PART 4. METHADONE TREATMENT AND OTHER CHEMOTHERAPY

R 325.14401 Drug treatment; license required.

401 A program shall not employ a treatment modality using a controlled substance unless it is licensed to provide service in the outpatient, inpatient, or residential service category and complies with R325.14402 to R 325.14423.

R 326.14402 Prescription drugs; nonexistence of federal or state rules for use in treatment programs.

402 If neither federal nor state rules exist specific to the use of prescription drugs in treatment programs, the treatment programs that use such drugs shall include, at a minimum, a complete medical history, comprehensive physical examination, and the necessary laboratory tests for each patient at admission.

R 325.14403 Medical staffing patterns.

403(1) A program licensed under this part shall employ 1 full-time physician, duly licensed and registered, per 300 clients to deliver the medical services described in this part. This ratio shall be maintained in programs serving less than 300 clients.

403(2) A program licensed under this part shall employ 2 full-time nurses, duly licensed and registered, per 300 clients to administer medication and deliver other nursing services. This ratio shall be maintained in programs serving less than 300 clients.

403(3) A physician's assistant, duly licensed and registered, may be utilized to meet up to 30% of the physician's hours if supervised by an approved physician as specified in session 16103(1) of the act.

R 325.14404 Medical director; designation; medical director and other physicians; responsibilities; minimum client-physician encounters.

404(1) A program shall have a designated medical director who assumes responsibility for the administration of all medical services performed by the program. The medical director and other authorized program physicians shall be licensed to practice in the jurisdiction in which the program is located. The medical director shall be responsible for ensuring that the program complies with all federal, state, and local laws, rules, and regulations regarding medical treatment of narcotic addiction.

404(2) The responsibilities of the medical director and other authorized physicians within the program shall include all of the following:

(a) Ensuring that evidence of current physiologic dependence, length of history of addiction, or exceptions to criteria for admission are documented in the patient's record before the patient receives the initial methadone dose.

(b) Ensuring that a medical evaluation, including a medical history and physical examination, has been performed before the patient receives the initial methadone dose. However, in an emergency situation the initial dose of methadone may be given before the physical examination.

(c) Ensuring that appropriate laboratory studies have been performed and reviewed.

(d) Signing or countersigning all oral medical orders as required by federal or state law. Such medical orders include all of the following;

(i) Initial medication orders,

(ii) Subsequent medication order changes.
(iii) Changes in the frequency of take-home medication.
(iv) Medication orders for additional take-home methadone for emergency situations.

(e) Reviewing and countersigning treatment plans as follows;

(I) The program physician or counselor shall review, reevaluate, and alter, where necessary, each client's treatment plan at least once every 60 days.
(ii) The program physician shall ensure that the treatment plan becomes part of each client's chart and that it is signed and dated in the client's chart by the counselor and is counter-signed and dated by the supervisory counselor,
(iii) At least once a year, the program physician shall date, review, and countersign the treatment-plan recorded in each client's chart and shall ensure that each client's progress or lack of progress in achieving the treatment goals is entered in the client's counseling record. When appropriate, the treatment plan and progress notes shall deal with the client's mental and physical problems, apart from drug abuse, and shall include reasons for prescribing any medication for emotional or physical problems.

(f) Ensuring that justification is recorded in the patient's record when the frequency of clinic visits for observed medication is reduced.

404(2) There shall be a minimum of 1 client per physician encounter every 60 days. This contact shall be documented in the client's record.

R 325.14405 Ancillary medical services.

405 A client record shall indicate that ancillary medical services were made available to a client whose physical exam, medical history, or complaints indicated abnormalities that could require ancillary medical services.

R 325.14406 Urinalysis services.

406(1) Urinalysis shall be performed for clients in maintenance treatment at least once a week for opiates, methadone, barbiturates, amphetamines, cocaine, and ether drugs as appropriate. Urine shall be collected randomly in a manner which minimizes falsification of the samples.

