies may be utilized to administer and dispense the drug for analgesia in remote areas without hospitals on the recommendation of the State authority and approval by FDA after consultation with BNDD.

8. Several comments expressed concern that restricted distribution will invite larger prescriptions resulting in poorer control and that such practice would be further encouraged by the needless recordkeeping requirements placed on hospitals which may cause them not to apply, thus promoting even more restricted distribution than the regulation is designed to provide. The Commissioner recognizes these possibilities but concludes that hospitals, as they have in the past, will respond to the needs of the community by making methadone available for its legitimate uses. It is further concluded that the hospital reporting system in the regulation will serve as an indicator of inordinate prescribing which can be corrected when necessary.

9. One comment suggested restricting the use of other orally effective narcotics to prevent them from being used as a substitute for methadone. The Commissioner rejects this comment at this time since he has no information that such drugs are being used for this purpose or that these drugs would be substituted.

10. Several comments urged that the regulation provide for minimum qualifications of program personnel and perhaps certification of physicians to use methadone in treating addicts. It was also suggested that staffing patterns be included in the guidelines. The regulation does provide for the submission of information concerning the scientific training and experience of professional personnel having major responsibility for the programs and the rehabilitative efforts which are part of the approval criteria. The regulation has been changed to include staffing guidelines.

11. There was comment that ambiguity exists regarding the terminology used for administering and dispensing medication and the ultimate responsibility for the medication. Some complained that program costs will be prohibitive unless a variety of "competent agents" of the physician, such as pharmacists, registered nurses, and licensed practical nurses be permitted to administer and dispense medication. In an effort to clarify these responsibilities, the regulation has been amended to indicate that methadone can be administered and dispensed by such "competent agents" supervised by and pursuant to the order of the practitioner licensed under appropriate State or Federal law to order narcotic drugs. The responsibilities of the practitioner have been further clarified.

12. Several comments objected to the threat of criminal prosecution of program directors and physicians within programs which may serve to discourage them from assuming program responsibility and may do little to insure compliance. Lack of administrative control by physicians and dependence on other agencies for funding serve to remove the physician or director from policy decisions, yet he is held responsible for any deviation from the submitted protocol. Although it is recognized that program directors and physicians may have limited control within the program, their ultimate responsibility for the care and treatment of patients and to the public health cannot be minimized or avoided.

13. Several comments objected to the regulation by describing it as extremely discouraging and representing a severely exaggerated, punitive and logically incorrect response to the problem of drug diversion. These comments also stated that the regulation will only serve to divert money away from new services, prevent the expansion of existing programs, further widen the gap between government agencies and the practitioner, and perhaps even compound the problem of illicit diversion. Some urged that implementation be gradual and that every effort be made to address the need for Federal funds to assure adequate service. One comment objected to the regulation's interference with the organizational structure of programs to the point of prescribing a mode of treatment. It is recognized that problems of treatment are not uniform in different regions of the country and that flexibility is needed while attempting to maintain basic standards of control. The regulation has been revised to include a provision for specific exemptions or to establish revised standards for programs where they can be adequately justified.

14. Several comments objected to the implication that methadone is itself a complete and adequate treatment for narcotic addiction in all cases. Any such implication which the proposal may have conveyed was unintentional, and an attempt has been made to remove such implication.

15. One comment was critical of FDA's response to applications or other submissions in that the agency response is too slow to require that no changes be made without prior approval. It was suggested that changes be allowed to automatically take effect 10 days after certified receipt of a submission by FDA unless specifically rejected in that time. FDA regrets any delay in previous responses and is aware of the need for prompt action in this critical public health problem but without specific information regarding the reported delays the agency must reject this proposal. The regulation provides for a 60-day approval or denial period.

16. Another comment proposed a review board to review actions of the FDA, BNDD, or the State authority in denying or revoking program approvals. The Commissioner concludes that the law requires him to exercise this authority, though the final regulation does provide for State approval and consultation with the BNDD prior to FDA approval.

17. One comment suggested that the FDA develop a list of interested persons and to assure that such persons would be notified of changes in the FDA regulation. Changes in regulations are effected by publication in the FEDERAL REGISTER and are published for comment prior to promulgation. Subscriptions to this publication can be purchased for a nominal fee. In addition, the FDA will notify persons responsible for a program (those persons signing the latest amended applications for approval of a program) of any changes in the regulation.

18. One comment suggested recodifying and rearranging the regulation for the purpose of better identification and reference. In an effort to obtain greater clarity the regulation has been placed in § 130.44 and the substantive requirements have been stated separately as well as incorporated in the forms. As experience with the forms and application of the regulation accumulates, it may become advisable to amend the regulation further for clarity.

19. Several comments stated that provisions should be made for expediting reentry into a program of patients who have undergone unsuccessful voluntary withdrawal so that they are not subjected to long waiting periods and that patients should be informed of the potential for successful withdrawal. The FDA encourages such policies but believes that this should be a program decision based on the particular circumstances and not a legal requirement.

20. Several comments suggested that the protocol comment on the pregnant addict and those patients with serious illness. The FDA recognizes that these patients may present special problems in treatment and should be carefully evaluated prior to and during treatment. Experience has shown that programs have effectively dealt with patients of this type and that guidelines for every specific type of patient would be difficult to develop because treatment is usually individualized. It is recommended that caution be exercised in the treatment of the pregnant patient and that the lowest possible dosage level be maintained.

21. A number of comments called attention to the fact that problems of treatment are not uniform throughout the country and suggested that exceptions be granted where they can be justified. This concept has merit and it is felt that some degree of flexibility is needed while attempting to maintain basic standards of control. Therefore, a program may request exemptions from specific requirements of the regulation or to establish revised standards. These exemptions or revisions of standards must first be approved by the State authority and by the FDA. The regulation has been revised to detail the procedures for granting such exemptions.

22. Several comments were received regarding the distribution system established by the proposed regulation. Some individuals were concerned that the system is too limited and will prevent the drug from being available in some areas or for some special and/or emergency situation. It was suggested that, in some regions or States, wholesale pharmacy outlets be authorized to stock the drug for that area and then to transship it to approved programs, hospital pharmacies, or, in exceptional cases, selected community pharmacies. It is believed that in many instances this would provide greater security and expedite shipments. The regulation has been revised to include provisions for such outlets on the recommendation of State authorities.

23. After consideration of available data and current investigations, the Commissioner concludes that it is inappropriate to require manufacturers to develop additional data from chronic animal toxicity studies. This information is being developed through other sources. Therefore, § 130.48(b) (1) (ii) of the proposal has been deleted.

24. Numerous comments were received regarding the concept of a "satellite" and whether or not a private practitioner, a community pharmacy, and/or hospital pharmacy, could provide this kind of service. The term "satellite" was regarded as confusing and clarification of this term was requested. In addition, differentiation was needed between a program, individual components of a program, a "satellite" unit, and other organizational units. Because of the confusion connected with the term "satellite" and the number of objections it precipitated, particularly with regard to its size, the term has been deleted. In the interest of clarity, paragraphs (a) and (b) of § 130.44 have been inserted to define the terms used in the application forms.

25. Several persons commented on the approval of programs by a State authority. Some contended that the proposed regulations are inconsistent with the provisions of Public Law 92–255 regarding the responsible State authority. Others requested clarification of the sequence of approval by the various governmental authorities and the exact role of the State authority. Recourse in the event of State disapproval was requested. Since the problems of treatment are not uniform in different regions, flexibility was recommended to decentralize rule making and enforcement. This is particularly a problem in some areas where local governmental agencies are charged with the responsibility of drug abuse programing. Finally, some persons suggested prior approval of hospital pharmacies by the State authority to maintain consistency and to enable the State authorities to be informed of methadone distribution within their States. The FDA agrees that State authorities are essential in adequately controlling methadone, in assuring that the need for a methadone program exists within any specified geographic area, and in establishing criteria and guidance for program standards. The regulation has been revised to clarify the role of responsible authorities in the approval of programs, their components, and hospital or community pharmacies, and to provide a process whereby exemptions may be granted.

26. A large percentage of the comments referred to the proposal's sections concerning admission criteria, patient selection, and terminations. These comments were directed to: (a) Voluntary participation, (b) evaluation of addiction, (c) exception provisions, (d) age requirements, and (e) termination.

a. Several comments requested clarification of the term "voluntary participation" as it relates to those cases where courts or prisons may in effect require participation by providing no other reasonable alternatives. The FDA recognizes that this situation exists and has revised the regulation to provide for written informed consent of the patient. A standardized consent form for methadone treatment, Form FD 2635, "Consent to Methadone Treatment," has been added to the regulation.

b. Many of the comments indicated that the requirements for determining the state of addiction were excessive and too inflexible. They argued that determination of addiction should be based primarily on a careful history, particularly to determine a minimal period of heroin use. These comments state that withdrawal symptoms can be mimicked and that waiting periods place an unrealistic burden upon the applicant and the program. FDA agrees that flexibility is needed in this regard and the regulation has been revised to indicate that the selection of patients should be based on a careful and documented history of dependence on heroin or other morphine-like drugs beginning 2 years or more prior to application for treatment and evidence of current physiologic dependence on morphine-like drugs.

c. Some comments expressed concern about the limited exceptions to the requirement for evidence of current physiologic dependence on narcotic drugs. These comments favored the initiation of methadone treatment for an individual who has been detoxified and believes he is compelled to start heroin use again or an individual with a documented history of heroin use who has been drug free but believes he is compelled to start heroin again. The Commissioner concludes that a program should exhaust other methods of treatment of these patients in an effort to deter such patients from reinstituting their drug use, and that use of methadone automatically under these circumstances would not be in the best interest of the patient or the public health.

d. A large number of comments addressed themselves to the use of methadone in the treatment of adolescents. Some noted that the age of initial addiction to narcotic drugs has been dropping (at least in the large metropolitan areas) and that the longer one waits to treat the adolescent addict the more difficult it would be to change his life style. These comments argued that to place limitations on treating patients under 18 would mean that many chronic, compulsive heroin users would have to experience at least a few years of criminal activity and arrests if they could not avail themselves of the limited nondrug treatment programs. Others argued that the benefits of methadone treatment, despite any possible risks due to its effects on development or the risk of creating a de novo state of addiction within this age group, far outweigh the social and medical risks of continued heroin use. They argued that special emphasis and even priority should be assigned to the adolescent heroin user to avoid an even greater public health problem in the future. These arguments pointed out that current non-drug treatment programs cannot manage the large numbers of adolescent heroin users and that detoxification alone has not been successful. The comments either stated or implied that there must be still a lower-age limit for inclusion into methadone treatment programs and many indicated that the requirements for acceptance of the adolescent heroin user into treatment differ from the requirements for the adult. A number of suggestions have been made: (i) Lower the age limit to 16 and provide special requirements for approval of those under that age; (ii) lower the age limit to 16 and permit detoxification of those below this age; (iii) state conditions for approved treatment of those under age 18 and require the submission of a protocol rather than inclusion of these patients; (iv) allow treatment of patients under age 18 with concurrence of two physicians and/or approval by the State or local authority; (v) provide only supervised detoxification of patients under age 18 along with vigorous rehabilitative efforts as the therapeutic modality of choice in this age group; and (vi) maintain the present requirements but permit continued treatment of patients under 18 who are already enrolled in the treatment program as of a given date.

After careful consideration of these comments, the Commissioner concludes that adolescent patients present unique problems of clinical evaluation and treatment which preclude unrestricted use of methadone as a modality of treatment. Preventing the creation of a de novo state of addiction, which is often difficult to do in patients under age 16, is of major concern and further complicates treatment. Further study is required to determine whether the possible risks of special toxicity and negative developmental effects of the drug outweigh the benefits which may derive from such unrestricted treatment in patients under age 16.

In view of the inadequate data concerning methadone treatment and toxicity within the adolescent group but the limited availability of other modalities of treatment, the Commissioner concludes that in certain cases treatment of patients under age 18 is justifiable.

Patients between 16 and 18 years of age who are enrolled and under treatment in approved programs on the date of publication of this regulation may continue in maintenance treatment. No new patients between 16 and 18 years of age may be admitted to a maintenance treatment program after the date of publication of this regulation unless a parent, legal guardian, or responsible adult designated by the State authority completes and signs Form FD 2635 "Consent to Methadone Treatment". Methadone treatment of new patients between the ages of 16 and 18 years may be permitted after the date of publication of this regulation only with a documented history of two or more successful attempts at detoxification and a documented history of dependence on heroin or other morphine-like drugs beginning 2 years or more prior to application for treatment. No new patient under age 16 may be continued or started on methadone treatment after the date of publication of this regulation but these patients may be detoxified and retained in the program in a drug free state for followup and after care. Patients under age 18 who are not placed in maintenance treatment may be detoxified. Detoxification may not exceed 3 weeks. A repeat episode of detoxification may not be initiated until 4 weeks after the completion of the previous detoxification.

e. Several comments were received concerning the clinical records which indicated a need for clarification of these provisions. Some persons interpreted the statements to mean that a patient literally must be terminated (dropped) from a program or readmitted rather than understanding that this is solely a recordkeeping requirement. The paragraph has been revised to indicate that for recordkeeping purposes, if a patient misses appointments for 2 weeks without notifying the program, the episode of care is considered terminated and so noted in the clinical record. This does not mean that the patient cannot return for treatment. If the patient does return for treatment and is accepted into the program, this would be considered a readmission and so noted in the clinical record. This method of recordkeeping insures the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of methadone (e.g., the patient who has received no medication for several days or more and upon return receives the usual stabilization dose).

27. There were several adverse comments regarding the requirement to participate in local, regional, or national identification systems. These comments express particular concern about the confidentiality of patient records and the identification of patients to extra-program authorities for purposes other than those related to patient care or the monitoring of programs for maintenance of program standards. The FDA is cognizant of the provisions of these statutes which provide for the confidentiality of records which are maintained in connection with the treatment of patients and has revised the statement to indicate that any identification system shall be in accord with them. Information that would identify a patient in such a system shall be kept confidential in compliance with 21 CFR Part 401, section 408 of Public Law 92–255, and section 3 of Public Law 91–513.

28. Several comments were made about the recommended dosage schedule for treatment and the guidelines for detoxification which indicate a need for clarification. These comments were critical of the rigidity or inappropriateness of the recommended dosage. The FDA is of the opinion that clinical judgment must ultimately determine the actual dosage regimen used for each patient. Consequently, with the exception of the maximum dosage level and maximum take-home dosage for maintenance treatment, the paragraphs dealing with the dosage are designated as recommended guidelines.

29. Some of the comments expressed concern over the severity of the detoxification schedule. Particular reference was made to daily reductions in dosage and the restrictions placed on length of detoxification. In view of recent data and the above comments, revisions have been made in the suggested daily reductions in dosage, but the Commissioner rejects the concept of prolonged detoxification. If methadone is administered for more than 3 weeks, the procedure is considered to have progressed from detoxification or treatment of acute withdrawal symptoms to that of maintenance treatment even if the goal is eventual total withdrawal.

30. The greatest number of comments, including several thousand petition signatures from persons connected with treatment programs, objected to the more severe requirements concerning the frequency of visits and take-home privileges. It was contended that the requirements are, for many patients, contra-therapeutic and ignore the social progress of patients who have been in treatment for periods of years. It was urged by many that allowance be made for the exercise of medical judgment, since strict adherence to such requirements could produce a large dropout rate followed by relapse and might handicap rehabilitation efforts. It was argued that the present schedule would bind the patient to his treatment center, interfere with jobs of addicts or cause loss of employment, and place burdens on mentally and physically ill patients. Many persons, particularly from the larger metropolitan areas, complained that this schedule would increase the program costs, make adequate staffing almost impossible, over-burden the physical facilities of a program and prevent the expansion of services. Some individuals recommended a schedule of decreasing frequency of visits as a patient continues in the program and demonstrates evidence of successful rehabilitation (e.g., employment). A number of persons suggested an initial schedule of five times per week visits and several urged no more than once weekly visits after successful stabilization.

Since January 1, 1972, the FDA in cooperation with the National Institute of Mental Health (NIMH), has undertaken an intensified inspection of all methadone treatment programs currently in operation. This inspection program has resulted in several corrective actions by the FDA to eliminate major program deficiencies. In addition, the agency has become aware of increased diversion and misuse of methadone which mandates strict control over the distribution and use of the drug in a manner similar to that proposed. For this reason, the Commissioner has rejected the comments which propose more liberal distribution and control.

Because of the information obtained through these inspections and consultation with the BNDD, the take-home privilege provisions have been revised to provide the following: The patient initially will ingest the drug under observation daily, or at least 6 days a week, for the first 3 months. After demonstrating satisfactory adherence to the program regulations for at least 3 months, and showing substantial progress in rehabilitation by participating actively in the program activities and/or by participation in educational, vocational, and homemaking activities, those patients whose employment, education or homemaking responsibilities would be hindered by daily attendance may be permitted to reduce to three times weekly the times when they must ingest the drug under observation. They shall receive no more than a 2-day take-home supply. With continuing adherence to the program requirements and progressive rehabilitation for at least 2 years after entrance into the program, such patients may be permitted twice weekly visits to the program for drug ingestion under observation with a 3-day take-home supply. Prior to reducing the frequency of visits, documentation of the patient's progress and the need for reducing the frequency of visits shall be recorded.

31. There were a substantial number of adverse comments received on the section of the regulation dealing with urine testing. The major objections were on economic and clinical grounds. It was contended that weekly urine testing is too expensive for patients and/or programs and that the money could be spent more effectively in treatment and rehabilitation. The proposed schedule and procedure for urine testing was suggested as too stringent and as interfering with the patient-doctor relationship as well as interfering with clinical judgment. Some comments contended that this requirement is a violation of patient's rights and creates a police-like atmosphere. Several persons recommended a decreasing frequency of urine testing with an ultimate schedule of random urine sampling a few times yearly. A few persons suggested testing for other drugs such as barbiturates, amphetamines, cocaine, and, once treatment was initiated, for methadone.

For the reasons stated in paragraph 30 above and in the interest of providing accurate urine test results, the Commissioner rejects the comments suggesting more lenient scheduling and has also made several revisions in the requirements. Testing randomly for barbiturates and amphetamines and other drugs if indicated at monthly intervals is an added requirement based on evidence of increased abuse of these substances. In addition, provision is made for the use of only those laboratories which participate in and are approved by any proficiency testing program designated by the FDA. Any changes made in laboratories used for urine testing shall have prior approval of the FDA.

32. Several persons commented on use of particular dosage forms in order to prevent diversion and abuse and a requirement for poison prevention packaging. The regulation provides that dosage forms used in programs shall be formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion. Although tablet, syrup concentrate, or other formulations may be distributed, only a liquid formulation may be administered or dispensed. Regarding poison prevention packaging, the FDA has promulgated regulations under the Poison Prevention Packaging Act of 1970 which require that controlled substances be packaged for household use in "special packaging" which is designed to prevent poisoning in children. All methadone dispensed for outpatient use shall be in such containers as specified in 21 CFR 295.2(a)(4) of the regulations, published in the FEDERAL REGISTER of April 27, 1972 (37 F.R. 8433).

33. Some comments contended that the closed distribution system established in the proposal is outside the legal authority of the Food and Drug Administration, and that the Commissioner must retain the drug under exclusively investigational controls, approve it for unrestricted and uncontrolled distribution and dispensing, or withdraw it completely from use. The Commissioner rejects this contention. Congress intended to provide in the Federal Food, Drug, and Cosmetic Act sufficient flexibility to assure the safe and effective distribution and use of all drugs. Most of the comments recognized the legal validity and factual justification for utilizing a controlled system of distribution in the unique circumstances posed by methadone. Nothing in the law precludes concurrent use of both IND and NDA controls, and comments so stated. Counsel for the Food and Drug Administration has reviewed the final regulations and has provided his opinion that they are authorized by the Act.

34. Questions were raised about the procedure for denial or revocation of approval of a program or any portion thereof. Because the new regulation provides for approval of methadone as a new drug and removes it from what was previously exclusively an investigational status, new procedures for denial or revocation of approval are appropriate. The final regulations therefore provide that denial or revocation of a program or any portion thereof will initially be the subject of an informal conference with the Director of the Bureau of Drugs. The applicant then has an opportunity to appeal an adverse decision to the Commissioner who, if he finds that the applicant cannot justify approval, will issue a notice of opportunity for a hearing with respect to the matter in the same manner as for withdrawal of an NDA or portion thereof.

35. For the reasons stated in the FEDERAL REGISTER of April 6, 1972 (37 F.R. 6940), and in this order, the Commissioner concludes that there is a lack of substantial evidence that methadone is safe and effective for detoxification, analgesia, or antitussive use under the conditions of use that presently exist. Therefore, notice is given to the holders of the new drug applications for methadone that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the following new drug applications and all amendments and supplements thereto:

1. Methadone (Dolophine) HCl Tablets, Injectable, Suppository; by Eli Lilly & Co., Box 618, Indianapolis, IN 46206. (NDA 6134).

2. Methadone HCl Tablet, Injectable; by Hoffmann-LaRoche Inc., Nutley, N.J. 07110. (NDA 6305).

3. Methadone HCl Injectable, Tablets, Elixir; by Parke, Davis & Co., Joseph Campau Avenue, At the River, Detroit, MI 48232. (NDA 6310).

4. Methadone HCl Tablets, Injectable; by the Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49002. (NDA 6311).

5. Methadone HCl Ampuls; by S. E. Massengill Co., 527 Fifth Street, Bristol, TN 37620. (NDA 6345).

6. Methadone HCl Tablets, Injectable; by Wm. S. Merrell Co., Div. Richardson-Merrell Inc., 110 E. Amity Road, Cincinnati, OH 45215. (NDA 6370).

7. Methadone HCl Tablets; by Mallinckrodt Chemical Works, 3600 North Second Street, Box 5439, St. Louis, MO 63160. (NDA 6383).

8. Methadone (Amidone) HCl Tablets, Elixir, Injectable; by S. F. Durst & Co., Inc., 5317 North Third Street, Philadelphia, PA 19120. (NDA 6504).

A notice of oportunity for hearing, published elsewhere in this issue of the FEDERAL REGISTER, states:

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355), and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner hereby gives the applicants an opportunity for a hearing to show why approval of the new drug applications should not be withdrawn.

Within 30 days after publication hereof in the FEDERAL REGISTER the applicants are required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, a written appearance electing whether or not to avail themselves of the opportunity for a hearing. Failure of an applicant to file a written appearance of election within said 30 days will constitute an election by him not to avail himself of the opportunty for a hearing.

If no applicant elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the applications.

If an applicant elects to avail himself of the opportunity for a hearing, he must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons why approval of the new drug applications should not be withdrawn, together with a well-organized and full factual analysis of the data he is prepared to prove in support of his opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing (21 CFR 130.14(b)).

If review of the data submitted by an applicant warrants the conclusion that there exists substantial evidence demonstrating the safety and effectiveness of the product under existing conditions of use, the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the applications and data submitted by the applicants in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the conclusion that no genuine and substantial issue of fact precludes the withdrawal of approval of the applications, the Commissioner will enter an order of withdrawal making findings and conclusions on such data.

If, upon the request of the new drug applicants, a hearing is justified, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after the expiration of such 30 days, a written notice of the time and place at which the hearing will commence. The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

Requests for a hearing and/or elections not to request a hearing may be seen in the Office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

New drug application holders may submit, within 30 days after the date of publication of this notice in the FEDERAL REGISTER, a supplemental new drug application requesting approval for the manufacture and distribution of methadone pursuant to §§ 130.44 and 130.48(b). Upon submission and approval of any such supplement the Commissioner will rescind this notice of opportunity for hearing for that applicant.

The Commissioner concludes that § 130.44 should be revised (see paragraph 18 of the preamble) and that § 130.48 should be amended to add a new paragraph (b) listing methadone as a drug subject to new-drug application approval and special studies, records and reports requirements. Therefore, pursuant to the provisions of sections 505 and 701(a), of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 355, 371(a)), section 303(a) of the Public Health Service Act as amended (42 U.S.C. 242a(a)), and section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 257(a)), and under authority delegated to the Commissioner (21 CFR 2.120), Subchapter C of Title 21, Code of Federal Regulations; is amended as follows:

1. Section 130.44 is revised to read as follows:

§ 130.44 Conditions for use of methadone.

(a) *Definitions.* (1) An individual is "drug dependent" when his addiction reaches a stage where a daily administration of heroin or other morphine-like drugs is required to avoid the onset of signs of withdrawal.

(2) "Detoxification treatment" using methadone is the administering or dispensing of methadone as a substitute narcotic drug in decreasing doses to reach a drug free state in a period not to exceed 21 days in order to withdraw an individual who is dependent on heroin or other morphine-like drugs from the use of these drugs.

(3) "Maintenance treatment" using methadone is the continued administering or dispensing of methadone, in conjunction with provision of appropriate social and medical services, at relatively stable dosage levels for a period in excess of 21 days as an oral substitute for heroin or other morphine-like drugs, for an individual dependent on heroin. An eventual drug free state is the treatment goal for patients but it is recognized that for some patients the drug may be needed for long periods of time.

(4) "State authority" means the State authority designated pursuant to section 409 of Public Law 92–255, the Drug Abuse Office and Treatment Act of 1972, or in lieu thereof any other State authority designated by the Governor for purposes of exercising the authority under this section. If no State authority is so designated, the provisions in this section relating to approval by the State authority shall be inapplicable with respect to that State.

(b) *Organizational structures and approval requirements.*—(1) *Methadone treatment program.*—(i) *Defined.* A methadone treatment program is defined as a person or organization furnishing a comprehensive range of services using methadone for the detoxification and/or maintenance treatment of narcotic addicts, conducting initial evaluation of patients and providing ongoing treatment at a specified location or locations. If there is a centralized organizational structure, consisting of a primary facility and other outpatient facilities, all of which conduct initial evaluation of patients and administer or dispense medication, both the primary facility and each outpatient facility shall be considered a separate program, even though some services may be shared (e.g. the same hospital or rehabilitative services).

(ii) *Services.* A methadone treatment program, in addition to providing medication and/or evaluation, shall provide, as a minimum, counseling, rehabilitative, and other social services (e.g. vocational and educational guidance, employment placement), which will help the patient become a well functioning member of society. These services should normally be made available at the primary outpatient facility, but the program sponsor is permitted to enter into a formal, documented agreement with private or public agencies, organizations or institutions for these services if they are available elsewhere. Evidence will be required to demonstrate that the services are fully available and are being utilized.

(iii) *Hospital affiliation.* If a program is not physically located within a hospital which has agreed to provide any needed medical care for drug related problems for the program's patients, there shall be a formal, documented agreement between the program sponsor and a responsible hospital official demonstrating that hospital care, both inpatient and outpatient, is fully available to any patient who may need it for such problems. It is suggested that the program sponsor enter into an agreement with the hospital official to provide general medical care for patients. Neither the program sponsor nor the hospital are required to assume financial responsibility for the patient's medical care.

(iv) *Private practitioners.* A private practitioner constitutes a separate program if he conducts initial evaluation of patients, administers and dispenses medication, provides a comprehensive range of services, and otherwise meets all of the requirements for a program established in this section. A private practitioner who qualifies and is approved as a program is permitted to serve as many patients as he desires, but will be required to meet all the requirements of this regulation, including staffing requirements, unless permission is granted by the Food and Drug Administration and the State authority for exemption from or revision of these requirements.

(v) *Program approval.* In order lawfully to operate a methadone treatment program, each separate program, whether an out-patient facility or a private practitioner, shall submit the applications specified in this section simultaneously to the Food and Drug Administration and the State authority and shall receive the approval of both, except as provided for in paragraph (h)(5) of this section. Before granting approval the Food and Drug Administration will first consult with the Bureau of Narcotics and Dangerous Drugs to determine compliance with Federal controlled substances laws. Each physical location within any program shall be identified and listed in the approval application. At the time of application for approval the program sponsor shall indicate whether medication will be administered or dispensed at the facility. If medication is to be administered or dispensed at a location not previously used for this purpose, prior approval from both agencies shall be obtained. If a facility in which medication is administered or dispensed is deleted by a program the Food and Drug Administration and the State authority shall be notified within 3 weeks. Addition or deletion of facilities which provide services other than administering or dispensing medication is permitted with notification within 3 weeks to the Food and Drug Administration and the State authority.

(2) *Methadone treatment medication unit.*—(i) *Defined.* A methadone treatment "medication unit" is a facility, established by a program sponsor as part of his program, from which licensed private practitioners and community pharmacists are permitted to administer and dispense methadone. These medication units may also collect urine for urine testing for narcotic drugs. Any such facility shall be geographically dispersed from the primary facility and other medication units that have been established. The enrollment in a medication unit shall be of reasonable size in relation to the space available for treatment and the size of the staff at the facility, and may not exceed 30 patients.

