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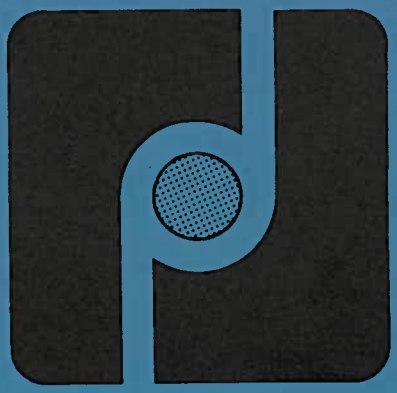

RESIDENTIAL METHADONE TREATMENT MANUAL

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

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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 actual implementation phase of a Residential Methadone program. The concept of the residential methadone program, its goals, treatment plans, and methods of operation, are described in this Monograph with specific implementation guidelines.

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

Robert L. DuPont, M.D.
Director

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I Introduction

Residential methadone programs may be characterized as short-term highly structured treatment regimens for that segment of the addict population having particular difficulty with methadone stabilization or detoxification. Through intensive counseling, support, and supervision, residential methadone programs provide a therapeutic regimen that is oriented toward consideration of individual needs. Moreover, the residential setting facilitates 24-hour clinical observation of clients' reactions to methadone. Geared for rapid turnover, residential methadone programs have as their treatment objective two basic goals: to help clients stabilize or detoxify; and to return clients to outpatient maintenance or abstinence programs for continued rehabilitation and reintegration into society.

Once the need for this type of service has been determined, and the decision is made to provide it, some problems may be anticipated before the program is a reality. Ideological opposition, cost, and citizen responsiveness all figure prominently in the initial decision. Once authorization has been obtained and the go-ahead is given, however, responsible officials are then faced with what may prove to be an even more complicated question: how do we implement this kind of program?

The purpose of this manual is to answer that question. It is meant to serve the program administrator as a guide both in early planning stages and in the actual implementation phase.

Essentially, this manual describes a model residential methadone program. For the purposes of this document, it is assumed that the residence 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).

A. What is residential methadone treatment?

Residential methadone treatment, like residential drug-free, provides a structured environment to assist the addict with rehabilitation. But, unlike the drug-free community approach, residential methadone treatment is geared for fairly rapid turnover. Its objective is to stabilize the client on methadone or detoxify him via methadone so that after a period of three to six weeks he can re-establish himself in the community while continuing in an outpatient methadone maintenance or abstinence clinic.

In a residential methadone treatment program, clients live and work together 24 hours a day for a period of three to six weeks. The major therapeutic activities include encounter group therapy, vocational readiness seminars, individual counseling, and family therapy as indicated. Individual vocational counseling is available as needed. Each client has a job assignment which is necessary to program functioning (i.e., housekeeping and food preparation). As soon as possible, each client is enrolled in educational or job training programs or employed.

Persons addicted to opiates who are placed on methadone maintenance often experience physical and emotional problems in the initial treatment period. In most instances, these are problems which existed prior to treatment but which were masked by opiate abuse. For some addicts, the change in life style presents severe problems (e.g., loneliness, boredom, guilt, etc.). Many of these problems can be dealt with by a counselor on an outpatient basis, but there will be some clients who require the intensive support and structure provided by a residential program. Methadone maintenance clients requiring residential care should be referred by their outpatient clinic. Staff at the residential program will then decide if the referred client will be accepted and when return to the referring clinic should occur.

Residential programs are especially useful for clients who are detoxifying. FDA regulations permit the use of methadone for detoxification from heroin for a period not to exceed 21 days. If any change in life style is to be effected during this period, intensive therapy must be available. The residential community provides an ideal environment for this kind of rehabilitation effort. Clients who are to be detoxified may be admitted directly to the residential program or may be referred from an outpatient clinic. For clients in both modalities a stay of about three to six weeks in the residential program should be sufficient.

1. *Methadone Maintenance*

According to FDA regulations, methadone maintenance is the treatment classification for all clients who receive methadone for more than 21 consecutive days. For purposes of clarification, 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.

Methadone itself 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.

Addicts meeting certain eligibility criteria are placed on methadone maintenance and given daily dosages of methadone which relieve "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 this capability, then, which defines the role of methadone maintenance in the treatment of heroin addiction.

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.

Clients opting for the maintenance category should be urged to continue in treatment after leaving the residential program until their life situations have been stabilized for at least six months to a year. Likewise, staff have a responsibility to remind clients that they 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, clients often express 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.

2. *Methadone Detoxification*

Methadone detoxification is the treatment classification for clients receiving decreasing dosages of methadone for a period not exceeding 21 days. Addicts who apply for methadone treatment but do not meet the requirements for maintenance may be detoxified providing they are over 16 and have the proper consent forms signed.

