STANDARDS

FOR LICENSURE OF

AMBULATORY CARE FACILITIES

NJSDH

NEW JERSEY STATE DEPARTMENT OF HEALTH

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INTRODUCTION

These standards are prepared by the State of New Jersey Department of Health for licensure of freestanding ambulatory care programs and facilities. Standards for the following types of ambulatory care programs are included:

1. A facility providing primary care to adults and children.
2. A facility providing comprehensive pediatric care.
3. A facility providing family planning services.
4. A facility providing prenatal and postpartum care.
5. A facility providing surgical services.
6. A facility providing drug abuse treatment services.
7. A facility providing intermediate dialysis treatment services.
8. A facility providing family practice services.
9. A facility providing health maintenance organization services.
10. A facility providing computerized axial tomography services.

Hospital-based facilities must meet the standards promulgated in the Manual of Standards for Hospital Facilities of the New Jersey State Department of Health.

Facilities providing a single diagnostic service or a single therapeutic modality other than those enumerated above will not be licensed at the present time. This is not an all-inclusive list of the potential ambulatory care facilities which may be licensed. Standards will be developed as the need arises.

To serve the residents of New Jersey, these standards are promulgated with the following objectives:

1. To ensure access to comprehensive health and medical services, through the licensure of facilities.
2. To protect the patient by establishing minimum standards for quality health care.
3. To protect the safety of each patient receiving health care services, with due regard for patient amenities.
4. To reduce the financial burden of health care services by promoting cost containment.
5. To protect the dignity of the patient.

1.0 Definitions and/or Qualifications

1.1 Administrator - A person with a baccalaureate degree and two years of executive or supervisory experience in a health care agency, or the equivalent in years of experience and/or training in a health care agency.

1.2 Available - Shall mean not onsite at all times.

1.3 Cleaning - The removal by scrubbing and washing, as with hot water, soap or detergent, and vacuuming, of infectious agents and of organic matter from surfaces on which and in which infectious agents may find conditions for surviving or multiplying.

1.4 Commissioner - The New Jersey State Commissioner of Health.

1.5 Communicable Disease - An illness due to a specific infectious agent or its toxic products, which occurs through transmission of that agent or its products from a reservoir to a susceptible host.

1.6 Contamination - The presence of an infectious agent in the air, on a body surface, or on/in clothes, bedding, instruments, or dressings, or other inanimate articles or substances, including water, milk, and food.

1.7 Dentist - A person who is licensed by the New Jersey State Board of Dentistry as a dentist, pursuant to N.J.S.A. 45:6 et seq.

1.8 Department - The New Jersey State Department of Health.

1.9 Dietitian or Nutritionist - May be either an ADA dietitian or a registered dietitian.

ADA Dietitian - A person with a baccalaureate degree from an accredited college or university with courses meeting the academic standards of the American Dietetic Association plus a dietetic internship or dietetic traineeship, or master's degree plus six months' experience.

Registered Dietitian - An ADA dietitian who has met current requirements for registration.

Nutritionist - A person who has graduated from an accredited college or university with a major in foods or nutrition or the equivalent course work for a major in the subject area, and two years of full-time professional experience in nutrition.

Successful completion of a dietetic internship or traineeship in hospital or community nutrition approved by the American Dietetic Association or completion of a master's degree in the subject area may be substituted for the two years of full-time experience.

1.10 Disinfection - The killing of infectious agents outside the body, or organisms transmitting such agents, by chemical and physical means, directly applied.

1.10.1 Concurrent disinfection - The application of measures of disinfection as soon as possible after the discharge of infectious material from the body of an infected person, or after the soiling of articles with such infectious discharges, all personal contact with such discharges or articles being minimized prior to such disinfection.

1.10.2 Terminal disinfection - The application of measures of disinfection after the patient has died or been removed to a hospital, or has ceased to be a source of infection, or after the facility's isolation practices have been discontinued. Terminal disinfection is rarely practiced; terminal cleaning generally suffices along with airing and sunning of rooms, furniture, and bedding. Terminal disinfection is necessary only for diseases spread by indirect contact.

1.11 Enrollee - An individual who has been enrolled in the facility for a program of comprehensive primary care and not for emergency or walk-in services.

1.12 Freestanding Facility - A facility which is not located in the hospital or on its campus, but may or may not be under its auspices.

1.13 Full-Time - A time period established as a full working week by the facility as defined in its policy.

1.14 Governing Authority - The organization, person, or persons incorporated or functioning under N.J.S.A. 26:3-1 et seq., designated to assume full legal responsibility for the policy determination, management, operation, and financial viability of the facility.

1.15 Licensed Practical Nurse - A person who is licensed by the State of New Jersey as a practical nurse, pursuant to N.J.S.A. 45:11-27 et seq.

1.16 Medical Director - A physician authorized to practice medicine in the State of New Jersey with two years of administrative experience.

1.17 Nurse Midwife - A registered nurse who is also a graduate of an accredited school certified by the American College of Nurse Midwives and licensed in the State of New Jersey.

1.18 Pharmacist - A person who is registered as a pharmacist in the State of New Jersey pursuant to N.J.S.A. 45:14 et seq.

1.19 Physician - A person who is authorized by the Board of Medical Examiners to practice medicine in the State of New Jersey, pursuant to N.J.S.A. 45:9-1 et seq.

1.20 Primary Care - The patient contact for medical and health care with assumption of responsibility for ongoing care.

1.21 Progress Note - A signed, dated notation by a professional member of the health team summarizing information about medical or health care and the patient's response to various modalities during a given period of time.

1.22 Public Health Nurse - A person licensed as a registered professional nurse, who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or post-baccalaureate study which includes content approved by the National League for Nursing for public health nursing preparation.

1.23 Registered Professional Nurse - A person who is licensed by the State of New Jersey as a registered professional nurse, pursuant to N.J.S.A. 45:11-26 et seq.

1.24 Secondary Care - Care delivered by referral to a specialist or subspecialist by the primary care source. This may include ambulatory or inpatient care.

1.25 Social Worker - A person who has a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education and at least one year of social work experience in a hospital or related clinical setting.

1.26 Staff Education Plan - A written plan developed and revised at least annually and implemented throughout the year, which describes a coordinated program for staff education for each service, including inservice programs and education, training in patient rights, staff development, on-the-job training, and continuing education, and the intervals and times at which these shall be given. Each employee shall receive education to develop skills and increase knowledge so as to improve patient care. (Occasional attendance at programs or conventions, or speakers invited to the facility, do not solely constitute an acceptable staff education plan.)