406(2) If the patient has maintained drug-free urines for a period of 6 months, and for as long as the patient maintains drug-free urines. urinalysis may be performed on a monthly basis for opiates, methadone, barbiturates, amphetamines, cocaine, and other drugs as appropriate. A positive urine for drugs other than methadone or legally prescribed drugs shall require resumption of a weekly schedule of urinalysis.

R 325.14407 Vocational rehabilitation services.

407(1) A program shall provide opportunities, directly or through referral to community resources, for those patients who desire, or who have been deemed ready by the program staff, to participate in education or job training programs or to obtain gainful employment. A program shall maintain a list of referral resources it vocational rehabilitative activities are not directly provided. The referral resources shall include agendas with resources to provide vocational training, education, and employment in addition to the community resources that might be available to provide assistance for such activities.

407(2) A client's needs and readiness for vocational rehabilitation, education, and employment shall be evaluated and recorded in the client's records during the preparation of the initial treatment plan and shall be reviewed and updated, as appropriate, in subsequent treatment plan evaluations. It is recognized that

some clients are not ready for, or are not in need of, these services. Such a statement in the record shall suffice to meet the requirement of subrule (1) of this rule. For a client who is deemed ready and who is referred for such services, a program staff member shall document in the client's record the type of referral made and the results of the referral.

R 325.14408 Informed consent.

408(1) There shall be a fully completed and signed FD-2635 "Consent to Methadone Treatment form for all active clients. A new consent form shall be completed for any readmission or for a client who transfers from another program either permanently or temporarily. Care shall be exercised to indicate the pregnancy status for females.

408(2) Upon being informed of the benefits and hazards of the drug ordered by the physician, the client or parent or guardian shall sign a consent form authorizing the program to commence such chemotherapy. The consent form shall be witnessed and dated and shall become part **of** the client's case record.

R 325.14409 Methadone maintenance program; minimum standards for admission.

409(1) Each person who is selected as a client for a methadone maintenance program, regardless of age, shall be determined by a staff physician to be currently physiologically dependent upon narcotics and shall have first become physiologically dependent at least 1 year before admission to methadone maintenance treatment. A 1-year history of drug dependence means that an applicant for admission to a methadone maintenance program has been continuously physiologically addicted to a narcotic for at least 1 year before admission to a program.

409(2) In determining current physiologic dependence, the physician shall consider signs and symptoms of intoxication, a positive urine specimen for a narcotic drug, and old or fresh needle marks. Other evidence of current physiologic dependence can be obtained by noting early signs of withdrawal, such as lacrimation, rhinorrhea, pupillary dilation, and piloerection, during the initial period of abstinence. Withdrawal signs may be observed during the initial period of hospitalization or while the person is an outpatient undergoing diagnostic evaluation, such as medical and personal history, physical examinations, and laboratory studies. 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, but possible, that a person could be currently dependent on narcotic drugs without having a positive urine test for narcotics. Thus, a urine sample that is positive for narcotics is not a requirement for admission to detoxification or maintenance treatment.

409(3) A patient who has been treated and subsequently detoxified from methadone maintenance treatment may be readmitted to methadone maintenance treatment without evidence to support findings of current physiologic dependence up to 6 months after discharge provided that prior methadone maintenance treatment of 6 months or more is documented from the program attended and that the admitting program physician, in his or her reasonable clinical judgment, finds readmission to methadone maintenance treatment to be medically justified. For patients meeting these criteria, the quantity of take-home medication shall be determined in the reasonable clinical judgment of the program physician, but in no case shall the quantity of take-home medication be greater than would have **been** allowed at the time that person terminated previous treatment. Documented evidence of prior treatment and evidence of all other findings and criteria used to determine such findings shall be recorded in the patient's chart by the admitting program physician or program personnel under supervision of the admitting program physician. The admitting program physician shall date and sign the recordings or date, review, and countersign such recordings in the patient's chart prior to the administration of the initial methadone dose to the patient.