Anyone who detoxifies from methadone maintenance at the residential program should be urged to stay in treatment until he is detoxified and after he has achieved abstinence to return to an outpatient program for a period of approximately three months. During this time, urine testing and counseling should continue.

B. What are the Goals of Residential Methadone Treatment?

Goals described here are general in nature and applicable to all residential methadone treatment programs. In essence, they represent a consensus drawn from other programs' experience to date.

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 clients and that they are capable of measurement.

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

1. *Elimination of Illegal Drug Use.*

Although not every client receiving methadone 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 barbiturates and amphetamines, 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 and should definitely not be permitted in the residence. 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 a Productive and Self-fulfilling Life Style.*

This goal poses the greatest challenge for both clients 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. Attempts to involve clients, especially those

being detoxified, in job training, continued education, or employment must begin on admission if there are to be any concrete results in three to six weeks.

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. Methadone programs bear a responsibility to both clients and the larger community, so redirection from the criminal life style reaps benefits for both.

4. *Stabilization of Clients on Methadone Maintenance*

There will be clients referred to the residential program whose immediate problems (e.g., no visible means of support) so interfere with treatment that resolution of these will be the primary goal of the residential program. This may prove frustrating to staff who perceive the severity of certain deeply-rooted behavioral problems and understand their continuing impact on the client's life. However, since six weeks is suggested for residential rehabilitation, counselors should concentrate on the more immediate, solvable problems, note the others, and communicate those observations to the outpatient counselor who will, hopefully, work with the client over a period of months. Of course, clinical indications for an abbreviated or lengthened residence must be considered.

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 all clients. 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 clients. In that model, methadone was compared to the use of insulin for diabetics and so perceived as a life-saving 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 socially-oriented counseling.

Indeed, current FDA regulations and the Federal Funding Criteria have standardized the approach used in methadone treatment 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; counseling efforts, therefore, are viewed as equal components of the program. Most decisions, then, are made jointly, based on input from both, although the counselor has the authority to make all non-medical decisions.

In this approach, the counselor serves as the primary therapist and the conduit through which clients voice their needs. For example, requests for a change in medication dose, 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 to obtain their input; a 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.

Since the counselor in the residential program will have more contact with his clients than other staff members and will be responsible for most treatment decisions, the choice of qualified staff is imperative.

Professionals experienced in counseling opiate abusers must be hired. These staff members, in addition to their treatment functions, should be used to supervise and train any paraprofessional staff employed.

Because counselors and medical staff work together, paraprofessionals can be supervised more readily in the counseling area since their case management is scrutinized regularly by the medical staff as well as by the counseling supervisor. The team approach by its very nature assures 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.

II Administrator's Guide to Planning

Once the responsible local officials have decided that a residential methadone treatment program 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 helpful in developing a budget, hiring staff, and explaining the program, itself, to interested government and community groups.

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 which 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 well 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 range in cost exists based on the program size. As of January, 1974, a program treating 30 clients in residence cost approximately $151,116. A detailed budget for a program this size is attached to this manual (See Exhibit 4).

It is useful for administrators to remember, though, that personnel costs constitute the single largest budget item (approximately 80% of the budget) and that minimum staff requirements as contained in the FDA regulations will not be sufficient for a residential program. (See Exhibit 6 for sample organizational charts.) However, while flexibility is constrained by necessity in fiscal matters, some play can be found in certain line items and usually that amount will be determined by regional costs for lab fees, rent, etc.

One major cost that administrators should 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, 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, at any time, 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.

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[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 clinics' 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 also be included. The policy manual then should grow out of the weekly staff meeting. 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. This should be convenient to public transportation so that staff are not required to act as chauffers for clients who have job interviews, medical appointments, etc. Often these facilities are located in hospitals; but if this is not planned, a large residence which can be renovated to provide adequate living and working space should be found. The cost and time necessary for renovations must be one of the prime considerations when evaluating sites. Given the length of time in residence, clients cannot be expected to renovate the facility, so administrators should restrict their choice to fairly well-maintained buildings. Such a choice may lead the administrator to an area of the city where zoning may prove a problem. As a first step, then, the administrator should familiarize himself with appropriate zoning ordinances, health, and other housing regulations applicable for joint residential and commercial use. Having done this, the administrator should weigh the pros and cons of locating the program in a high drug area. Although opposition from residents of the high drug area chosen should be expected, it is oftentimes less vociferous and of shorter duration than that from a more solidly middle-class area. It may be, then, the most pragmatic choice for the administrator eager to implement his program.