1.27 Staff Orientation Plan - A written plan for the orientation of each new employee to the duties and responsibilities of the service to which he/she has been assigned, as well as to the personnel policies of the facility. Each service shall provide an orientation for each new employee, to begin no later than the first day of employment.

1.28 Sterilization - A process of destroying all microorganisms including those bearing spores.

1.29 Tertiary Care - Specialized inpatient care, for example, care received in a burn or cardiac center.

2.0 Licensure Procedure

2.1 Certificate of Need

2.1.1 According to Chapters 136 and 138, Laws of New Jersey, 1971, Health Care Facilities Planning Act, a health care facility shall not be instituted, constructed, expanded, or licensed to operate except upon application for and receipt of a Certificate of Need issued by the Commissioner.

Application forms for a Certificate of Need and instructions for completion may be obtained from:

Division of Health Planning and Resources Development
Review and Comment Unit
New Jersey State Department of Health
John Fitch Plaza
P.O. Box 1540
Trenton, NJ 08625

2.2 Newly Constructed or Expanded Facilities

2.2.1 The application for license for a new ambulatory care facility shall include written approval of final architectural plans by the Office of Health Facility Construction and Monitoring, Division of Health Planning Resources, Department of Health.

2.2.2 A temporary permit may be issued to a newly constructed facility for the first six months of operation depending on the following conditions:

2.2.2.1 An office conference has taken place between the Licensure, Certification and Standards Program and the facility owner, administrator, and appropriate administrative personnel, for a comprehensive review of the conditions for licensure and operation;

2.2.2.2 Written approvals are on file with the Department from the local zoning, fire, health, and building authorities;

2.2.2.3 Written approvals of the water supply and sewage disposal system by the Environmental Protection Agency and local officials are on file;

2.2.2.4 A final onsite inspection visit has been made by representatives of Health Facilities Construction and Monitoring, and Licensing, Certification and Standards, who verify that the building has been constructed in accordance with the final architectural plans approved by the Department; and

2.2.2.5 Availability of professional personnel is in compliance with staffing standards established by the Department.

2.2.2.6 No health care facility shall accept patients until the facility has the written approval and license issued by the Department.

2.2.2.7 Any health care facility with a construction program, whether a Certificate of Need is required or not, must submit plans to the Department for review and approval prior to the initiation of any work.

2.3 Application for Licensure

2.3.1 Following acquisition of a Certificate of Need, any person, organization, or corporation desiring to operate an ambulatory care facility shall make application to the Commissioner of Health for a license on forms prescribed by the Department. Such forms can be obtained by submitting a request to the Division of Health Facilities Evaluation, New Jersey State Department of Health, John Fitch Plaza, P.O. Box 1540, Trenton, New Jersey 08625.

2.3.2 The Department shall charge a non-refundable fee of $100 for the filing of an application for licensure of an ambulatory care facility and any renewal thereof. Facilities providing a single diagnostic service or a single therapeutic modality as enumerated in the standards shall be charged a non-refundable fee of $50 for the filing of an application for licensure and any renewal thereof.

2.3.3 Any individual or individuals considering application for license to operate an ambulatory care facility should make an appointment for a preliminary conference at the Department with the Licensing, Certification and Standards Program.

2.3.4 No health care facility shall be owned or operated by a person convicted of a high misdemeanor relating adversely to his/her capability of owning or operating that facility unless that person is considered rehabilitated as stipulated in the Rehabilitated Convicted Offenders Act, N.J.S.A. 2A:168A-1 et seq.

2.4 Surveys

2.4.1 When the written application for licensure is approved and the building is said to be ready for occupancy, a survey of the facility by representatives of the Department shall be conducted.

2.4.2 The findings of the survey with respect to adherence to the licensure standards shall be documented and a letter noting any deficiencies found forwarded to the facility.

2.4.3 Following receipt of the letter noting deficiencies, the facility shall notify the Department when the deficiencies have been corrected.

2.4.4 A resurvey of the facility, to be conducted by the Department following correction of the deficiencies, will be scheduled prior to occupancy as needed.

2.4.5 If, on the basis of the Departmental survey, the facility meets the licensure standards, the facility will be issued a temporary permit valid for six months.

2.4.6 Survey visits, including the review of all agency and patient records and conferences with patients may be made to an ambulatory care facility at any time by authorized staff of the Department.

2.5 Full License

2.5.1 A full license shall be issued on expiration of the temporary permit, if periodic surveys by the Department have determined that the health care facility is operated in the manner required by Chapters 136 and 138, Laws of New Jersey, 1971, Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq. and by the rules and regulations pursuant thereto.

2.5.1.1 A license shall be granted for a period of one year or less as determined by the Department.

2.5.1.2 The license shall be conspicuously posted in the facility.

2.5.1.3 A license is not assignable or transferable. It shall be immediately void if the facility ceases to operate or if its ownership changes.

2.5.1.4 A license, unless sooner suspended or revoked, shall be renewed annually on the date, or within 30 days, of the original licensure date. The facility will receive a request for renewal fee 30 days prior to expiration of the license. A renewal license shall not be issued unless the licensure fee is received by the Department.

2.6 Surrender of License

2.6.1 The facility shall directly notify each patient concerned or the patient's responsible relative, the patient's physician, and any third party payors concerned at least 30 days prior to the voluntary surrender of a license, or as directed under an order of revocation or suspension of license. The license shall be returned to the Department.

2.7 Waiver

2.7.1 In order not to discourage the establishment of ambulatory health services essential to the improvement of access of care to New Jersey citizens, and to help control the costs of health care, the Commissioner may, in accordance with the general purposes and intent

of this document, waiver sections of these regulations if, in the opinion of the Commissioner, waiver of such regulations would not endanger the life, safety, or health of the patient. The Commissioner will state in writing the reasons for granting a waiver to a facility.

The governing authority of any presently operational program or any new program seeking approval that does not or will not meet the standards set forth herein shall apply to the Commissioner for possible waiver. The application shall provide complete information as to:

2.7.1.1 Requirements not met or not to be met in whole or in part;

2.7.1.2 Budget (actual or proposed);

2.7.1.3 Sources of funding;

2.7.1.4 Cost per patient visit;

2.7.1.5 Estimated cost per patient visit if all requirements were met; and

2.7.1.6 Projected time schedule when all requirements can be met and patient load necessary to support them.

FACILITIES PROVIDING PRIMARY HEALTH AND MEDICAL SERVICES

3.0 General Requirements

3.1 The facility shall provide preventive, diagnostic, and therapeutic services. The provision of primary care shall include, but not be limited to, health and medical services for adults, health and medical services for children, and prenatal, postpartum, and gynecological care.