409(4) Documented evidence of prior treatment and evidence of all other findings and criteria used **to** determine such findings shall be recorded in the client's chart by the admitting program physician or program personnel under supervision of the admitting program physician. The admitting program physician shall date, review, and countersign such recordings in the client's chart before the. administration of the initial methadone dose to the client.

409(5) A person who is between the ages of 16 and 18 years shall have had 2 documented attempts at detoxification and at least a 1-year history of addiction before admission to maintenance. A 1-year history of dependence means that an applicant for admission to a maintenance program shall have been continuously physiologically dependent to a narcotic for at least 1 year before admission to a program. A person under 16 years of age is not eligible for methadone maintenance treatment without the prior approval of the state methadone authority and the food and drug administration. This, subrule does not preclude a person who is under 18 years of age and who is currently physiologically dependent on a narcotic from being detoxified with methadone if it is deemed medically appropriate by the program physician and is in accordance with the requirements for detoxification.

R 325.14410 Detoxification treatment; minimum standards.

410(1) For detoxification from narcotic drugs, methadone shall be administered daily by the program under close observation in reducing dosages over a period of not more than 21 days. All requirements that pertain to maintenance treatment apply to detoxification treatment, with the following exceptions:

(a) Take-home medication shall not be allowed during detoxification.

(b) A history of a 1-year physiologic dependence shall not be required for admission to detoxification.

(c) Clients who have been determined by the program physician to be currently physiologically dependent on narcotics may be detoxified with methadone regardless of age.

(d) Urine testing is not required, except for initial drug screening.

(e) An Initial treatment plan and periodic treatment plan evaluation are not required, except that a counselor shall be assigned to monitor the client's progress toward achievement of realistic short-term goals designed to be completed by the client within 21 days.

410(2) A waiting period of at least 1 week shall be required between detoxification attempts. Before a detoxification attempt is repeated, the program physician shall document in the client's record that the client continues to be or is again physiologically dependent on narcotic drugs.

410(3) Detoxification treatment is not recommended for A pregnant client,

R 325.14411 Admission procedures.

411(1) A program shall provide its clients access to a comprehensive range of medical services and shall inform a new client in writing which services are available on-site and which are available by referral as part of an orientation procedure.

411(2) A program that is licensed and authorized to use controlled substances shall have the results of a complete physical examination, a medical history, and a personal history before dispensing or administering medication. Appropriate lab work shall be entered in the client's file within 30 days of admission.

411(3) A prior physical examination that is completed by a physician may be utilized if it meets the criteria outlined in R 325.14412 and if it is dated not more than 90 days before the current admission date. The staff physician shall document his or her evaluation of the prior examination.

R 325.14412 Physical examination.

412(1**)** A complete physical examination shall consist of all of the following:

(a) A physical examination stressing infectious disease; pulmonary, liver, and cardiac abnormalities; dermatologic sequelae of addiction; and possible concurrent surgical problems,
(b) A complete blood count and differential.
(c) Serologic tests for syphilis.
(d) Routine and microscopic urinalysis.
(e) Urine screening for drugs, (toxicology).
(F) Sequela multiple analyzer 12/60 or equivalent.
(g) Australian antigen test.
(h) Tuberculin skin test or chest x-ray,
(i) Sickle cell test, as appropriate.
(j) A test **for** pregnancy, **as** appropriate.

412(2) The licensed staff physician shall document the number of years that the individual has been dependent on, or addicted to opiates or opiate-like drugs.

R 325.14413 Medical history.

413(1) A complete medical history shall contain all of the following:

(a) Head Injuries.
(b) Nervous diseases.
(c) Convulsive diseases,
(d) Major and minor operations.
(e) Major accidents.
(f) Fractures.
(g) Venereal infections.
(h) Cardiovascular diseases.
(I) Respiratory diseases.
(j) Endocrine diseases.
(k) Rheumatic diseases.
(l) Gastrointestinal **diseases.**
(m) Allergic **diseases.**
(n) Gynecological-obstetrical history.