2. *Space Needs*

If possible, the major operations of the program should exist on one floor (i.e., medical unit, counseling areas, kitchen, and dining room), with the sleeping area on a separate level. Adequate space for group sessions as well as smaller rooms for individual counseling must be available. Group rooms can double as recreation areas for the residents when not in use.

The medical unit 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 can then be easily attributed to a small group. The arrangement of the medical unit must be approved by the Drug Enforcement Administration (DEA) prior to opening the residence.

The physician's office should be separate from the medical unit and accessible through a separate entrance. This is to prevent clients with doctor's appointments from passing through the medical unit.

Separate sleeping areas for male and female clients are necessary. A dormitory arrangement should provide the most bed space for the least cost. It is important, however, that these areas be painted and decorated as attractively as possible. Toilet and shower facilities sufficient for the estimated client census and staff should be adjacent to, or at least located nearby, each dormitory.

The kitchen should be sufficiently large and well-equipped so that meals can be prepared for residents and staff. The dining room should be convenient to the kitchen and large enough to seat everyone for each meal. If this kind of space is not available, meal shifts should be organized.

Because of differing budgets, time deadlines, and site choices, administrators may be compelled to select a facility which 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 cleanliness can make the clinic comfortable for both clients and staff. Crowded and dirty facilities generally breed chaos, but when a residence is well-maintained and orderly, clients respond accordingly.

3. *Security*

Security is a complex issue for staff, clients, and the community because of the fear generated in the community by addicts and because of the clients' mistrust of the police.

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 set-up of the medical unit to assure that the

medication is adequately safeguarded (See Exhibit 5). Since the facility will be occupied at all times, additional security for the building itself will not be necessary; however, any petty cash belonging to the program or funds belonging to residents should be locked in a secure area with limited access. Entrance doors should be locked when the reception area is unattended to prevent entrance by unauthorized outsiders; all visitors should be screened by the receptionist.

D. Community Planning

Because clients live in, residential programs are less visible to the surrounding community than are outpatient programs. However, they usually do not escape notice entirely, so community planning must begin early and continue for the duration of the program. Since many such programs obtain facilities in areas where large homes are being converted into apartments and business establishments, opposition is received from both sectors. Inviting residents of the area to visit the facility and learn about the program often promotes a better understanding on both sides.

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, and Rotarians 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 program 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 of 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, however reluctant, the next step is to let the community-at-large know about the program's existence. If there is, in fact, a demand for treatment, clients will come, initially, through the "grapevine." But administrators should not rely on this alone. In the beginning stages, the administrator should embark on a vigorous campaign directed towards the courts, social service agencies, schools, and churches to establish channels for client referral. Meetings with judges and parole and probation officers involving an explanation of the program's goals and objectives and a tour of the proposed facilities serve a dual purpose; they involve them 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 can assist the program in establishing inroads to those health and welfare services which are potentially valuable to its clients.

When a program is fully functioning, additional steps can be taken to re-enforce 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 about the younger addict. Combined support from both the school and the residential program is often-times very helpful in dealing with the adolescent addict.

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

The point behind these suggestions is to emphasize the necessity of enlisting community support from the outset by involving those individuals who influence community attitudes. Residential methadone treatment programs cannot remain aloof 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, however, recruiting strategies must be developed; qualifications must be considered; training needs must be continuously assessed and reassessed; and the role 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).

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. Ideally, non-live-in counseling staff should rotate shifts and weekends so that continuity of treatment can be maintained. All staff should be aware of, and accountable for, total program activities.

Choosing staff for residential methadone treatment 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.

Many programs believe it is therapeutically sound to hire ex-addicts into counselor positions since they offer a desirable role model. Unfortunately, programs often accept the first street-wise ex-addict interviewed and have 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 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 in this regard. 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? Has he had any experience with therapeutic communities or other structured group environments exclusive of those within a penitentiary setting? The administrator will probably want to select at least one ex-addict counselor with this background. Usually, ex-addicts are fairly glib and can handle a verbal interview skillfully. However,

effective counseling requires good recordkeeping skills, as well, so the administrator should request a written sample progress note and insure that the report is, in fact, written by the candidate.

In outpatient methadone clinics, the frustrations and adjustment problems of staff (particularly ex-addict staff) are usually handled patiently and sympathetically. However, in a residential methadone program, manifestations of all staff problems must be minimal. In the residential program, staff are highly visible as role models. Residential methadone clients need strong examples and are not secure enough to tolerate behavioral defects in the staff with whom they identify. Secondly, although the stay is short-term, tension is high because of the communal living arrangement. Withstanding the pressure generated by the residents requires a healthy ego and informed sense of self. Although new recruits may have potential as counselors, maladjustments and personal problems exhibited on-the-job should not be tolerated. Administrators must demand a consistently high level of performance and commitment from methadone residential staff.