3.2 The facility shall comply with applicable federal, state, and local regulations and requirements including, but not limited to:

3.2.1 Building;

3.2.2 Zoning;

3.2.3 Fire;

3.2.4 Safety;

3.2.5 Health; and

3.2.6 Civil rights.

3.3 The facility shall comply with all applicable provisions contained in Chapters 136 and 138, Laws of New Jersey, 1971, Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq.

3.4 No health care facility shall be owned or operated by a person convicted of a misdemeanor or a high misdemeanor relating adversely to his/her capability of owning or operating that facility unless that person is considered rehabilitated as stipulated in the Rehabilitated Convicted Offenders Act, N.J.S.A. 2A:168A-1 et seq.

3.5 All professional personnel shall be licensed or authorized under the appropriate laws or regulations of the State of New Jersey.

3.6 The facility shall have a recognized agency of auspices (governing authority) which is either incorporated or functioning under N.J.S.A. 26:3-1 et seq.

3.7 A written narrative of the program shall be submitted by the agency of auspices to the Department describing the services provided, staffing patterns, functional space requirements, departmental relationships, and other basic information relating to the fulfillment of its objectives.

3.8 The facility shall be so organized that clear lines of authority, responsibility, and accountability are present and functioning so as to ensure an integrated continuum of services for the patient. (An organizational chart shall be provided delineating the lines of authority for the delegation of responsibility down to the patient care level.)

3.9 The facility shall have a written contractual arrangement for mandated or proposed services not provided at the facility. This arrangement can be with a licensed hospital or laboratory/radiological facility approved by the Department. The services shall include, but not be limited to: specialized ambulatory care; inpatient care; specialized radiological services; laboratory and other diagnostic services.

3.10 Services shall be provided on a scheduled basis, a minimum of five days per week (except for facilities providing a single modality of care).

3.11 A policy and procedure manual shall be developed as a guide for organization and operation of the facility. It shall be kept current utilizing the input of supervisory staff of individuals directly involved with the delivery of care. The manual shall include:

3.11.1 A description of the organization, structure, and allocation of responsibility and accountability;

3.11.2 A description of the modalities of health and medical services provided, including a listing of services and procedures which may and may not be performed in the facility;

3.11.3 A description of referrals and linkages with other ambulatory care and inpatient facilities so that patients can receive continuity of care;

3.11.4 A description of the system for maintenance of patient records;

3.11.5 A description of the process of evaluation of patient care;

3.11.6 A staff orientation and a staff education plan, including plans for each service; and

3.11.7 Policies and procedures for the guidance of personnel.

3.12 The manual shall be available and readily accessible to all staff.

3.13 The facility shall have a designated medical director and an administrator, as appropriate.

3.14 The facility shall establish and implement procedures for staff, approved by the Department, including:

3.14.1 A system of staff pre-employment physical examinations and subsequent health examinations. The content and frequency of such examinations shall be documented in the facility policy manual; and

3.14.2 Staff orientation and education for each service, as specified in the staff orientation and education plans. Each service shall maintain written records of these activities, including the names of persons attending, methods used, and an evaluation of their effectiveness.

3.15 The facility shall establish and describe a mechanism for dealing with both staff and patient grievances.

3.16 The facility shall develop written policies on means of patient transportation to linked services and facilities.

3.17 If the facility provides services other than those noted in Section 3.1, it shall comply with the regulations corresponding to the service(s) offered as contained in "Facilities Providing a Single Modality of Care."

3.18 All facilities shall comply with the physical plant requirements contained in Section 40.0 of this document.

3.19 The facility shall have a written plan and procedures to be followed in case of medical emergencies, equipment breakdown, fire, or other disaster. The plan shall be developed with the assistance of fire and safety experts from local municipalities. Emergency procedures shall, at a minimum, include the following:

3.19.1 Procedures for emergencies shall specify persons to be notified, locations of emergency equipment and alarm signals, evacuation routes, procedures for evacuating patients, frequency of fire drill, and assignment of specific tasks and responsibilities of all personnel.

3.19.2 Simulated drills of all plans shall be conducted at least four times a year and a record of each drill written which includes the date, hour, description of the drill, staff participation, and name of the person in charge.

4.0 Auspices

4.1 The facility shall have a governing authority.

4.2 The governing authority shall assume full legal responsibility for the policy determination, management, operation, and financial viability of the facility, personnel policies, and employment.

4.3 The governing authority shall be responsible for:

4.3.1 Services provided in the facility and the quality of care rendered to patients;

4.3.2 Provision of a safe physical plant equipped and staffed to maintain the facilities and services;

4.3.3 Adoption and annual review of written bylaws or an acceptable equivalent which shall be submitted to the Department;

4.3.4 The holding of meetings at least quarterly and documentation of such meetings through minutes, including a record of attendance; and

4.3.5 Establishment and implementation of a system whereby staff and patient grievances can be identified within the facility. This system shall include a feedback mechanism through management to the governing authority indicating that remedial action was taken.

4.4 The governing authority shall notify the Commissioner of any change in administrator and/or modalities of service offered.

5.0 Administration

5.1 A full-time administrator shall be appointed in all facilities having more than 20,000 patient visits per year. Facilities with less than 20,000 patient visits shall have a part-time administrator or an administrator available through the parent institution.

5.2 The administrator shall be responsible for:

5.2.1 Planning for and administration of the total management, operational, fiscal, and reporting components of the facility. This shall include development of appropriate patient registration, appointment, and follow-up systems;

5.2.2 Assumption of responsibility for employment and placement within the facility of all non-professional staff;

5.2.3 Together with the medical director, development and implementation of appropriate processes for:

5.2.3.1 Maintaining administrative relationships and communication with support services and community resources; and

5.2.3.2 Communication with staff, such as group meetings, individual staff conferences, written memoranda, and other methods of exchanging information among staff;

5.2.4 Participation in policy and administrative decision-making;

5.2.5 Administration and supervision of the non-clinical operations of the program; and

5.2.6 Acting as a liaison to the governing authority on behalf of the medical director, the staff, and the patients.

5.3 The administrator or his/her designee shall be directly or indirectly accountable to the governing authority.

5.4 An alternate shall be designated in writing to act in the absence of the administrator.

5.5 A physician shall be designated as medical director.

5.5.1 In facilities having less than 10,000 patient visits per year, the medical director may serve as administrator and provide direct patient care.

5.5.2 In facilities having between 10,000 and 20,000 patient visits per year, the medical director may either serve as administrator or provide direct patient care.