413(2) The licensed staff physician shall document his or her review of the medical history.

R 325.14414 Personal history.

414 A complete personal history shall contain all of the following information:

(a) Name, address, and telephone number.
(b) Educational history.
(c) Date *of* birth and sex.
(d) Psychosocial and family **history.**
(e) Employment and vocational history.
(f) Prior treatment experience or attempts at detoxification, or **both,**
(g) Legal or court-related history,
(h) Thorough substance abuse history.
(i) Name of referring agency, when appropriate.
(j) Name, address, and telephone number of nearest relative in case **of** emergency.
(k) Name, address, and telephone number of most recent family or private physician.

R 325.14415 Take-home medication.

415(1) Take-home medication shall be formulated in such a way as to minimize parenteral abuse and shall be packaged pursuant to section 3 of the poison prevention packaging act, 15 U.S.C. §1472.

415(2) Take-home medication shall be labeled with all **of** the following information:

(a) The name of the medication.
(b) The treatment center's name, address, and phone number.
(c) Client name or **code** number.
(d) Medical director's name.
(e) Directions for use.
(f) Date to be used.
(g) A cautionary statement that the drug should be kept out of the reach *of* children.

R 325.14416 Take-home methadone; determination of client responsibility.

416(1**)** Take-home methadone shall only be given to a client who, in the reasonable clinical judgment of the program physician, is responsible in the handling of methadone. Before reducing the frequency of clinic visits, the rationale for this decision shall be recorded in the client's chart by a program physician or one of his or her designated staff. If a physician's designated staff member records the rationale for the decision, a program physician shall review, countersign, and date the client's record. Additionally, take-home methadone shall only be dispensed in an oral, liquid form so as to minimize its potential for abuse.

416(2) It is recommended practice that this liquid vehicle be non-sweetened and contain a preservative so that a client can be instructed to keep take-home methadone out of the refrigerator in an attempt to minimize its likelihood of accidental overdoses by children and fermentation of the vehicle.

416(3) The program physician shall, in the exercise of his or her reasonable clinical judgment, utilize all of the following information in determining whether or not a client is responsible enough to handle take-home methadone;

(a) Background and history of the client.

(b) General and special characteristics of the client and the community in which the client resides.

(c) Absence of recent abuse of non-narcotic drugs, including alcohol

(d) Absence of current abuse of non-narcotic drugs and alcohol and narcotic drugs, including methadone.

(e) Regularity of clinic attendance.

(f) Absence of serious behavioral problems in the clinic.

(g) Stability of the client's home environment and social relationships.

(h) Absence of recent criminal activity.

(i) Length of time in methadone maintenance treatment.

(j) Assurance that take-home medication can be safely stored at home.

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

R 325.14417 Take-home medication; procedures, exceptions.

417(1) A Client who is in maintenance treatment shall ingest the drug under observation daily of not less than 6 days a week for a minimum of the first 3 months.

417(2) if, in the judgment of the program, physician; a client demonstrates satisfactory adherence to program rules for not less than 3 months; has made substantial progress in rehabilitation; is responsible in the handling of methadone; and is working, enrolled in an educational or training program, or has homemaking responsibilities, and If the client's rehabilitative progress will be enhanced by decreasing the frequency of clinic attendance, the client may be permitted to reduce the frequency of clinic attendance for drug ingestion under observation to 3 times weekly. Such a client shall not receive more than a 2-day take-home supply of methadone.

417(3) If, In the judgment of the program physician, a client demonstrates satisfactory adherence to program rules for not less than 2 years from the time of entrance into the program; has made substantial progress in rehabilitation: is responsible in the handling of methadone; and Is working, enrolled in an educational or training program, or has homemaking responsibilities, and if the client's rehabilitative progress will be enhanced by decreasing the frequency of clinic; attendance, the client may be permitted to reduce the frequency of clinic attendance for drug ingestion under observation to twice weekly. Such a client shall not receive more than a 3-day take-home supply of methadone.