Administrators should, likewise, be aware of certain problems which have been common to professional staff in regard to their job performance. With his qualifications, the professional may bring a superior attitude related to 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 program duties such as urine surveillance and rotating shifts may be unacceptable to professional staff members and lead to their refusal to perform them. This situation may pose a dilemma for the administrator and prejudice him against 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, and those opting to take the position do so aware of the full range of their responsibilities (i.e., urine surveillance, providing urine specimens, rotating shifts and weekends).

Hiring medical staff may also pose a problem. Many medical professionals are not used to working in concert with non-medical staff. Again, a clear explanation of the job and the philosophy of the program are indispensable if later misunderstanding is to be avoided (e.g., program policy regarding the prescribing of psychotropics must be adhered to by the physician).

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 a residential methadone treatment 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 involved in each job as well as their relative position in the clinic. The following is a brief overview of each units' 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*

All clients entering treatment must receive, or have recently had, a complete physical examination (administrators should seriously consider contracting out for physicals). Blood tests and a chest x-ray as specified by Federal regulations must be included as well as routine and microscopic urinalysis and urine screening for drugs (toxicology) as specified in the Federal Funding Criteria. The residence doctor should read and initial all physical examination reports from the intake examination and make the appropriate referrals. He is responsible for making sure that clients' medical needs are periodically reviewed and that clients receive adequate medical treatment for any illness or chronic physical problems. Again, if clients receive any prescription medicine as part of treatment, they must be seen by the physician at least once every four weeks.

In addition, the duties of the medical staff consist of prescribing medication and schedules (doctor), preparing and dispensing all medication (nurses), and observing patients for any medically-related problems (entire unit). In the latter case, the counselor should be immediately informed. The doctor should be available (by phone if not in person) to handle any medical problems requiring his attention, and the nurses may be responsible for medically-related training of other staff (side effects of methadone, etc.).

b. *Counseling Unit*

Each client entering treatment should be assigned a primary counselor who will be responsible for developing a treatment plan, making revisions in this plan as indicated, and monitoring and recording the client's progress. Other counselors will be involved in the client's treatment and should be included in the planning process as well, since they will be leading groups and supervising activities involving all clients.

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 as well as participate in hiring and evaluating counselors.

In a residential methadone community, the counselors bear the primary responsibility for client care. They arrange the clients' daily schedule, provide individual counseling, as indicated, conduct or set up group therapy sessions, and initiate referrals for extra-clinic services (e.g., public assistance, vocational rehabilitation testing).

Administrators should be aware that the Federal Funding Criteria require that a minimum of 10 hours per week of formalized counseling shall be available for each client. This means that counselors must be responsive to clients' needs for such service, if indicated, based on the treatment plan. Of course, some clients may need more or less than the 10 hours per week. This determination will be made by the counselor, based on input from the team. In addition, at least 5 hours per week of psychiatric consultation per 100 clients must be provided so that staff receive assistance in client management and referral for psychiatric services.

3. *Training*

Training is an on-going need in residential methadone programs and is essential if quality care is to be provided. Training can 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 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 is didactic in purpose and involves the presentation of clear information about addict behavior, methadone, and residence procedures and how they relate 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 re-enforced through role-playing and sample situations. Examples of some useful training aids are attached 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 residence and should involve the entire staff. Simply stated, the case review is a forum for exchanging information on specific clients' cases. What happens during this process is that each member learns both from 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 understand them realistically 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 assure 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 about problems or issues confronting the program, 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, that is, hours, staff rotations, pay increases, need for supplies, etc.; and they should be kept separate from case reviews. 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 explained in the context of client care. This promotes not only learning but understanding and thus contributes to the cooperative spirit which should exist in the residence.

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

b. *Specific Skills Training*

Once the program 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 programs have access to private institutions which teach such subjects as group dynamics, encounter, etc. Program 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 program, 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 assure 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, numbers and status of outside agency referrals, and metahdone 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 methadone treatment 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 records' 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 clients' 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 all 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 aids for counselors in the 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 nurse's 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 Exhibits 11 and 12 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 a detailed 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 by history or 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 receive any prescribed medication.
    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, a physician, only, may give telephone or verbal orders, but 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: for medication, the physician notes correct date, the medication needed, its strength, directions for use, amount to be dispensed, duration, and then signs the order; for verbal or telephone orders, the nurse follows the above procedures and signs the order as follows: V.O./Dr. M. Welby/C. Ivory, R.N. The nurse should review all orders and initial them.
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 treatment programs. This information will then be used as the basis for the treatment plan since the plan requires that short- and long-term goals be described, as well as the type and frequency of counseling and supportive services. 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 sessions, 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, antagonists, antibiotics, etc.) scheduled and dispensed for each day of the month 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.