(ii) *Referral.* The patient shall be stabilized at his optimal dosage level before he may be referred to a medication unit. Since the medication unit will not provide a range of services, the program sponsor shall determine that the patient to be referred is not in need of frequent counseling, rehabilitative, and other services which are only available at the primary program facility. A patient may not be referred to a medication unit before he has demonstrated progress towards rehabilitation. The nature of this progress shall be entered in the patient's record.

(iii) *Responsibility for patient.* After a patient is referred to a medication unit, the program sponsor retains continuing responsibility for the patient's care. The program sponsor is responsible for assuring that the patient reports weekly for urinalysis at either the primary facility or the medication unit and receives needed medical and social services at least monthly at the primary facility.

(iv) *Services.* Medication units are limited to the administering or dispensing of medication and the collection of urine for urine testing, following the procedures outlined in paragraph (d)(6)(ii) of this section. If a private practitioner wishes to provide other services in addition to administering or dispensing medication and collecting urine samples, he shall be considered a program and shall be required to submit an application for separate approval.

(v) *Medication unit approval.* In order lawfully to operate a medication unit, the program shall obtain approval for each separate unit from both the Food

and Drug Administration and the State authority, except as provided for in paragraph (h)(5) of this section. Approval will be based on the distribution of these units within a particular geographic area. Any new medication unit shall receive such approval before commencing operation.

(vi) *Revocation of approval.* If the primary program's approval is revoked by the Food and Drug Administration the approval for the medication unit is automatically revoked. If a particular medication unit's approval is revoked, the approval of the primary program will remain in effect unless it is also revoked.

(vii) *Methadone supply.* The medication unit will receive its supply of the drug directly from the stocks of the primary facility. Only persons permitted to administer or dispense the drug or security personnel licensed or otherwise authorized by State law may deliver the drug to a medication unit.

(3) *Organizational structure; central administration.* (i) The program sponsor shall submit to the Food and Drug Administration and the State authority a description of the organizational structure of the program applying for approval, listing the name of the person responsible for the particular program, the address, and the responsibilities of each facility or medication unit. The sources of funding for each program shall be listed and the name and address of each governmental agency providing funding shall be stated.

(ii) Where two or more programs share a central administration (e.g., a city or state-wide organization), the person responsible for the organization (Administrator) shall be listed as program sponsor for each separate program participating. An individual program shall indicate its participation in the central organization at the time of its application. The Administrator is permitted to fulfill all recordkeeping and reporting requirements for these programs, but it is emphasized that the programs will continue to receive separate approval.

(iii) One individual is permitted to assume primary medical responsibility for more than one program and be listed as medical director. If an individual assumes medical responsibility for more than one program, the feasibility of such an arrangement shall be documented and attached to the application.

(4) *Prohibition against unapproved use of methadone.* No individual, practitioner, organization, or legal entity, may prescribe, administer, or dispense methadone without prior approval by the Food and Drug Administration and the State authority, except as provided for in paragraph (h)(5) of this section, unless specifically exempted by this section.

(c) *Conditions for approval of the use of methadone in a treatment program.*—(1) *Applicants.* An individual listed as program sponsor for a treatment program using methadone need not personally be a licensed practitioner but shall employ a licensed physician for the position of medical director. Persons responsible for administering or dispensing the medication shall be practitioners as defined by section 102(20) of the Controlled Substances Act (21 U.S.C. 802 (20)) licensed to practice by the State in which the program is to be established.

(2) *Assent to regulation.* A person who sponsors a methadone treatment program, and any person responsible for a particular program, shall agree to adhere to all the rules, directives, and procedures, set forth in this regulation, and any regulation regarding the use of methadone which may be promulgated in the future. The program sponsor, and person responsible for a particular program, shall agree to assume responsibility for any practitioners, employees, agents, or other individuals providing services, who work in their programs at the primary facility or at other facilities or medication units. The responsible persons shall agree to inform these people of the provisions of this regulation and to monitor their activities to assure compliance with the provisions. The Food and Drug Administration and the State authority shall be notified within 3 weeks of any replacement of the program sponsor or medical director. Activities in violation of this regulation may give rise to the sanctions set forth in paragraph (i) of this section.

(3) *Facilities.* To obtain program approval, the applicant shall demonstrate that he will have access to adequate physical facilities to provide all necessary services. The physical facilities should be sufficiently spacious and well maintained to provide appropriate conditions for conducting individual and/or group counseling.

(4) *Submission of proper applications.* The following applications shall be filed simultaneously with both the Food and Drug Administration and the State authority.

(i) Form FD 2632 "Application for Approval of Use of Methadone in a Treatment Program." This form, set forth in paragraph (k)(1) of this section, shall be completed and signed by the program sponsor and submitted in triplicate to the Food and Drug Administration and the State authority.

(ii) Form FD 2633 "Medical Responsibility Statement for Use of Methadone in a Treatment Program." This form, set forth in paragraph (k)(2) of this section, shall be completed and signed by each licensed physician authorized to administer or dispense methadone and submitted in triplicate to the Food and Drug Administration and the State authority. The names of any other persons licensed by law to administer or dispense narcotic drugs working in the program shall be listed, even if they are not at present responsible for administering or dispensing the drug.

(iii) Form FD 2634 "Annual Report for Treatment Program Using Methadone." This form, set forth in paragraph (k)(3) of this section, shall be completed and signed by the program sponsor for every program over which he has responsibility for each calendar year of operation. It shall be submitted in triplicate to the Food and Drug Administration and the State authority on or before January 30 of each year.

(5) *State and Federal approval of treatment programs.* Treatment programs using methadone shall have been reviewed by the State authority and must conform to all State requirements for conducting a methadone treatment program. The Food and Drug Administration must have received notification of the program's approval by the State agency. Only after the State authority has given its approval will the Food and Drug Administration grant approval to a program. The Food and Drug Administration will also revoke approval when recommended by the State authority. If State approval of a program is denied or revoked the program shall have a right of appeal to the Commissioner, as provided for in paragraph (h)(5) of this section. Prior to granting or withholding approval, the Food and Drug Administration will consult with the Bureau of Narcotics and Dangerous Drugs to determine the applicant's compliance with Federal controlled substances laws. No shipment of methadone may lawfully be made to any program which has not received approval from the Food and Drug Administration. The program sponsor will receive notification of approval or denial or a request for additional information, when necessary, within 60 days after receipt of the application by the Food and Drug Administration.

(d) *Requirements for operation of methadone treatment program.*—(1) *Description of facilities.* A program shall have ready access to a comprehensive range of medical and rehabilitative services. The name, address, and description of each hospital, institution, clinical laboratory, or other facility available to provide the necessary services shall be given to the Food and Drug Administration and the State authority. This listing shall include the name and address of each medication unit.

(2) *Approximate number of patients to be treated.* The program sponsor shall submit to the Food and Drug Administration and the State authority an approximation of the number of patients who will be treated, based on past history, addict population in the area, treatment capacity, or other relevant information.

(3) *Minimum admission standards.*—(i) *Voluntary participation; consent form.* Each patient shall be fully informed concerning the possible risk associated with the use of methadone. Participation in any program shall be voluntary. The person responsible for the program shall insure that all the relevant facts concerning the use of methadone are clearly and adequately explained to the patient and that all patients (including those under age 18) sign, with full knowledge and understanding of its contents, the first part of Form FD 2635 "Consent for Methadone Treatment" set forth in paragraph (k)(4) of this section and the parents or guardians of patients under age 18 sign the second part of that form.

(ii) *Physiologic addiction standards; records.* The mere use of a narcotic drug, even if periodic or intermittent, cannot be equated with narcotic addiction. Care

shall be exercised in the selection of patients to prevent the possibility of admitting a person who was not first dependent upon heroin or other morphine-like drugs at least 2 years prior to admission to maintenance treatment. This drug history and evidence of current physiologic dependence on morphine-like drugs shall be documented. Evidence of physical dependence should be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilation, and piloerection) during the initial period of abstinence. Withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation (e.g., medical and personal history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely that an individual would be currently dependent on narcotic drugs without having a positive urine test for one or more of these drugs. Additional evidence can be obtained by noting the presence of old and fresh needle marks, and by obtaining additional history from relatives and friends.

(iii) *Exceptions to physiologic addiction standards; justification.* An exception to the requirement for evidence of current physiologic dependence on narcotic drugs will be allowed only under exceptional circumstances. For example, maintenance treatment may be indicated prior to or within 1 week of release from a stay of 1 month or longer in a penal or chronic care institution, if an individual has a predetention history of dependence upon heroin or other morphine-like drugs at least 2 years prior to admission to the institution. Justification for any such exception shall be noted in the patient's record.

(iv) *Special limitations; treatment of patients under age 18.* (a) The safety and effectiveness of methadone when used in the treatment of adolescents has not been proven by adequate clinical study. Special procedures are therefore necessary to assure that patients under age 16 will not be admitted to a program and that patients between 16 and 18 years of age be admitted to maintenance treatment only under limited conditions.

(b) Patients between 16 and 18 years of age who are enrolled and under treatment in approved programs on the date of publication of this regulation may continue in maintenance treatment. No new patients between 16 and 18 years of age may be admitted to a maintenance treatment program after the date of publication of this regulation unless a parent, legal guardian, or responsible adult designated by the State authority completes and signs Form FD 2635 "Consent to Methadone Treatment," set forth in paragraph (k)(4) of this section. Methadone treatment of new patients between the ages of 16 and 18 years will be permitted after December 15, 1972, only with a documented history of two or more unsuccessful attempts at detoxification and a documented history of dependence on heroin or other morphine-like drugs beginning 2 years or more prior to application for treatment. No patient under age 16 may be continued or started on methadone treatment after December 15, 1972, but these patients may be detoxified and retained in the program in a drug free state for follow-up and after care.

(c) Patients under age 18 who are not placed in maintenance treatment may be detoxified. Detoxification may not exceed 3 weeks. A repeat episode of detoxification may not be initiated until 4 weeks after the completion of the previous detoxification.

(v) *Denial of admission.* If in the professional judgment of the medical director a particular patient would not benefit from methadone treatment, he may be refused such treatment even if he meets the admission standards.

(vi) *Patient evaluation; admission record.* An admission evaluation and record shall be made and maintained for each patient upon admission to the program. This evaluation and record shall consist of a personal history, a medical history, a physical examination, and any laboratory or other special examinations indicated in the judgment of the attending physician. It is recommended that a complete blood count, liver function tests, and a serologic test for lues be part of the admission evaluation.

(a) *Personal history.* A personal history record will be completed for each patient accepted for admission and will include at least age, sex, educational level, employment history, criminal history, past history of drug abuse of all types and prior treatment for drug abuse.

(b) *Medical history.* A thorough medical history record will be completed for each patient accepted for admission.

(c) *Physical examination.* The findings of a comprehensive physical examination will be recorded.

(4) *Staffing requirements.* As a minimum standard for the staffing of a treatment program there shall be the equivalent of one full-time physician licensed by and registered by State or Federal law to order, dispense, and administer methadone, two nurses (registered nurse or licensed practical nurse), and four counselors, for every 300 patients receiving maintenance treatment. The staffing pattern may be varied to fit the operational pattern and population characteristics of the program, but there shall always be at least one medical or osteopathic physician available for initial medical evaluation and follow-up care and to supervise the patient medication schedules for each 300 patients. This staffing pattern is not the recommended pattern, but the minimum staffing pattern acceptable.

(5) *Acess to a range of services.* A treatment program shall provide a comprehensive range of medical and rehabilitative services to its patients. These services normally should be provided at the primary facility, but the program sponsor may enter into formally documented agreements with other public or private agencies, institutions, or organizations to render these services. Such facilities must be located so as to provide ease of access to the patient. Any service not furnished at the primary facility shall be listed, and the agreements to furnish those services shall be documented, when application for approval is submitted to the Food and Drug Administration and the State authority. Modification of the services shall be submitted in triplicate to the Food and Drug Administration as services are added or deleted.

(6) *Minimum procedures for ongoing care.*—(i) *Dosage and administration requirements—(a) Form; packaging.* The methadone shall be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive methadone in parenteral form, when in the attending physican's professional judgment it is deemed advisable. Although tablet, syrup concentrate, or other formulations are permitted to be distributed to the program, all oral medication shall be administered or dispensed in a liquid formulation. The dosage will be formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion and packaged for outpatient use in special packaging as required by § 295.2 of this chapter. Any take-out medication shall be labeled with the treatment center's name, address and telephone number. Exceptions may be granted when any of the provisions of this subsection are in conflict with State law with regard to the administering or dispensing of drugs.

(b) *Detoxification treatment.* In detoxification the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The dosage schedules indicated below are recommended but could be varied depending upon clinical judgment. Initially, a single oral dose of 15–20 milligrams of methadone will often be sufficient to suppress withdrawal symptoms. Additional methadone may be provided if withdrawal symptoms are not suppressed or whenever symptoms reappear. When patients are physically dependent on high doses of methadone, it may be necessary to exceed these levels. Forty milligrams per day in single or divided doses will usually constitute an adequate stabilizing dose level. Stabilization can be continued 2 to 3 days and then the amount of methadone will normally be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or in 2-day intervals, but the amount of intake shall always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and will cause little discomfort. In ambulatory patients, a somewhat slower schedule may be needed. If methadone is administered for more than 3 weeks, the procedure is considered to have progressed from detoxification or treatment of the acute withdrawal syn-

drome to maintenance treatment, even though the goal and intent may be eventual total withdrawal.

(c) *Maintenance treatment; special considerations for a pregnant patient.* (1) In maintenance treatment the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of narcotic drugs, but should not be so great as to cause sedation, respiratory depression, or other effects of acute intoxication. It is important that the initial dosage be adjusted on an individual basis to the narcotic tolerance of the new patient. If such a patient has been a heavy user of heroin up to the day of admission, he may be given 20 milligrams 4 to 8 hours later, or 40 milligrams in a single oral dose. If he enters treatment with little or no narcotic tolerance (e.g. if he has recently been released from jail or other confinement), the initial dosage may be one-half these quantities. When there is any doubt, the smaller dose should be used initially. The patient should then be kept under observation, and, if symptoms of abstinence are distressing, additional 10 milligram doses may be administered as needed. Subsequently, the dosage should be adjusted individually, as tolerated and required, up to a level of 120 milligrams daily. For daily dosages above 100 milligrams patients shall ingest medication under observation 6 days per week. These patients will be allowed take-home medication for 1 day per week only. Those patients in treatment on the date this regulation becomes effective who are receiving a take-home dose of more than 100 milligrams per day shall have their dosage level reduced to 100 milligrams per day or less by June 13, 1973. A daily dose of 120 milligrams or more shall be justified in the medical record. For daily dosages above 120 milligrams, prior approval from State authority and the Food and Drug Administration shall be obtained beginning on March 15, 1973. For take-home doses above 100 milligrams per day, prior approval from the State authority and the Food and Drug Administration shall be obtained beginning on June 13, 1973. A regular review of dosage level should be made by the responsible physician with careful consideration given for reduction of dosage as indicated on an individual basis. A new dosage level is only a test level until stability is achieved.

(2) Caution shall be taken in the maintenance treatment of pregnant patients. Dosage levels shall be maintained as low as possible if continued methadone treatment is deemed necessary. It is the responsibility of the program sponsor to assure that each female patient is fully informed concerning the possible risks to a pregnant woman or her unborn child from the use of methadone.

(d) *Authorized dispensers of methadone; responsibility.* Methadone will be administered or dispensed by a practitioner licensed or registered under appropriate State or Federal law to order narcotic drugs for patients or by an agent of the practitioner, supervised by and pursuant to the order of the practitioner. This agent may only be a pharmacist, registered nurse, or licensed practical nurse depending upon the State regulations regarding narcotic drug dispensing and administering. The licensed practitioner assumes responsibility for the amounts of methadone administered or dispensed and all changes in dosage schedule will be recorded and signed by the licensed practitioner.

(7) *Frequency of attendance; take-home medication.*—(i) *For detoxification, the drug shall be administered daily under close observation.* In maintenance treatment the patient will initially ingest the drug under observation daily, or at least 6 days a week, for the first 3 months. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administration. It is also recognized, however, that daily attendance at a program facility may be incompatible with gainful employment, education, and responsible homemaking. After demonstrating satisfactory adherence to the program regulations for at least 3 months, and showing substantial progress in rehabilitation by participating actively in the program activities and/or by participation in educational, vocational, and homemaking activities, those patients whose employment, education, or homemaking responsibilities would be hindered by daily attendance may be permitted to reduce to three times weekly the times when they must ingest the drug under observation. They shall receive no more than a 2-day take-home supply. With continuing adherence to the program's requirements and progressive rehabilitation for at least 2 years after entrance into the program, such patients may be permitted twice weekly visits to the program for drug ingestion under observation with a 3-day take-home supply. Prior to reducing the frequency of visits, documentation of the patient's progress and the need for reducing the frequency of visits shall be recorded. The requirements and schedule for when the drug must be ingested under observation may be relaxed if the patient has a serious physical disability which would prevent frequent visits to the program facility. The Food and Drug Administration and the State authority shall be notified of such cases. Additional medication may also be provided in exceptional circumstances such as acute illness, family crises, or necessary travel when hardship would result from requiring the customary observed medication intake for the specific period. In these circumstances the reasons for providing additional medication will be recorded. In circumstances of severe illness, infirmity or physical disability, an authorized individual (e.g. a licensed practitioner) may deliver or obtain the medication.

(ii) *Urine testing—(a) Schedule of testing; substances tested for.* In maintenance treatment, a urinalysis will be performed randomly at least weekly for morphine and monthly for methadone, barbiturates, amphetamines and other drugs if indicated. Those patients receiving their doses of the drug from medication units will also adhere to this schedule. The urine shall be collected at the program's primary facility or at the medication unit.

(b) *Method of collection.* Urine shall be collected in a manner which minimizes falsification of the samples. The reliability of this collection procedure shall be demonstrated.

(c) *Laboratories.* Laboratories used for urine testing shall participate in and be approved by any proficiency testing program designated by the Food and Drug Administration. Any changes made in laboratories used for urine testing shall have prior approval of the Food and Drug Administration.

(iii) *Patient's clinical record.* An adequate clinical record will be maintained for each patient. The record will contain a copy of the signed consent form(s), the date of each visit, the amount of methadone administered or dispensed, the results of each urinalysis, a detailed account of any adverse reactions, which will also be reported within 2 weeks to the Food and Drug Administration on Form FD–1639, "Drug Experience Report," any significant physical or psychological disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for 2 weeks or more without notifying the program, the episode of care is considered terminated and so noted in the clinical record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and so noted in the clinical record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of methadone (e.g., the patient who has received no medication for several days or more and upon return receives the usual stabilization dose). An annual evaluation of the patient's progress will be recorded in the clinical record(s).

(8) *Discontinuation of methadone use.* All patients in treatment will be given careful consideration for discontinuation of methadone use, especially after reaching a 10–20 milligram dosage level. Social rehabilitation shall have been maintained for a reasonable period of time. Patients should be encouraged to pursue the goal of eventual withdrawal from methadone and becoming completely drug free. Upon successfully reaching a drug-free state the patient should be retained in the program for as long as necessary to assure stability in the drug-free state, with the frequency of his required visits adjusted at the discretion of the director.

(9) *Record of drug dispensing.* Accurate records traceable to specific patients shall be maintained showing dates, quantity, and batch or code marks of the drug dispensed. These records shall be retained for a period of 3 years.

(10) *Security of drug stocks.* Adequate security shall be maintained over stocks of methadone, over the manner in which it is administered or dispensed, over the manner in which it is distributed to medication units, and over the manner in which it is stored to guard against theft and diversion of the drug. The security standards for the distribution and storage of controlled substances as required by the Bureau of Narcotics and Dangerous Drugs (§§ 301.72–301.76 of this title) shall be met by the program.

(11) *Inspections of programs; patient confidentiality.* Inspection of a program may be undertaken by the State authority, by the Food and Drug Administration and by the Bureau of Narcotics and Dangerous Drugs in accordance with Federal controlled substances laws. The identity of patients will be kept confidential except (i) when it is necessary to make follow-up investigations on adverse effect information related to use of the drug, (ii) when the medical welfare of the patient would be threatened by a failure to reveal such information, or (iii) when it is necessary to verify records relating to approval of the program or any portion thereof. In all circumstances the provision of 21 CFR Part 401 shall be followed.

(12) *Exemptions from specific program standards.*—(i) A program is permitted, at the time of application or any time thereafter, to request exemption from or revision of specific program standards. The rationale for an exemption or revision shall be thoroughly documented in an appendix to be submitted with the application or at some later time. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients and requests exemption from some of the staffing and service standards in a nonmetropolitan area with few physicians and no rehabilitative services geographically accessible. The Food and Drug Administration will approve such exemptions or revisions of program standards at the time of application with the concurrence of the State authority.

(ii) The Food and Drug Administration has the right to withhold the granting of an exemption until such time as a program is in actual operation in order to assess if the exemption is necessary. If periodic inspections of the program reveal that discrepancies or adverse conditions exist, the Food and Drug Administration shall reserve the right to revoke any or all exemptions previously granted.

(13) *Additional reporting requirements.*—(i) *Deaths.* The program sponsor shall report any patient death which is considered methadone related to the Food and Drug Administration within 2 weeks, using Form FD–1639 "Drug Experience Report."

(ii) *Newborns.* The program sponsor shall report to the Food and Drug Administration the birth of any child to a female patient, if the newborn is premature or shows any adverse reactions which, in the opinion of the attending physician, are due to methadone, within 1 month of the birth, using Form FD–1639 "Drug Experience Report."

(e) *Multiple enrollments.*—(1) *Administering or dispensing to patients enrolled in other programs.* There is a danger of drug dependent persons attempting to enroll in more than one methadone treatment program to obtain quantities of methadone for the purpose of self-administration or illicit marketing. Therefore, except in an emergency situation, methadone shall not be provided to a patient who is known to be currently receiving the drug from another treatment program using methadone.

(2) *Patient attendance requirements.* The patient shall always report to the same treatment facility unless prior approval is obtained from the program sponsor for treatment at another program. Permission to report for treatment at the facility of another program shall be granted only in exceptional circumstances and shall be noted on the patient's clinical record.

(3) *Multiple enrollment prevention.* To prevent multiple enrollments, the program shall agree to participate in any patient identification system that exists or is designated and approved by the Food and Drug Administration. Information that would identify a patient shall be kept confidential in compliance with Part 401 of this title.

(f) *Conditions for use of methadone in hospitals for analgesia in severe pain, for detoxification, and for temporary maintenance treatment*—(1) *Form.* The drug may be administered or dispensed in either oral or parenteral form.

(2) *Use of methadone in hospitals*—(i) *Approved uses.* Methadone is permitted to be administered or dispensed only for detoxification or temporary treatment of hospitalized patients, and for analgesia in severe pain for hospitalized patients and outpatients. If methadone is administered for treatment of heroin dependence for more than 3 weeks, the procedure passes from treatment of the acute withdrawal syndrome (detoxification) to maintenance treatment. Maintenance treatment is permitted to be undertaken only by approved methadone programs. This does not preclude the maintenance treatment of an addict who is hospitalized for treatment of medical conditions other than addiction and who requires temporary maintenance treatment during the critical period of his stay or whose enrollment in a program which has approval for maintenance treatment using methadone has been verified. Any hospital which already has received approval under this paragraph (f) may be permitted to serve as a temporary methadone treatment program when an approved methadone treatment program has been terminated and there is no other facility immediately available in the area to provide methadone treatment for the patients. The Food and Drug Administration may give this approval upon the request of the State authority or the hospital, when no State authority has been established.

(ii) *Individual responsible for supplies.* The name of the individual (pharmacist) responsible for receiving and securing supplies of methadone shall be submitted to the Food and Drug Administration and the State authority. Individuals not authorized by Federal or State law shall not receive supplies of methadone.

(iii) *General description.* A general description of the hospital including the number of beds, specialized treatment facilities for drug dependence, and nature of patient care undertaken shall be submitted.

(iv) *Anticipated quantity of drug needed.* The anticipated quantity of methadone needed per year shall be submitted.

(v) *Records.* The hospital shall maintain accurate records showing dates, quantity, and batch or code marks of the drug used for in patient and out patient treatment. The records shall be retained for a period of 3 years.

(vi) *Inspections.* The Food and Drug Administration and the State authority may inspect supplies of the drug and evaluate the uses to which the drug is being put. The identity of the patient will be kept confidential except (a) when it is necessary to make followup investigations on adverse effect information related to the drug, (b) when the medical welfare of the patient would be threatened by a failure to reveal such information, or (c) when it is necessary to verify records relating to approval of the hospital or any portion thereof. The confidentiality requirements of Part 401 of this title shall be followed. Records relating to the receipt, storage, and distribution of narcotic medication shall also be subject to inspection as provided by Federal controlled substances laws; but use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(vii) *Approval of hospital pharmacy.* Application for a hospital pharmacy to provide methadone for analgesia, detoxification and temporary treatment will be submitted to the Food and Drug Administration and the State authority and shall receive approval from both, except as provided for in paragraph (h)(5) of this section. Within 60 days after receipt of the application by the Food and Drug Administration, the applicant will receive notification of approval or denial or a request for additional information, when necessary.

(viii) *Approval of shipments to hospital pharmacies.* Before a hospital pharmacy may lawfully receive shipments of methadone for use as an analgesic for severe pain and for detoxification or temporary maintenance treatment, a responsible hospital official shall complete,

sign, and file in triplicate with the Food and Drug Administration and the State authority Form FD 2636, "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification and Temporary Maintenance Treatment" set forth in paragraph (k)(5) of this section and shall receive a notice of approval thereof from the Food and Drug Administration.

(ix) *Sanctions.* Failure to abide by the requirements described in this section may result in revocation of approval to receive shipments of methadone, seizure of the drug supply on hand, injunction, and criminal prosecution.

(3) *Treatment of outpatients.*—(i) If in a physician's professional judgment methadone would be the drug of choice as an analgesic for treating a patient in severe pain, the drug will be available for use on an out-patient basis from an approved hospital pharmacy, or in a remote area from an approved community pharmacy. Prior to filing a physician's prescription for methadone for outpatients, the pharmacy shall obtain from the physician a statement indicating that all such prescriptions written by him will be limited to use for analgesia in severe pain. The physician shall agree to maintain records to substantiate such use. These records will be available in the hospital or made available at the request of the hospital administrator. In remote areas the approved community pharmacy is permitted to maintain these records or they may be forwarded to the State authority. On January 30 of each year, the names and addresses of all physicians who prescribed methadone for analgesia on an outpatient basis during the previous year shall be reported to the Food and Drug Administration.

(ii) Prescriptions for analgesia may be filled only if they are written by a physician who has submitted the required statement to the approved hospital or community pharmacy.

(4) *Shipments to remote areas.* In remote areas or in certain exceptional circumstances where there are no approved hospitals, community pharmacies may be approved by the Food and Drug Administration to receive shipments of methadone for administering or dispensing for analgesia upon the recommendation of the State authority and after consultation with the Bureau of Narcotics and Dangerous Drugs.

(g) *Confidentiality of patient records.*—(1) Except as provided in subparagraph (2) of this paragraph, disclosure of patient records maintained by any program shall be governed by the provisions of Part 401 of this title, and every program shall comply with the provisions of that part. Records relating to the receipt, storage, and distribution of narcotic medication shall also be subject to inspection as provided by Federal controlled substances laws; but use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(2) In addition to the restrictions upon disclosure in Part 401 of this title, and in accordance with the authority conferred by section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)), every program is hereby further authorized to protect the privacy of patients therein by withholding from all persons not employed by such program or otherwise connected with the conduct of its operations the names or other identifying characteristics of such patients under any circumstances under which such program has reasonable grounds to believe that such information may be used to conduct any criminal investigation or prosecution of a patient. Programs may not be compelled in any Federal, State, or local civil, criminal, administrative, or other proceedings to furnish such information, but this subparagraph does not authorize the withholding of information authorized to be furnished pursuant to § 401.44 of this title nor does it invalidate any legal process to compel the furnishing of information in accordance with § 401.44 of this title. Records relating to the receipt, storage, and distribution of narcotic medication shall also be subject to inspection as provided by Federal controlled substances laws; but use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(3) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Food and Drug Administration to have access to and to copy all records relating to the use of methadone. Patient identities shall be revealed (i) when it is necessary to make follow-up investigations on adverse effect information related to the drug, (ii) when the medical welfare of the patient would be threatened by a failure to reveal such information, or (iii) when it is necessary to verify records relating to any approval or any portion thereof under this section. The Food and Drug Administration will retain such identities in confidence pursuant to § 401.44 of this title and shall reveal them only when necessary in a related administrative or court proceeding.