5.6 The medical director shall be responsible for:

5.6.1 Planning and provision of medical direction and leadership, and maintenance of the quality of patient care provided;

5.6.2 Planning for, participation in, and implementation of the policy objectives and provision of services of the facility;

5.6.3 Development and direction of an ongoing training program in primary care for staff professionals and paraprofessionals;

5.6.4 Development and maintenance of a system of audit and evaluation of patient care. This will include responsibility for maintenance of adequate patient records;

5.6.5 Training and supervision of medical students, interns, residents, and nurse midwives if utilized in the facility; and

5.6.6 Establishment of effective collaborative relations with support services and community resources.

5.7 The medical director shall be directly or indirectly responsible to the governing authority.

6.0 Organization and Delivery of Health Services and Medical Care Services

The facility shall provide preventive, diagnostic, and therapeutic health services to patients. This shall also include health maintenance, health education, social services, and referral when necessary to appropriate health and social facilities and programs.

6.1 Medical Services

The general medical services shall care for adults over 16 years of age and shall provide comprehensive ambulatory health services, i.e. diagnosis, treatment, and follow-up for acute and chronic conditions and periodic health evaluations with appropriate diagnostic and screening procedures for the well individual, which shall include a complete medical history, physical examination, and diagnostic procedures appropriate to the age and sex of the individual.

6.1.1 Vital signs (height, weight, blood pressure, temperature, pulse rate, respiratory rate) shall be recorded for all patients.

6.1.2 Routine screening procedures for new enrollees attending the medical service shall include, but not be limited to:

6.1.2.1 Complete blood count;

6.1.2.2 Urine analysis;

6.1.2.3 Serological test for syphilis (when appropriate);

6.1.2.4 Tuberculin test with indicated follow-up if the enrollee is in close contact with a diagnosed case of tuberculosis or is from a high incidence area as designated by the Department;

6.1.2.5 Papanicolaou smear (when appropriate);

6.1.2.6 Smear and culture for gonorrhea (when appropriate);

6.1.2.7 Electrocardiogram (over 40); and

6.1.2.8 Glaucoma screening (over 35).

6.1.3 Emergency dental services shall be available on the premises or through a referral mechanism with a dental facility or office.

6.1.4 The facility shall have a written plan for management and triage of walk-in patients for a specific or episodic service.

6.2 Pediatric Services

6.2.1 The general pediatric services shall provide preventive, diagnostic, and therapeutic health services for children from birth to 16 years of age.

6.2.2 Well infant and child care shall include a complete medical history and physical examination, an assessment of growth and development, immunization, and appropriate diagnostic screening procedures. The recommendations of the American Academy of Pediatrics and the State Child Health Conference Manual of Standards and Procedures shall be followed in terms of:

6.2.2.1 Frequency of visits;

6.2.2.2 Immunization schedules; and

6.2.2.3 Appropriate screening procedures.

6.2.3 Routine screening procedures for children from birth to 16 years of age shall include, but not be limited to:

6.2.3.1 Urine analysis;

6.2.3.2 P.K.U. testing on all children who did not have the test after being on protein feeding for 48 hours;

6.2.3.3 Complete blood count;

6.2.3.4 Sickle cell preparation (when appropriate);

6.2.3.5 Blood lead level (when appropriate);

6.2.3.6 Visual screening on all children over three and one-half years of age. Visual screening shall include testing for near and far vision and for fusion;

6.2.3.7 Blood pressure determination (routinely initiated at age three and repeated annually thereafter);

6.2.3.8 Auditory screening on all children over age one;

6.2.3.9 Serological test for syphilis (when appropriate); and

6.2.3.10 Tuberculin test at one year of age with repeated testing upon becoming at risk.

6.2.4 All children over the age of three attending the pediatric service shall be referred for dental examination, prophylaxis, preventive, and emergency dental services. A referral mechanism shall be established with a dental facility or office if dental care is not provided on the premises.

6.3 Prenatal, Postpartum, and Gynecological Services

6.3.1 The prenatal, postpartum, and gynecological services of an ambulatory care facility providing primary care shall conform to the standards set forth in Section 26.0, Prenatal and Postpartum Care.

6.3.2 There shall be an agreement with one or more backup hospitals for delivery of patients and to ensure continuity of care.

6.3.3 As soon as possible after patient registration, agreements for delivery of the patient shall be made and the name and address of the hospital responsible for delivery recorded in the patient's chart.

6.3.4 A system approved by the Commissioner shall be established for availability of patient records at all times to the hospital where delivery is to take place.

6.3.5 The facility shall provide postpartum examinations to patients four to six weeks after delivery. A summary of the patient's hospital course, including data on the labor and delivery or a copy of the labor and delivery record, shall be available at the patient's postpartum visit. Onsite counseling, referral, and family services shall be available to the patient and the services offered documented in the medical record.

6.3.6 All patients receiving prenatal or postpartum care shall be registered in the general medical or general pediatric service for ongoing care.

6.3.7 Every effort shall be made to register the infant in the pediatric service of the primary care facility.

6.3.8 All female patients attending the general medical service shall be referred to the gynecological service for the following procedures if these are not performed in the medical service:

6.3.8.1 Papanicolaou smear;

6.3.8.2 Smear and culture for gonorrhea (when appropriate); and

6.3.8.3 Pelvic examination.

6.4 Radiology Services

6.4.1 A written contractual arrangement shall be made for provision of X-ray, diagnostic, and therapeutic services which are not available at the facility.

6.4.2 All X-ray films shall be available upon request to physicians at the time of the patient visit.

6.5 Electrocardiogram Services

6.5.1 An electrocardiogram machine with someone competent to operate the machine shall be available at the facility and a physician qualified to interpret electrocardiograms shall be available to the facility.

6.6 Laboratory Services

6.6.1 Basic laboratory services shall be provided at the facility or by written arrangement with a licensed laboratory or hospital.

6.6.2 On the days the facility is in operation, a system for pickup of specimens and reporting of test results shall be implemented.

6.6.3 Basic laboratory screening procedures shall be provided on the premises. These shall include, but not be limited to:

6.6.3.1 Urine analysis test for protein, blood, sugar, and ketone;

6.6.3.2 Micro-hematocrit; and

6.6.3.3 Agar plates and incubator for throat cultures (hemolytic streptococci).

6.6.4 Timing of follow-up visits and reporting of test results shall be coordinated so that information is available at the time of the patient's visit.

6.7 Health Education and Counseling

6.7.1 Health education and counseling at the facility shall be given or supervised by a public health nurse or an acceptable substitute as defined in the program narrative.