The usual way a counselor records client information is through the use of running progress notes. Unfortunately, though, it is also commonplace for these notes to be 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 above. 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 a series of dirty urines, his request to begin detoxification should not be granted.

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 he 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 referral or 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.
- Development of a treatment plan begins 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 (even though the long-term goals are outside the scope of the residential methadone program), the assignment of a primary counselor, a description of those additional supportive services required by the client, and the number of urine specimens which must be given.
- 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 program 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 weekly 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 weekly summary should reflect a composite picture of the client's progress and not merely repeat entries made during the week.
- 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., 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 13 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 residential treatment until completion, termination, or referral for additional treatment.

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.

Clients entering the residential program on methadone maintenance should be referred from an outpatient methadone clinic where they will return after stabilization is completed. Clients being detoxified may either be referred by another program or admitted directly. Individuals seeking direct admission to a residential methadone treatment program must be required to present staff with adequate identification. This should contain name, age, and, if at all possible, 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 already in treatment elsewhere. In many areas, the existence of a central registry makes this unnecessary. The belongings of all new admissions should be searched for contraband.

Applicants or referrals for treatment should be interviewed to determine eligibility and to 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. Verification of the applicant's age must be obtained, since FDA regulations require that an individual be at least 18 years of age to qualify for methadone maintenance. 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). This aspect of intake should have been completed prior to referral by the outpatient clinic, but this should be verified by the staff at the residential program. In addition, if a decision is made during treatment to transfer a client from detoxification to maintenance, these criteria must be adhered to.

Applicants not desiring methadone maintenance may be detoxified, but they must be at least 16 years of age and addicted to opiates. This procedure may not exceed three weeks, and a repeat episode may not be initiated until four weeks after completion of the previous detoxification.

For client admissions, after eligibility has been determined via the applicant's social and drug history, a urine specimen should be obtained to assist in documenting present 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, pupillary reactions, in conjunction with the urine specimen results, can be used to document present dependence on opiates. For clients referred from another clinic, the physical examination should be updated or repeated if one has not been done within the last six months. Records should be examined to insure that for individuals placed on methadone maintenance symptoms of past dependence such as old needle marks and tracks have been 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 methadone candidate.

After completion of the physical examination, the initial or revised 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 prior treatment progress, social history, program guidelines, CODAP standards, and the Federal Funding Criteria. Included in this plan should be short- and long-term goals, the assignment of a primary counselor, the number of urine specimens that must be given per week, as well as referrals to be made to alleviate problems the client has on admission (e.g., housing, medical). 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 separate "Manual on Central Intake Units" available from the National Institute on Drug Abuse.)

2. *Orientation*

The first week after admission to treatment should be considered an induction phase. Within one day 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 imparted previously during the admission procedure but 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.

a. *Medication*

One of the major concerns of clients new to treatment is their medication. Many clients are fearful that their dose will be insufficient to prevent withdrawal symptoms and must be reassured that, while the initial dose may indeed be insufficient to render them physically comfortable, this dose will be increased until they are. However, it must be emphasized to clients that the dose of methadone will not be increased to a level where it will mask symptoms of physical or emotional problems as heroin may have done.

Since methadone dose is a major concern for clients 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.

Some programs do not disclose individual doses to their clients. 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 posture is assumed, it is imperative that staff, as a group, support that posture and understand the principle which underlies it.

There are side effects of methadone which cause some clients distress. The most common of these is constipation which is also the only one which usually persists. However, mild laxatives are very effective in alleviating the condition if it does continue after the client has been stabilized. Another common side effect is 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.

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. Clients who have 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. These clients 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.

b. *Job Assignments*

The assignment of jobs in-house to residents should be incorporated into the treatment plan. Since clients will be in-residence for a reasonably short duration, the development of skills through these assignments is unlikely, but assigned duties will assist in developing a sense of responsibility. All residents must tidy up their sleeping area before breakfast. In addition, clients should be assigned on a rotating basis by the administrator, depending on their number, to the following areas:

1) *Kitchen Assignment*

The purpose of this assignment is not to train chefs and kitchen helpers but to teach people to work together responsibly and to develop self-confidence. The kitchen is unique in that all residents evaluate the results three times a day and are usually vocal when errors are made. From this experience, clients begin to learn to function responsibly in the face of criticism.

While the full-time cook is responsible for producing all meals and for maintenance of the kitchen, residents should be assigned to assist in planning menus, preparing and serving the meals, cleaning up and caring for equipment, ordering supplies, and keeping inventory.

2) *Housekeeping or Service Assignment*

The purpose of this assignment is *NOT* to train people to be janitors but to teach people to work together responsibly and to follow directions.