417(4) In calculating 2 years of methadone maintenance treatment, the period shall be considered **to** begin upon the first day of administration of methadone or upon readmission of a client who has had a continuous absence of 90 days or more, Cumulative time spent by the client in more than 1 program shall be counted toward the 2 years of treatment, unless there has been a continuous absence of 9O days or more.

417(5) If a client is found to have a physical disability which interferes with his **or** her ability to conform to the applicable mandatory schedule, he or she may be permitted a temporarily or permanently reduced schedule if he or she is also found to be responsible in the handling of methadone as specified in R 325.14416(3)(a) *to* (k).

417(6) If because of exceptional circumstances, such as Illness or personal or family crisis, a client is unable to conform to the applicable mandatory schedule, he or she may be permitted a temporarily reduced schedule if he or she is also found to be responsible in the handling of methadone as specified in R 325.14416(3)(a) to (k). In any event, a client

shall not be given more than a 1-week supply of methadone at one time without the prior approval of the state "methadone authority and the food and drug administration.

R 325.14418 **Methadone** treatment; **voluntary** withdrawal, **discontinuation of use.**

418(1) A client in treatment shall be given careful consideration for discontinuation of methadone use. Social rehabilitation shall have been maintained for a reasonable period of time. A client shall be encouraged to pursue the goals of eventual voluntary withdrawal from methadone and of becoming completely drug-free. Upon successfully reaching *a.* drug-free state, the client shall be retained in the program for as ion as necessary to assure stability in the drug-free state, with the frequency of his or her required visits adjusted in accordance with the treatment plan.

418(2) Maintenance treatment shall be discontinued within *2* years after such treatment has begun, unless, based on the recorded clinical judgment of the staff physician, justification is provided to continue maintenance beyond the 2-year limitation. This justification shall be reviewed and updated every year thereafter by the staff physician.

R 325.14419 Client **records,**

419(1) **A** client record shall be maintained by a program for a period of 3 years after services are terminated.

419(2) A client record shall contain, at a minimum, all of the following information:

(a) A signed consent form (use federal food and drug administration form FD-2635).
(b) The date of each visit for medication or counseling, or both.
(c) The amount of methadone dispensed for take-out or administered on-site.
(d) The results of each urinalysis.
(e) A detailed account of any adverse reactions to medication (use federal food and drug administration form FD-1639, "Drug Experience Report").
(f) Any significant physical or psychological disability and plans for referral or on-site treatment.
(g) Twice monthly progress reports by the counselor, signed and dated.
(h) The termination and readmission evaluation written or endorsed and dated by the program physician.
(i) Monthly medical progress notes by the dispensing nurse.
(j) Monthly renewal of the methadone order.
(k) Documentation of a physician-client encounter every 60 days.
(l) Documentation of methadone authority approval of any exceptions to the applicable rules and regulations.
(m) The Initial treatment plan.
(n) The periodic treatment plan evaluation by the program physician or counselor at least once every 60 days.
(o) The annual treatment plan review by the program physician.

419(3) Deaths which may be methadone related shall be reported to the federal food and drug administration on form FD-1639, "Drug Experience Report" within 2 weeks of the death. Births to clients that are premature or show signs of adverse reaction to methadone shall also he reported on form FD-1639.

R 325.14420 Holiday dispensing.

420(1) Where it is not contrary to state law and where the state methadone authority has given approval, a 1-day's supply of methadone may be dispensed to all clients regardless of time in treatment, for the following holidays:

(a). July 4.
(b). Thanksgiving Day.
(c). Christmas Day.
(d). New Year's Day.