6.7.2 Individual patient and family as well as group health education programs shall be offered at the facility.

6.7.3 Assistance shall be given to families in solving psychosocial and socioeconomic crisis situations, and referrals shall be made as needed for treatment and care by other agencies (e.g. day care centers, residential facilities, nursing homes, mental health programs).

6.8 Emergency Medical Care

6.8.1 The facility shall provide emergency medical services on the premises during the hours of operation. Services that cannot be provided at the facility shall be provided through contractual arrangement with a backup hospital. Information regarding availability of emergency services at the backup hospital(s) during the hours the facility is not in operation shall be provided to all patients. (See 28.11.4)

6.8.2 Each facility shall maintain, as a minimum, the following emergency equipment:

Oxygen
Defibrillator
Meperidine hydrochloride (injectable)
Sodium amobarbital (injectable)
50 percent glucose (parenteral)
Syrup of ipecac
Splints
Ambu bag and mask
Epinephrine
Lidocaine
Diazepam (injectable)
Aminophylline
Tourniquets
Betadine and vaseline gauze
Extension cord

Cardiac arrest board	Suction equipment with catheter tip
I.V. pole	Needles
Scissors	I.V. solution
Syringes	Intubation tubes
I.V. cutdown tray	Airway
Multi-sized catheters	

6.9 Pharmacy Service

6.9.1 If a pharmaceutical service is offered directly by the facility, it shall be provided in accordance with federal and state laws.

7.0 Staffing Patterns

7.1 The facility shall provide medical and ancillary staff necessary for its operation as follows:

7.1.1 A full-time administrator for a facility with 20,000 or more annual patient visits (See 5.1);

7.1.2 A full-time medical director (See 5.5);

7.1.3 One full-time internist or family practice specialist who is board-certified or board-eligible or the full-time equivalent per 10,000 annual patient visits of adults over 16 years of age.

7.1.4 One full-time pediatrician or family practice specialist who is board-certified or board-eligible or the full-time equivalent per 10,000 annual patient visits of children under 17 years of age.

7.1.5 A half-time obstetrician/gynecologist or family practice specialist who is board-certified or board-eligible; or the half-time equivalent per 5,000 annual female patient visits of all ages.

7.2 All physicians shall be licensed or authorized to practice in New Jersey. They need not be board-certified but must have experience in the service area to which they are assigned.

7.3 Facilities with annual patient visits of 20,000 or more shall have:

7.3.1 A minimum of one full-time public health nurse. In facilities providing less than 20,000 patient visits, a public health nurse shall be available on a half-time basis;

7.3.2 Ancillary personnel to perform functions listed in Section 7.5; and

7.3.3 Clerical personnel to perform functions listed in Section 7.6.

7.4 The duties of the public health nurse shall include, but not be limited to, health education and counseling for individual patients and families, organized group instruction, in-service education for staff, utilization of community resources, and referrals to community agencies.

7.5 Registered nurses, licensed practical nurses, and ancillary staff shall perform functions including, but not limited to:

7.5.1 Assisting the physicians;

7.5.2 Performance of vital signs;

7.5.3 Interpretation and reinforcement of physician's instructions;

7.5.4 Initiation of follow-up on broken appointments of patients;

7.5.5 Instruction of patients regarding laboratory and diagnostic procedures; and

7.5.6 Home visits and outreach services.

7.6 Clerical staff shall be available to perform functions involved in:

7.6.1 Patient registration system;

7.6.2 Patient appointment system;

7.6.3 Financial investigation;

7.6.4 Payment, billing, and reimbursement mechanism; and

7.6.5 Delivery and return of patient medical records.

7.7 The clerical staff shall be responsible to the administrator of the facility.

7.8 If the patient population speaks a foreign language, there shall be an interpreter available or a mechanism for interpretation established. The interpreter may be a professional or clerical staff member of the facility.

8.0 Patient Flow

8.1 A registration and appointment system shall be established.

8.2 Identification data shall be recorded upon registration. (See Section 10.1)

8.3 A system whereby informed written consent is obtained for all patients for services provided in the facility shall be implemented.

8.4 A block or individual appointment system shall be maintained.

8.5 A system for follow-up of broken appointments including those for diagnostic procedures shall be implemented and maintained.

8.6 The facility shall function on both an appointment and a walk-in basis.

8.7 The hours of operation of the facility shall be such that the patient population can be served at times convenient for transportation and for their working hours. Evening and/or weekend hours of service shall be available to enable continuity of care.

8.8 Fee schedules shall be made available to the patient upon registration.

8.9 The facility shall adopt written policies regarding the rights and responsibilities of patients. This document shall be made available to patients upon registration.

9.0 Continuity of Care

A system of patient registration shall be established whereby a patient is ensured enrollment in a program of care. Registration will initiate a system which will lead into a scheduling and alerting system to ensure that all necessary appointments and follow-up visits for preventive, diagnostic, and therapeutic health services take place. The dignity and personal privacy of the patient shall not be infringed upon by the registration system.

9.1 A system shall be established whereby, whenever possible, the patient is cared for by the same health professional.

9.2 Printed or written instructions, including multilingual as indicated, shall be available to the patient in addition to verbal instruction provided by physicians, nurses, or other staff.

9.3 Telephone consultation with a professional staff member shall be available to patients during the hours the facility is in operation. A system for referrals to appropriate specialists, as indicated, shall be established.

9.4 Results of all consultations, including telephone consultation and referrals both within the facility and with other health and health-related agencies, shall be available in the patient's record prior to the patient's next scheduled visit to the facility.

9.5 A formal system of referrals and linkages shall be established with all sources of ambulatory and inpatient care, in order to attempt to provide continuity of care to each individual attending the facility. Written agreements shall be established with all facilities which provide secondary and tertiary care.

9.6 A method of transfer of relevant patient information to and from the sending facility and to and from the receiving facility shall be implemented.

10.0 Medical Records

10.1 Accurate and complete medical records shall be kept for each patient and filed in an accessible area within the facility. A complete medical record is one which includes, but is not limited to, patient identification data (name, address, date of birth, race (optional), sex, referral source, financial data, chief complaint, history of present illness, past history, personal and family history, physical examination, diagnosis, therapy, physician's orders and results of all specialized examinations, etc., treatment, medications provided, plan of care, and appropriate signatures.

10.2 Each record shall contain a plan of care for the patient which includes immediate therapy, long-range care and a listing of all necessary referrals for health and health-related problems.

10.3 A progress note shall be made on the patient's medical record at each visit by each health professional who has contact with the patient.

10.4 A unit record shall be maintained for each patient. The record shall incorporate services provided in the facility and summaries of services both ambulatory and inpatient provided at other health and health-related facilities. This patient record shall be filed as a single unit together with laboratory, X-ray, and other pertinent reports.