The administrator assigns workers to sweep floors daily, wash and polish floors as needed, wash windows and walls, clean offices and other common areas, and take responsibility for arranging furniture and equipment for any special activities. Clients with this assignment assume the responsibility for disciplining other residents concerning facility maintenance.

c. *Counseling*

The goal of most methadone treatment programs is to effect a sufficient change in the client's life style so that ultimately abstinence may be 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 him to cease using illegal drugs. Another client may be interested in some of these services but reject others, which the program staff feel would be beneficial, as irrelevant to his goals. Still another will present immediate needs which must be dealt with before these services can be considered. For this reason, the client should be informed that his needs and goals will be considered in determining a treatment plan and in subsequent revisions of that plan. While the client should be counseled in the direction of the program's goals, it must be remembered that these cannot be forced upon him, unless program policies are being violated. Rather, the client should be encouraged to adopt eventually these goals as his own.

It is important that the client participate in the development of his own treatment plan. He should be consulted; and, with complete understanding, he must agree to it. It is especially necessary that during the induction phase the client be made aware of his responsibility to adhere to this plan. His failure to do so should initiate intensified clinical activity and review in conjunction with appropriate disciplinary measures. For instance, if urine results demonstrate the continued use of illegal opiates, the counselor should increase 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. Simultaneous disciplinary measures, in this instance, could include increasing the number of weekly urine specimens required. In the event that additional counseling, the adjustment in methadone dose, and appropriate discipline 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 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 is in treatment. This is especially true of behavioral problems which may not be detected during the intake process but which manifest 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 clients, providing more intensive counseling, or, if the problem is severe, referral to a mental health facility. Revision of the treatment plan may be appropriate and should be accomplished with the client's full knowledge and agreement.

The treatment plan will contain some items which apply to all residents. Urine specimens must be collected on a random basis weekly for all clients on methadone maintenance and undergoing detoxification. In the case of detoxifying clients, the administrator may want to increase the number of urines. All clients will be assigned individual counseling depending on their need. Being a residential program, emphasis will be placed on group therapy sessions, and these must be assigned as part of the plan. (Administrators should be aware that the Federal Funding Criteria require that groups range in size between 5 and 15 individuals. In addition, the criteria state that a minimum of 10 hours per client per week of counseling shall be available. Not all clients, of course, will need this much, but programs are required to provide counseling in this amount, if indicated, based on the treatment plan.)

1) *Supportive Group or Probe*

The purpose of the supportive group or probe is to provide a structured opportunity for clients to alleviate excessive guilt. The group meets twice a week, preferably in the evening, in a relaxed setting (dimmed lights, comfortable chairs). The discussion focuses on experiences from the past about which residents still feel guilt. Any group member may begin the session. Others in the group verbally identify with his experiences or give advice as to how to handle the guilt feelings. Acceptance of the person, regardless of his past behavior, is emphasized. Such material as homosexual activities (especially for people who have been incarcerated), mistreatment of relatives and friends, physical violence, feelings about self-image, etc. are discussed. No laughter or ridicule is allowed. Nothing said in the group can be repeated outside the group. No observers are ever allowed. All participants (especially staff) must be willing to expose their own feelings because onlookers and observers, even in a staff role, are destructive to the process. It is often useful to have one group per week for all residents and to divide the second so that males and females are separated and may express their concerns more freely.

In the supportive group or probe, individuals are encouraged to develop a sense of conscience; therefore, the goal is not to eliminate all guilty feelings but to gain insight into feelings so that excessive and crippling guilt may be reduced.

The supportive group is a potent therapeutic tool and should not be attempted without a trained leader who is thoroughly versed in its conduct and experienced in nonjudgmental counseling.

The group leader's experience is stressed because implementing a supportive group can be difficult. The leader must recognize when the group is off-target and re-focus it, must be able to elicit participation from passive members, and must understand when the group exhausts a subject and subtly redirect it to another topic about which the group may have some concern.

2) *Relatives Group*

The purpose of this group is to orient families to the program, its concepts, rules and regulations, and to help families learn about more constructive ways of dealing with the client.

The relatives group is a weekly evening session conducted by a staff member for clients' relatives and close friends, but it excludes the clients, themselves. The group affords the family/friends opportunities to ventilate hostility or anxiety about the client and/or the program without interfering with the clients' treatment. Problems concerning clients' demands on the family and methods for dealing with these are material for this group. This is a vital effort since the client will soon return to his family and friends who may be instrumental in his rehabilitation.