(h) *Denial or revocation of approval.*—(1) Complete or partial denial or revocation of approval of an application to receive shipments of methadone (Forms FD 2632 "Application for Approval of Use of Methadone in a Treatment Program" and FD 2636 "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification and Maintenance Treatment") may be proposed to the Commissioner of Food and Drugs by the Director of the Food and Drug Administration's Bureau of Drugs, on his own initiative or at the request of representatives of the Bureau of Narcotics and Dangerous Drugs, National Institute of Mental Health, the State authority, or any other interested person.

(2) Before presenting such a proposal to the Commissioner, the Director of the Bureau of Drugs or his representative will notify the applicant in writing of the proposed action and the reasons therefor and will offer him an opportunity to explain the matters in question in an informal conference and/or in writing within 10 days after receipt of such notification. The applicant shall have the right to hear and to question the information on which the proposal to deny or revoke approval is based, and may present any oral or written information and views.

(3) If the explanation offered by the applicant is not accepted by the Bureau of Drugs as sufficient to justify approval of the application, and denial or revocation of approval is therefore proposed, the Commissioner will evaluate information obtained in the informal hearing before the Director of the Bureau of Drugs. If he finds that the applicant has failed to submit adequate assurance justifying approval of the application, he shall issue a notice of opportunity for hearing with respect to the matter pursuant to § 130.14 and the matter shall thereafter be handled in accordance with established procedures for denial or revocation of approval of a new drug application. If the Secretary determines that there is an imminent hazard to health, revocation of approval will become effective immediately and any administrative procedures will be expedited. Upon revocation of approval of an application, the Commissioner will notify the applicant, the State authority, the Bureau of Narcotics and Dangerous Drugs, and all other appropriate persons that the applicant may no longer receive shipments of methadone, and will require the recall of all methadone from the applicant. Revocation of approval may also result in criminal prosecution.

(4) Denial or revocation of approval may be reversed when the Commissioner determines that the applicant has justified approval of the application.

(5) A treatment program or medication unit or any part thereof, including any facility or any individual, may appeal to the Food and Drug Administration a complete or partial denial or revocation of approval by the State authority unless the denial or revocation is based upon a State law or regulation. The appeal shall first be made to the Director of the Bureau of Drugs, who shall hold an informal conference on the matter in accordance with subparagraph (2) of this paragraph. The State authority may participate in the conference. The appellant or the State authority may appeal the Director's decision to the Commissioner, who shall decide the matter in accordance with subparagraph (3) of this paragraph. If the Commissioner denies or revokes approval, such action shall be handled in accordance with subparagraph (3) of this paragraph. The Commissioner may not grant or retain Food and Drug Administration approval if he finds that the appellant is not in compliance with all applicable State laws and regulations and with this section.

(i) *Sanctions.*—(1) *Program sponsor or individual responsible for a particular program.* If the program sponsor or the person responsible for a particular program fails to abide by all the requirements set forth in these regulations, or

fails to adequately monitor the activities of those employed in the program, he may have the approval of his application revoked, his methadone supply seized, an injunction granted precluding operation of his program, and criminal prosecution instituted against him.

(2) *Persons responsible for administering or dispensing methadone.* If a person responsible for administering or dispensing methadone fails to abide by all the requirements set forth in these regulations, criminal prosecution may be instituted against him, his drug supply may be seized, the approval of the program may be revoked, and an injunction may be granted precluding operation of the program.

(j) *Requirements for distribution of methadone by manufacturers.*—(1) *Distribution requirements.* Shipments of the drug are restricted to direct shipments by manufacturers of methadone to approved treatment programs using methadone, to approved hospital pharmacies, and to approved selected community pharmacies. If requested by a manufacturer or State authority, wholesale pharmacy outlets in some regions or States may be authorized to stock methadone for that area and then trans-ship the drug to approved methadone treatment programs and approved hospital and community pharmacies. Alternative methods of distribution will be permitted if they are approved by the Food and Drug Administration and the State authority. Prior to any approval of an alternative method of distribution there will be consultation with the Bureau of Narcotics and Dangerous Drugs to assure compliance with its regulations regarding controlled substance distribution.

(2) *Information regarding approved programs, hospitals, and community pharmacies.* The Food and Drug Administration will provide methadone manufacturers and the public with the names and locations of programs, hospitals, and selected community pharmacies that have been approved to receive shipments of the drug. All information contained in the forms set out in paragraph (k) of this section is available for public disclosure except for names or other identifying information with respect to patients.

(3) *Acceptance of delivery.* Delivery shall only be made to a licensed practitioner employed at the facility. At the time of delivery the licensed practitioner shall sign for the methadone and place his specific title and identification number on any invoice. Copies of these signed invoices shall be kept by the manufacturer.

(k) *Program forms.*—(1) *Treatment Program Application.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD 2632 Application for Approval of Use of Methadone in a Treatment Program

Name or other identification of program_____

Address _____

Name of program sponsor_____

Commissioner,
Food and Drug Administration,
Bureau of Drugs (BD–106),
Rockville, Md. 20852.

DEAR SIR: As the person responsible for this program, I submit this request for approval of a treatment program using methadone to provide detoxification and maintenance treatment for narcotic addicts in accordance with § 130.44 of the new drug regulations. I understand that failure to abide by the requirements described below may cause revocation of approval of my application, seizure of my drug supply, an injunction, and criminal prosecution.

I. Attached is the name, complete address, and a summary of the scientific training and experience of each physician and all other professional personnel having major responsibilities for the program and rehabilitative efforts, and a signed Form FD 2633 "Medical Responsibility Statement for Use of Methadone in a Treatment Program" for every licensed practitioner authorized to prescribe, dispense, or administer methadone under the program. (If the Medical Director of this program has been listed for a program in a previous application, the feasibility of serving as Medical Director for this program must be documented and this documentation attached to this application.)

II. Attached is a description of the organizational structure of this program and the name and complete address of any central administration or larger organizational structure to which this program is responsible.

III. Attached is a listing of the sources of funding for this program. (The name and address for each governmental agency providing funding must be provided.)

IV. The program shall have ready access to a comprehensive range of medical and rehabilitative services. Attached is the name, address, and description of each hospital, institution, clinical laboratory facility, or other facility available to provide the necessary services and a statement for each facility as to whether or not methadone will be administered or dispensed at that facility. These facilities shall comply with any guidelines established by Federal or State authorities. (This listing should include the address of each medication unit. If any medical or rehabilitative service is not available at the primary facility, there must be a formal, documented agreement with private or public agencies, organizations, or institutions for these services.)

V. Attached is a statement of the approximate number of addicts to be included in the program.

VI. The following minimal treatment standards shall be followed:

A. A statement shall be given to the addicts to inform them about the program. A voluntary request and consent Form FD 2635 "Consent to Methadone Treatment" shall be signed by each patient. Participation in the program shall be voluntary.

B. I concur that the mere use of a narcotic drug, even if periodic or intermittent, cannot be equated with narcotic addiction. Care shall be exercised in the selection of patients to prevent the possibility of admitting a person who was not first dependent upon heroin or other morphine-like drugs at least 2 years prior to admission to maintenance treatment. This drug history and evidence of current physiologic dependence on morphine-like drugs shall be documented. Evidence of physical dependence should be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilation, and piloerection) during the initial period of abstinence. (Withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation—(medical and personal history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely that an individual would be currently dependent on narcotic drugs without having a positive urine test for one or more of these drugs. Additional evidence can be obtained by noting the presence of old and fresh needle marks, and by obtaining additional history from relatives and friends.)

C. An exception to the requirement for evidence of current physiologic dependence on narcotic drugs will be allowed under exceptional circumstances. For example, methadone treatment may be initiated prior to or within 1 week of release from a stay of 1 month or longer in a penal or chronic care institution if an individual has a pre-detention history of dependence upon heroin or other morphine-like drugs at least 2 years prior to admission to the institution. Justification for any such exception shall be noted on the patient's record.

D. Patients between 16 and 18 years of age who are enrolled and under treatment in approved programs on December 15, 1973 may continue in maintenance treatment. No new patients between 16 and 18 years of age may be admitted to a maintenance treatment program after such date unless a parent, legal guardian, or responsible adult designated by the State authority completes and signs consent form, Form FD 2635 "Consent to Methadone Treatment." Methadone treatment of new patients between the ages of 16 and 18 years of age will be permitted after such date only with a documented history of two or more unsuccessful attempts at detoxification and a documented history of dependence on heroin or other morphine-like drugs beginning 2 years or more prior to application for treatment. No patient under age 16 may be continued or started on methadone treatment after such date but these patients may be detoxified and retained in the program in a drug-free state for follow-up and aftercare. Patients under age 18 who are not placed in maintenance treatment may be detoxified. Detoxification may not exceed 3 weeks. A repeat episode of detoxification may not be initiated until 4 weeks after the completion of the previous detoxification.

VII. An admission evaluation and record shall be made and maintained for each patient upon admission to the program. This evaluation and record shall consist of a personal history, a medical history, a physical examination, and any laboratory or other special examinations as indicated in the judgment of the attending physician. (It is recommended that a complete blood count, liver function tests, and a serologic test for lues be part of the admission evaluation.)

A. A personal history record will include at least age, sex, educational level, employment history, criminal history, past history of drug abuse of all types, and prior treatment for drug abuse.

B. Medical history. A thorough medical history record will be completed for each patient accepted for admission.

C. Physical examination. The findings of a comprehensive physical examination will be recorded.

VIII. I understand that there is a danger of drug dependent persons attempting to enroll in more than one methadone treatment program to obtain quantities of methadone either for the purpose of self-administration or illicit marketing. To prevent such multiple enrollments, I will participate in whatever local, regional, or national patient identification system exists and I state my

intention to participate in any system that may be developed and approved by the Food and Drug Administration unless I notify the Food and Drug Administration, in writing, to the contrary. I understand failure to participate may cause revocation of approval of my application. Except in an emergency situation, methadone will not be provided to a patient who is known to be currently receiving the drug from another treatment program using methadone. Except as provided in item XV of this form, information that could identify the patient will be kept confidential in compliance with 21 CFR Part 401.

IX. The following minimal procedures will be used for ongoing care.

A. Dosage and administration for detoxification and maintenance treatment:

1. Methadone will be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for medical or surgical condition are permitted to receive methadone in parenteral form, when in the attending physician's professional judgment it is deemed advisable. Although tablet, sirup concentrate, or other formulations are permitted to be distributed to the program, all oral medication shall be administered or dispensed in a liquid formulation. The dosage shall be formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion, and packaged for outpatient use in special packaging as required by 21 CFR 295.2. Any take-out medication shall be labeled with the treatment center's name, address, and telephone number. Exceptions may be granted when any of the provisions of this subsection are in conflict with State law with regard to the administering or dispensing of drugs.

2. In detoxification, the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The dosage schedules indicated below are recommended but may be varied depending upon clinical judgment. Initially, a single oral dose of 15–20 milligrams of methadone will often be sufficient to suppress withdrawal symptoms. Additional methadone may be provided if withdrawal symptoms are not suppressed or whenever symptoms reappear. When patients are physically dependent on high doses of methadone, it may be necessary to exceed these levels. Forty milligrams per day in single or divided doses will usually constitute an adequate stabilizing dose level. Stabilization can be continued for 2 to 3 days and then the amount of methadone will normally be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or in 2-day intervals, but the amount of intake shall always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and will cause little discomfort. In ambulatory patients, a somewhat slower schedule may be needed. If methadone is administered for more than 3 weeks, the procedure is considered to have progressed from detoxification or treatment of the acute withdrawal syndrome to maintenance treatment, even though the goal and intent may be eventual total withdrawal.

3. In maintenance treatment the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of narcotic drugs but should not be so great as to cause sedation, respiratory depression, or other effects of acute intoxification. It is important that the initial dosage be adjusted on an individual basis to the narcotic tolerance of the new patient. If such a patient has been a heavy user of heroin up to the day of admission, he may be given 20 milligrams orally for the first dose and another 20 milligrams 4 to 8 hours later, or 40 milligrams in a single oral dose. If he enters treatment with little or no narcotic tolerance (e.g., if he has recently been released from jail or other confinement), the initial dosage may be one-half these quantities. When there is any doubt, the smaller dose should be used initially. The patient should then be kept under observation, and, if symptoms of abstinence are distressing, additional 10-milligram doses may be repeated as needed. Subsequently, the dosage should be adjusted individually, as tolerated and required, to a level of 120 milligrams daily. For daily dosages above 100 milligrams patients shall ingest medication under observation 6 days per week. These patients will be allowed take-home medication for 1 day per week only. Those patients in treatment on December 15, 1972 who are receiving a take-home dose of more than 100 milligrams per day shall have their dosage level reduced to 100 milligrams per day or less by June 13, 1973. A daily dose of 120 milligrams or more shall be justified in the medical record. For daily dosages above 120 milligrams or, beginning June 13, 1973, for take-home doses above 100 milligrams per day, prior approval shall be obtained from the Food and Drug Administration and the State authority. A regular review of dosage level should be made by the responsible physician with careful consideration given for reduction of dosage as indicated on an individual basis. A new dosage level is only a test level until stability is achieved.

4. Caution shall be taken in the maintenance treatment of pregnant patients. Dosage levels shall be maintained as low as possible if continued methadone treatment is deemed necessary. It is the responsibility of the program to assure that each female patient is fully informed concerning the possible risks to a pregnant woman or her unborn child from the use of methadone.

5. Methadone will be administered or dispensed by a practitioner licensed or registered under appropriate State or Federal law to order narcotic drugs for patients or by an agent of the practitioner, supervised by and pursuant to the order of the practitioner. This agent may be a pharmacist, registered nurse, or licensed practical nurse, depending upon the State regulations regarding narcotic drug dispensing and administering. The licensed practitioner assumes responsibility for the amounts of methadone administered or dispensed and all changes in dosage schedule shall be recorded and signed by the licensed practitioner.

6. For detoxification, the drug shall be administered daily under close observation. In maintenance treatment the patient initially will ingest the drug under observation daily, or at least 6 days a week, for the first 3 months. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administration. It is also recognized, however, that daily attendance at a program facility may be incompatible with gainful employment, education, and responsible homemaking. After demonstrating satisfactory adherence to the program regulations for at least 3 months and showing substantial progress in rehabilitation by participating actively in the program activities and/or by participation in educational, vocational, and homemaking activities, those patients whose employment, education, or homemaking responsibilities would be hindered by daily attendance may be permitted to reduce to 3 times weekly the times when they must ingest the drug under observation. They shall receive no more than a 2 day take-home supply. With continuing adherence to the program's requirements and progressive rehabilitation for at least 2 years after entrance into the program, such patients may be permitted twice weekly visits to the program for drug ingestion under observation with a 3 day take-home supply. Prior to reducing the frequency of visits, documentation of the patient's progress and the need for reducing the frequency of visits shall be recorded. The requirements and schedule for when the drug must be ingested under supervision may be relaxed if the patient has a serious physical disability which would prevent frequent visits to the program facility. The Food and Drug Administration and the State authority shall be notified of such cases. Additional medication may also be provided in exceptional circumstances such as acute illness, family crises, or necessary travel when hardship would result from requiring the customary observed medication intake for the specific period. In such circumstances the reasons for providing additional medication will be recorded in the clinical record. In circumstances of severe illness, infirmity or physical disability, an authorized individual (e.g., a licensed practitioner) may deliver or obtain the medication.

B. In maintenance treatment, a urinalysis will be performed randomly at least weekly for morphine and monthly for methadone, barbiturates, amphetamines, and other drugs if indicated. Those patients receiving their doses of the drug from medication units will also adhere to this schedule. The urine shall be collected in a manner which minimizes falsification of the samples. The reliability of this collection procedure shall be demonstrated. Laboratories used for urine testing shall participate in and be approved by any proficiency testing program designated by the Food and Drug Administration. Any changes in laboratories used for urine testing shall have prior approval of the Food and Drug Administration.

C. An adequate clinical record will be maintained for each patient. The record will contain a copy of the signed consent form(s), the date of each visit, the amount of methadone administered or dispensed, the results of each urinalysis, a detailed account of any adverse reactions, which will also be reported within 2 weeks to the Food and Drug Administration on Form FD–1639, "Drug Experience Report", any significant physical or psychologic disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for 2 weeks or more without notifying the program, the episode of care is considered terminated and so noted in the clinical record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and so noted in the clinical record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of methadone (e.g., the patient who has received no medication for several days or more and upon return receives the usual stabilization dose). An annual evaluation of the patient's progress will be recorded in the clinical record.

D. All patients in maintenance treatment will be given careful consideration for discontinuance of methadone, especially after reaching a 10–20 milligram dosage level. Social rehabilitation shall have been maintained for a reasonable period of time. Patients should be encouraged to pursue the goal of eventual withdrawal from methadone and becoming completely drug-free. Upon successfully reaching a drug-free state the patient should be retained in the program for as long as necessary to assure stability in the drug-free state, with the frequency of

his required visits adjusted at the discretion of the director.

X. To prevent diversion into illicit channels, adequate security shall be maintained over stocks of methadone and over the manner in which it is distributed, as required by the Bureau of Narcotics and Dangerous Drugs.

XI. Accurate records traceable to patients shall be maintained showing dates, quantity, and batch or code marks of the drug used. These records shall be retained for a period of 3 years.

XII. The program director may establish geographically dispersed medication units of reasonable size for administering and dispensing medication to patients stabilized at their optimal dosage level. The approval of such units for any geographic area shall be based upon the number and distribution of such units within the area. No more than 30 patients shall be under care at a medication unit at any one time. These units shall be responsible only for administering and dispensing medication. Private practitioners and community pharmacies may serve as medication units. Only after patients have been stabilized at their optimal initial dosage level may they be referred to a medication unit. Subsequent to such referral, the program director shall retain continuing responsibility for the patient's care and the patient shall be seen at the primary program facility at least monthly for medical evaluation and ancillary service. If a private practitioner wishes to provide other service in addition to administering and dispensing medication and collecting urine samples, the practitioner is considered a program component or a separate program, depending upon the type of services provided. In such case the restrictions on the number of patients served shall be determined by the staffing pattern and resources available.

XIII. All representations in this application are currently accurate, and no changes shall be made in the program until they have been approved by the Food and Drug Administration and the State authority.

XIV. If the program or any individual under the program is disapproved, the program director shall recall the methadone from the disapproved sources and return the drug to the manufacturer in a manner prescribed by the Bureau of Narcotics and Dangerous Drugs.

XV. Inspections of this program may be undertaken by the State authority, by the Food and Drug Administration and by the Bureau of Narcotics and Dangerous Drugs in accordance with Federal controlled substances laws. The identity of patients will be kept confidential except when it is necessary to make follow-up investigations on adverse effect information related to use of the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records relating to approval of the program or any portion thereof. In all circumstances the provisions of 21 CFR Part 401 shall be followed.

Signature _____
(Program sponsor)

(2) *Medical Responsibility Statement.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD *2633* Medical Responsibility Statement for Use of Methadone in a Treatment Program

(To be completed by each physician licensed to dispense or administer methadone under an approved program.)

Date _____
Name of program _____
Address _____
Telephone number _____

Medical Director for this facility (licensed by law to administer or dispense drugs and responsible for all medication administered or dispensed at this facility).

_____
Address of this facility _____
Telephone number of this facility _____

I. The undersigned agrees to assume responsibility for the administration and dispensing of methadone under the above identified program and to abide by the required standards for methadone detoxification and maintenance treatment.

II. The name of each patient treated at a facility and the frequency of visits shall be registered with the medical director. An annual report Form FD 2634 "Annual Report for Treatment Program Using Methadone" shall be submitted to the program sponsor for submission to the Food and Drug Administration. The patient shall always report to the same facility unless prior approval is obtained from the medical director for treatment at another operation.

III. The following minimal treatment standards shall be followed.

A. A statement shall be given to the addicts to inform them about the program. A voluntary request and consent Form FD 2635 "Consent to Methadone Treatment" shall be signed by each patient. Participation in the program shall be voluntary.

B. The mere use of a narcotic drug, even if periodic or intermittent, cannot be equated with narcotic addiction. Care shall be exercised in the selection of patients to prevent the possibility of admitting a person who was not first dependent upon heroin or other morphine-like drugs at least 2 years prior to admission to maintenance treatment. This drug history and evidence of current physiologic dependence on morphine-like drugs shall be documented. Evidence of physical dependence should be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilation, and piloerection) during the initial period of abstinence. Withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation (medical and personal history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely that an individual would be currently dependent on narcotic drugs without having a positive urine test for one or more of these drugs. Additional evidence can be obtained by noting the presence of old and fresh needle marks, and by obtaining additional history from relatives and friends.

C. An exception to the requirement for evidence of current physiologic dependence on narcotic drugs will be allowed under exceptional circumstances. For example, methadone treatment may be initiated prior to or within 1 week of release from a stay of 1 month or longer in in a penal or chronic care institution if an individual has a pre-detention history of dependence upon heroin or other morphine-like drugs at least 2 years prior to admission to the institute. Justification for any such exception should be noted on the patient's record.

D. Patients between 16 and 18 years of age who are enrolled and under treatment in approved programs on December 15, 1972 may continue in maintenance treatment. No new patients between 16 and 18 years of age may be admitted to a maintenance treatment after such date unless a parent, legal guardian, or responsible adult designated by the State authority completes and signs consent form, Form FD 2635, "Consent to Methadone Treatment". Methadone treatment of new patients between ages 16 and 18 years of age will be permitted after such date only with a documented history of two or more unsuccessful attempts at detoxification and a documented history of dependence on heroin or other morphine-like drugs beginning 2 years or more prior to application for treatment. No patient under age 16 may be continued or started on methadone treatment after such date, but these patients may be detoxified and retained in the program in a drug-free state for follow-up and aftercare. Patients under age 18 who are not placed in maintenance treatment may be detoxified. Detoxification may not exceed 3 weeks. A repeat episode of detoxification may not be initiated until 4 weeks after the completion of the previous detoxification.

IV. An admission evaluation and record shall be made and maintained for each patient upon admission to the program. This evaluation and record shall consist of a personal history, a medical history, and a physical examination, and any laboratory or other special examinations as indicated in the judgment of the attending physician. (It is recommended that a complete blood count, liver function tests, and a serologic test for lues be part of the admission evaluation.)

A. A personal history record will include at least age, sex, educational level, employment history, criminal history, past history of drug abuse of all types, and prior treatment for drug abuse.

B. Medical history. A thorough medical history record will be completed for each patient accepted for admission.

C. Physical examination. The findings of a comprehensive physical examination will be recorded.

V. I understand that there is a danger of drug dependent persons attempting to enroll in more than one methadone treatment program to obtain quantities of methadone either for the purpose of self-administration or illicit marketing. To prevent such multiple enrollments, I will participate in whatever local, regional, or national patient identification system that exists and I state my intention to participate in any system that may be developed and approved by the Food and Drug Administration unless I notify the Food and Drug Administration, in writing, to the contrary. I understand failure to participate may cause revocation of approval of my application. Except in an emergency situation, methadone will not be provided to a patient who is known to be currently receiving the drug from another treatment program using methadone. Except as provided in item XI of this form, information that could identify the patient will be kept confidential in compliance with 21 CFR Part 401.

VI. The following minimal procedures will be used for ongoing care.

A. Dosage and administration for detoxification and maintenance treatment:

1. Methadone will be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive methadone in parenteral form, when in the attending physician's professional judgment it is deemed advisable. Although tablet, syrup concentrate, or other formulations are permitted to be distributed to the program, all

oral medication shall be administered or dispensed in a liquid formulation. The dosage shall be formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion, and packaged for outpatient use in special packaging as required by 21 CFR 295.2. Any take-out medication shall be labeled with the treatment center's name, address and telephone number. Exceptions may be granted when any of the provisions of this subsection are in conflict with State law with regard to the administering or dispensing of drugs.

2. In detoxification, the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The dosage schedules indicated below are recommended but may be varied depending upon clinical judgment. Initially, a single oral dose of 15-20 milligrams of methadone will often be sufficient to suppress withdrawal symptoms. Additional methadone may be provided if withdrawal symptoms are not suppressed or whenever symptoms reappear. When patients are physically dependent on high doses of methadone, it may be necessary to exceed these levels. 40 milligrams per day in single or divided doses will usually constitute an adequate stabilizing dose level. Stabilization can be continued for 2 to 3 days and then the amount of methadone will normally be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or in 2 day intervals, but the amount of intake shall always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and will cause little discomfort. In ambulatory patients, a somewhat slower schedule may be needed. If methadone is administered for more than 3 weeks, the procedure is considered to have progressed from detoxification or treatment of the acute withdrawal syndrome to maintenance treatment, even though the goal and intent may be eventual total withdrawal.

3. In maintenance treatment the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of narcotic drugs but should not be so great as to cause sedation, respiratory depression, or other effects of acute intoxification. It is important that the initial dosage be adjusted on an individual basis to the narcotic tolerance of the new patient. If such a patient has been a heavy user of heroin up to the day of admission, he may be given 20 milligrams orally for the first dose and another 20 milligrams 4 to 8 hours later, or 40 milligrams in a single oral dose. If he enters treatment with little or no narcotic tolerance (e.g., if he has recently been released from jail or other confinement), the initial dosage may be one-half these quantities. When there is any doubt, the smaller dose should be used initially. The patient should then be kept under observation, and, if symptoms of abstinence are distressing, additional 10 milligram doses may be repeated as needed. Subsequently, the dosage should be adjusted individually, as tolerated and required, to a level of 120 milligrams daily. For daily dosages above 100 milligrams patients shall ingest medication under observation 6 days per week. These patients will be allowed take-home medication for 1 day per week only. Those patients in treatment on December 15, 1972 who are receiving a take-home dose of more than 100 milligrams per day shall have their dosage level reduced to 100 milligrams per day or less by June 13, 1973. A daily dose of 120 milligrams or more shall be justified in the medical record. For daily dosages above 120 milligrams or, beginning June 13, 1973, for take-home doses above 100 milligrams per day, prior approval shall be obtained from the Food and Drug Administration and the State authority. A regular review of dosage level should be made by the responsible physician with careful consideration given for reduction of dosage as indicated on an individual basis. A new dosage level is only a test level until stability is achieved.

4. Caution shall be taken in the maintenance treatment of pregnant patients. Dosage levels shall be maintained as low as possible if continued methadone treatment is deemed necessary. It is the responsibility of the program sponsor to assure that each female patient is fully informed concerning the possible risks to a pregnant woman or her unborn child from the use of methadone.

5. Methadone will be administered or dispensed by a practitioner licensed or registered under appropriate State or Federal law to order narcotic drugs for patients or by an agent of the practitioner, supervised by and pursuant to the order of the practitioner. This agent may only be a pharmacist, registered nurse, or licensed practical nurse depending upon the State regulations regarding narcotic drug dispensing and administering administration. The licensed practitioner assumes responsibility for the amounts of methadone administered or dispensed and all changes in dosage schedule shall be recorded and signed by the licensed practitioner.

6. For detoxification, the drug shall be administered daily under close observation. In maintenance treatment the patient initially will ingest the drug under the observation daily, or at least 6 days a week, for the first 3 months. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administraion. It is also recognized, however, that daily attendance at a program facility may be incompatible with gainful employment, education, and responsible homemaking. After demonstrating satisfactory adherence to the program regulations for at least 3 months and showing substantial progress in rehabilitation by participating actively in the program activities and/or by participation in educational, vocational, and homemaking activities, those patients whose employment, education or homemaking responsibilities would be hindered by daily attendance may be permitted to reduce to three times weekly the times when they must ingest the drug under observation. They shall receive no more than a 2-day take-home supply. With continuing adherence to the program's requirements and progressive rehabilitation for at least 2 years after entrance into the program, such patients may be permitted twice weekly visits to the program for drug ingestion under observation with a 3-day take-home supply. Prior to reducing the frequency of visits, documentation of the patient's progress and the need for reducing the frequency of visits shall be recorded. The requirements and schedule for when the drug must be ingested under supervision may be relaxed if the patient has a serious physical disability which would prevent frequent visits to the program facility. The Food and Drug Administration and the State authority shall be notified of such cases. Additional medication may also be provided in exceptional circumstances such as acute illness, family crises, or necessary travel when hardship would result from requiring the customary observed medication intake for the specific period. In such circumstances the reasons for providing additional medication will be recorded in the clinical record. In circumstances of severe illness, infirmity or physical disability, an authorized individual (e.g., a licensed practitioner) may deliver or obtain the medication.

B. In maintenance treatment, a urinalysis will be performed randomly at least weekly for morphine and monthly for methadone, barbiturates, amphetamines, and other drugs if indicated. Those patients receiving their doses of the drug from medication units will also adhere to this schedule. The urine shall be collected in a manner which minimizes falsification of the samples. The reliability of this collection procedure shall be demonstrated. Laboratories used for testing must participate in and be approved by any proficiency testing program designated by the Food and Drug Administration. Any changes made in laboratories used for urine testing shall have prior approval of the Food and Drug Administration.