420(2) Subject to state law and the state methadone authority's approval, an additional 1-day supply of methadone may be provided to all clients for the holidays in subrule (1) of this rule which fall on Monday. The client who has to ingest methadone 6 days per weak would be dispensed a supply for Sunday and Monday. A client who is allowed a 2-day take-home supply of methadone would be allowed a 3-day take-home supply when he or she presents himself or herself for medication on the Friday preceding the Monday Holiday. When 1 of the above holidays falls on Friday, clients who must attend the program 6 days per weak to obtain medication may be given a take-home supply for that Friday. These clients shall report on Saturday to obtain the usual seventh day take-home dose normally allowed, if Sunday is the customary day to provide the 1 take-home dose. The remainder of the clients may be provided additional quantities of take-home methadone.

420(3} Subject to state law and the state methadone authority's approval, an additional 1-day supply of take-home medication may be given for official state holidays without prior FDA approval. These holidays are as follows:

(a) New Year's Day.
(b) Lincoln's and Washington's birthdays.
(c) Memorial Day.
(d) July 4.
(e) Labor Day.
(f) Veterans' Day.
(g) Thanksgiving Day.
(h) Christmas Day.

420(4) Not more than a 3-day supply of methadone shall be dispensed to any client because of holidays without prior approval from the state methadone authority.

R 325.14421 Security of drug stocks and dispensing area.

42l(1) A program of adequate security shall be maintained over drug stocks. The storage of drug stocks shall be in accordance with federal drug enforcement administration criteria for controlled substances, 21 C.F.R. §1301.71-1301.93 (April 1, 1979). The criteria set forth in 21 C.F.R. §1301,71-1301.93 may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, at a cost of $4.25 or from the Office of Substance Abuse Services, Department of Public Health, 3500 North Logan, Box 30035, Lansing, Michigan 48909, at a cost of $4.25. Records shall be maintained which show the dates that shipments of methadone are received, the quantity received, and the lot numbers. Tile Inventory of methadone stocks shall reflect daily usage and balance on hand.

421 (2) Accurate drug-dispensing records shall be maintained which show all of the following information:

(a) The date of client visit
(b) The amount dispensed.
(c) Whether the drug was ingested on-site or was dispensed for take-home purpose.
(d) The client's signature.
(e) The signature or initials of the dispensing licensed practitioner.

421(3) If a client fails to show for a visit, his or her absence shall be recorded and the record shall be signed or initialed by the dispensing licensed practitioner. Information shall be recorded for each client as he or she is seen. Dispensing records and records that document receipt of substances shall comply with the provisions of 21 C.F.R. §1304.28 and 1304.29 (April 1, 1979). The criteria set forth in 21 C.F.R. §1304.28 and 1304.29 are incorporated in these rules by reference. Copies of 21 C.F.R. §1304.28 and 1304.29 may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington. **D.C.** 20402, at a cost of $4.25 or from the Office of Substance Abuse Services, Department of Public Health, 3500 North Logan, Box 30035, Lansing, Michigan 48909, at a cost of §4.25.

421(4) A program that is involved in dispensing or administering medication as a part of its treatment regimen shall not allow any person inside the dispensing area who is not a licensed practitioner. Exceptions may be granted on an individual basis by the state methadone authority. Under exceptional circumstances, for specific purposes, other individuals may be allowed to accompany the licensed practitioner inside the dispensing area. The reasons for these exceptional cases shall be documented by the practitioner, and the record shall be maintained in the dispensing area.

R 325.14422 Medication control; qualification of individual in charge; formulation of written policies and procedures required; written policy to medication removal in absence of pharmacist required; reporting medication errors and adverse drug reactions; dispensing medication **order** and prescriptions; *orders* that involve abbreviations and chemical symbols; prescribing drugs with abuse potential; informing client of benefits and hazards of drug; observation of medication ingestion during clinic visit; provision for self-administration of drugs with abuse potential.