3) *Encounter or Confrontation Therapy Group*

The encounter or confrontation therapy group is an essential tool in the residential methadone program and should be scheduled three times weekly. The group encourages catharsis by allowing clients to verbalize hostile feelings through shouting and profanity or other acting-out mechanisms. The group serves as a vehicle for behavioral change during which clients describe how each other's negative behavior is perceived and demand that changes be made regarding those aspects that are unacceptable to them.

The encounter therapy process has three elements: 1) direct confrontation about behavior or attitudes; 2) provision of information regarding changes that can be made; and 3) "patch-up" to assure that the individual understands that the particular behavior, not the person, is unacceptable.

Encounter groups should be led only by counselors with strong directive abilities since they serve as the catalyst for group interaction. The group leader must steer the group toward real issues and understand various techniques for this kind of control. (For example, if one group member attempts to take control, the leader must be skilled enough to confront him about his behavior, or arouse the group to question the member's tactics, or distract the group with another issue.) In addition, the leader must be able to recognize and halt encounters that are unproductive or detrimental.

For effective encounter groups, it is helpful to maintain as consistent a composition as possible. The group gains strength as members come to know each other and no longer rely on forced issues. For this reason, the introduction of strangers (new clients) into an on-going group is not recommended.

In general, encounter groups establish two rules: 1) violent actions are prohibited; and 2) no outside discussions about the group are permitted.

Staff should be cautioned about admitting clients whose patterns for dealing with problems are personally destructive. Experience has demonstrated that clients with histories of substantial amphetamine abuse often fall into this category.

4) *Medical Groups*

The program nurse should be assigned to conduct groups at least weekly dealing with medical concerns. Areas covered should include the effects of methadone, medical problems common to opiate abusers (e.g., liver diseases and resulting damage, abscesses), physical effects of combining other drugs (including alcohol) with methadone, nutrition, and family planning. In general, opiate abusers have severely neglected personal health needs, and the medical group is necessary to provoke more responsible concern in this area. Clients with chronic medical problems should also receive individual counseling from the nurse.

5) *Ancillary Counseling*

Ancillary counseling in methadone treatment programs 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 10 hours per week to evaluate employment needs, clients' abilities, etc. and refer clients 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, a formal written agreement should exist which specifies that 10 hours of services will be provided. Vocational rehabilitation counselors may also assist clients in getting involved in training programs through city agencies (e.g., Department of Vocational Rehabilitation). The FDA and the Federal Funding Criteria, likewise, require that programs have a formal, documented arrangement with a local hospital to assure that clients receive necessary in- or outpatient care, and the Federal Funding Criteria require that either in-house or referrals for legal services are available and documented, as well. 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.

3. *Progress in Treatment*

The goal of methadone treatment is to affect a change 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 can then assist 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.

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.

All methadone residential programs 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 primary counselor aware of results of referrals, of counseling done by other staff?).

It is the responsibility of the supervisory counselor and the clinic administrator to insure that appropriate cases are reviewed. Although the counselor may select "problem cases," it is equally important that progress of other clients be 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, copious 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 counselor's progress notes for the past week. The administrator and supervisory counselor come to the meeting, then, equipped with some insights about the week's events and which counselors either participate or remain uninvolved in sessions. Generally, to insure 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).

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

4. *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 (interagency). Clients completing treatment who were referred to the residential program from an outpatient clinic should be returned to that clinic in most instances. Transfers to a different clinic 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, abstinence). Clients, therefore, in instances of various treatment needs, may be transferred to the program most appropriate for that need. In some cases, clients are leaving town or going on extended vacations and will require out-of-town transfers (temporary or permanent). Whatever the situation, transfers should be handled as smoothly as possible so that there is no serious interruption in the provision of services to the client. Clients completing detoxification who were admitted directly to the residential program should be transferred to, and encouraged to attend, a program providing abstinence counseling.

The procedure for local transfer should involve the counselor, the medical staff, the administrator, and whoever may be assigned the responsibility for delivering program records. After the counselor has determined that residential treatment is no longer indicated or that the need for transfer is clear from the client's need for specific care, the 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. This is very important as transfer is often quite trying and a difficult transition to make. A real introduction should be arranged to facilitiate the switch.

For clients who desire a transfer to a new program because they are going on vacation or relocating in 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 a 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.

Additional mechanisms and resources, through which to locate and contact treatment programs in other cities, do exist. There are certainly effective alternatives to TRIPS. On the State level, State agencies which operate and/or regulate (drug abuse, methadone) treatment programs can be consulted. And, of course, the National Institute of Drug Abuse in Rockville, Maryland, can be contacted.

b. *Detoxification*

At this point, a distinction should be drawn between detox from heroin and detox from methadone. The use of methadone to detox from heroin is limited by the FDA regulations to a 21-day schedule, whereas detox from methadone may occur over a longer period of time.