C. An adequate clinical record will be maintained for each patient. The record will contain a copy of the signed consent form(s), the date of each visit, the amount of methadone administered or dispensed, the results of each urinalysis, a detailed account of any adverse reactions, which will also be reported within 2 weeks to the Food and Drug Administration on Form FD–1639, "Drug Experience Report," any significant physical or psychologic disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for 2 weeks or more without notifying the program, the episode of care is considered terminated and so noted in the clinical record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and so noted in the clinical record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of methadone (e.g., the patient who has received no medication for several days or more and upon return receives the usual stabilization dose). An annual evaluation of the patient's progress will be recorded in the clinical record.

D. All patients in maintenance treatment will be given careful consideration for discontinuance of methadone especially after reaching a 10 to 20 milligrams dosage level. Social rehabilitation shall have been maintained for a reasonable period of time. Patients should be encouraged to pursue the goal of eventual withdrawal from methadone and becoming completely drug-free. Upon successfully reaching a drug-free state the patient should be retained in the program for as long as necessary to assure stability in the drug-free state, with the frequency of his required visits adjusted at the discretion of the director.

VII. To prevent diversion into illicit channels, adequate security shall be maintained over stocks of methadone and over the manner in which it is distributed, as required by the Bureau of Narcotics and Dangerous Drugs.

VIII. The program director may establish geographically dispersed medication units of reasonable size for administering and dispensing medication to patients stabilized at their optimal dosage level. The approval of such units for any geographic area shall be based upon the number and distribution of such units within the area. No more than 30 patients shall be under care at a medication unit at any one time. These units shall be responsible only for administering and dispensing medication. Private practitioners and community pharmacies may serve as medication units. Only after patients have been stabilized at their optimal initial dosage level may they be referred to a medication unit. Subsequent to such referral, the program director shall retain continuing responsibility for the patient's care and the patient shall be seen at the primary program facility at least monthly for medical evaluation and ancillary service. If a private practitioner wishes to provide other service in addition to administering and dispensing medication and collecting urine samples, the practitioner is considered a program component or a separate program, depending upon the type of services provided. In such case the restrictions on the number of patients served shall be determined by the staffing pattern and resources available.

IX. All representations in this application are currently accurate, and no changes shall be made in the program until they have been approved by the Food and Drug Administration and the State authority.

X. If the program or any individual under the program is disapproved, the program director shall recall the methadone from the disapproved sources and return the drug to the manufacturer in a manner prescribed by the Bureau of Narcotics and Dangerous Drugs.

XI. Inspections of this program may be undertaken by the State authority, by the Food and Drug Administration and by the Bureau of Narcotics and Dangerous Drugs in accordance with Federal controlled substances laws. The identity of patients will be kept confidential except when it is necessary to make follow-up investigations on adverse effect information related to use of the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records relating to approval of the program or any portion thereof. In all circumstances the provisions of 21 CFR Part 401 shall be followed.

Signature:_____

(3) *Annual Report Form.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD 2634 Annual Report for Treatment Program Using Methadone

This form shall be completed in triplicate by the program sponsor for each calendar year.

One copy is to be sent to the Food and Drug Administration and one copy to the State authority on or before January 30.

I. Name or other identification of program

_____

_____

Address _____

_____

II. Total Treatment Capacity _____

III. Amount of methadone dispensed (in grams) during the year: _____

IV. Number of individuals who applied to the program but were not admitted or given admission evaluation _____

V. Number of individuals who were provided only detoxification one or more times _____

VI. Census of patients provided methadone maintenance treatment _____

A. Number under care at the beginning of the year being reported _____

B. Of those in treatment at the beginning of the year:

1. Number continuously under care through the year being reported (still under care) _____

2. Number discharged or transferred to other types of programs and not readmitted _____

3. Number discharged or transferred to other types of programs and readmitted (still under care) _____

4. Number discharged and readmitted (no longer under care) _____

C. Number admitted to care during year ----, not previously treated in this program:

1. Number still under care at the end of the year _____

2. Number discharged or transferred to other types of programs and not readmitted _____

3. Number discharged or transferred to other types of programs and readmitted (still under care) _____

4. Number discharged and readmitted (no longer under care) _____

D. Number admitted to care during the year ----, previously treated in this program prior to the past year:

1. Number still under care at the end of the year _____

2. Number discharged or transferred to other types of programs and not readmitted _____

3. Number discharged and transferred to other types of programs and readmitted (still under care) _____

4. Number discharged and readmitted (no longer under care) _____

VII. Demographic and treatment characteristics of patients under care at the end of the year being reported:

A. By age and sex:

Age	Total	Male	Female
Under 14			
14–15			
16–17			
18–20			
21–25			
26–35			
36–45			
46+			

B. For the year being reported, give the number of patients who have been under continuous care for the following periods of time:

Under 3 months _____
3 months to 1 year_____
1 to 2 years_____
2 to 5 years_____
Over 5 years_____

C. Total number of individuals treated to date _____

D. For the year being reported, give the number of patients stabilized at each dosage level:

Daily dosage, mgm.	*Number of patients*
Under 20	
20–39	
40–59	
60–79	
80–99	
100–119	
Over 120	

E. For the year being reported, give the number of patients seen in the past 8 weeks who have fallen in the following categories:

No positive urinalysis for morphine for 2 months or more_____

Occasional positive urinalysis for morphine (monthly or less) _____

Frequent positive urinalysis for morphine (more than once per month) _____

In program for less than 2 months_____

For the year being reported, give the number of patients treated who were pregnant _____

VIII. Give the number of patients having significant adverse reactions, particularly reactions related to hematopoietic, cardiovascular, endocrine, neurologic, and immunological functions (attach a completed copy of Form FD–1639, "Drug Experience Report," for each incident not previously reported to the Food and Drug Administration):

Type of reaction	*Number of patients*

IX. Give the number of patients who have died while under methadone care (attach a completed copy of Form FD–1639, "Drug Experience Report", for each incident not previously reported to the Food and Drug Administation):

	Number of patients
A. Definitely methadone-related	
B. Not methadone-related	

Signature _____
(Program sponsor)

(4) *Patient Consent Form.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD 2635 Consent for Methadone Treatment

Patient _____ Date _____
Name of practitioner explaining procedures _____

(Provisions of this consent form may be modified to conform to any applicable State law.)

I hereby authorize and give my voluntary consent to Dr. _____
(Program medical director)

and/or any appropriately authorized assistants he may select, to administer or prescribe the drug methadone as an element in the treatment for my dependence on heroin or other narcotic drugs.

The procedures necessary to treat my condition have been explained to me and I understand that it will involve my taking daily dosages of methadone, or other drugs, which will help control my dependence on heroin or other narcotic drugs.

It has been explained to me that methadone is a narcoitc drug which can be harmful if taken without medical supervision. I further understand that methadone is an addictive medication and may, like other drugs used in medical practice, produce adverse results. The alternative methods of treatment, the possible risks involved, and the possibilities of complications have been explained to me, but I still desire to receive methadone due to the risk of my return to the use of heroin or other drugs.

The goal of methadone treatment is total rehabilitation of the patient. Eventual withdrawal from the use of all drugs, including methadone, is an appropriate treatment goal. I realize that for some patients methadone treatment may continue for relatively long periods of time but that periodic consideration shall be given concerning my complete withdrawal from methadone use.

I understand that I may withdraw from this treatment program and discontinue the use of the drug at any time and I shall be afforded detoxification under medical supervision.

I agree that I shall inform any doctor who may treat me for any medical problem that I am enrolled in a methadone treatment program, since the use of other drugs in conjunction with methadone may cause me harm.

I also understand that during the course of treatment, certain conditions may make it necessary to use additional or different procedures than those explained to me. I understand that these alternate procedures shall be used when in the Program or Medical Director's professional judgment it is considered advisable.

_____
(For female patients of child-bearing age)

To the best of my knowledge, I (am/am not) pregnant at this time.

Besides the possible risks involved with the long-term use of methadone, I further understand that, like heroin and other narcotic drugs, information on its effects on

pregnant women and on their unborn children is at present inadequate to guarantee that it may not produce significant or serious side effects.

It has been explained to me and I understand that methadone is transmitted to the unborn child and will cause physical dependence. Thus, if I am pregnant and suddenly stop taking methadone, I or the unborn child may show signs of withdrawal which may adversely affect my pregnancy or the child. I shall use no other drugs without the medical director or his assistants' approval, since these drugs, particularly as they might interact with methadone, may harm me or my unborn child. I shall inform any other doctor who sees me during my present or any future pregnancy or who sees the child after birth, of my current or past participation in a methadone treatment program in order that he may properly care for my child and me.

It has been explained to me that after the birth of my child I should not nurse the baby because methadone is transmitted through the milk to the baby and this may cause physical dependence on methadone in the child. I understand that for a brief period following birth, the child may show temporary irritability or other ill effects due to my use of methadone. It is essential for the child's physician to know of my participation in a methadone treatment program so that he may provide appropriate medical treatment for the child.

All the above possible effects of methadone have been fully explained to me and I understand that at present, there have not been enough studies conducted on the long term use of the drug to assure complete safety to my child. With full knowledge of this, I consent to its use and promise to inform the Medical Director or one of his assistants immediately if I become pregnant in the future.

(For patients under 18 years of age)

The patient is a minor, _____ years of age, born, _____
The risks of the use of methadone have been explained to (me/us) and (I/we) understand that methadone is a drug on which long-term studies are still being conducted and that information on its effects in adolescents is incomplete. It has been explained to (me/us) that methadone is being used in the minor's treatment only because the risk of (his/her) return to the use of heroin is sufficiently great to justify this treatment. (I/We) declare that participation in the methadone treatment program is wholly voluntary on the part of both the (parent(s)/guardian(s)) and the patient and that methadone treatment may be stopped at any time on (my/our) request or that of the patient. With full knowledge of the potential benefits and possible risks involved with the use of methadone in the treatment of an adolescent, (I/we) consent to its use upon the minor, since (I/we) realize that otherwise (he/she) shall continue to be dependent upon heroin or other narcotic drugs.

I certify that no guarantee or assurance has been made as to the results that may be obtained from methadone treatment. With full knowledge of the potential benefits and possible risks involved, I consent to methadone treatment, since I realize that I would otherwise continue to be dependent on heroin or other narcotic drugs.

Patient _____
Date _____
Date of birth _____
Parent(s) or guardian(s) _____
Relationship _____
Witness _____

(5) *Hospital Application.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD 2636 Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification and Temporary Maintenance Treatment

Name of hospital _____
Address _____
Commissioner,
Food and Drug Administration,
Bureau of Drugs (BD-106),
Rockville, Md. 20852.

DEAR SIR: As hospital administrator, I submit this request for approval to receive supplies of methadone to be used for analgesia in severe pain and for detoxification and and maintenance treatment in accord with § 130.44 of the new drug regulations. I understand that the failure to abide by the requirements described below may result in revocation of approval to receive shipments of methadone, seizure of the drug supply on hand, injunction, and criminal prosecution.

I. The name of the individual (pharmacist) responsible for receiving and securing supplies of methadone is _____.

II. There are a total of _____ beds in the hospital.

III. A general description of the hospital and nature of patient care undertaken is attached.

IV. The anticipated quantity of methadone needed per year is _____ (Gms.).

V. Methadone is permitted to be administered or dispensed only for detoxification or temporary treatment of hospitalized patients, and for analgesia in severe pain for hospitalized patients and outpatients. If methadone is administered for treatment of heroin dependence for more than 3 weeks, the procedure passes from treatment of the acute withdrawal syndrome (detoxification) to maintenance treatment. Maintenance treatment is permitted to be undertaken only by approved methadone programs. This does not preclude the maintenance treatment of an addict who is hospitalized for treatment of medical conditions other than addiction and who requires temporary maintenance treatment during the critical period of his stay whose enrollment in a program which has approval for maintenance treatment using methadone has been verified.

VI. Prior to filing a physician's prescription for methadone for outpatients, I shall obtain from the physician a statement indicating that all such prescriptions written by him shall be limited to use for analgesia in ssvere pain and his agreement to maintain records to substantiate such use. These records will be available in the hospital or made available at the request of the hospital administrator. On January 30 of each year, the hospital shall report to the Food and Drug Administration the names and addresses of all physicians who prescribed methadone for analgesia on an outpatient basis during the previous year.

VII. Prescriptions for analgesia may be filled only if they are written by a physician who has submitted the required statement to the hospital.

VIII. Accurate records shall be maintained showing dates, quantity, and batch or code marks of the drug for inpatient and outpatient treatment. The records shall be retained for a period of 3 years.

IX. The Food and Drug Administration and the State authority may inspect supplies of the drug and evaluate the uses to which the drug is being put. The identity of the patient will be kept confidential except when it is necessary to make follow-up investigations on adverse effect information related to the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records relating to approval of the hospital or any portion thereof. The confidentiality requirements of 21 CFR Part 401 shall be followed.

Signature _____
(Hospital official)

2. A new paragraph (b) is added to § 130.48 as follows:

§ 130.48 Drugs that are subjects of approved new-drug applications and that require special studies, records, and reports.

* * * * *

(b) *Methadone.* Methadone may be used as an analgesic in severe pain, for the detoxification of narcotic addicts, and as an oral substitute for heroin or other morphine-like drugs, in the maintenance treatment of narcotic addicts, pursuant to the conditions established in § 130.44. Further data and information are required to establish the safety and effectiveness of methadone under a variety of conditions during widespread and long-term use. In view of the tremendous public health and social problems associated with the use of heroin, the demonstrated usefulness of methadone in treatment, the lack of a safe and effective alternative drug or treatment modality, the need for additional safety and effectiveness data on methadone, and the danger to health that could be created by uncontrolled distribution and use of methadone, the Commissioner of Food and Drugs finds that it is not in the public interest either to withhold the drug from the market until it has been proved safe and effective under all conditions of use or to grant full approval for unrestricted distribution, prescription, dispensing, or administration of methadone. The Commissioner therefore concludes that it is essential to the public interest to prescribe detailed conditions for safe and effective use of methadone, utilizing the IND and NDA control mechanisms and the authority granted under the Comprehensive Drug Abuse Prevention and Control Act of 1970, to assure that the required additional information for assessing the safety and effectiveness of methadone is obtained, to maintain close control over the safe distribution, administration, and dispensing of the drug, and to detail responsibilities for such control. The conditions established in § 130.44 constitute a determination of the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts with respect to the use of methadone, pursuant to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

(1) *Effective date.* Paragraphs (d)(3)(ii), (d)(3)(iv), (g)(1), (g)(2), and (g)(3) of § 130.44, become effective December 15, 1972. The remainder of § 130.44 and § 130.48 become effective March 15, 1973.

Dated: December 7, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-21306 Filed 12-14-72;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. FDC-D-575]

METHADONE

Proposed Withdrawal of New Drug Applications; Notice of Opportunity for Hearing

In the FEDERAL REGISTER of January 7, 1972 (37 F.R. 201), the Commissioner of Food and Drugs added a new § 130.48 *Drugs that are subjects of approved new-drug applications and that require special studies, records, and reports* to the new drug regulations. In the FEDERAL REGISTER of April 6, 1972 (37 F.R. 6940), the Commissioner proposed special requirements for use of methadone. A final order regarding this proposal is published elsewhere in this issue of the FEDERAL REGISTER.

For reasons stated in the April 6, 1972 proposal, and the final order, the Commissioner concludes that there is a lack of substantial evidence that methadone is safe and effective for detoxification, analgesia, or antitussive use under the conditions of use that presently exist. Therefore, notice is given to the holders of the new drug applications for methadone that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the following new drug applications and all amendments and supplements thereto:

1. Methadone (Dolophine) HCl Tablets, Injectable, Suppository; by Eli Lilly & Co., Box 618, Indianapolis, Ind. 46206. (NDA 6134).

2. Methadone HCl Tablets, Injectable; by Hoffmann-LaRoche Inc., Nutley, N.J. 07110. (NDA 6305).

3. Methadone HCl Injectable, Tablets, Elixir; by Parke, Davis & Co., Joseph Campau Avenue, At the River, Detroit, Mich. 48232. (NDA 6310).

4. Methadone HCl Tablets, Injectable; by The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49002. (NDA 6311).

5. Methadone HCl Ampuls; by S. E. Massengill Co., 527 Fifth Street, Bristol, Tenn. 37620. (NDA 6345).

6. Methadone HCl Tablets, Injectable; by Wm S. Merrell Co., Division Richardson-Merrell Inc., 110 East Amity Road, Cincinnati, Ohio 45215. (NDA 6370).

7. Methadone HCl Tablets; by Mallinckrodt Chemical Works, 3600 North Second Street, Box 5439, St. Louis, Mo. 63160. (NDA 6383).

8. Methadone (Amidone) HCl Tablets, Elixir, Injectable; by S. F. Durst & Co., Inc., 5317 North Third Street, Philadelphia, Pa. 19120. (NDA 6504).

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355), and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner hereby gives the applicants an opportunity for a hearing to show why approval of the new drug applications should not be withdrawn.

Within 30 days after publication hereof in the FEDERAL REGISTER the applicants are required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, a written appearance electing whether or not to avail themselves of the opportunity for a hearing. Failure of an applicant to file a written appearance of election within said 30 days will constitute an election by him not to avail himself of the opportunity for a hearing.

If no applicant elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the applications.

If an applicant elects to avail himself of the opportunity for a hearing, he must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons why approval of the new drug applications should not be withdrawn, together with a well-organized and full factual analysis of the data he is prepared to prove in support of his opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing (21 CFR 130.14(b)).

If review of the data submitted by an applicant warrants the conclusion that there exists substantial evidence demonstrating the safety and effectiveness of the product under existing conditions of use, the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the applications and data submitted by the applicants in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the conclusion that no genuine and substantial issue of fact precludes the withdrawal of approval of the applications, the Commissioner will enter an order of withdrawal making findings and conclusions on such data.

If, upon the request of the new drug applicants, a hearing is justified, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after the expiration of such 30 days, a written notice of the time and place at which the hearing will commence. The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

Requests for a hearing and/or elections not to request a hearing may be seen in the Office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

New drug application holders may submit, within 30 days after the date of publication of this notice in the FEDERAL REGISTER, a supplemental new drug application requesting approval for the manufacture and distribution of methadone pursuant to §§ 130.44 and 130.48(b). Upon submission and approval of any such supplement the Commissioner will rescind this notice of opportunity for hearing for that applicant.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat 1052-1053, as amended; 21 U.S.C. 355) and under the authority delegated to the Commissioner (21 CFR 2.120).

Dated: December 7, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc. 72-21305 Filed 12-14-72;8:45 am]

ance with any provision of this part, the Board may by order modify such company rule to the extent necessary to conform the rule to the provisions of the part.

Effective July 10, 1973.

Adopted May 7, 1973.

By the Civil Aeronautics Board.

[SEAL] EDWIN Z. HOLLAND, *Secretary.*

[FR Doc.73-9320 Filed 5-9-73;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS

PART 130—NEW DRUGS

Listing of Methadone With Special Requirements for Use

The Honorable Paul G. Rogers, Member of Congress from Florida, Chairman of the Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, U.S. House of Representatives, has written the Commissioner of Food and Drugs to request revision of the regulations governing methadone, published in the FEDERAL REGISTER of December 15, 1972 (37 FR 26789), to include a requirement for discontinuance of methadone after 2 years of treatment unless, based on clinical judgment, the patient's status indicates that treatment with methadone should be continued for a longer period of time. The Commissioner concurs in this suggestion and regards it as a clarification of the intent of the regulations.

Therefore, pursuant to the provisions of sections 505 and 701(a) of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 355, 371(a)), section 303(a) of the Public Health Service Act as amended (42 U.S.C. 242a(a)), and section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 257(a)), and under authority delegated to the Commissioner (21 CFR 2.120), part 130 is amended in § 130.44 by adding two new sentences to the end of paragraph (d)(8), by adding the same two new sentences to the end of item IX.D. of Form FD 2632 in paragraph (k)(1), and by adding the same two new sentences to the end of item VI.D. of Form FD 2633 in paragraph (k)(2), as follows:

§ 130.44 Conditions for use of methadone.

* * *

(d) * * *

* * *

(8) * * * Maintenance treatment using methadone shall be discontinued within 2 years after such treatment is begun unless, based upon clinical judgment recorded in the clinical record for the patient, the patient's status indicates that such treatment should be continued for a longer period of time. Any patient continued on methadone for longer than 2 years shall be subject to periodic reconsideration for discontinuance of such treatment.

* * *

(k) * * *

(1) * * *

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD 2632 Application for Approval of Use of Methadone in a Treatment Program

* * *

IX. * * *

* * *

D. * * * Maintenance treatment using methadone shall be discontinued within 2 years after such treatment is begun unless, based upon clinical judgment recorded in the clinical record for the patient, the patient's status indicates that such treatment should be continued for a longer period of time. Any patient continued on methadone for longer than 2 years shall be subject to periodic reconsideration for discontinuance of such treatment.

* * *

(2) * * *

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD 2633 Medical Responsibility Statement for Use of Methadone in a Treatment Program

* * *

VI. * * *

* * *

D. * * * Maintenance treatment using methadone shall be discontinued within 2 years after such treatment is begun unless, based upon clinical judgment recorded in the clinical record for the patient, the patient's status indicates that such treatment should be continued for a longer period of time. Any patient continued on methadone for longer than 2 years shall be subject to periodic reconsideration for discontinuance of such treatment.

* * *

The Commissioner finds that publication of a proposal on this matter, time for comment, and delayed effective date, are impracticable, unnecessary, and contrary to the public interest, since the change made is merely a clarification of the intent of the regulation previously published and the regulation is just being implemented throughout the country and should therefore include this clarification immediately. The clarification further protects the health and safety of patients treated with methadone and is consistent with the earlier regulation on which substantial relevant comment was received, and no further purpose would be served by delaying this clarification until further comment of the type already received has been obtained.

Effective date.—This order shall become effective on May 10, 1973.

(Secs. 505 and 701(a) of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 355, 371(a)), sec. 303(a) of the Public Health Service Act as amended (42 U.S.C. 242a(a)), and section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 257(a)).)

Dated May 4, 1973.

SAM D. FINE, *Associate Commissioner for Compliance.*

[FR Doc.73-9261 Filed 5-9-73;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Recodification Docket No. 5]

Reorganization and Republication

The Commissioner of Food and Drugs, for the purposes of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations.

This is the fifth document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.

The volume of regulatory material for human drugs under Subchapter C—Drugs requires that these regulations be recodified in two documents. This, the fifth document, recodifies drug regulations in current Parts 130, 131, 164, 165, and 167. Another, a sixth document, pertaining to procedural regulations and individual drug monographs for antibiotic drugs for human use, will be published in the FEDERAL REGISTER prior to the revision of the annual volume of the Code of Federal Regulations relating to Parts 141 through 599, which is scheduled for May 1, 1974.

Regulations for human drugs formerly under Parts 130, 131, 164, 165, and 167 of Subchapter C—Drugs have been reorganized into a new Subchapter D—Drugs for Human Use in an effort to provide greater clarity and convenience to the user. The following table shows the relationship of the CFR section numbers under Subchapter C prior to this republication to their redesignation reflected in the new Parts 310, 312, 314, 328, 329, 330, 369, and 429 of Subchapter D:

Old section	*New section*
130.1	310.3
130.2	310.4
130.3	312.1
130.3a	312.9
130.3b	312.10
130.4	314.1
130.5	314.110
130.6	314.100
130.7	314.6
130.8	314.7
130.9	314.8
130.10	314.105
130.11	314.9
130.12	314.111
130.13	310.300
130.13a	310.301
130.13b	314.13
130.14	314.200
130.15	314.201
130.16	314.202
130.17	314.203
130.18	314.204
130.19	314.220
130.20	314.221
130.21	314.222
130.22	314.206
130.23	314.206
130.24	314.230
130.25	314.231
130.26	314.232
130.27	314.115
130.28	314.120
130.29	314.121
130.30	314.12
130.31	314.235
130.32	314.11
130.33	314.10
130.34	314.116
130.35	310.302
130.36	310.101
130.37	310.102
130.38	310.9
130.39	310.100
130.40	310.6
130.41	310.103
130.44	310.505 *Methadone*
130.45	310.501
130.46	310.504
130.47	310.303
130.48	310.304
130.49	310.503
130.50	310.502
130.51	310.500
130.101	310.200
130.102	310.201
130.201	314.300
130.301(a)(1) through (12)	330.10
130.301(a)(13)	330.11
130.301(b)	330.5
130.302	330.1
130.303	330.12
131.1	369.1
131.2	369.2
131.3	369.3
131.4	369.4
131.5	369.5
131.6	369.6
131.7	369.7
131.8	369.8
131.9	369.9
131.10	369.10
131.15	369.20
131.16	369.21
131.17	369.22
131.25	369.30
164.1	429.3
164.2	429.40
164.3	429.41
164.4	429.45
164.5	429.10
164.6	429.11
164.7	429.12
164.8	429.60
164.9	429.47
164.10	429.55
164.11	429.25
164.12	429.26
164.15	429.30
164.16	429.50
165.1	329.1
165.2	329.10
165.5	329.20
167.1	328.3
167.2	328.10
167.3	328.30
167.4	328.4
167.5	328.34
167.6	328.35
167.7	328.20

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation. For the convenience of the user, the entire text of Parts 310, 312, 314, 328, 329, 330, 369, and 429 of Subchapter D are set forth below.

Dated: March 27, 1974.

SAM D. FINE, *Associate Commissioner for Compliance.*

Therefore, 21 CFR is amended by redesignating Parts 130, 131, 164, 165, and 167 of Subchapter C as Parts 310, 312, 314, 328, 329, 330, 369, and 429 of Subchapter D—Drugs for Human Use, and republished to read as follows:

Suchapter D—Drugs for Human Use

PART 310—NEW DRUGS

Subpart A—General Provisions

Subpart B—Specific Administrative Rulings and Decisions

Subpart C—New Drugs Exempted From Prescription-Dispensing Requirements

Subpart D—Records and Reports

Subpart E—Requirements for Specific New Drugs or Devices

AUTHORITY: Secs. 502, 503, 505, 701, 52 Stat. 1051, 1052, 1053, 1055, as amended (21 U.S.C. 352, 353, 355, 371) (5 U.S.C. 554), unless otherwise noted.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 310]

METHADONE

Multiple Enrollment Prevention

Section 310.505(e)(3) (21 CFR 310.505(e)(3)), formerly § 130.44(e)(3) of Part 130, recodified in the FEDERAL REGISTER of March 29, 1974 (39 FR 11680), was promulgated in contemplation of the development of an identification system, one of the purposes of which would be to indicate when a drug abuse patient was simultaneously enrolled in two or more methadone programs. No Federal system has thus far been developed, and to the extent that multiple enrollment has been a problem, it has been dealt with on a local basis. The present requirement of an agreement to participate in a patient identification system designated and approved by the Food and Drug Administration therefore serves no useful purpose, and has been the source of some confusion.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 701(a), 52 Stat. 1052–1053, as amended, 1055; 21 U.S.C. 355, 371(a)), section 303(a) of the Public Health Service Act as amended (sec. 303, 60 Stat. 423, as amended; 42 U.S.C. 242a(a)), and section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (sec. 4, 84 Stat. 1241; 42 U.S.C. 257a), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), it is proposed that § 310.505 *Conditions for use of Methadone* be amended by deleting paragraph (e)(3).

Interested persons may, on or before June 17, 1974, file with the Hearing Clerk, Food and Drug Administration, Room 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: May 13, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc 74-11390 Filed 5-15-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved
OMB No. 057R 0098

DATE

CONSENT TO METHADONE TREATMENT

(Provisions of this form may be modified to conform to any applicable State law)

NAME OF PATIENT

NAME OF PRACTITIONER EXPLAINING PROCEDURES

NAME OF PROGRAM MEDICAL DIRECTOR

I hereby authorize and give my voluntary consent to the above named Program Medical Director and/or any appropriately authorized assistants he may select, to administer or prescribe the drug methadone as an element in the treatment for my dependence on heroin or other narcotic drugs.

The procedures necessary to treat my condition have been explained to me and I understand that it will involve my taking daily dosages of methadone, or other drugs, which will help control my dependence on heroin or other narcotic drugs.

It has been explained to me that methadone is a narcotic drug which can be harmful if taken without medical supervision. I further understand that methadone is an addictive medication and may, like other drugs used in medical practice, produce adverse results. The alternative methods of treatment, the possible risks involved, and the possibilities of complications have been explained to me, but I still desire to receive methadone due to the risk of my return to the use of heroin or other drugs.