422(1) The individual in charge of medication control shall be a duly licensed physician or duly licensed pharmacist, unless another licensed medical staff member is authorized in writing by the physician or pharmacist. A registered nurse or licensed practical nurse, in conjunction with the licensed physician, shall formulate written policies and procedures for all of the following:

(a) The sale storage, handing, prescribing, and dispensing of drugs, especially controlled substances, investigational drugs, and hazardous drugs and chemicals.

(b) Controlling the activities of representatives of pharmaceutical manufacturers and suppliers who make contact with the program.

(c) Procuring drugs, chemicals, and pharmaceutical preparations in accordance with the provisions of 21 C.P.R- **§1035** and **1301.74(2).**

(d) Pharmaceutical services **to** be provided by outside resources.

(e) Record keeping.

422(2) There shall be a written policy that designates which licensed practitioner is authorized to remove medications from the pharmacy or bulk storage area when a pharmacist is not available. This policy shall assure that only prepackaged, properly labeled drugs are removed and removed only in amounts sufficient to meet immediate therapeutic needs. A written record of such withdrawals shall be made and shall be verified by a pharmacist

422(3) A medication error and adverse drug reaction shall be reported promptly to the responsible physician and to the coordinator of the medication control component. A dated entry of the medication given and any drug reaction shall be recorded in the client's case record. The coordinator shall take steps to insure that any unexpected or significant adverse drug reactions are reported to the federal food and drug

administration and to the manufacturer and are reported in a manner that does not violate the client's right to confidentiality.

422(4) Only medication orders and prescriptions that originate within the program shall be dispensed by the program pharmacy or administered by licensed medical staff members.

422{5) An order that involves abbreviations and chemical symbols shall be carried out only if it appears on a list of approved abbreviations and symbols. An order for medication and a dose of medication administered **on-site** shall be recorded in the client's case record using a standardized form and in a manner that complies with **established** program policy.

422{6) The prescribing of drugs that have abuse potential shall be undertaken only when all of the following requirements have been met:

(a) There is a written set of policies and procedures covering the use of these drugs in the program.

(b) A staff physician has reviewed the client's case record and has entered into the record the reasons for prescribing the given drug.

(c) The drug to be prescribed appears in the program's formulary.

422(7) Before the initiation of chemotherapy utilizing controlled substances other than methadone, the client and, where required by law, the parent or guardian shall be informed both orally and in writing, in the client's native language it possible, of the benefits and hazards of the drug to be ordered. The information given shall include all of the following:

(a) The drug to be ordered.

(b) What the drug is expected to accomplish,

(c) The method and frequency of administration.

(d) The drug's ability to bring about a state of physiological **or** psychological dependence, or both.

(e) Where applicable**,** the nature of the tolerance that may develop with continued use, as well as the ordered drug's ability to affect; the client's tolerance to other drugs.

(f) The dangers of the use of the ordered drug in conjunction with **other** drugs.

(g) A general description of adverse reactions.

(h) Emergency procedures to be followed when there is an adverse reaction, overdose, or withdrawal.

(i) What alternative therapies exist to treat the problem and what the risks and benefits are of each,

422(8) At the time of a clinic visit, a client shall ingest medication under the direct observation of the dispensing licensed practitioner. There shall be only 1 client in the dispensing area at a time.

422(9) When drugs with abuse potential are dispensed to clients for self-administration, the reason shall be clearly documented in the client's case record.

422(10) If a program permits the self-administration of drugs with-abuse potential, there shall be a written policy governing such **activity.** The **policy** shall require that decisions to permit self-administration be based on individual needs and be undertaken in a manner

that complies with any laws and regulations applicable to such acts. Such policy shall be approved by the governing authority.

422(11) A client who receives drugs for self-administration shall be given instructions concerning the safe storage and usage of such drugs and the appropriate emergency procedures, especially when there are children living with the client.

R 325.14423 Additional medication controls; labeling and packaging; compiling list of pharmaceutical reference materials; automatic stop orders; monthly review of client case record; development OF written emergency procedure for programs using controlled substances as part of chemotherapeutic regimen; development of formulary of pharmaceuticals; control records; inspections; development of policies to define qualifications of staff members; verbal orders for medication; acceptance and receipt of controlled substances.