The request for detoxification from methadone maintenance should be initiated by the client, not by the staff, unless it occurs as a disciplinary action. In the latter event, staff from the residential program and from the outpatient program must concur in the decision. If detoxification is voluntarily requested, staff from both programs should be involved in discussing and planning this with the client. The client and counselor should 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 client, and all the points previously made by the counselor should be re-enforced. A physical examination may be appropriate at this time. Staff may decide that detoxification is not indicated now, but if the client persists in his request, it must be instituted. Should a client on maintenance request detox toward the end of his planned stay, he may be referred to an outpatient methadone maintenance/detoxification clinic for detoxification services.

The time involved in the detox process may vary, since the rate of medication decrease may be more frequent for some individuals than others. If the client has any specific date by which he desires the detox to be complete, 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. Clients should be advised that detoxification from methadone may be a lengthy process, and they 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. Once detox is completed, the client should be encouraged to continue his rehabilitation efforts at an outpatient abstinence program.

c. *Completed Medical Treatment*

A client who has successfully completed medical treatment before dropping out should be considered in this category. For the residential program this will apply only to clients completing detoxification since clients on maintenance will be transferred to an outpatient clinic for continued treatment. However, while the medical aspect of treatment is defined as complete, detoxified clients should be transferred to an abstinence program to continue the total rehabilitation process. Progress as an abstinence client can then be monitored. During this period, there is very high risk of relapse to heroin use. Therefore, 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 then the client is more likely to feel that someone actually cares about him. Drop-outs can also be reduced when immediate follow-up takes place.

The counselor and supervisory counselor should work strenuously in 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.

Programs must establish guidelines regarding the length of time a client may absent himself from the facility and still return to treatment. In addition, a decision must be made regarding acceptance of clients who drop out of the residential program and are later re-referred there by an outpatient clinic. Although these guidelines should be flexible enough to permit evaluation of each case, they must be sufficiently structured to prohibit client manipulation and arbitrary decision-making.

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 a one week 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 the client's best interest to suspend him from the residential program. This can be done immediately, if the client was a referral, by returning him to his original clinic. If the client was a direct admission for detoxification, the detoxification process must be accomplished rapidly but within a defined period of time (e.g., 3 weeks). It is the goal of the residential methadone program to maintain a consistent level of expectation toward which clients should strive. Suspension is one method of reminding them of this clear expectation.

There are other circumstances under which treatment may be interrupted, if not terminated. The most common of these are hospitalization and arrest. In the case of hospitalization, the client should inform 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.

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 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 administrators believe that it is in the best interests of the client to seek such a change, they should send a written request to the following:

A. *For an exception to the FDA Regulations*

Methadone Monitoring Staff
Office of Compliance
Room 10B-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

No. 242—Pt. III——1

T. 21—FOOD AND DRUGS

Cha I—Food and Drug Adminis-trc, Department of Health, Ed-ucc, and Welfare

SUBCHAPTER C—DRUGS

RT 130—NEW DRUGS

Approv New Drugs Requiring Continua of Long-Term Studies, Recor and Reports; Listing of Metha ne With Special Requirements r Use

In the FERAL REGISTER of January 7, 1972 (37 F 201), the Commissioner of Food and ugs added a new section, § 130.48 *Dhs that are subjects of approved new ug applications and that require spect studies, records, and reports,* to Part 30—New Drugs, Subpart A—Procedura and Interpretative Regulations. In the EDERAL REGISTER of April 6, 1972 (37 F.R. 940), the Commissioner proposed specia requirements for use of methadone, by ding a new paragraph (b) to § 130.48, ich would place methadone on the li of drugs subject to special studies, rec rds, and reports, provide for the drug to be considered no longer exclusively nvestigative, establish special requirements for use of the drug, no longer aprove its use as an antitussive, and revoe § 130.44 *Conditions for investigatioal use of methadone for maintenance rograms for narcotic addicts* (21 CFR 30.44) 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 I 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 non-drug 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 pres-

ent 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 acordance 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 pa-

tients 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 pro-

gram 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 Administration):

	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 severe 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]

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	314.205
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.

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 3 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]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 310]

METHADONE

Multiple Enrollment Prevention

Section 310.505(c)(3) (21 CFR 310.505(c)(3)), formerly § 130.44,(c)(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 (c)(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]

P

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)

P

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 Directors, Staff Counselors, and FDA Districts

DATE: November, 1973

FROM : Methadone Monitoring 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.

# # #

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.

(2) MMS will shortly be sending a letter to all methadone treatment programs emphasizing the requirement that all methadone dispensed for take-home comsumption 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.

# # #

(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 perrogative 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; and specify the 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 an 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 done 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 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 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. 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 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 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 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