The goal of methadone treatment is total rehabilitation of the patient. Eventual withdrawal from the use of all drugs, including methadone, is an appropriate treatment goal. I realize that for some patients methadone treatment may continue for relatively long periods of time but that periodic consideration shall be given concerning my complete withdrawal from methadone use.

I understand that I may withdraw from this treatment program and discontinue the use of the drug at any time and I shall be afforded detoxification under medical supervision.

I agree that I shall inform any doctor who may treat me for any medical problem that I am enrolled in a methadone treatment program, since the use of other drugs in conjunction with methadone may cause me harm.

I also understand that during the course of treatment, certain conditions may make it necessary to use additional or different procedures than those explained to me. I understand that these alternate procedures shall be used when in the Program or Medical Director's professional judgment it is considered advisable.

(See reverse of this sheet for additional consent elements)

FORM FD 2635 (12/72)

FEMALE PATIENTS OF CHILD-BEARING AGE	PATIENTS UNDER 18 YEARS OF AGE
To the best of my knowledge, I ☐ am ☐ am not pregnant at this time. Besides the possible risks involved with the long-term use of methadone, I further understand that, like heroin and other narcotic drugs, information on its effects on pregnant women and on their unborn children is at present inadequate to guarantee that it may not produce significant or serious side effects. It has been explained to me and I understand that methadone is transmitted to the unborn child and will cause physical dependence. Thus, if I am pregnant and suddenly stop taking methadone, I or the unborn child may show signs of withdrawal which may adversely affect my pregnancy or the child. I shall use no other drugs without the Medical Director or his assistants' approval, since these drugs, particularly as they might interact with methadone, may harm me or my unborn child. I shall inform any other doctor who sees me during my present or any future pregnancy or who sees the child after birth, of my current or past participation in a methadone treatment program in order that he may properly care for my child and me. It has been explained to me that after the birth of my child I should not nurse the baby because methadone is transmitted through the milk to the baby and this may cause physical dependence on methadone in the child. I understand that for a brief period following birth, the child may show temporary irritability or other ill effects due to my use of methadone. It is essential for the child's physician to know of my participation in a methadone treatment program so that he may provide appropriate medical treatment for the child. All the above possible effects of methadone have been fully explained to me and I understand that at present, there have not been enough studies conducted on the long term use of the drug to assure complete safety to my child. With full knowledge of this, I consent to its use and promise to inform the Medical Director or one of his assistants immediately if I become pregnant in the future.	The patient is a minor, ____ years of age, born, _____. The risks of the use of methadone have been explained to (me/us) and (I/we) understand that methadone is a drug on which long-term studies are still being conducted and that information on its effects in adolescents is incomplete. It has been explained to (me/us) that methadone is being used in the minor's treatment only because the risk of (his/her) return to the use of heroin is sufficiently great to justify this treatment. (I/We) declare that participation in the methadone treatment program is wholly voluntary on the part of both the (parent(s)/guardian(s)) and the patient and that methadone treatment may be stopped at any time on (my/our) request or that of the patient. With full knowledge of the potential benefits and possible risks involved with the use of methadone in the treatment of an adolescent, (I/we) consent to its use upon the minor, since (I/we) realize that otherwise (he/she) shall continue to be dependent upon heroin or other narcotic drugs.

I certify that no guarantee or assurance has been made as to the results that may be obtained from methadone treatment. With full knowledge of the potential benefits and possible risks involved, I consent to methadone treatment, since I realize that I would otherwise continue to be dependent on heroin or other narcotic drugs.

SIGNATURE OF PATIENT	DATE OF BIRTH	DATE
SIGNATURE OF PARENT(S) OR GUARDIAN(S)	RELATIONSHIP	DATE
SIGNATURE OF WITNESS		DATE

TO : All Methadone Treatment Program Sponsors, Medical Director, and FDA Districts

DATE: May, 1974

FROM : Methadone Maintenance Staff
Bureau of Drugs, FDA

SUBJECT: Items of Interest to Methadone Treatment Programs

From time to time the Methadone Monitoring Staff (MMS) will be sending items of interest to treatment programs in an effort to keep those responsible for direction of the programs abreast with new ideas and interpretations of regulations and procedures.

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FROM MMS: (1) The Methadone Monitoring Staff (MMS) has been relocated to Room 18B-04 in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852. The new telephone number is 301-443-3415. Please note the change if you have received correspondence requesting reply to the former address indicating Room 10B-04.

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(2) MMS will shortly be sending a letter to all methadone treatment programs emphasizing the requirement that all methadone dispensed for take-home consumption must be packaged in containers complying with Section 295.2. These are commonly referred to as "safety closures" or "childproof containers." It is expected that any program not complying with this requirement, within 15 days after such notification, will be required to stop all take-home privileges and operate solely on a seven-day confrontation basis, unless the program has on file an executed purchase order *and* a request to the seller to expedite fulfillment of the order because of the urgent nature of the requirement.

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(3) MMS is developing a *Federal Register* announcement dealing with an exemption from the two-year addiction history requirement for pregnant patients. This exemption would be in effect until one month after delivery of the newborn, at which time the patient must be detoxified if the requirement for two years of dependency has not been satisfied. It would give the physician the prerogative of detoxification or maintenance during this period for patients which he certifies are pregnant. MMS will not enforce the two-year addiction history to be required of pregnant patients between now and publication of the Notice. As with other *Federal Register* announcements concerning methadone, copies of the announcement will be sent to all treatment programs and interested persons.

Exhibit 2

CODAP Summary

FEDERALLY REQUIRED DATA

Federal standards require that certain kinds of information be collected on persons entering and undergoing treatment in methadone maintenance programs. The kinds of information that must be collected on persons undergoing treatment fall into five separate categories, some of which have a direct impact on the content of counselor's notes. These five categories include:

1. Counseling and Supportive Services
2. Medical Services
3. Chemotherapy
4. Urinalysis
5. Client Progress

Explanations of the meaning of each of these categories follow.

Counseling and Supportive Services

The data to be recorded under this category generally include the type of services *scheduled*, the type of services actually provided, and the amount of services provided.

Medical Services

These data, considered together, indicate if the medical service is provided in-house or out-of-house; show a summary of the client's medical problems identified during the intake physical and the follow-up indicated; specify the client's current medical problems; medication prescribed, dosages, directions and limitations.

Chemotherapy

These data include medication (i.e., methadone or antagonists) scheduled and dispensed for each day of the month, pick-up method, and medication reactions, if any.

Urinalysis

These data include the date the tests were scheduled, the date the tests were administered (i.e., specimen taken) and the results of the testing.

Client Progress

Client response to treatment should be reviewed at least monthly. That review is to include such things as drug problems, employment, behavioral problems, legal problems, medical problems, alcohol problems, psychiatric/psychological problems, program assignment changes, etc.

IMPLICATIONS FOR COUNSELORS

The usual way a counselor records client information is through the use of running progress notes. It is also quite typical that such notes are haphazardly recorded and quite uneven in their quality. The thrust of the federal standards for documentation is to force a more thorough approach to recording client information. The key to this is understanding the relationship among those five categories of information mentioned earlier. The first four of these categories must be the basis upon which the assessments of client progress are made. This means that the kinds of data specified by those first four categories must appear in the client's record and must bear a clear and consistent relationship to the judgements of category five. For example, if a client has shown four dirty urines during the course of a month, has missed a number of counseling sessions and has missed his medication for several days, there should not be an entry stating that the client is being given take-home privileges. Rather the counselor's notes should reflect and appropriate action clearly consistent with the client's performance.

Not only should client progress assessments be made consistent with the recorded data, but also any other actions, such as referrals, should reflect the reasons for such actions. The treatment plan itself is an example of this. If that plan includes referrals to vocational rehabilitation services or for legal help, then the reasons for including these elements in the plan ought to be clearly spelled out. If this is not done, reasons for changing such a plan are going to appear vague or arbitrary. Furthermore, such referrals must be followed-up by the counselor. There is nothing wrong with a drug counselor keeping closely in touch with a vocational rehabilitation counselor to whom the former has referred his client. In fact, this should be done and contacts between them should be recorded. What follows is an example of how running progress notes should be recorded.

The following is a list of information that must be included in a counseling record:

- A record must be made of the initial client-counselor interview. The client's name, age, race, and sex should be the first information obtained, followed by the length of primary drug abuse, attempts at prior treatment, and reason for seeking treatment at this time. Next the counselor should record the treatment modality to which the client has been assigned and comment on the client's understanding of this modality. Finally, the client's problems should be addressed, e.g., does he have housing, does he have legal problems, etc. If problems are discovered which necessitate referral to another person or agency, this should be done and recorded. In the event of a readmission, some assessment must be recorded regarding the circumstances of prior discharge(s), attitude changes, motivation, etc. All notes must be signed.
- A treatment plan must be developed soon after the patient's admission and explained to him: how many days a week medication must be picked up, urine specimens given, group counseling sessions attended, and individual counseling obtained. If a patient requires referral services on a continuing basis (i.e., medical, psychiatric, legal, etc.), these should be included in the development of the plan.
- A note should be written after each meaningful client/counselor contact and should include the counselor's observations, problem(s) presented, resolutions proposed, and the approximate length of time spent with the client.
- Copies of referral forms should be included in the patient's folder. Specific reasons for referrals and information regarding the results of referrals should be obtained and documented.
- The results of counseling conducted by any other person in the clinic should be noted on the patient's chart, by either the patient's counselor or the counselor involved.
- A patient's progress should be reviewed at least monthly and summarized. The treatment plan should be reconsidered in view of the progress and either altered or continued. The summary must include: the patient's legal status, both criminal and civil; employment status; current drug use including alcohol; and any other current problems and their severity. The monthly summary should reflect a composite picture of the patient's progress and not merely repeat entries made during the month.
- The date urine specimens are scheduled to be given, are given, and the results must appear in the counselor's record. Any change in methadone dosage and reasons prompting the counselor to recommend these changes must be noted.
- If a member fails to keep a scheduled appointment (e.g., medication pick-up, group counseling, individual counseling, referral service appointments, etc.), it must be documented.

It is suggested that a copy of the intake form be reviewed by the counselor prior to the initial patient interview. This form provides much of the information required in the admission note and eliminates duplicate processing.

Date	Notes
11/29/72 Admission Note	Jane C. Doe, a 33 year-old black female was admitted to Clinic Q for methadone maintenance. This member states that she has been abusing heroin since 1965 and has attempted to detoxify in several programs in New York City. She has recently moved here with her husband and two small children because her husband was offered a better job. Ms. Dow was arrested last week for possession of a small amount of heroin and is out on bond. She states that she planned to seek treatment anyway but admits that she and her attorney feel being in treatment will help her case. Since her prior attempts at detoxification failed, Ms. Doe feels that she needs maintenance and seems to have a good understanding of this treatment. Spent 40 minutes with Ms. Doe. James Harris
11/30/72 Treatment Plan	Ms. Doe will be reporting to the clinic six days a week for medication and will give a urine specimen weekly. I have told her to see me daily when she reports for medication. This member seems very anxious to succeed in treatment and has agreed to this schedule. Spent 30 minutes with Ms. Doe. James Harris
12/4/72 Description of an average counseling session	Ms. Doe reported for medication today and appeared very upset. She talked with Mr. Smith, the nurse on duty, and stated that her husband wants her to discontinue treatment. Mr. Doe wants his wife to be drug-free and fears that she will never achieve this state if she continues on methadone. Mr. Doe has no history of drug abuse. I requested that Ms. Doe bring her husband to see me before she leaves treatment. She stated that she will come with him on 12/8/72 at 3 p.m. Spent 30 minutes with Ms. Doe. James Harris

12/8/72 Counseling done by other staff	I did not see Ms. Doe yesterday as she reported to the clinic in the evening for medication, but I was informed by Ms. Landry (counselor) that she remains very upset about her husband's attitude. Ms. Landry spent 20 minutes with Ms. Doe. I will see her and her husband this afternoon. James Harris
12/8/72 5 p.m. Description of an average counseling session.	Ms. Doe and her husband came to the clinic at 3:30 p.m. In talking with Mr. Doe it became evident that he had many misconceptions about methadone maintenance. I explained this modality to him and he was very relieved to discover that it did not mean lifetime maintenance. He agreed to support his wife in her treatment attempt and to wait for her to decide when she is ready for withdrawal. Mr. Doe's greatest concern seems to be his wife's ability to care for their two small children. He feels she had neglected them while using heroin and has seen no improvement in her care since she started treatment. Ms. Doe admitted that this is the first day she has not used illegal drugs since she began treatment but that she plans to remain clean and feels she can give her children the care they need if she does. Mr. Doe has my phone number and was told that if he has any further concerns about his wife to call me. Spent 1 1/2 hours with Mr. and Ms. Doe. James Harris
12/13/72 Medication change	Ms. Doe requested a decrease in medication today because she gets tired very easily. Mr. Smith, the nurse, scheduled an appointment for her to see Dr. Jones with me on 12/15/72 at 10 a.m. I asked Ms. Doe if she is trying to withdraw on her own. She assured me that she is not, that she does not feel ready to. Spent 20 minutes with Ms. Doe. James Harris
12/15/72 Break in schedule	I saw Dr. Jones with Ms. Doe today. He agreed to decrease her dose as this could be the cause of her fatigue. Dr. Jones ordered a decrease of 5 mg. from 30 mg. to 25 mg. Ms. Doe and I then discussed her absence from the clinic yesterday. She stated that she was unable to find anyone to care for her children – she expected her husband to be home but he had to work late. This is the first day she has missed. Spent 30 minutes with Ms. Doe. James Harris
12/21/72	Ms. Doe did not give a urine specimen today as scheduled. She stated that she forgot and voided before coming to the clinic. Considering the patient's recent request for decrease and the fact that she missed her medication on Tuesday, I suspect she may be using drugs again. She denies this. I have asked the nurses to withhold her medication until she gives a specimen. Spent 45 minutes with Ms. Doe. James Harris

12/29/72 Monthly Summary	Ms. Doe has been in treatment for 30 days and remains on methadone maintenance at 25 mg. daily. Her urines, with the exception of the first two, have been clean. She gives no appearance of abusing any drugs including alcohol. The preliminary hearing on her case for possession of heroin is scheduled for 2/1/73. She has no other cases pending. Ms. Doe spends all of her time with her children except when she comes to the clinic. A neighbor cares for them during that time because Mr. Doe does not want them in the clinic. Ms. Doe states that she feels she is making up to her children for her prior neglect. I feel that she is making good progress but will make no changes in her treatment plan at this time. James Harris
1/3/73 Referral	Ms. Doe states that she would like to find a job as she and her husband would like to buy a house but need extra income to do so. Ms. Doe took some typing courses in high school but has not used this skill since she graduated. She is interested in getting secretarial training. Ms. Doe has been meeting the requirements of this program and in my opinion is stablized enough to be considered for training. I contacted Mr. Henry at the New Careers program and he agreed to see Ms. Doe on 1/7/73 at 11:30 a.m. Spent 1 hour with Ms. Doe. James Harris
1/8/73 Results of Referral Follow-up	I called Mr. Henry this morning. He saw Ms. Doe yesterday and agrees that she seems a good candidate for secretarial training. She begins testing tomorrow. James Harris

Exhibit 3

Federal Funding Criteria

FEDERAL FUNDING CRITERIA FOR TREATMENT SERVICES*

The contractor/grantee, as an independent contractor/grantee and not as an agent of the Government, shall provide the necessary facilities, material, services, and qualified personnel to furnish treatment and rehabilitation to drug dependent persons in accordance with the following:

1. The contractor/grantee shall provide and operate or shall engage subcontractor/affiliate to provide and operate such _____ (modality), as may be appropriate, at a site or sites to be approved by the Government.

2. Criteria to be used for patient admissions and terminations shall be established.

3. All facilities shall be maintained in a clean, safe, and attractive condition and in accordance with appropriate local, state and Federal codes and other laws.

4. Appropriate furnishings for a _____ (modality) shall be provided.

5. At intake, an initial personal history, medical history, and drug history must be taken. It is important to conduct this intake process as rapidly as possible so that clients are not discouraged from pursuing treatment. An intake not exceeding three days is optimal. The purpose of taking a medical and drug history is to immediately identify the client experiencing flashbacks, psychotic manifestations and/or severe physical illness requiring immediate psychiatric or medical care. Only when this information is collected and reviewed can the program be reasonably assured of preparing the best possible treatment plan for the client. It is in this context that a complete personal, medical, and drug history is essential for all treatment modalities.

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*For the following treatment modalities: Outpatient Methadone, Residential Methadone, Residential Drug Free, Outpatient Drug Free, and Day Care Drug Free.

Programs having difficulty complying with any of the Federal Funding Criteria should request technical assistance from their Program Development Specialist, Division of Community Assistance, National Institute on Drug Abuse, 11400 Rockville Pike, Rockville, Maryland 20852.

6. At intake a physical examination and laboratory examination shall be performed by qualified personnel. Programs shall perform physical examinations on clients as soon as possible after entering treatment but no later than 21 days. The physical examination shall be detailed in the treatment plan. It is particularly important that residential drug free programs perform physical examinations as soon as possible because of the possibility of infectious diseases and the close client contact. If the residential program has an induction phase, it is recommended that the physical examination be performed during this time period. This criterion is not meant to supercede FDA regulations requiring a physical examination at intake. The minimum for a physical and laboratory examination may consist of the following:

   a. Physical examination stressing infectious disease, pulmonary, liver, cardiac abnormalities, dermatologic sequelae of addiction and possible concurrent surgical problems.

   b. Complete blood count and differential.

   c. Serologic test(s) for syphilis.

   d. Routine and microscopic urinalysis.

   e. Urine screening for drugs (toxicology).

   f. SMA 12/60 or equivalent.

   g. Chest X-ray.

   h. Sickle cell, as appropriate.

   i. Australian antigen, as appropriate.

   j. EKG and biological test for pregnancy, as appropriate.

7. Each new admission or readmission shall be interviewed by a mental health professional. Mental health professional is defined as "a person who, by virtue of training and experience, is capable of assessing the psychological and sociological background of a client to determine the optimal treatment plan." The staff shall take a complete personal history: family; education; vocation; legal and related areas; drug history, including kinds of drugs abused and when begun, prior treatment attempts; and any other relevant information. The admission interview is regarded as the first step in treatment for all treatment modalities. The purpose of the admission

interview is to determine whether the selected mode of treatment is most appropriate for the client and to ensure that the client understands the nature of the program and the program's expectations of him. Again, our primary concern is that enough information is exchanged between the client and the program to ensure that the best possible treatment plan is designed for the client in light of his treatment needs and the program's expectations. (Note: Where a Central Intake Unit (CIU) provides the intake screening, it is the responsibility of the program to which the referral is made, to develop the individual treatment plan for each patient after careful review of the records and an interview with the client.)

Individual treatment plans shall be reviewed and redetermined by the treatment team no less than every 90 days for outpatient programs. For all other modalities, the individual treatment plan shall be reviewed and redetermined every 30 days. Evidence of this review shall be recorded in each patient's medical record. Every treatment plan must include documented evidence of:

   a. A statement of short and long-term goals for treatment generated by both staff and client.

   b. The assignment of a primary counselor.

   c. A delineation of the type and frequency of counseling services to be provided.

   d. A delineation of those supportive services needed by the individual patient.

8. The program shall designate a medical director who must take medical responsibility for the program and be licensed in the jurisdiction within which the program exists. He shall ensure that the initial evaluation is appropriately performed and that the medical needs of individual patients are periodically assayed and that, when appropriate, emergency medical services are provided. It is the responsibility of the medical director to determine what emergency medical equipment and supplies are needed in order to deal with possible overdoses and other medical emergencies. Medical services, in general, should be provided through city or county medical facilities. Provision of such services is not the program's responsibility.

   For those patients receiving prescription medication (other than methadone), through the program, contact with a program physician is required at least once every four (4) weeks or more frequently, depending on patient needs.

9. A formal written agreement must exist between the program and a licensed hospital or hospitals in the community for provision of emergency, inpatient, and ambulatory medical services as appropriate. Such services will not be paid for under this contract/grant.

10. At least five hours per week of professional mental health consultation per 100 patients must be provided. The purpose of this consultation is to review selected cases and to provide assistance to staff in patient management or referral for psychiatric services.

11. A variety of counseling techniques may be utilized in individual, family or group counseling sessions conducted by trained personnel under the supervision of an appropriately qualified professional. In any group counseling, the size of the group shall, in general, range between 5 and 15 individuals. In outpatient methadone and outpatient drug free programs, each patient shall have available to him a minimum of 3 hours per week of counseling. In residential drug free, residential methadone, and day care drug free programs, a minimum of ten hours per week of formalized counseling shall be available for each patient. These counseling guidelines should be considered minimum for planning purposes; however, the actual counseling time allotted should be based upon individual client needs.

12. The following supportive services must be provided:

    a. Education.

    b. Vocational counseling and training.

    c. Job development and placement.

    d. Legal services.

    To the maximum extent possible, programs shall utilize community resources. Documentation of any agreements to provide the above services must be obtained. If any program can adequately demonstrate inability to obtain the requisite supportive services, it may submit a formal request for the direct provision of these services.

13. The following procedures must be observed for urine surveillance except for outpatient drug free:

    a. Urine specimens from each patient must be collected under appropriate supervision on a randomly scheduled

basis at least once a week and analyzed for morphine, methadone, cocaine, codeine, amphetamines, barbiturates, as well as other drugs if indicated. Breath analysis is acceptable for alcohol testing where appropriate.

    b. Laboratories used for urine testing must comply with all state and Federal proficiency testing programs.

    c. Urine testing results shall be used as a diagnostic tool and in patient management and in the determination of patient treatment plans. Patient records shall reflect the manner in which test results are utilized.

    d. Provision for urine testing of outpatient drug free clients should be made, and used by program staff as appropriate.

14. Every patient shall be encouraged to enroll in either an education program, a job training program or gainful employment as soon as appropriate, but not later than 120 days; or in the case of a referral from a residential program, not later than 60 days after the date of transfer. Any exception to this requirement shall, in every instance, be recorded and justified in the patient's record. Clients have the right not to become involved in these programs; however, they should be encouraged to do so as a basic element of the treatment plan.

15. Each program shall establish a follow-up policy which encourages a schedule of minimum contact available for discharged patients.

16. Each program shall establish a patient record system to document and monitor patient care. This system must comply with all state and Federal reporting and confidentiality requirements.

17. An effort must be made to gear the program's hours of operation to meet client needs. For outpatient treatment programs, consideration should be given to those clients who are employed and consequently must be able to visit the clinic outside of working hours. Clients who are not employed or involved in school or training programs are expected to schedule other activities around clinic hours. The traditional 9:00 a.m. to 5:00 p.m. work day regimen is not adequate for outpatient treatment. In fact, in clinics with large client populations, twelve-

hour clinic operations may prove necessary. However, the minimum hours of operation shall be maintained.

a. Outpatient Methadone -- no less than 7 days per week: 5 days per week at 8 hours per day (in all cases at least 2 hours must be outside 9 a.m. - 5 p.m.) and 2 days per week at 4 hours per day.

b. Residential Methadone and Residential Drug Free -- 7 days per week, 24 hours per day.

c. Outpatient Drug Free -- no less than 6 days per week: 5 days at 8 hours per day (in all cases at least 2 hours must be outside 9 a.m. - 5 p.m.) and one day at 5 hours.

d. Day Care Drug Free -- 6 days at 10 hours per day.

e. Central Intake Unit -- 5 days per week at 8 hours per day.

18. Residential methadone and residential drug free programs must provide a minimum of 3 meals per day per patient. Day care drug free programs may provide one meal per patient per day.

19. All programs which use methadone for detoxification and maintenance treatment must comply with the regulations of the Food and Drug Administration and also must function in compliance with all other relevant Federal and state regulations and guidelines.

Exceptions to the underlined criteria, when in line with patient needs, may be granted by your Program Development Specialist, Division of Community Assistance, National Institute on Drug Abuse, 11400 Rockville Pike, Rockville, Maryland 20852. Exceptions to other criteria will be made by: Director, Division of Community Assistance, under the advisement of the Clinical Review Board.

FEDERAL FUNDING CRITERIA FOR TREATMENT SERVICES
CENTRAL INTAKE UNIT

The contractor/grantee, as an independent.contractor/grantee and not as an agent of the Government, shall provide the necessary facilities, materials, services, and qualified personnel to provide central intake services to service delivery systems which furnish treatment and rehabilitation to drug dependent persons in accordance with the following:

A. The contractor/grantee shall provide and operate or shall engage a subcontractor/affiliate to provide and operate a Central Intake Unit (CIU) at a site approved by the Government.

B. The contractor/grantee shall require that each participating program submit criteria to be used for admissions and terminations.

C. The contractor/grantee shall make available a Central Intake Unit to provide uniform, standardized initial patient orientation, multi-phasic health screening and referral to an appropriate treatment modality for new and readmitted patients.

D. The CIU shall provide at least the following and such other items of patient care as may be prescribed by the Government:

1. A central intake facility for patients to remain open no fewer than 5 days per week, and no fewer than 8 hours per day.

2. A facility maintained in clean, safe and attractive condition and in accordance with appropriate local, state and Federal codes and other laws.

3. Appropriate furnishings for a central intake facility.

4. At intake, an initial personal history, medical history, and drug history.

5. At intake a physical examination and laboratory examination performed by qualified personnel.

   Physical examination stressing infectious diseases, pulmonary, liver, cardiac abnormalities, dermatologic sequelae of addiction and possible concurrent surgical problems.

Laboratory examination, including the following:

a. Complete blood count and differential

b. Serologic test(s) for syphilis

c. Routine and microscopic urinalysis

d. Urine screening for drugs (toxicology)

e. SMA 12/60 or equivalent

f. Chest X-ray

g. Australian antigen, as appropriate

h. Sickle cell, as appropriate

i. Pap smear and gonorrhea culture, as appropriate

j. Tetanus toxoid, as appropriate

k. EKG and biological test for pregnancy, as appropriate

6. Services of a medical director licensed in the jurisdiction within which the CIU exists. He shall insure that the initial evaluation is appropriately performed and that medical needs of individual patients are properly assessed and treated/referred, as appropriate. Medical services shall include initial diagnostic work-up, identification of medical and surgical problems for referral to other treatment facilities, and review of patient's records. The physician should, when appropriate, request a copy of the patient's previous medical records and forward them to the appropriate treatment center.

7. A formal written agreement between the CIU and a licensed hospital or hospitals in the community for provision of emergency, inpatient and ambulatory hospital services as appropriate. Such services will not be paid for under this contract/grant.

8. Interview of each new admission or readmission shall be performed by a mental health professional or by a qualified intake counselor under the supervision of the former. The intake staff shall take a complete personal history--family, education, vocation, legal and related areas, drug history, including kinds of drugs abused, when begun, and prior treatment attempts. The staff shall then present the various treatment modalities available for the patient. After

discussing these in light of the patient's particular situation (including the results of the physician's evaluation), a treatment modality shall be selected by mutual agreement with the applicant and the appropriate referral made.

9. A patient index of all drug dependent individuals referred for treatment through its screening and referral unit must be maintained. This index shall be updated by the participating agencies as transfers to other programs and termination occur.

10. The CIU must have the capability of referring a drug dependent individual with duplicate intake records to an appropriate treatment modality within 48 hours.

11. Uniform intake procedures must be established so that it will not be necessary for programs which receive patients from the CIU to duplicate services.

12. Urine surveillance according to the following procedures:

- Urine specimens from each patient must be collected under appropriate supervision during the intake process. The specimens must be analyzed for morphine, methadone, cocaine, codeine, amphetamines, barbiturates, as well as other drugs if indicated. Breath analysis is acceptable for alcohol testing.

- Laboratories used for urine testing must comply with all state and Federal proficiency testing programs.

E. If methadone is to be administered at the Central Intake Unit, the CIU must comply with the regulations of the Food and Drug Administration and also must function in compliance with all other relevant Federal and state regulations and guidelines.

F. Each CIU shall establish an approved patient record-keeping system adequate to fulfill state and Federal reporting requirements.

G. Each CIU shall establish and have evidence of formal agreements between the CIU and community-based drug treatment programs, documenting the program's agreement to utilize the CIU for patient intake functions and not to duplicate those functions; and to accept only patients who have been processed through the CIU.

H. Each CIU shall define: The procedures by which applicants shall be oriented to available treatment options; the decision-making process for determining recommended referral; the decision-making process for "mutual agreement" between applicants, programs, and CIU staff regarding referral; and procedures for meeting the needs of patients referred to the CIU for rescreening and re-referral to a more suitable modality or program. These shall be subject to state and Federal approval.