423(1) A dispensed drug shall be labeled and packaged according to R 338.479. administered by the board of pharmacy of the Michigan state department of licensing and regulation, and the regulations of the food and drug administration and the consumer product safety commission. The provisions of 21 C.F.R. §291.505 (April *1,* 1978) and 16 C.F.R. §1700.14 (May 14, 1973) are incorporated in these rules by reference. Copies of 21 C.F.R. §291.505 and ''.5 C.F.FI. §1700.14 may be obtained from the Superintendent of Documents. U.S. Government Printing Office, Washington, DC 20402, at a cost of $4,25 or from the Office of Substance Abuse Services, Department of Public Health, 3500 North Logan, Box 30035, Lansing, Michigan 48909, at a cost of $4.25.

423(2) The coordinator of the medication control component shall compile a list of up-to-date pharmaceutical reference materials to be procured and made available on-site.

423(3) There shall be automatic stop orders in dispensing all medications.

423(4) A program that uses controlled substances as part of a chemotherapeutic regimen shall develop a written emergency procedure to be implemented in the case of an employee strike, tire, or other emergency situation which would stop or substantially interfere with, normal dispensing procedures.' The emergency procedure shall include all of the following:

(a) Arrangements with security providers for immediate security of drug stocks.
(b) Written agreements, updated annually, with back-up medical personnel, such as a physician or nurses, for the coverage of dispensing and other medical-needs if regular personnel are not available.
(c) A reliable system to confirm the identities of clients before dispensing.
(d) Written agreements, updated annually, for the use of an alternate program, hospital, or other site for dispensing during an emergency period.

423(5) The individual in charge of medication control shall, with the advice of licensed start physicians, develop a formulary of those pharmaceuticals that are to be used in the program. The formulary shall serve as a program's catalog of approved therapeutic agents and shall include Information regarding the use, dosage, contraindications, and unit dispensing size of the agents. There shall be a procedure for adding drugs and dosage forms to, or deleting them from, the formulary. There shall be a mechanism for notifying appropriate staff members of changes in the formulary.

423(6) Prescriptions, medication orders, narcotic records, and inventory control records shall! be kept in an organized and easily retrievable manner, shall be maintained in accordance with federal and state law, and shall be retained by a program for not less than 5 years.

423(7) At least quarterly, the individual In charge of medication control shall make an inspection of all drug storage areas, medication centers, and nurse stations to insure that these areas are maintained in compliance with federal, state, and local regulations. A dated record of these inspections shall be maintained to verify that all of the following requirements are met:

(a) Disinfectants and drugs for external use are stored separately from oral and injectable drugs.

(b) Drugs that require special conditions for storage to insure stability are properly stored.

(c) Containers for bulk storage for flammable liquids comply with local fire safety regulations.

(d) No outdated drugs are stocked.

(e) Distribution, administration, and receipt of controlled drugs are adequately documented.

(j) Controlled substances and other abusable *drugs* are stored in accordance with federal, state, and program rules and regulations,

(k) Drugs listed in the formulary are in adequate and proper supply.

(l) Copies of the formulary and other program drug-related rules and regulations are available in appropriate areas.

(1) Metric and apothecary weight and measure conversion charts are posted where needed.

423(8) A program shall develop policies that define the qualifications for staff members who dispense and administer medications. These policies shall be in accordance with laws and regulations governing such acts and shall be approved in writing by the governing authority.

423(9) A verbal order for medication shall be given only by a program physician and shall be received only by another physician, a pharmacist, or a registered or licensed practical nurse. When a verbal or telephone order is given, it shall be authenticated in writing by a physician not later than 48 hours after the order was originally given.

423(10) A supply of controlled substances that is delivered to a program shall be accepted and receipted by a licensed physician, pharmacist, registered nurse or licensed practical nurse.