10.5 Records shall be available to the professional staff prior to the patient's appointment in order to permit review.

10.6 All professional staff shall write progress notes on the patient's medical record so that a sequential history of the patient's health status shall be available.

10.7 A medication sheet shall be incorporated into the patient's medical record indicating the drug profile, e.g. the name, date, dosage, and duration of all medications prescribed.

10.8 All orders for treatment or medication shall be written, dated, and signed by the physician. All reports, including progress notes contained in the patient's medical record shall be typewritten or written in ink, legible, and dated and signed by the recording person.

10.9 All medical records shall be preserved as required by N.J.S.A. 26:8-5 et seq.

10.10 Medical record information shall be safeguarded against loss or unauthorized use. Written procedures shall govern the use and removal of records and conditions for release of information. The patient's written consent shall be obtained for release of information not required by law.

10.11 Upon transfer of a patient to another health care facility, ambulatory or inpatient, a summary of the patient's medical record or an abstract thereof shall be sent promptly to the receiving facility with the written consent of the patient. In the event of denial of permission, a copy of the patient's written denial shall be kept in the patient's medical record at the facility. If the patient refuses to sign the permission denial form, a written statement to that effect by a staff member, appropriately witnessed, shall be included in the record.

11.0 Patient Care Statistics

11.1 Patient care information shall be collected monthly and submitted annually to the Department. The data to be collected shall include, but not be limited to:

11.1.1 Total number of patients served per year;

11.1.2 Number of new patients per year; and

11.1.3 Number of patient visits per year.

11.1.4 This information shall be broken down by unit of service provided.

12.0 Financial Data

12.1 Upon development of a uniform cost reporting system approved by the Health Care Administration Board, the facility shall adopt and maintain the uniform system of cost reporting from which reports will be prepared to meet the requirements of the Commissioner as stated in Chapters 136 and 138, Laws of New Jersey, 1971, Health Care Facilities Planning Act, N.J.S.A. 26:2H-1, et seq.

12.2 An annual financial report shall be submitted to the Department which will include a statement of income and expenditures by unit of service.

13.0 Audit and Evaluation

13.1 A multidisciplinary audit committee shall be appointed.

13.2 A plan for audit and evaluation of patient care shall be developed by the facility and submitted in writing to the Department for review and approval. This plan shall include ongoing monitoring of professional and program activities and audit of patient medical records. The following shall be included in the audit and evaluation system:

13.2.1 Annual review of professional staff qualifications;

13.2.2 Periodic review of educational programs in which professional staff participate;

13.2.3 Periodic evaluation of the processes by which medical care and health services are delivered, i.e. patient utilization, registration and appointment systems, follow-up on broken appointments, staffing patterns, maintenance of physical facilities and equipment; and

13.2.4 Audit of patient charts on an ongoing basis by means of:

13.2.4.1 Determination of objective criteria for a modality of patient care;

13.2.4.2 Review of patient medical records in terms of conformity to established criteria;

13.2.4.3 Recording of deficiencies found;

13.2.4.4 Specific recommendations for correction of the deficiencies found; and

13.2.4.5 Follow-up to ascertain if deficiencies have been corrected.

14.0 Dental Services

14.1 Dental services, other than required prophylaxis, preventive and emergency services, may be provided as a component of a primary care facility, a comprehensive pediatric care facility, a prenatal and postpartum facility, or a surgical service.

14.2 The dental service, if provided, shall include, but not be limited to:

14.2.1 Complete examination and diagnosis of the teeth and supporting structures;

14.2.2 Radiographs where indicated. These may be provided in the facility or by written agreement with another facility;

14.2.3 Elimination of pain and infection;

14.2.4 Restoration of carious or fractured teeth;

14.2.5 Maintenance or recovery of spaces when the space will have an effect on occlusion;

14.2.6 Treatment of injuries; and

14.2.7 Treatment of disease of bone and soft tissue.

14.3 All children over the age of three attending the pediatric service shall be referred for dental examination, prophylaxis, preventive and emergency services.

14.4 The dental service provided shall include a minimum of five half sessions or three full sessions per week for clinics open five days per week. (A session is equivalent to a six-hour period of time excluding lunch and a half session is equivalent to a three-hour period of time.)

14.5 The facility shall provide dental and ancillary staff necessary for its operation as follows:

14.5.1 A minimum of one dentist present at each session; and

14.5.2 A minimum of one full-time dental assistant or hygienist.

15.0 Infection Control

15.1 The facility shall establish a multidisciplinary Infection Control Committee, consisting of at least the medical director, the administrator, and a representative of the nursing service. A representative of each service offered by the facility shall serve on the Committee at least on a consultative basis.

15.2 The Committee shall be responsible for, but not limited to, the following:

15.2.1 In conformance with the New Jersey State Sanitary Code, development and implementation of a system for investigating, reporting, evaluating, and maintaining records for patients and personnel of infections which are reportable, or which may be related to activities and procedures of the facility, as a means of surveillance and monitoring of the effectiveness of infection control measures;

15.2.2 Development of written policies and procedures, approved by the Department, for cleaning, disinfection, and sterilization practices and techniques used in the facility, including, but not limited to, the following:

15.2.2.1 Care of utensils, instruments, solutions, dressings, articles, and surfaces;

15.2.2.2 Techniques to be used during each patient contact, including handwashing before and after caring for a patient;

15.2.2.3 Criteria for isolation of patients, and isolation procedures;

15.2.2.4 Procedures for care of equipment and other devices that provide a portal of entry for pathogenic microorganisms;

15.2.2.5 Selection, storage, use, and disposition of non-disposable patient care items;

15.2.2.6 Selection, storage, use, and disposition of disposable patient care items. Disposable items shall not be reused; and

15.2.2.7 Selection, storage, use, and disposition of hypodermic needles and syringes, in accordance with N.J.S.A. 2A:170-25.17.

15.3 Each service in the facility shall develop written infection control policies and procedures for that service, based upon those developed by the Infection Control Committee.

15.4 The occurrence of a reportable disease shall be reported, in conformance with Chapter 2 of the New Jersey State Sanitary Code. The facility shall also have written policies and procedures, developed by the Infection Control Committee, for reporting other diseases, according to Regulations 2 and 3 of Chapter 2. The Infection Control Committee shall develop policies and procedures for exclusion from work, and authorization to return to work, of employees with communicable diseases.

15.5 Written reports of state and local sanitary inspections, including cultures taken on food, equipment, and personnel, shall be sent to the Infection Control Committee for evaluation and corrective action.