Exhibit 4

Budgets for 100 and 300 Client Clinics

Outpatient Module for Methadone Treatment

Description

Described in the following pages will be the budgets and staffing patterns for methadone treatment centers of several different sizes. No distinction will be made between detoxification or maintenance treatment, and the dynamic-statis capacity ratio of 1.7 will be used. The assumption will be made that all of the centers below will be open seven days a week and will serve new clients as well as stablized clients. The staffing patterns will satisfy the FDA regulations but will be minimal in the areas of vocational rehabilitation and other supportive services as these are contained in separate modules. The programs will operate seven days a week, eight hours a day.

The first staffing pattern discussed is for a program designed to treat 300 clients at any given time. Appropriate medical services will be delivered and the assumption will be made that no Central Intake Unit exists at the location of this facility. Therefore, a complete medical examination will be done at a cost of $75 per client each year. Additionally, appropriate medical services will be provided with seven day a week coverage as required by the FDA, and a counselor-client ratio of 1/30 will exist. Methadone will be dispensed on-site, and counseling will be provided on-site.

Outpatient Module for Methadone Treatment
Budget - 300 Clients

A. Personnel		
Administrator	$ 15,000	
Assistant administrator	$ 11,000	
Secretary	$ 8,000	
Clerk-typist	$ 7,000	
One medical officer	$ 24,000	
Two nurses	$ 24,000	
Four licensed practical nurses	$ 34,000	
One vocational rehabilitation specialist	$ 14,000	
One chief counselor	$ 12,000	
Nine counselors	$ 81,000	
Total	$230,000	
Employee benefits @ 10%	$ 23,000	
Total Personnel Costs	$253,000	$253,000
B. Consultants		
Psychiatric	$ 10,000	$ 10,000
C. Travel		
Local for staff	$ 2,000	
Local for clients	$ 2,500	
Total	$ 4,500	$ 4,500

D. Equipment

Office	$ 4,000	
Clinic	$ 2,500	
Total	$ 6,500	$ 6,500

E. Intake Medical Examinations

510 examinations assuming 1.7 dynamic to static capacity ratio @ $75 per exam	$ 38,250	$ 38,250

F. Other

Utilities and Communication	$ 2,400	
Rent	$ 12,000	
Supplies and Materials	$ 8,000	
Training	$ 1,500	
*Laboratory Services Contract	$ 52,000	$ 75,900
TOTAL COST OF CLINIC WITH 300 CLIENT STATIC CAPACITY	$388,150	$388,150

*$52,000 for urine costs assumes that there will be 400 urines per week submitted @ $2.50 per urine. Although only 300 urines per week are required by FDA regulations, it is assumed that an extra one hundred will be done on an as indicated basis.

The other outpatient chemotherapeutic module budgeted below will be for a clinic with a 100 client static capacity. This unit will also stay open seven days a week and therefore certain fixed costs as well as staff time will be higher than in the 300 client unit. This unit will essentially provide the same services as the unit described above.

Outpatient Module for Methadone Treatment cont'd.
(Budget - 100 Clients)

A. Personnel

Administrator	$ 15,000	
Assistant administrator	$ 11,000	
Secretary	$ 8,000	
Clerk-typist	$ 7,000	
Half-time physician	$ 12,000	
One nurse	$ 12,000	
Three licensed practical nurses	$ 25,000	
Half-time vocational rehabilitation specialist	$ 7,000	
One chief counselor	$ 12,000	
Three counselors	$ 27,000	
Total	$136,500	
Employee benefits @ 10%	$ 13,650	
Total Personnel Costs	$150,150	$150,150

B. Consultants

Psychiatric	$ 5,000	$ 5,000
C. Travel	$ 1,500	$ 1,500
D. Equipment	$ 3,000	$ 3,000

E. Intake Medical Services

$75 per patient based on 170 complete physical laboratory and x-ray exams	$ 12,750	$ 12,750

F. Other

Communcation and Utilities	$ 1,500	
Rent	$ 9,000	
Supplies	$ 6,000	
Training	$ 1,000	
*Laboratory services contract for urinalysis	$ 21,840	
Total	$ 38,340	$ 38,340
TOTAL COST OF CLINIC WITH 100 CLIENT STATIC CAPACITY	$210,740	$210,740

*The figure $21,840 is based on 140 urines per week at $3.00 per urine test. The 140 urines again are more than required by FDA but probably what would be indicated for a clinic of this size, and the increase of $3.00 instead of $2.50 in the earlier clinic is based on expected change in price per urine due to the decreased volume.

General Budget Comments

The assumptions made in the text of these budgets are that there are essentially no job development, job placement, education or client training costs or central administrative costs included in the operation of any of the clinics. It is assumed that these costs will be in other modules. However, in many locations, it will not be cost-effective to have centralized services outside each clinic; therefore, the costs in the preceding modules may have to increase when this is the case.

Even with these costs excluded, we find a cost per client year in the first module (the 300 client clinic) at about $1,300 per client year and in the second at about $2,100 per client year. If the number of each of these clinics is about equal, then $1,700 per client year appears to be a feasible cost when the services above are paid for in some other way. However, since we assumed earlier that this probably will not happen in many cases, we might again assume that the cost for each clinic, which would have to provide comprehensive seven day a week outpatient care with chemotherapy and appropriate medical and counseling services, would be closer to $2,000 per client year.

Exhibit 5

DEA Regulations

NARCOTIC ADDICT TREATMENT ACT OF 1974

Proceedings and Debates of the 93rd Congress, Second Session
Congressional Record, Washington, Wednesday, May 1, 1974, No. 60

That this Act may be cited as the "Narcotic Addict Treatment Act of 1974".

Sec. 2. Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by adding the following after paragraph (26):

"(27) The term 'maintenance treatment' means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

"(28) The term 'detoxification treatment' means the dispensing, for a period not in excess of twenty-one days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period."

Sec. 3. Section 303 of the Controlled Substances Act (21 U'S'C' 823) is amended by adding the following after subsection (f):

"(g) Practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)—

"(1) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

"(2) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records (in accordance with section 307) on such drugs; and

"(3) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment".

Sec. 4. (a) Section 304(a) of the Controlled Substances Act (21 U.S.C. 824(a)) is amended by adding after the below paragraph (3) the following: "A registration pursuant to section 303(g) to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 303(g)."

Section 304(d) of such Act is amended by inserting after the first sentence the following: "A failure to comply with a standard referred to in section 303(g) may be treated under this subsection as grounds for immediate suspension of a registration granted under such section."; and (2) by striking out "Such suspension" and inserting in lieu thereof "A suspension under this subsection".

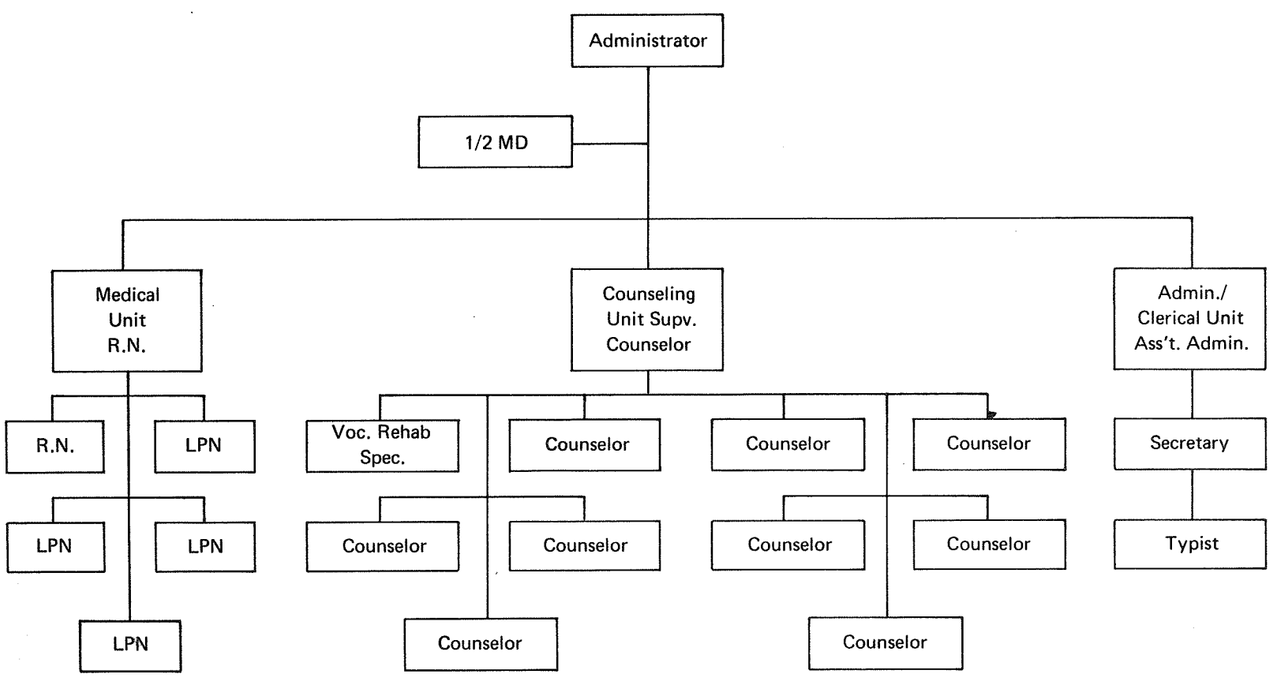
Sec. 5. Section 307(c) (1) (A) of the Controlled Substances Act (21 U.S.C. 827(c) (1) (A)) is amended to read as follows:

"(1) (A) with respect to any narcotic controlled substance in schedule II, III, IV, or V, to the prescribing or administering of such substance by a practitioner in the lawful course of his professional practice unless such substance was prescribed or administered in the course of maintenance treatment or detoxification treatment of an individual; or".

Exhibit 6

Sample Organizational Chart

SAMPLE ORGANIZATIONAL CHART – 300 CLIENTS



SAMPLE ORGANIZATIONAL CHART – 100 CLIENTS

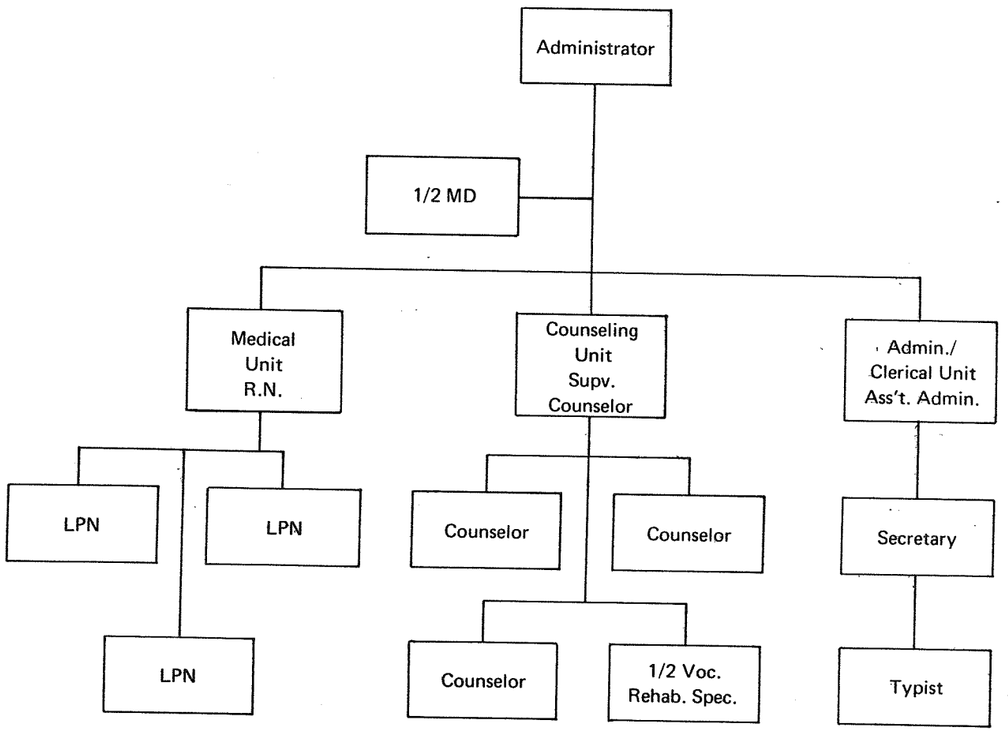


Exhibit 7

Sample Position Descriptions

Sample Job Descriptions: Counselor

A. *Supervisory Counselor*

Position Controls:

Incumbent works under the direct supervision of the Program Director. Supervisor is available for assistance on unforeseen problems encountered. Work is reviewed for adequacy and compliance with instructions and available quidelines.

Duties and Responsibilities:

Supervises counselors and counselor aides in day-to-day client management. Independently assesses training needs of supervised staff and provides necessary training where feasible. In other instances, will report training needs to supervisor. Orients new counseling personnel.

Assigns incoming clients to individual counselors and makes changes when deemed necessary. Evaluates counselors and conducts periodic, scheduled caseload reviews with individual counselors.

Coordinates all treatment functions with outside agencies and screens inter-agency communications from counselors to these agencies (e.g., Department of Vocational Rehabilitation, Department of Welfare, hospitals, etc.).

Conducts and/or provides individual or group therapy. Acts as therapy supervisory for counselor and provides on-going training in this area.

Along with program director, chief nurse, and medical director, formulates clinic policy and participates in its revision. Acts as program supervisor in absence of program director.

Coordinates drop-out, after-care, outreach and recreational activities within the program. Receives progress reports of same. Conducts treatment meetings in the absence of the program director. May represent program in community meetings.

Attends professional meetings and conferences as approved by the program director and performs other duties as assigned.

B. *Journeyman Counselor*

Position Controls:

Receives general technical and administrative supervision from supervisory counselor. Assignments are well defined and on-the-job training is given to develop counseling skills. Supervisor is available for assistance on unforeseen problems with instructions and available guidelines.

Guidelines are available for consultation and study and include policy and procedural guides and clinical case records and reports.

Duties and Responsibilities:

Collects supplemental information on designated clients using families, previous employers or co-workers, social and drug histories, and other sources as indicated for effective rehabilitation. Conducts orientation session for newly admitted clients.

Records all client activity at intervals designated by program policy. Maintains data on clients in organized, well-documented fashion; submits for periodic review by supervisory counselor.

Prepares individual treatment plans for clients upon intake, revising these when necessary. Evaluates treatment plans at least every 30 days.

Advises supervisor of problems encountered in caseload management and recommends various approaches (e.g., increased privileges, increased counseling, disciplinary measures). Presents these in weekly treatment team meetings.

Participates in group and/or individual counseling, using supervisory counselor as resource for problem clients.

Uses various objective indicators to supplement treatment strategies (e.g., urine results) and communicates with other members of treatment staff to improve these. Documents all contacts and/or contacts of other staff with clients. Is very observant of clients' behavior.

Initiates all referrals for client and performs follow-up. Utilizes available resources in complient referral (i.e., nurse or physician for medical services, vocational rehabilitation counselor, etc.).

Attends professional conferences and meetings as directed.

Participates in urine surveillance assignments, submits urines upon request, and performs other duties as assigned.

C. *Counselor Aide or Beginning Counselor*

Position Controls:

Receives close technical and administrative supervision from an experienced counselor. Assignments are well defined and on-the-job training is provided. Supervisor is available for assistance on unforeseen problems encountered. Work is reviewed and periodic discussions are conducted by supervisor as a part of incumbent's training. Guidelines include policy and procedural guides, and clinical case records and reports.

Duties and Responsibilities:

As directed by experienced counselor, may interview newly admitted clients and record data. Observes orientation groups for new clients, gradually assuming responsibility for these groups.

Receives in-service training in interviewing techniques, program policies and procedures, and other areas to be applied in assignments. Participates in group and individual therapy as part of this training.

Establishes superficial relationships with clients designated as desirable by supervisor. Begins to utilize standard client management techniques as recommended by supervisor and as fits into program policy.

Performs other duties as assigned and receives increased responsibility as indicated.

D. *Job Development Counselor*

*Position Controls:

Works under the general supervision of the supervisory counselor. Technical supervision may be available from centralized vocational rehabilitation unit, or city Vocational Rehabilitation Department. Work is reviewed by supervisory counselor and program director.

Duties and Responsibilities:

Collects available social, educational, economic and vocational information which can be used in securing suitable employment. Obtains information to aid in securing jobs for clients through social agencies, close contact with the counselors, field visits to home and other relevant means in order to secure meaningful employment. Is responsible for follow-up contact with prospective employers and providing counselors with follow-up information. Conducts employment adjustment sessions with clients (e.g., resume preparation, promptness, etc.).

Maintains good public relations and participates in team conferences and training with community agencies and local employment offices.

*If a vocational rehabilitation specialist is employed by the program, the counselor may be responsible to him for both general and technical supervision. The vocational rehabilitation specialist would then be directly responsible to the program director.

Maintains accurate records for the program's statistical purposes of numbers of clients referred by counselors, numbers of clients referred to various agencies, employment retaining rates among clients, etc. Provides these to supervisory counselor upon request.

Keep records collected on intake and updated periodically, of employment needs, previous employment records, apprenticeships and skills of all clients, training needs, etc.

Participates in treatment team meetings.

Performs other duties as assigned.

Sample Job Descriptions: Nurse

A. *Chief Nurse*

Position Controls:

Overall nursing objectives are established jointly by program director and clinic physician. Exercises initiative and professional judgment in executing nursing services. Work is reviewed for overall effectiveness by program director. Receives technical supervision from clinic physician. Utilizes pertinent laws and regulations in the use of narcotics and dangerous drugs.

Duties and Responsibilities:

Plans, organizes, and directs activities of the medical staff. Makes appropriate assignments in accordance with the employees' skills. Evaluates employees and recommends appropriate action (i.e., reward for performance, disciplinary action). Arranges staff schedules for adequate clinic coverage. Collaborates with program director, supervisory counselor, and clinic physician in establishing program policy.

Supervises nursing staff in methadone dispensing and is responsible for proper accountability of the drug. Provides traditional nursing services appropriate in an outpatient setting (e.g., medication, developing treatment plans, etc.). Coordinates treatment plans with counseling staff through participation in treatment team meetings.

Assists the physician in assessing clients' health needs when medical care is not immediately available. Determines priority of need and refers clients to appropriate resources. Ensures that results of referral are documented in client folders.

May function in emergency situations in the physician's absence (e.g., methadone dose may be adjusted via telephone order from the physician and recorded by the nurse. This must be signed by the physician as soon as possible).

Ensures that medical records are complete, accurate, and meaningful and are maintained in an organized way. Reviews these records at regularly scheduled intervals.

Participates in urine surveillance as requested.

Attends professional conferences and meetings as required and performs other duties as assigned.

B. *Staff Nurse (RN or LPN)*

Position Controls:

Works under direct supervision of the Chief Nurse. Utilizes pertinent laws and regulations in the use of narcotics and dangerous drugs. Work is reviewed for overall effectiveness.

Duties and Responsibilities:

Orients newly-admitted clients regarding the medical aspects of the treatment to be undertaken (i.e., maintenance, detoxification), and may interpret these to the client's family at his request. Accepts requests from counseling staff for clients' appointments with clinic physician and works with counselors in screening appropriateness of request.

Daily assesses clients' reactions to methadone, records these, and reports them to counselors. Participates in treatment team meetings, providing information which will be useful to counselors in client management.

Maintains accurate, well-organized client folders and submits these for review to the chief nurse upon request. Also maintains accurate methadone accountability records, documents any discrepancies immediately, and reports them to supervisor.

Prepares daily "missed list" and distributes to counselors, notifying them of clients not receiving medication on the previous day.

May serve as counselor for a reduced caseload or co-counselor with member of the counseling staff. Receives technical supervision from supervisory counselor when acting in this capacity.

May be designated "in charge" responsibility at any time.

Participates in urine surveillance responsibilities as requested and performs other duties as assigned.

Exhibit 8

Sample On-the-Job Training Aids

Client Management

Objectives: – To provide forum for discussion of program policy regarding client management.
– To provide staff with basics of effective management tools for addicts in treatment.

Points for Discussion:

A. Intake process

1. Elements
2. Duration
3. Staff

B. Client assignment and orientation

C. Record keeping

1. CODAP Standards
2. Individual program policy

D. Client types

Anger

Discussion points:

1. Angry clients are often resistant to their own feelings.
2. Carefully structure questions about the *source* of the anger. Otherwise, client may become further infuriated.
3. Attempt to point out area where client has directed immediate anger and deal from there.
4. Do not try to get at all causes of anger - especially if some have already been expressed. This minimizes those problems.
5. Do not give client the impression that you are avoiding his behavior.

Fear

Discussion points:

1. Avoid giving unsolicited advice.
2. Try to get client to explore feelings about a given situation.
3. Time your responses; avoid premature, investigating questions.
4. Explore possibilities to resolve conflict.

Anxiety

Discussion points:

1. Use approach that is sensitive to client's feelings.
2. Make responses emphasize sensitivity to feeling rather than content of conversation.
3. Attempt to continuously get information which adds to material already discussed.
4. Deal in the here and now if information about the past can be gathered later.
5. Avoid trying to resolve issue during the first interview.

E. Counseling

1. Individual

a. Assist client in taking risks. Help him discard old familiar ways of responding because he thinks they are safe.
b. Avoid stereotype labels. These allow the client to shift responsibility for his actions to the condition the label implies (i.e., dependent).
c. Assist client in identifying his own faults instead of encouraging him to identifying to society's.
d. Avoid comparisons (husband-wife; brother-sister, etc.) These allow the client to maintain a poor concept of himself and come out second best. Another excuse for irresponsibility.
e. Define client's fears with him. Do not allow him to bring up previous defeats as a motive for not venturing ahead.
f. Avoid (whenever possible) argumentative episodes with the client. He may often use this defense to prevent you from probing deeper areas.
g. Discourage client from blaming his past for his present behavior.
h. Attempt to define various client-defenses (i.e., clients with marital problems are often engaged in numerous activities to avoid admitting they may be lonely).
i. Note positive behavior
j. Discard illusion that only you have problems.
k. Develop alternatives
l. Avoid false accusations.

2. Groups (Residential setting)

a. Encounter

- Utilizes confrontation (attack) approach.
- Emphasizes behavior occurring in the here and now.
- Anger is openly expressed and dealt with.
- Leader assumes directive role.

b. Non-authoritarian (Tavistock Model)

- Forces members to assume responsibility; no "leader" scapegoat.
- Content centers around here and now.
- Leader assumes unattainable role, responses are limited to interpretations, provides little overt direction to the group.
- Not strongly recommended for new admissions.

c. Supportive

- Soft pedals hostility, anger and anxiety.
- Emotions are accepted, atmosphere is one of openess.
- Leader is compassionate, empathetic, directive; may even defend certain members.
- Recommended group type for amphetamine abusers.

d. Re-entry

3. Groups (Ambulatory setting)

Groups conducted on an outpatient basis have generally proven to be unsuccessful. Clients seldom *want* to attend because they feel little, if anything, will be accomplished. We, therefore, advocate

goal-oriented groups for clients in outpatient clinics. A skilled leader is necessary, however, since therapy most certainly occurs.

The following are recommended as workable with ambulatory clients:

Detox groups - required for all clients *actively* undergoing methadone and/or heroin detoxification.

Family groups - may consist of any member of clients families or specific members (e.g., mother's group).

Pregnant-mother groups - for women either pregnant or recently delivered.

Employment adjustment groups - for clients who have met certain prerequisites and have been referred to vocational counselor.

Task group - for select clients who have demonstrated adequate responsibility assumption. Utilize in planning activities for clinic (e.g., picnics).

Alchoholic groups - for clients with drinking problems in addition to drug problems.

4. Ancillary services

a. criteria for referral
b. follow-up responsibility

5. Communication

6. Exercise

History and Nature of Addiction

Objectives: – To familiarize staff with classes of narcotics, their uses, and their relevance to addiction.

– To incorporate pertinent facts about the "why" of addiction.

– To introduce concepts (other than medical) about treatment of addiction.

Points for Discussion:

A. Classes of addictive drugs, medical uses, differences, similarities and instances of abuse

1. Narcotic analgesics
2. Barbiturates and other sedatives and hypnotics
3. Alcohol
4. Cocaine
5. Amphetamines
6. Marijuana

B. Pharmacological properties

1. Tolerance
2. Physical dependence
3. Psychological dependence

C. Psychiatric factors

1. Personality aberrations
2. Arrested psychosexual development
3. Pharmacodynamic formulation

Chemotherapy

Objectives: – To provide comprehensive understanding of methadone as a tool for treatment.

– To assist staff in recognizing situations in which methadone treatment is feasible (maintenance, detox, and slow withdrawal).

– To acquaint staff with commonly accepted treatment philosophies about methadone.

– To familiarize staff with chemotherapeutic agents used in drug treatment other than methadone.

Points for Discussion:

A. Theories about methadone

1. Metabolic Theory – Dole and Nyswander
2. Conditioning Theory – Goldstein

B. Uses of methadone

1. Maintenance
2. Slow withdrawal
3. Detoxification
4. Analgesia

C. Antagonists

1. Types

2. Uses

D. Other drugs

1. Tranquilizers
2. Barbiturates

E. Methadone in pregnancy

1. Dose adjustment
2. Withdrawals in the newborn

Administrative Responsibility

Objective: – To acquaint staff with legal/moral/programmatic responsibilities to the program and to clients.

Points for Discussion:

A. Federal

1. FDA Regulations
2. SAODAP as coordinating office

B. State

C. Administrative, Statistical, Financial

D. Wrap-up

FACT SHEET

The Opiates

In discussing opiate abuse, the specific drugs of concern are the following:

- Morphine is a natural alkaloid constituting 10 percent by weight of the raw opium.
- Heroin. Because heroin is produced by chemical treatment of morphine with acetic acid, the technical name for it is diacetyl morphine. In terms of analgesic effect, ***heroin*** is a little over ***three times as potent as morphine*** – for example, it takes three milligrams of heroin to produce the same analgesic effect as 10 milligrams of morphine.

Although heroin is the principal opiate of abuse in the United States, most research has been done with the more readily available morphine. In the opinion of experts, such research is applicable to heroin if the dosage difference is considered, because ***heroin rapidly breaks down into morphine*** in the body. Thus, its subsequent pharmacological action is the same.

- Methadone is a synthetic opiate of approximately the same strength as morphine.
- Meperidine is another synthetic opiate that is about 10 to 20 percent as potent as morphine. It is better known under its trade name, Demerol.

METHADONE MAINTENANCE

Characteristics of Methadone

Methadone is a synthetic opiate. For purposes of understanding its use in the treatment of heroin addiction, its most important characteristics are as follows:

- It is a substitute for heroin, in that it will prevent an addict from having or feeling withdrawal symptoms if he replaces his usual drug with methadone.
- Unlike the heroin available in this country, it is effective when taken orally.
- If the dosage is sufficient (the exact level depending on the addict's level of tolerance to heroin), the methadone will block the action of heroin, so that the addict receives no euphoric effect if he tries heroin. At lower doses, methadone will not block this effect of heroin, but it will suppress the "narcotic hunger" – described by Dr. Jerome Jaffe as a "felt sense of physical abnormality" – that an addict feels without his drug.
- The effective action of methadone is about 24 hours, as opposed to about six hours for heroin. Thus, it needs to be taken only once a day.

- When taken orally in constant doses, methadone does not produce a euphoric effect.
- Heroin has a short duration of action and involves wide emotional swings, from euphoria after administration to the threshold of withdrawal six hours later. The rapidity of this cycle forces a totally drug-oriented existence on the addict. If he does not concentrate on procurement of the drug to the exclusion of virtually everything else, he is not going to have it when he needs it. Methadone, with its twenty-four hour action and gentler swings, allows the addict the luxury of thinking about something besides drugs.
- Methadone programs, with or without supporting services, give the addict a good deal of psychological support. The staff is concerned with his well-being and is giving him a medicine in which they have obvious confidence. Medical practice has long known that this placebo effect is important.
- Heroin addiction imposes a structure and purpose on the addict's life— getting the drug. Daily visits to the methadone clinic may provide comparable structure.
- The life style and personal associations of an addict provide great pressures to relapse after a period of abstinence. An abstinence program located where the addict will not live in the future (e.g., Lexington) does nothing about this problem, because the addict does not build up an alternative life style and alternative associations and will probably return to the old ones after release. Methadone protects him from heroin while he builds new patterns of behavior and loses touch with the addict culture. In this view, after new patterns have been developed, it might be possible to withdraw the addict from methadone because his altered environment would not put pressure on him to relapse.
- Studies have indicated that monitoring an ex-addict is an important factor in keeping him off drugs. The crucial ingredient of methadone treatment may be not the methadone per se but the urinalysis. Addiction to methadone is necessary only to force the patient to come to the program.
- Methadone and the other opiates exhibit crosstolerance. A person tolerant to one of them is tolerant to equipotent doses of another.
- No significantly harmful side effects of methadone have been discovered.

Exhibit 9

Confidentiality Regulations

federal register

THURSDAY, DECEMBER 6, 1973
WASHINGTON, D.C.