16.0 Housekeeping Services

16.1 The facility shall maintain the organization, management, and operation of housekeeping services in accordance with a written organizational plan which shall describe the responsibility, authority, and accountability relationships of personnel, the functional structure of the service, and the relationship of the housekeeping service to other services.

16.2 The administrator or his/her designee shall ensure that:

16.2.1 A written work plan for cleaning operations is developed, with categorization as to daily, weekly, monthly, or annual assignment for each area of the facility;

16.2.2 All housekeeping personnel are assigned duties, supervised, and evaluated;

16.2.3 Housekeeping personnel are trained in procedures of cleaning, including the use, cleaning, and care of equipment;

16.2.4 Procedures are developed for selection and use of housekeeping and cleaning products and equipment; and

16.2.5 Housekeeping services are evaluated.

16.3 The facility shall comply with the provisions of the New Jersey State Sanitary Code and with the following:

16.3.1 The facility and its contents shall be free from dust, dirt, and debris;

16.3.2 Nonskid wax shall be used on all waxed floors;

16.3.3 All rooms shall be ventilated to help prevent condensation, mold growth, and noxious odors;

16.3.4 Throw rugs or scatter rugs shall not be used in the facility;

16.3.5 All mechanical equipment shall be in working order, covered to protect from contamination, and accessible for cleaning and inspection;

16.3.6 All equipment shall have unobstructed space provided for operation;

16.3.7 All equipment and materials necessary for cleaning, disinfection, and sterilization shall be provided;

16.3.8 Thermometers shall be maintained in refrigerators and storerooms used for perishable items;

16.3.9 All poisonous and toxic materials shall be identified, labeled, and stored in a locked cabinet or room that is used for no other purpose;

16.3.10 Pesticides shall be applied so as to prevent contamination to patients and food. Vapona (insecticidal) strips shall not be used anywhere in the facility;

16.3.11 Articles in storage shall be elevated from the floor to facilitate cleaning and eliminate rodent harborages;

16.3.12 Unobstructed aisles shall be provided between articles in storage;

16.3.13 A program shall be maintained to keep rodents, insects, vermin, birds, animals, dust, and contamination out of the facility;

16.3.14 Insect and rodent harborages shall be eliminated from the facility;

16.3.15 Toilet tissue shall be provided at each toilet at all times;

16.3.16 Solid or liquid waste, garbage, and trash shall be disposed of or stored in a manner approved by the Department and so as to prevent fire, contamination, or transmission of disease. Solid waste shall be stored in insect and rodent-proof, fireproof, nonabsorbent, watertight containers with tightfitting covers;

16.3.17 Draperies, upholstery, and other fabrics or decorations shall be fire-resistant and flameproof; and

16.3.18 All patient areas shall be free from noxious odors.

16.4 If a commercial housekeeping service is used, it shall be required to maintain at least the standards outlined herein.

16.5 Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times. Hot water at shower, bathing, and handwashing facilities shall not exceed 110 degrees F.(43 degrees C.).

16.6 The administrator or his/her designee shall ensure that:

16.6.1 Written policies and procedures for linen and laundry services, including methods of storage and transportation, are developed and implemented;

16.6.2 Soiled linen and laundry are collected so as to avoid microbial dissemination into the environment, and are placed in impervious bags or containers that are closed at the site of collection. Separate containers shall be used for transporting clean linen and laundry, and soiled linen and laundry; and

16.6.3 Soiled linen and laundry are stored in a ventilated area separate from any other supplies, and are not stored, sorted, rinsed, or laundered in patient rooms, bathrooms, areas of food preparation and/or storage, or areas in which clean material and equipment are stored.

FACILITIES PROVIDING A SINGLE MODALITY OF CARE

21.0 Facilities Providing Family Practice

21.1 When family practice services solely are offered by a facility having an AMA approved educational program in conjunction with a hospital, the services shall be provided in accordance with Sections 1.2 through 6.6.4, 6.8, 6.9.7.7 through 13.2.4.5. In addition, these facilities shall meet the service requirements for Sections 25.0, 26.0, 27.0, and 28.0 in the event such services are offered.

21.1.1 The services provided in a family practice program shall be flexible. However, ambulatory care shall be offered in the following areas as a minimum:

21.1.1.1 Internal medicine;

21.1.1.2 Pediatrics;

21.1.1.3 Obstetrics and gynecology;

21.1.1.4 Surgery; and

21.1.1.5 Psychiatry.

21.2 Staffing Patterns

The facility shall provide medical and ancillary staff on the premises for its operation in accordance with the following:

21.2.1 One full-time program director (the physician who is administratively responsible for educational programs provided by the facility) shall be responsible for direction of the services provided. The program director shall be a family physician, defined as one who:

21.2.1.1 Serves as the physician of first contact with the patient and provides entry into the health care system;

21.2.1.2 Evaluates the patient's health needs, provides personal medical care within one or more fields of medicine, and refers the patient when indicated to appropriate sources of care while preserving the continuity of his/her care; and

21.2.1.3 Develops a responsibility for the patient's continued health care and acts as a coordinator of the health services provided to the patient.

21.2.2 The family practice shall be so organized that the services of a public health nurse, social worker, pharmacist, dietitian, and health educator are available on the premises or through written contractual arrangements.

21.2.3 Consultant services shall be available.

21.3 Physicial Plant Requirements

All facilities shall comply with the physical plant requirements contained in Section 40.0 of this document.

FACILITIES PROVIDING HEALTH MAINTENANCE ORGANIZATION SERVICES

22.0 Health Maintenance Organization Services

22.1 Definitions

22.1.1 Enrollee - An individual who has been enrolled with a health maintenance organization (N.J.S.A. 26:2J-1 et seq.).

22.1.2 Health Maintenance Organization - Any person which directly or through contracts with providers furnishes at least basic comprehensive health care services on a prepaid basis to enrollees in a designated geographical area (N.J.S.A. 26:2J-1 et seq.).

22.1.3 Medical Director - A physician authorized to practice medicine in the State of New Jersey pursuant to N.J.S.A. 49:9-1 et seq.