Volume 38 ■ Number 234

PART IV

SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION

■

CONFIDENTIALITY OF DRUG ABUSE PATIENT RECORDS

No. 234—Pt. IV——1

Title 21—Food and Drugs

CHAPTER III—SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION

PART 1401—CONFIDENTIALITY OF DRUG ABUSE PATIENT RECORDS

In the FEDERAL REGISTER of November 17, 1972 (Vol. 37, No. 223, pages 24636–24639), a new Part 401 was added to Title 21 of the Code of Federal Regulations entitled "Confidentiality of Drug Abuse Patient Records." (37 CFR 401). This part was promulgated as an interpretative regulation to deal comprehensively with both substantive and procedural problems which had arisen under section 408 of Public Law 92–255 (21 U.S.C. 1175), the Drug Abuse Office and Treatment Act of 1972.

By order published in the FEDERAL REGISTER on September 24, 1973 (38 FR 26111), Part 401, Chapter III of Title 21 of the Code of Federal Regulations was redesignated as Part 1401, Chapter III of Title 21 and §§ 401.01 through 401.73 therein were redesignated as 1401.01 to 1401.73, respectively. Accordingly, all references and changes herein relate to the numbered sections as redesignated rather than the numbered sections as originally published.

To provide information necessary to aid the Director of the Special Action Office for Drug Abuse Prevention in determining whether this regulation should be amended, revoked, or reissued, interested persons were invited to submit written data, views, and arguments. Numerous comments, suggestions, and recommendations were received from professional and other organizations and individuals as well as known authorities in the field of drug abuse treatment and rehabilitation. Without exception, the comments supported the underlying policy of protecting the privacy of patients in federally authorized or supported drug abuse prevention programs as a necessary step in reducing the incidence of drug abuse in our society.

The Special Action Office has given serious consideration to all of the comments, suggestions, and recommendations. Many of them could not be adopted without changes in section 408 of the act. Several were based on a misconstruction of the regulations and required no changes. Others raised questions regarding certain sections of the regulation which required clarification or changes. The Director has determined that all of the amendments, which are hereinafter set forth, are necessary or desirable in furtherance of the Government's policy of securing the privacy of patient records as an important part of its program of minimizing the adverse social consequences of drug abuse.

A summary review of the comments and recommendations and the action taken with respect to each are set forth below, followed by the full text of the regulation as revised.

1. *Definition of drug abuse prevention function.* Through inadvertence, the definition of "drug abuse prevention function authorized or assisted under provisions of the act or any act amended by the act" as appearing in § 1401.01 of the regulations, embraced only those programs which (1) are conducted by an agency or department of the United States Government or (2) are conducted by virtue of a license, permit, or other authorization from any such agency or department. It was intended that this definition also should include any drug abuse prevention function which is supported by any agency or department of the United States pursuant to Federal law. Section 1401.01 is so amended.

2. *Definition of medical personnel.* Under § 1401.01(g) the definition of "medical personnel" includes physicians, nurses, psychologists, counsellors, and supporting clerical and technical personnel. A recommendation has been made that this definition be clarified with respect to social workers and staff members in training positions. Section 1401.01(g) has been amended to make it clear that these persons are included in the definition, as well as to explicitly include financial and administrative personnel such as those processing insurance claims directly related to treatment.

3. *Definition of records.* Section 408(a) provides that: "Records of the identity, diagnosis, * * *" are to be kept confidential. The comment has been made that this section does not refer to "communications" and the question has been raised as to whether communications and other types of information were intended to be protected against unauthorized disclosures. While it is true that section 408 does not refer to "communications," it is obvious that the policy of the section would be defeated if drug treatment personnel were allowed to disclose communications or other unrecorded information received from the patient, whether or not they were permitted to disclose the records based upon such communications. Any other interpretation would defeat the principal objective of section 408 in attempting to encourage drug addicts to volunteer in a drug treatment program. We have construed section 408 as applying not only to "records" but also to all communications and other information relating to the patient's identity, diagnosis, prognosis, or treatment in a federally authorized or supported drug abuse prevention activity. Therefore, if information would be treated as confidential if recorded, it should receive the same protection if not recorded. Paragraph (h) of § 1401.01 has been added to express this interpretation.

4. *Applicability prior to March 1, 1972.* An inquiry has been received as to whether section 408 applies to records in existence prior to the publication of the regulations or the enactment of the statute. Section 408 of P.L. 92–255 applies to records "maintained in connection with the performance of any drug abuse prevention function authorized or assisted under any provision of this act or any act amended by this act." This is implemented by § 1401.02 which makes section 408 applicable to records made on or after March 21, 1972, the date of enactment of P.L. 92–255. Therefore, provisions of section 408 would apply to any records of a patient generated after March 21, 1972. Also, they would apply to all records of a patient generated prior to March 21, 1972, provided he was an active participant in a treatment program on that date and such participation represented a single continuous program. Therefore, the record of a patient actively participating in a federally authorized or supported drug abuse prevention program on March 21, 1972, should be considered as confidential in its entirety even though part of it was generated immediately prior to that date. Section 1401.02(a) of the regulations is amended to clarify this point.

5. *Disclosure to governmental personnel for purposes of obtaining benefits.* Section 1401.23 provides for disclosure with the patient's consent for the purpose of obtaining public benefits. A recommendation has been made that limitations should be set upon the nature and extent of the information legitimately needed to qualify for benefits. In effect, the patient already has the right to limit the extent of disclosure for purposes of obtaining these benefits. Section 1401.06 limits disclosure to information necessary in the light of the need or purpose for the disclosure and under § 1401.21, the patient in granting consent, must specify the type of information to be disclosed. In view of the restrictions in these two sections, no further limitations are deemed necessary in § 1401.23.

6. *Disclosure in connection with judicial or administrative proceedings.* Section 408(b)(1)(B) permits a patient to consent to disclosure to governmental personnel for the purpose of obtaining benefits to which the patient is entitled. Numerous questions have been raised concerning the authority of a patient to consent to a disclosure in a judicial or administrative proceeding which involves an issue relating to a patient's claim, benefit, or a right to which the patient is entitled. Under § 1401.24, similar disclosures are authorized in connection with parole, probation, or suspension of prosecution. To clarify this question, a new paragraph (d) has been added to § 1401.23. This section provides that whenever a patient is entitled to any claim or other benefit which is an issue in any judicial or administrative proceeding and some part or all of his drug abuse record is relevant to, and necessary in support of, such claim or benefit, such patient may consent to disclosure of his record to the extent needed to support such claim or other benefit. When any such disclosure is authorized, the court, administrative tribunal, or other governmental body or official should be alerted as to the need to maintain confidentiality and to avoid, to the extent practicable, any further disclosure of the record or the patient's identification.

7. *Evaluation of employment data for purposes of rehabilitation.* Section 408(b)(1)(B) of Public Law 92–255 (21 U.S.C. 1175(b)(1)(B)) permits disclosure with the patient's consent "to government

personnel for the purpose of obtaining benefits to which the patient is entitled." Section 101 of the Act contains an express finding that the success of Federal drug abuse programs and activities requires a recognition that education, treatment, and rehabilitation are interrelated. Section 103(b) defines "drug abuse prevention function" as any program relating to education, training, treatment, rehabilitation or research and includes "any such function even when performed by an organization whose primary mission is in the field of drug traffic prevention functions or is unrelated to drugs." The Director of the Special Action Office has determined that employers, employment agencies and employment services which have demonstrated their willingness to assist in the employment of persons who are present or past patients in a drug abuse treatment or rehabilitation program are performing an essential drug abuse prevention function. Section 1401.26 now provides that an evaluation of patient's progress or status in a treatment program may be furnished to an employer but only after the patient has been employed or has been accepted for employment. This section is now revised to permit limited disclosures to employers and employment agencies and services which have agreed to assist such patients, both present and past, in obtaining gainful employment. Disclosure is permitted only with the patient's consent and is limited to an evaluation of such patient's status or progress in treatment or rehabilitation program. Section 1401.26 is amended accordingly.

8. *Consent of a minor patient to disclose to parents.* Two questions have been raised concerning the disclosure of the records of a minor patient to his parents. The first question concerns the authority for such disclosure. The second question inquires as to whether a minor patient is authorized to give consent. The answer to the first question is set forth in § 1401.26(b) of the regulations. This section provides that information in the nature of a general evaluation of a patient's present or past status in a treatment program may be furnished to members of the patient's family if, in the judgement of a qualified physician or counsellor, such information would be helpful in the treatment or rehabilitation of the patient and the patient makes a written request that such information be furnished. It should be noted that this provision is limited to the disclosure of a mere evaluation of the patient's status or progress in a treatment program and also can only be done if requested by the minor.

Regarding the second question, whether a minor would have authority to consent to disclosure where otherwise permitted, the answer to this question would depend upon local law in view of the fact that section 408 establishes no specific rule on the question. Of course, if the minor is considered incompetent under local law, consent can then be rendered by a guardian or conservator or if deceased by his personal representative as provided in § 1401.04. However, this would apply only in cases where disclosure is otherwise authorized with patient's consent under section 408 or the regulations.

Neither of these comments require any change in the regulations since they have been dealt with already to the extent permissible under law. Therefore, no revisions are considered necessary.

9. *Health and other insurance claims.* There have been numerous instances in which patients, or former patients in a drug abuse prevention program, have encountered difficulty in supporting their claims for reimbursement or payment under health or other insurance arrangements or programs under which they are beneficiaries. A major cause of this difficulty is attributable to the reluctance of drug abuse programs to disclose the necessary information from the patient's record to support the claim notwithstanding the fact that any such payment or reimbursement is directly related to the patient's treatment, which is part of the definition of "drug abuse prevention function" in section 103(b) of Public Law 92–255. Therefore, in order to clarify the law governing records pertaining to such claims, a new § 1401.27 has been added specifically authorizing a limited disclosure of information in a patient's record with his consent to the extent necessary to support a claim for payment or reimbursement under a health or other insurance program for the benefit of the patient and under circumstances in which such claim is related to the performance of a drug abuse prevention function, i.e., treatment or rehabilitation.

10. *Disclosure to a registry.* Section 1401.43 of the regulations permits disclosure among programs and to a registry serving such programs. It has been suggested that the regulations should spell out the extent of supervision necessary for the maintenance of a registry. Otherwise, it has been argued, the potential for abuse of a centralized listing of persons so closely affiliated with illicit behavior could undermine the basic policy of confidentiality in section 408. Section 1401.43 is intended to permit the operation of a central intake facility to prevent simultaneous registration in more than one methadone program and to assure that potential patients are made aware of vacancies in any participating programs. Such a registry is simply an extension of the treatment program and since the registry is prohibited from making any disclosure except as authorized under section 408 and the regulations, there is adequate protection of the privacy of patients against unauthorized disclosures. Moreover, the information which can be collected or retained by such a registry is strictly limited to that which is necessary to the performance of its functions. Therefore, the Special Action Office deems it unnecessary to specify additional limitations at this time.

11. *Research, audits and program evaluations.* Referring to the fact that section 408(b)(2)(B) authorizes disclosure without the consent of the patient to "qualified personnel" for the purpose of conducting scientific research, management or financial audits or program evaluations, it was noted that § 1401.44 of the regulations does not offer any guidance as to what persons come under the classification of "qualified personnel."

"Qualified personnel" under section 408(b)(2)(B) of the act applies principally to two groups. The first group includes personnel making management or financial audits and program evaluations. Except in special circumstances, these functions would be performed only by Federal, State, or local governmental licensing, regulatory, or accrediting agencies which have oversight or other official responsibility with respect to such functions. The second group includes personnel conducting scientific research or evaluations. This group would include principally individuals, groups or organizations having primary responsibility for the collection, evaluation, and dissemination of information in connection with a scientific or program evaluation study for which actual drug abuse data is needed. Paragraph (b) has been added to § 1401.44 to define "qualified personnel" as used in section 408(b)(2)(B).

12. *Disclosure to State agencies as required by statute.* Several comments have been made that State statutes, in many instances, require a disclosure to the State Public Health Department or other State boards or agencies to carry out some local policy objective, such as a check on doctors to determine possible abuse in the treatment of drug addicted patients. Apparently, some doubt has been expressed that section 408 and the regulations do not cover this situation. Attention is directed to § 1401.44 which authorizes disclosure without the consent of a patient to qualified personnel for purposes of conducting scientific research, management audits, financial audits, or program evaluations. To the extent that personnel of State agencies or boards are serving some legitimate objective related to one of the purposes indicated in this section, disclosure to such personnel would seem to come within the intent of section 408(b)(2)(B) of Public Law 92–255 and § 1401.44 of the regulations. Attention is specifically invited, however, to the fact that section 408(b)(2)(B) protects the patient in that any qualified personnel receiving patient information is prohibited from disclosing, directly or indirectly, the identity of any individual patient. If any State law provided otherwise, the Federal policy as set forth in section 408(b)(2)(B) would prevail. Consequently, if the State personnel involved meet the qualifications test by reason of conducting scientific research, management or financial audits or program evaluations and they remain subject to the policy in section 408 with respect to further disclosure, in most instances disclosure to such personnel is authorized. However, a program director need not authorize a disclosure under section 408

(b)(2)(B) if he does not have assurance that the patient's rights of confidentiality are respected. It is believed, therefore, that a reasonable interpretation of this section will accommodate most problems that might arise thereunder and therefore no changes are being made at this time.

13. *Disclosure in court proceedings—court orders.* Several questions have been raised regarding disclosures in court proceedings and the procedure and authority for making such disclosures in certain situations.

(a) One comment referred to a situation in which the drug addiction of the husband was a ground for divorce and therefore was relevant to a proceeding for divorce initiated by the wife. Assuming other evidence is not available, the proper procedure in such a case would be to obtain a court order under section 408(b)(2)(C) based upon a showing of good cause. This would be done under § 1401.72 of the regulations and the court should be asked to receive the evidence in camera.

(b) Another question related to the lack of a requirement of notice to the patient and an opportunity to participate in a court proceeding under section 408(b)(2)(C) of the act. This question raised the issue that due process should require an opportunity to participate in what may be a critical stage of a criminal proceeding, otherwise the proceedings would be ex parte with only the applicant and the judge present. The further comment is made that the regulations contain no definitional guidance as to what constitutes the "public interest" in the granting of a court order and recommends that more specific guidance be included in any revision of the regulations. Attention is invited to § 1401.72 which sets forth information which should be included in an application for a court order under section 408(b)(2)(C) of the act. This information is intended to assist the court in making a finding as to whether disclosure in any particular case would be in the public interest. Until there is compelling evidence of a need to provide further clarification, the Special Action Office deems it undesirable to make additional changes on these points.

(c) A related comment suggests that section 408 requires that the court consider the possible injury to the patient and to the physician-patient relationship in any proceeding to determine whether an order should be granted in the public interest. It is indicated that in any such proceeding the identity of the patient will be disclosed and information concerning him as a patient will be the subject of discussion at the hearing and consequently in effect would constitute a damaging disclosure in violation of the intent of section 408. This is a valid comment but it assumes that the patient's identification will be disclosed at the hearing. Counsel, as well as the court, should be alerted to the dangers of such disclosure in order to avoid the identification of a specific patient as the subject of the hearing. This can be done by an agreement between counsel and the court that the patient's name will not be identified in the proceedings. Also, whenever it will serve the interests of justice, disclosure should be made in camera and the record sealed.

In view of the foregoing recommendations, it is hereby found that good cause exists to make the amendments in the regulation as described above. It is hereby determined that good cause exists to make these amendments effective immediately, that such amendments constitute interpretative rules within the meaning of section 553(b) of title 5, United States Code, and accordingly that notice and public procedure thereon prior to their effectiveness are not required by law. Therefore, it is ordered that title 21, Chapter III, Part 1401 of the Code of Federal Regulations be amended accordingly and as amended will read as hereinafter set forth, effective upon publication in the FEDERAL REGISTER.

By order of the Director of the Special Action Office for Drug Abuse Prevention, November 29, 1973.

GRASTY CREWS II,
General Counsel.

GENERAL PROVISIONS

AUTHORITY: The provisions of this Part 1401 are authorized under sections 213, 221, 222, and 408 of the Drug Abuse Office and Treatment Act of 1972 (Public Law 92-255; 21 U.S.C. 1122, 1131, 1132, and 1175), and other relevant provisions of law.

GENERAL PROVISIONS

§ 1401.01 Definitions.

For the purposes of this part, the following words shall have the meanings indicated:

(a) The term "Act" means the Drug Abuse Office and Treatment Act of 1972 (Public Law 92-255) including such amendments thereto as may be in effect at the time the provision referring to it is applied.

(b) The term "Director" means the Director of the Special Action Office for Drug Abuse Prevention.

(c) The term "drug abuse prevention function" means any program or activity relating to drug abuse education, training, treatment, rehabilitation, or research, and includes any such function even when performed by an organization whose primary mission is in the field of drug traffic prevention functions (as defined in 21 U.S.C. 1103(c)), or is unrelated to drugs.

(d) The term "drug abuse prevention function authorized or assisted under any provision of the Act or any act amended by the Act" means any drug abuse prevention function—

(1) Which is conducted or supported, in whole or in part, by any department, agency, or instrumentality of the United States, or

(2) For the lawful conduct of which in whole or part any license, permit, or other authorization is required to be granted by any department or agency of the United States.

(e) The term "patient" means any person who is or has been interviewed, examined, diagnosed, treated, or rehabilitated in connection with any drug abuse prevention function and includes any person who, after arrest on a criminal charge, is interviewed and/or tested in connection with drug abuse preliminary to a determination as to eligibility to participate in a drug abuse prevention program with the approval of the court.

(f) The term "governmental personnel" means those persons who are employed by the U.S. Government, by any State government, or by any agency or political subdivision of either, and includes Veterans Administration personnel as described in § 1401.23(b).

(g) The term "medical personnel" includes physicians, nurses, psychologists, counselors, social workers, and supporting administrative, financial, clerical, and technical personnel.

(h) The term "records" as used in section 408(a) shall include communications and other information, whether recorded or not, relating to the identity, diagnosis, prognosis or treatment of a patient.

§ 1401.02 Applicability.

(a) Except as provided in paragraph (b) of this section, this part applies to records or any part thereof made on or after March 21, 1972, of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function authorized or assisted under the Act or any act amended by the Act. This part applies also to records maintained for patients actively participating in a treatment program prior to March 21, 1972 where such prior treatment is part of one continuous treatment activity still subsisting on that date.

(b) The provisions of section 408 of the Act (21 U.S.C. 1175) and the remaining provisions of this part do not apply to any interchange of records entirely within the Armed Forces, within those components of the Veterans Administration furnishing health care to veterans, or between such components and the Armed Forces, but otherwise such section and this part apply to any communication to or from any person outside the Armed Forces or such components of the Veterans Administration.

§ 1401.03 General rules regarding confidentiality.

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function shall be confidential, may be disclosed only as authorized by this part, and may not otherwise be divulged in any civil, criminal, administrative, or legislative proceeding conducted by any Federal, State, or local authority, whether such proceeding is commenced before or after the effective date of this part.

§ 1401.04 Incompetent or deceased patients.

In any case in which disclosure is authorized with the consent of the patient, such consent may be given by a guardian, conservator, or other court-appointed designee in the case of an incompetent patient, and by an executor, administrator, or other personal representative in the case of a deceased patient.

§ 1401.05 Security precautions.

(a) Appropriate precautions should be taken for the security of records to which this part applies. The succeeding paragraphs of this section set forth examples of such precautions, but these should be added to or may be modified in the light of individual circumstances.

(b) The file of each patient maintained in connection with the performance of any drug abuse prevention function should be marked "Confidential Patient Information," as should any record identifying an individual as a drug abuse patient, including photographs, fingerprints, reports of skin abrasions indicating drug use, or other documentation of patient identification.

(c) Each file drawer, cabinet, or other container in which such files are kept should be conspicuously labeled with a cautionary statement such as the following:

CONFIDENTIAL PATIENT INFORMATION
Any unauthorized disclosure is a Federal offense.

§ 1401.06 Extent of disclosure.

Any disclosure made under this part, whether with or without the patient's consent, shall be limited to information necessary in the light of the need or purpose for the disclosure.

DISCLOSURES WITHOUT COURT AUTHORIZATION AND WITH CONSENT OF PATIENT

§ 1401.21 Form of consent.

(a) Where disclosure is authorized with the consent of the patient, such consent must, except as otherwise provided, be in writing and signed by the patient. Such consent must state—

(1) The name of the person or organization to whom disclosure is to be made,

(2) The specific type of information to be disclosed, and

(3) The purpose or need for such disclosure.

§ 1401.22 Disclosure to medical personnel.

With the patient's consent, disclosure to medical personnel is authorized for the purposes of diagnosis or treatment. The consent must be in writing and in the form prescribed in § 1401.21. All medical personnel to whom disclosure is made shall be subject to all of the rules on confidentiality as set forth in this part.

§ 1401.23 Disclosure to governmental personnel for purpose of obtaining benefits.

(a) *Benefits generally.* With the written consent of a patient, disclosure is authorized to governmental personnel for the purpose of obtaining benefits to which the patient is entitled. For the purposes of this section, benefits to which a patient is entitled include, but are not limited to, any welfare, medicare, or other public financial assistance authorized by Federal, State, or local law, the suspension of prosecution, the granting of probation or parole, public pension or retirement benefits, and any other benefit conferred by lawful authority.

(b) *Veterans benefits.* Disclosure may be made to Veterans Administration personnel for the purpose of determining a patient's eligibility for hospitalization, pension, or other veterans' benefits. For the purpose of this section, Veterans Administration personnel includes any personnel (whether or not employed or compensated by the Veterans Administration) authorized by the Veterans Administration to assist patients in the preparation and submission of their claims.

(c) *Welfare benefits.* Where treatment for drug abuse has been made a condition to the granting or continuation of a welfare or other public benefit, disclosure is authorized to governmental personnel responsible for the administration or determination of such benefits.

(d) *Claims or benefits adjudicated in judicial or administrative proceedings.* In any proceeding before a court, an administrative tribunal, or other governmental body or official having authority to approve or disapprove, or to recommend approval or disapproval, of a claim or other benefit to which a patient is entitled and all or some part of such patient's drug abuse record is relevant and necessary to the determination of such claim or other benefit, such patient may consent to, and authorize the disclosure of such record or portion thereof deemed necessary to support such claim or benefit. When any such disclosure is authorized, the court, administrative tribunal, or other governmental body or official should be alerted as to the need to maintain confidentiality and to avoid, to the extent practicable, any further disclosure of the record or the patient's identification.

§ 1401.24 Disclosure in connection with parole, probation, or suspension of prosecution.

(a) In the case of a drug abuser charged with a criminal offense or who is subject to parole or other probationary action and who has agreed to participate in a drug abuse prevention treatment program as a condition of release from confinement or as a condition to the dropping, deferral, or suspension of charges or judgment, disclosure of such person's treatment records in connection with such program is authorized if the patient consents in writing to participate in such program and consents to disclosure in accordance with § 1401.21.

(b) Disclosure pursuant to this section shall be limited to the patient's attorney and to governmental personnel having responsibility with respect to the prosecution of the patient or for supervising his probation or parole.

§ 1401.25 Disclosure to legal counsel.

(a) In any situation in which disclosure is permitted with the patient's consent for one or more of the authorized purposes as stated in this part and the patient has secured the advice of legal counsel, disclosure may be made to the patient's attorney upon the written application of the patient endorsed by the attorney.

(b) In any situation in which a patient seeks the advice of legal counsel on the question of waiving confidentiality, disclosure is authorized to the extent necessary to render such advice, if written application for such disclosure is made by the patient and endorsed by the attorney.

§ 1401.26 Evaluation in connection with rehabilitation.

(a) Whenever a patient or former patient has been employed or is seeking employment and such employment is conditioned upon his status or progress in a treatment program, an evaluation of such status or progress by qualified medical personnel may be furnished to responsible employment services, agencies, or employers which have demon-

strated their willingness to employ, or assist in the employment of, present or former drug abusers in a drug abuse treatment or rehabilitation program. Such organizations, agencies or employers shall maintain such evaluation as confidential and shall not disclose any part therof to any other person or organization. Any disclosure under this section shall be subject to all of the following conditions:

(1) The request for such an evaluation must be in writing and signed by the patient.

(2) The request must identify the employer (or official therein) cooperating in the patient's rehabilitation program.

(3) The treatment organization must verify the authenticity of the request by telephone or other means of communication and ascertain the extent that the information is need to verify the patient's treatment status.

(4) The information shall be limited to that reasonably necessary in view of the type of employment involved.

(5) No information may be furnished by a treatment organization unless the organization is satisfied on the basis of past experience or other credible information (which may in appropriate cases consist of a written statement by the employer) that such information will be used for the purpose of assisting in the rehabilitation of the patient and not for the purpose of identifying the individual as a patient in order to deny him employment or advancement because of his history of drug abuse.

(b) Information in the nature of a general evaluation of a patient's present or past status in a treatment program may be furnished to members of the patient's family if, in the judgment of a qualified physician or counsellor, such information would be helpful in treatment or rehabilitation of the patient and the patient makes a written request for such information to be furnished.

§ 1401.27 Disclosure for purposes of collecting health or other insurance claims.

A patient who has entered a drug abuse prevention program for diagnosis or treatment may for the purpose of such diagnosis or treatment (including the financing thereof) authorize the disclosure of information contained in his record to the extent necessary to support a claim for payment or reimbursement under a health or other insurance program carried by or in behalf of the patient and under which such patient is a beneficiary or participant. Any such disclosure shall be limited only to information which is directly relevant to, and necessary in support of, a claim for payment or reimbursement under such health or insurance program for the benefit of the patient and any information so disclosed remains subject to all of the restrictions of this part with respect to any further disclosure.

DISCLOSURES WITHOUT COURT AUTHORIZATION AND WITHOUT CONSENT OF PATIENT

§ 1401.41 Disclosure without consent in general.

(a) Disclosure of a patient's records may be made without the consent of the patient and without authority of a court order as follows:

(1) To medical personnel to meet a medical emergency; and

(2) To qualified personnel for purposes of research, audits, or program evaluation.

§ 1401.42 Medical emergency.

Disclosure to medical personnel, either private or governmental, is authorized without the consent of a patient only when necessary to meet a bona fide medical emergency and only to the extent necessary to meet such emergency. For the purposes of this section a bona fide emergency may be considered to exist whenever competent medical authority has determined that the life or health of the patient involved may be impaired and medical treatment without the record could be detrimental to the patient's health. Where, for example, a person is incarcerated and claims to be a patient in a methadone treatment program, this claim may be verified by inquiry to the treatment center administering the program or to a registry such as is referred to in § 1401.43 in order to avoid overdose on the one hand, or the danger of untreated withdrawal on the other.

§ 1401.43 Records maintained in connection with chemotherapeutic treatment.

The communication of information relating to patient identity and dosage between or among programs approved by the Commissioner of Food and Drugs pursuant to § 130.44 of this title, or between such programs and a registry serving them, shall not be considered as a disclosure in violation of section 408(a) of the Act (21 U.S.C. 1175(a)), but any such information received by any such registry shall be fully subject to section 408 of the Act and to the provisions of this part.

§ 1401.44 Research, udits, and program evaluation.

(a) Disclosure without consent is authorized to qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner. Information so obtained may be used in enforcing lawful requirements imposed with respect to the operation of treatment programs employing controlled substances, but section 408(c) of the Act (21 U.S.C. 1175(c)) specifically prohibits the use of patient records to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient, except as authorized under a court order granted under section 408(b)(2)(C) (21 U.S.C. 1175(b)(2)(C)). As used in this section, the term "qualified personnel" means persons whose training and experience are appropriate to the nature of the work in which they are engaged, and who are performing such work with adequate administrative safeguards against unauthorized disclosures.

CRIMINAL PENALTIES

§ 1401.51 Penalty for unauthorized disclosure.

Subsection (e) of section 408 of the Act (21 U.S.C. 1175) provides that except as authorized under subsection (b) of that section, any person who discloses the contents of any record referred to in subsection (a) of that section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

INTERPRETATION OF SECTION 408(b)(2)(C) IN RELATION TO OTHER LAWS

§ 1401.61 Relationship of section 408(b)(2)(C) to other provisions of section 408 and to other legislation generally.

Section 408(b)(2)(C) of the Act (21 U.S.C. 1175(b)(2)(C)) empowers the courts, in appropriate circumstances, to authorize disclosures which would otherwise be prohibited by section 408(a). Both the positioning of this authority in the bill as initially passed by the Senate and the explicit crossreference in section 408(a) of the final Act make clear the congressional intent that section 408(b)(2)(C) operate as a mechanism for the relief of the 408(a) strictures and not as an affirmative grant of jurisdiction to authorize disclosures prohibited by other provisions of law, whether Federal or State. By the same token, it should be noted that the authority which section 408(b)(2)(C) of the Act (21 U.S.C. 1175(b)(2)(C)) confers on courts to issue orders authorizing the disclosure of records applies only to records referred to in section 408(a) (21 U.S.C. 1175(a))—that is, the records maintained by operating treatment or research programs, and not to secondary records generated by the disclosure of the 408(a) records to researchers, auditors, or evaluators pursuant to section 408(b)(2)(B).

§ 1401.62 Scope of orders; relationship to confidentiality provisions of Public Law 91-513.

(a) It is abundantly clear that section 408(b)(2)(C) was not intended to confer jurisdiction on any court to compel disclosure of any information, but solely to authorize such disclosure. An order or provision of an order based on some other authority, or a subpoena, or other appropriate legal process, is required to compel disclosure. To illustrate, if a person who maintains records subject to section 408(a) of the Act is merely requested, or is even served with a subpoena, to disclose information contained therein which is a type whose disclosure is not authorized under section 408 of the Act or any of the foregoing provisions of this part, he must refuse such a request unless, and until, an order is issued under section 408(b)(2)(C). Such an order could authorize, but could not, of its own force, require disclosure. If there were no subpena or other compulsory process, the custodian of the records would have the discretion as to whether to disclose the information sought unless and until disclosure were ordered by means of appropriate legal process, the authority for which would have to be found in some source other than section 408 of the Act. This result is compelled by the language of section 408(b)(2) itself. The words used, "the content of such record may be disclosed * * * if authorized by an appropriate order" are too explicit and too well established as words of art to be interpreted as meaning "the content of such record shall be disclosed if required by an appropriate order."

(b)(1) This interpretation of the permissible scope of a 408(b)(2)(C) order is not only appropriate in the light of the purposes, language, and legislative history of the Act in which it appears, but also is necessary in order to harmonize that section with other legislation dealing with a narrower aspect of the same subject matter. By sections 3(a) and 502(c) of the Comprehensive Drug Abuse Control and Treatment Act of 1970 (42 U.S.C. 242a(a); 21 U.S.C. 872(c)), Congress conferred on the Secretary of Health, Education, and Welfare and on the Attorney General, respectively, power to authorize persons engaged in drug research to withhold names and other identifying characteristics of persons who are the subject of such research, and expressly provided that when such authority has been obtained, its holder may not be compelled to disclose identifying information "in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings * * *"

(2) If section 408 of the 1972 Act were to be interpreted as an independent grant of authority to compel testimony, it would obviously be in direct conflict with the provisions of the 1970 Act discussed above. This becomes significant, for example, in the case of methadone, which for the purpose of treating opiate addiction on a longer-range basis is classified as an experimental drug which may not be administered except in connection with research. Nothing in either the language or the legislative history of the Act indicates any intent on the part of Congress to amend the provisions of the 1970 Act or to reduce the protection which can be afforded under them. Since the language of section 408 permits, if it does not require, a construction which harmonizes with the 1970 Act, it clearly should not be construed to authorize a court order in derogation of any exercise of the authority of the Secretary of Health, Education, and Welfare under section 242a(a) of title 42, United States Code, or the Attorney General under section 872(c) of title 21, United States Code.

INTERPRETATIVE GUIDELINES FOR APPLICATIONS AND ORDERS UNDER SECTION 408(b)(2)(C)

§ 1401.71 Applications for orders should be restricted to records of specified patients.

Section 408(b)(2)(C) empowers courts of competent jurisdiction to authorize disclosure only on a showing of good cause. That section expressly provides that in assessing whether good cause exists, the court must weight the public interest and the need for disclosure against the injury (a) to the patient, (b) to the physician-patient relationship, and (c) to the treatment services. Because these factors can only be weighted with respect to the particular patient involved, any application for such an order should relate only to the records (or a part thereof) of a specific patient and should include an identification of the patient and an indication whether the application is being made with or without his consent. This conclusion is buttressed by the form of section 408, which appears to have been deliberately cast in terms of the individual patient, e.g. section 408(b)(1), "If the patient * * * gives his written consent * * *." and 408(b)(2), "If the patient * * * does not give his written consent * * *", suggesting an intention that the disclosure order be limited to the records of a particular patient who either did or did not consent to the disclosure.

§ 1401.72 Information which should be furnished in support of application.

In those cases in which an application is not made by or with the consent of the patient, or is not joined in or consented to by the person or organization responsible for the records to which it relates, the Act implicitly requires that such application be supported by adequate information to enable the court to make the following findings:

(a) The nature of the public interest that would be served by granting the application;

(b) Any actual or potential injury, either economic or social, that could result to the patient or to the relationship of the patient to his physician;

(c) The effect that an order of disclosure would have on the administration of the drug-abuse prevention program; and

(d) A clear showing that the interests of the public are substantial in relation to possible injury to the patient or to the patient-physician relationship.

§ 1401.73 Suggested safeguards against unnecessary disclosures.

Section 408(b)(2)(C) implicitly negatives any court order requiring unlimited disclosure when limited disclosure would serve the purpose. It states that "in determining the extent to which any disclosure of all or any part of any record is necessary," the court is required to impose appropriate safeguards against unauthorized disclosure. To facilitate compliance with this requirement, it would be within the intent and spirit of this provision of section 408 that any such court order:

(a) Limit disclosure to those parts of the patient's record deemed essential to fulfill the objective for which the order was granted;

(b) Limit disclosure to those persons whose need for the information is the basis for the order;

(c) Require, where appropriate, that all information disclosed be held in camera; and

(d) Include any other appropriate measures to keep disclosure to a minimum, consistent with the protection of the patient, the physician-patient relationship and the administration of the drug abuse prevention program.

[FR Doc.73-25965 Filed 12-5-73;8:45 am]

Exhibit 10

Sample Counseling Notes

Date	Notes
11/29/72 Admission Note	Jane C. Doe, a 33 year-old black female was admitted to Clinic Q for methadone maintenance. This member states that she has been abusing heroin since 1964 and has attempted to detoxify in several programs in New York City. She has recently moved here with her husband and two small children because her husband was offered a better job. Ms. Doe was arrested last week for possession of a small amount of heroin and is out on bond. She states that she planned to seek treatment anyway but admits that she and her attorney feel being in treatment will help her case. Since her prior attempts at detoxification failed, Ms. Doe feels that she needs maintenance and seems to have a good understanding of this treatment. Spent 40 minutes with Ms. Doe. James Harris
11/30/72 Treatment Plan	Ms. Doe will be reporting to the clinic six days a week for medication and will give a urine specimen weekly. I have told her to see me daily when she reports for medication. This member scems very anxious to succeed in treatment and has agreed to this schedule. Spent 30 minutes with Ms. Doe. James Harris
12/4/72 Description of an average counseling session	Ms. Doe reported for medication today and appeared very upset. She talked with Mr. Smith, the nurse on duty and stated that her husband wants her to discontinue treatment. Mr. Doe wants his wife to be drug-free and fears that she will never achieve this state if she continues on methadone. Mr. Doe has no history of drug abuse. I requested that Ms. Doe bring her husband to see me before she leaves treatment. She stated that she will come with him on 12/8/72 at 3 p.m. Spent 30 minutes with Ms. Doe. James Harris
12/8/72 Counseling done by other staff	I did not see Ms. Doe yesterday as she reported to the clinic in the evening for medication, but I was informed by Ms. Landry (counselor) that she remains very upset about her husband's attitude. Ms. Landry spent 20 minutes with Ms. Doe. I will see her and her husband this afternoon. James Harris
12/8/72 5 p.m. Description of an average counseling session	Ms. Doe and her husband came to the clinic at 3:30 p.m. In talking with Mr. Doe it became evident that he had many misconceptions about methadone maintenance. I explained this modality to him and he was very relieved to discover that it did not mean lifetime maintenance. He agreed to support his wife in her treatment attempt and to wait for her to decide when she is ready for withdrawal. Mr. Doe's greatest concern seems to be his wife's ability to care for their two small children. He feels she had neglected them while using heroin and has seen no improvement in her care since she started treatment. Ms. Doe admitted that this is the first day she has not used illegal drugs since she began treatment but that she plans to remain clean and feels she can give her children the care they need if she

does. Mr. Doe has my phone number and was told that if he has any further concerns about his wife to call me. Spent 1 1/2 hours with Mr. and Ms. Doe.

James Harris

12/13/72

Medication change

Ms. Doe requested a decrease in medication today because she gets tired very easily. Mr. Smith, the nurse, scheduled an appointment for her to see Dr. Jones with me on 12/15/72 at 10 a.m. I asked Ms. Doe if she is trying to withdraw on her own. She assured me that she is not, that she does not feel ready to. Spent 20 minutes with Ms. Doe.

James Harris

12/15/72

Break in Schedule

I saw Dr. Jones with Ms. Doe today. He agreed to decrease her dose as this could be the cause of her fatigue. Dr. Jones ordered a decrease of 5 mg. from 30 mg. to 25 mg. Ms. Doe and I then discussed her absence from the clinic yesterday. She stated that she was unable to find anyone to care for her children—she expected her husband to be home but he had to work late. This is the first day she has missed. Spent 30 minutes with Ms. Doe.

James Harris

12/21/72

Ms. Doe did not give a urine specimen today as scheduled. She stated that she forgot and voided before coming to the clinic. Considering the patient's recent request for decrease and the fact that she missed her medication on Tuesday, I suspect she may be using drugs again. She denies this. I have asked the nurses to withhold her medication until she gives a specimen. Spent 45 minutes with Ms. Doe.

James Harris

12/29/72

Monthly Summary

Ms. Doe has been in treatment for 30 days and remains on methadone maintenance at 25 mg. daily. Her urines, with the exception of the first two, have been clean. She gives no appearance of abusing any drugs including alcohol. The preliminary hearing on her case for possession of heroin is scheduled for 2/1/73. She has no other cases pending.

Ms. Doe spends all of her time with her children except when she comes to the clinic. A neighbor cares for them during that time because Mr. Doe does not want them in the clinic. Ms. Doe states that she feels she is making up to her children for her prior neglect. I feel that she is making good progress but will make no changes in her treatment plan at this time.

James Harris

1/3/73

Referral

Ms. Doe states that she would like to find a job as she and her husband would like to buy a house but need extra income to do so. Ms. Doe took some typing courses in high school but has not used this skill since she graduated. She is interested in getting secretarial training. Ms. Doe has been meeting the requirements of this program and in my opinion is stabilized enough to be considered for training. I contacted Mr. Henry at the New Careers program and he agreed to see Ms. Doe on 1/7/73 at 11:30 a.m. Spent 1 hour with Ms. Doe.

James Harris

1/8/73

Results of Referral Follow-up

I called Mr. Henry this morning. He saw Ms. Doe yesterday and agrees that she seems a good candidate for secretarial training. She begins testing tomorrow.

James Harris

Exhibit 11

Sample Medical Notes

11/29/72	Jane C. Doe, a 33 year-old black female, was admitted to Q Clinic for methadone maintenance. This member states that she has been abusing heroin since 1965 and has attempted to detoxify in several programs in New York City. Ms Doe states that she has been receiving treatment for Hodgkins Disease from a private physician here. She is presently receiving 30 mg. of methadone daily.
	J. Peters, LPN
12/3/72	City Hospital today notified the program of a partially calcified density in the left lower lung of Jane C. Doe found on her admission physical x-ray. Will schedule her to see Dr. Jones on 12/5/72.
	T. Smith, R.N.
12/4/72	Ms. Doe appeared very agitated and had obviously been crying when she reported to the clinic today. In talking with her, I learned that her husband is very upset about her decision to be on methadone maintenance. He wants her to be drug-free and fears that if she continues receiving methadone her chances of achieving this state are nil. Ms. Doe and I then discussed this problem with her counselor, James Harris, and made an appointment for her and her husband to see Mr. Harris before making any changes in her methadone regime. The appointment is scheduled for 12/8/72 at 3 p.m.
	J. Peters, LPN
12/5/72	Ms. Doe was seen by me regarding abnormal chest x-ray. To be scheduled for repeat x-ray. Reviewed treatment she has been receiving from her private physician, Samuel Knox, for Hodgkins Disease. Client will be seen again after receipt of repeat x-ray report. To be done by Dr. Knox.
	P. Jones, M.D.
12/7/72	Dr. Knox, Ms. Doe's private physician, did a repeat chest x-ray which revealed inflammation in the left lower lung. Dr. Knox has started Ms. Dow on tetracycline, 250 mg. qid.
	P. Jones, M.D.
12/13/72	Ms. Doe requested a decrease in medication today as she is constantly fatigued. Scheduled to see Dr. Jones with her counselor on 12/15/72 at 10 a.m.
	J. Peters, LPN

12/15/72	Ms. Doe did not report to the clinic for her medication yesterday. Her counselor, James Harris, was notified.
	T. Smith, R.N.
12/15/72	Saw Ms. Doe today regarding the above request, and will decrease her methadone from 30 mg. to 25 mg. daily as this may be the cause of her fatigue.
	P. Jones, M.D.
1/17/73	Ms. Doe was scheduled today for her post antibiotic therapy check-up on 1/21/73, at 10 a.m. She was given the appointment form and stated that she will be available at that time.
	J. Peters, LPN
1/21/73	Ms. Doe has completed her antibiotic therapy. Lungs sound clear. States she is comfortable on her present methadone dose (25 mg.). Will continue on this dose.
	P. Jones, M.D.

Exhibit 12

Sample Medication Sheet

MEDICATION SHEET

Allergic to:

CODE

A—Absent	Daily—8 A.M.	Blue Ink—7 AM-11 PM
R—Refused	B.I.D.—8-8	Red Ink—11 PM-7 AM
X—Discontinued	T.I.D.—8-2-8	
O—Unable to Swallow	Q.I.D.—8-12-4-8	

Order Date	Disc. Date	Medication	Hr.	Dates Given							

Last Name First Name Ward Year

PATIENT: ______________________________

PHYSICIAN'S ORDER SHEET

Name: Doe, Jane C. ID #: 1234

Age: 33 Sex: Female Clinic: Q

DATE	MEDICINES, THERAPIES, ETC.	DATE TO BE D/C.
11/29/72	Methadone, 30 mg. po daily	
	P. Jones, M.D.	
12/3/72	Schedule repeat chest x-ray, pa and lateral	
	P. Jones, M.D.	
1/29/73	Continue methadone 30 mg. po daily	
	P. Jones, M.D.	
3/6/73	Begin 3 day weekly pick-up schedule.	
	To report to clinic M-W-F	
	P. Jones, M.D.	

MSC:
(5/73)

Exhibit 13

Special Methadone Problems (Pregnancy, Alcohol, Overdose)

A. *Special Methadone Problems*

1. *Pregnancy*

Pregnant, narcotic addicted women and their offspring constitute a serious health and life-risk group within the addicted population. Many of these women suffer medical and obstetrical complications due to both their addiction and the effect this has in drawing their attention away from concern for their health, nutrition, prenatal care, psycho-social needs and responsibility toward their expected infants. Their babies, like those of untreated heroin addicts, often suffer the consequences of their mother's neglected environment and growth. While some suffer more severe neonatal withdrawal, many are faced with uncertain care and unstable home environments. Many addicted mothers are unable to cope with their babies, whom they describe as "irritable, hyperactive, and demanding." The emotional problems which can complicate these pregnancies, especially anxiety and depression, are often aggravated after childbirth and may require weeks or months of intensive therapy and/or assistance (including provision of visiting nurses, homemakers, etc.). It should be the aim of drug treatment centers to secure the early identification of all pregnant addicts both upon intake and during the course of treatment. While this is the responsibility of both staff and client, it is primarily the *counselors'* responsibility to identify their pregnant patients and arrange for a comprehensive range of services if the client does not have them available to her. Staff should be aware, too, that exceptions may be obtained for pregnant women in terms of meeting FDA eligibility for methadone maintenance treatment (See Summary for procedure).

Some programs have established separate treatment units for their pregnant clients. Others assign all pregnant clients to one counselor so that continuity of care is maximized. In other instances, programs have cooperative agreements with hospitals so that maternity staff are conscientious regarding specific needs when clients are admitted for delivery. If indicated, the child's father should be intimately involved in all facets of the client's treatment.

Specialized care appears very beneficial for pregnant clients and is best obtained in a centralized location. Total involvement in these specialized units focuses on the pregnant (or recently delivered) mother, and her treatment needs are met by a competent team. Even in cases, however, where centralized treatment is not feasible, specific management principles should be adopted. Prior to delivery, dosages should be slowly decreased to the lowest possible amount which still permits comfort yet avoids withdrawal symptoms. Rapid detox is contraindicated, since this may prove harmful to mother and fetus. In some instances, complete detoxification will be achieved. Excercise classes and seminars on caring for the expected baby are helpful during pregnancy; these prepare the mother to cope with the stress of labor and delivery and caring for the newborn.

During the post-partum period, homemakers' and visiting nurses' services may be indicated. These should be arranged for by the counselor if the client is unable to procure them for herself. Staff should be alert for signs of post-partum depression and should be trained in ways of dealing with it. Special attention should be given to the mother's relationship with her new infant since this may be an indication of her emotional stability at this time.

A description of any newborn who is premature or has any adverse reactions due to methadone within one month of birth should be forwarded to the FDA on FD-1639, "Drug Experience Report."

2. *Alcohol*

Alcohol can be dangerous to the client receiving methadone if it is used to excess, and the medical staff should be on the alert to notice inebriated clients. In such an instance, the counselor should explain to the client that he cannot receive medication under such conditions. The reasons should be clearly and simply explained to the client: continuous intravenous heroin injection of impure substances generally causes changes in the liver of narcotics addicts. When one drinks, alcohol causes even more detrimental effects on the liver. Metabolism of methadone occurs in the liver, and constant consumption of alcohol causes further deterioration of the liver. Consequently, daily doses of methadone may be improperly metabolized by a malfunctioning liver, not be excreted, built up in the system, and result in a clinical overdose. If a client is receiving take-home privileges and shows evidence of compulsive alcohol abuse, the take-home privilege

should be removed immediately and the client returned to daily visits to the clinic. If the problem becomes extremely severe, the counselor should consider referring the patient to an alcoholism center as adjunctive treatment.

Heroin addicts, and many other people, think of alcohol as relatively non-harmful. Also, as clients begin to change their life styles, they find a good deal of idle time. Alcohol then becomes a vehicle for filling this time. Alcoholism is a very serious and often fatal medical disease, and daily contacts with clients should be used to prevent this disease wherever possible. Clients should never be encouraged to drink, even moderately; for them, alcohol is a dangerous drug and a destructive way to deal with problems.

3. *Overdose*

Medical directors of programs which dispense methadone should be aware of the treatment of overdose and should attempt to educate hospital emergency room officials regarding this treatment. Perhaps the single most important point in this regard is the difference between methadone and heroin overdoses. In the early days of methadone treatment, several deaths occurred because physicians were not aware of this. The essential difference between a heroin and methadone overdose is reflected in the prolonged duration of the action of methadone. Treatment, then, must consist of appropriate response to the specific drug action, not only to the fact of overdose.

a. *Overdose in General*

In beginning the treatment of any overdose, the patient should have an adequate airway maintained and should be hospitalized as soon as possible. Initial treatment may begin on the way to the hospital.

b. *Methadone Overdose*

If a patient is comatose or semi-comatose as a result of methadone ingestion, an initial intravenous injection of 0.4 milligrams of naloxone hydrochloride (narcan) should immediately be administered. If no improvement in respiratory function is seen within two to three minutes, the injection *should be repeated*. It is suggested that the methadone overdose victim have his respiration and level of consciousness monitored for up to 48 hours after his initial response. If the desired improvement is noted, the physician must remain aware that the duration of action of naloxone is shorter than that of methadone. If the patient is left unattended, he may lapse into unconsciousness several hours later.

c. *Heroin Overdose*

In the case of a heroin overdose, an initial intravenous injection of 0.4 milligrams of naloxone hydrochloride (narcan) should be administered immediately. Since the duration of action of heroin is about the same as for naloxone, the client will usually respond to this injection and, generally, no other treatment is necessary.

d. *Choice of Medication*

Naloxone is preferable to nalline which was used formerly because of the absence of depressant effects. This is important particularly if the diagnosis was in error and the overdose was the result of another class of drugs such as barbiturates or a mixture of drugs. In that event, nalline's antagonistic effects may be additive to the effect of the other depressant while naloxone would have no effect.

e. *Reporting Requirement*

Should death result from a methadone overdose or appear to be methadone-related, in any way, it must be reported to the FDA within two weeks on FD-1639, "Drug Experience Report."

f. *Other Measures*

In addition to the procedures described above, the clinic's medical director should determine what emergency medical equipment and supplies are needed in the clinic, itself, in order to respond to emergencies which might occur there.

Exhibit 14

Sample Intake Form

CENTRAL MEDICAL INTAKE FORM
Patient Routing Card

Patient name:_____ I.D. #_____

CMI Counselor _____ CMI Date_____

☐Voluntary ☐CJS ☐Transfer_____

☐Complete New or Re	☐Partial Re	☐Annual P.E.
☐Clerk	☐Clerk	☐Clerk
☐Blood	☐Urine (drugs)	☐Blood
☐Urine (Complete)	☐Rx update	☐Urine (Medical)
☐Medical Rx	☐P.E. update	☐Medical Rx
☐Chest X-ray	☐Other_____	☐Chest X-ray
☐Physical exam	_____	☐Physical exam
☐Footprint	_____	☐Footprint
☐Interview	☐Interview	☐Interview
☐I.D. Card	☐I.D. File	☐I.D. File
Rec. Rx_____	Rec. Rx_____	Center_____
Center_____	Center_____	Time Out _____
Time Out _____	Time Out_____	

Comments_____

_____

Patient Name_____ Client No._____

How many times have you been hospitalized_____
For more than 24 hours (include all operations, OB & GYN)_____

Name Hospital_____ Date_____ Disease_____
Name Hospital_____ Date_____ Disease_____
Name Hospital_____ Date_____ Disease_____
Name Hospital_____ Date_____ Disease_____

Indicate Health Status: Excellent_____ Good_____ Fair_____ Poor_____

Name of personal physician or clinic_____
Address_____ Telephone_____
Medicaid No._____ Card Color_____
Hospitalization No._____

HAVE YOU RECENTLY:

Yes	No	
___	___	Had a sore tongue
___	___	Had "fever sores"
___	___	Had difficulty swallowing
___	___	Had excessive gas
___	___	Had abdominal pain
___	___	Been constipated often
___	___	Had diarrhea frequently
___	___	Had blood in your bowel movements
___	___	Had black bowel movements
___	___	Had light gray or white bowel movements
___	___	Had burning or discomfort when you urinate
___	___	Had very dark (green-brown) urine
___	___	Had stiffness, swelling or pain in your joints
___	___	Had frequent or severe headaches
___	___	Had persistent numbness or weakness any place in your body
___	___	Had dizziness or light-headedness
___	___	Had unsteadiness in walking or balance
___	___	Had difficulty falling or staying asleep
___	___	Felt tired after having enough sleep
___	___	Had difficulty trying to remember things
___	___	Had difficulty remaining awake during usual waking hours
___	___	Felt excessively tired or weak
___	___	Had any trouble with skin sores
___	___	Had excessive itching
___	___	Gained or lost 5 pounds of weight or more
___	___	Had any chills or fever
___	___	Had any difficulty with your vision
___	___	Been troubled with double vision
___	___	Had a buzzing or ringing in your ears
___	___	Had severe nose bleeds
___	___	Had difficulty breathing through either side of your nose

Patient Name _____ Client No. _____

HAVE YOU RECENTLY (continued)

Yes	No	
___	___	Had any hoarseness
___	___	Had a bad cough
___	___	Had night sweats
___	___	Felt short of breath easily
___	___	Noticed anything unusual about your heart beat
___	___	Had pain in your chest
___	___	Had hand swell
___	___	Had cramps while walking
___	___	Had a loss of appetite
___	___	Had nausea or vomiting
___	___	Had bleeding gums
___	___	Do you have unusual thirst or hunger
___	___	Had feet or ankles swell

Yes	No	Don't Know	
___	___	_____	Are you very shy or sensitive
___	___	_____	Are your feelings easily hurt
___	___	_____	Are you easily restless
___	___	_____	Are you nervous or "keyed up" most of the time
___	___	_____	Is it difficult for you to relax
___	___	_____	Are you easily irritated and upset
___	___	_____	Are you often depressed or blue
___	___	_____	Do you cry easily
___	___	_____	Do you have any unusual fears
___	___	_____	Have you had nightmares
___	___	_____	Do you worry very much
___	___	_____	Do you regard yourself as being nervous
___	___	_____	Have you ever been examined or treated for a nervous illness
___	___	_____	Have you ever had a nervous breakdown
___	___	_____	Are there any sexual matters or difficulties you would like to discuss
___	___	_____	Have you been married more than once
___	___	_____	Do you have any work problems which produce emotional stress
___	___	_____	Do you enjoy school work
___	___	_____	Do you enjoy on-job-training

I hereby give my consent for the following:

1. A physical examination
2. A blood test for blood chemistries and syphilis
3. Urinalysis to screen for abnormalities and drug content
4. Chest X-ray
5. Pregnancy test (female only)

I also understand that if my syphilis test or X-ray indicate the presence of communicable disease, the results will be released to the Department of Public Health for further confidential follow-up.

_____
Signature and Date

MEDICAL HISTORY REPORT FORM

Patient Name:________________________ Client No. ____________

YES	NO	HAVE YOU EVER HAD:
____	____	Anemia or Blood Disease (Sickle Cell Disease)
____	____	Cancers or Tumors
____	____	Rheumatic Fever
____	____	Heart Disease
____	____	Varicose Veins
____	____	Phlebitis or Infected Veins
____	____	Tuberculosis
____	____	Pneumonia or Pleurisy
____	____	Asthma
____	____	Hay Fever
____	____	Sinus Trouble
____	____	Allergy to Drugs or Foods
____	____	Hives
____	____	Dermatitis or Skin Disease
____	____	Eye Infection
____	____	Blindness
____	____	Color Blindness
____	____	Deafness or hearing loss
____	____	Seizure disorders or epilepsy
____	____	Severe back disease
____	____	Arthritis or Joint Disease
____	____	Stomach ulcers or ulcer disease
____	____	Gall bladder disease
____	____	Diabetes
____	____	Thyroid disease
____	____	Syphilis - date__________ Where treated__________
____	____	Gonorrhea
____	____	Hepatitis
____	____	Hypertension or High Blood Pressure
____	____	Malaria
____	____	Kidney disease
____	____	Typhoid fever
____	____	Gout
____	____	Hemorrhoid

What other diseases not on this list have you had:

1.____________________
2.____________________
3.____________________
4.____________________

When did you have your last regular physical examination____________
When did you last see your dentist____________
Where are your most recent medical records____________
Are your teeth in good repair currently____________
Do you wear eye glasses or contact lenses ____________
Do you need new eye glasses____________

FOR FEMALES ONLY

Patient Name:________________________ Client No. ____________

Age of your first period____________
Is your period regular____________
Period occurs every____________
Usual flow: Normal________ Heavy________ Light________
Has there been an: Increase ( ) Decrease ( ) in flow recently
Date of last normal period____________
Are you tensed or irritable before or during periods____________
Have you, within the past year, had vaginal bleeding other than at the time of your period________
Are you or do you think you are pregnant____________
Age of first pregnancy________ Number of living children________
Date of Birth____________
How many Abortions______ Dates______ Miscarriages______ Dates______
Stillbirth______ Dates______
Do you feel you have an unusual amount of vaginal discharge or itching________
Note: If you have ever been treated for a female disorder or been told you had any trouble with your female organs list here____________
Do you have hot flashes____________
Have your breasts recently changed in size____________
Have you recently had any breast discharge____________
When was your last pelvic (GYN or Vaginal) examination____________
Are you on birth control pills____________
What kind of pill________ How long________

* *

PROGRAM ON METHADONE IN MOTHERS AND INFANTS

Patient Name:____________ Referred by____________
ID No.____________ Date of referral____________
Date of Birth________ Marital status ( ) M ( ) D ( ) Sep. ( ) W ( ) S
Address____________ with whom living____________
Telephone: Home________ Work________
For Emergency Contact____________ Name ____________ Phone
Employment current ( ) Yes ( ) No Date begun________
Highest grade completed________ Medicaid ( ) Yes ( ) No ( ) Eligible
Other Insurance____________
Length Heroin use______ length present habit______ other drug use______
____
clinic patient attends____________
Counselor____________ Nurse____________
Treatment received: Meth. Maint.______ Detox______ Other______
Date Rx begun________ ended________
Prenatal care at clinic______ Hospital______ Private______ Name
None________ Date begun________
Patient to deliver at____________
Expected date of confinement____________
Referred to____________

Exhibit 15

Useful References

Useful References

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