22.2 General Requirements

A health maintenance organization shall provide services in accordance with Sections 1.0 (excluding 1.11, 1.16), 2.0, 6.0 (excluding 6.1.3, 6.2.4, 6.8.2), 7.0, 8.0 (excluding 8.6), 9.0 (excluding 9.5), 10.0, 11.0, 12.0, 13.0, 25.0 (excluding 25.1, 25.2.1.1), 26.0 (excluding 26.1, 26.2.4, 26.3.1.1), 27.0 (excluding 27.1, 27.2.1), and 28.0 (excluding 28.1, 28.2.1) of this document and with the following:

22.2.1 The facility shall meet all federal and state regulations regarding health maintenance organizations and shall possess a valid certificate of authority issued by the Commissioner of Health;

22.2.2 The facility shall provide either directly or through written agreement primary care including, but not limited to, health and medical services for adults and children and prenatal, postpartum, and gynecological care;

22.2.3 The governing authority of the facility shall be responsible for the holding of meetings at least annually, and for documentation of such meetings through minutes, including a record of attendance; and

22.2.4 The facility shall function on both an appointment and walk-in basis for its enrollees.

22.3 Staffing Patterns

22.3.1 The staffing patterns of the facility shall reflect the range of services offered to enrollees. Staffing patterns shall adhere to the standards listed in Section 7.0 and provide the functions and services listed for single modalities of care (Sections 25.0, 26.0, 27.0, 28.0) in this document.

22.3.2 A registered nurse may be utilized in more than one modality of service, provided he/she has training in the areas to which assigned.

22.4 Emergency Medical Care

22.4.1 A health maintenance organization housing its physicians in a centralized location and providing health services at that common location shall maintain at a minimum the following emergency equipment:

Oxygen
Defibrillator
Meperidine hydrochloride (injectable)
Sodium amobarbital (injectable)
50 percent glucose (parenteral)
Syrup of ipecac
Splints
Cardiac arrest board
I.V. poles
Scissors
Syringes
I.V. cutdown tray
Multi-sized catheters
Ambu bag and mask
Epinephrine
Lidocaine
Diazepam (injectable)
Aminophyllin e
Tourniquets
Betadine and vaseline gauze
Extension cord
Suction equipment with catheter tip
Needles
I.V. solution
Intubation tubes
Airway

22.5 Continuity of Care

22.5.1 The facility shall establish a system of referrals and linkages with all relevant sources of ambulatory and inpatient care so as to ensure continuity of care.

22.6 Patient Care Statistics

22.6.1 Information concerning patient care shall be collected as stated in Section 11.0. In addi-

tion, the health maintenance organization shall include in the reporting system the number of patients terminated from the organization.

22.7 Physical Plant Requirements

22.7.1 All health maintenance organization facilities shall comply with the physical plant requirements contained in Section 40.0 of this document.

23.0 Computerized Axial Tomography Services

23.1 Definitions

23.1.1 Ancillary Staff shall mean a person who has training and experience as specified in the facility's policy and procedure manual(s).

23.1.2 Medical Director shall mean a physician who is authorized to practice medicine in the State of New Jersey and has training and experience as specified in the facility's policy and procedure manual.

23.1.3 Radiologist shall mean a physician who meets the requirements for certification by the American Board of Radiology, Inc. or the American Osteopathic Board of Radiology; or who has specialized in radiology, and whose competence in the practice of radiology is approved by the governing authority of the facility.

23.1.4 Radiologic Technician shall mean a person who is authorized by the State Department of Environmental Protection to apply radiation to human beings pursuant to N.J.S.A. 45:25-1 et seq.

23.1.5 Radiation Physicist/Health Physicist shall mean a person who meets the requirements for certification as a specialist in radiation safety by the American Board of Radiology, Inc. or the American Association of Physicists in Medicine; or who has a master's degree with a major in medical radiation physics, health physics, or radiologic health.

23.2 General Requirements

A computerized axial tomography service shall provide services in accordance with Sections 1.0 (excluding 1.11, 1.16), 2.0, 3.0 (excluding 3.18), 4.0, 5.0 (excluding 5.1, 5.5, 5.5.1, and 5.5.2), 6.8, 6.8.1, 6.8.2, 7.6 through 7.8, 8.0 through 8.4, 8.8, 9.0 (excluding 9.1), 10.1, 10.3, 10.5, 10.7 through 10.10, and 12.0.

23.3 Staffing Requirements

23.3.1 The facility shall provide medical and ancillary staff for its operation on the premises in accordance with the following:

23.3.1.1 A physician shall be appointed medical director of the service. The medical director shall ensure that radiation safety principles and practices, as well as the standards specified in 5.6 through 5.6.6, are observed;

23.3.1.2 At least one full-time or full-time equivalent radiologist;

23.3.1.3 An administrator who shall be responsible for 5.2 through 5.4. The governing authority may designate the director to function as the administrator;

23.3.1.4 At least 1.8 full-time equivalent radiologic technicians who shall carry out the functions assigned to them by the facility's policy and procedure manual(s); and

23.3.1.5 A radiation physicist/health physicist who shall be available for safety evaluations of all equipment, storage and handling practices, and staff education.

23.4 Utilization Requirements

23.4.1 The facility shall perform at least 1,500 scans in its first year of operation as a licensed computerized axial tomography facility.

23.4.2 The facility shall perform at least 3,000 scans in its second and each succeeding year of operation.

23.5 Data Reporting

23.5.1 The facility shall maintain and provide statistical data on the operation of the unit as specified by the Department.

23.5.2 The data shall be reported on a quarterly basis on forms supplied by the Department.

23.6 Patient Rights

23.6.1 The facility shall not refuse referrals on the basis of the patient's race, religion, sex, age, or ability to pay.

23.6.2 The facility shall document the reason for refusal of a referral. This documentation shall be available to the patient and the Department.

23.6.3 The facility shall certify in writing to the Department that it is in compliance with 23.6.1 on an annual basis.

23.7 Physical Plant

23.7.1 Computerized axial tomography services in freestanding ambulatory care facilities shall be in accordance with the Uniform Construction Code of New Jersey for business occupancy.

23.7.2 Computerized axial tomography services plant and/or equipment in a freestanding ambulatory care facility shall be in accordance with regulations of the State Department of Environmental Protection, Bureau of Radiation Protection, regarding radiation protection.

23.7.3 The State Department of Environmental Protection, Bureau of Radiation Protection, shall approve the computerized axial tomography services plant and/or equipment, prior to the onset of operation.

FACILITIES PROVIDING A SINGLE MODALITY OF CARE

25.0 Family Planning Services

25.1 Where family planning services solely are offered by the facility, they shall be provided in accordance with Sections 1.2 through 5.7, 6.6, 6.7, 6.8, 6.9, and 7.6 through 13.2.4.5 of this document and with the following:

25.2 Staffing Patterns

25.2.1 The facility shall provide medical and ancillary staff on the premises for its operation in accordance with the following:

25.2.1.1 One administrator who has training and experience in health administration, including at least one year of administrative or supervisory experience in a health care agency;

25.2.1.2 A minimum of one physician, board-certified or board-eligible in obstetrics and gynecology or experienced in the service to which assigned, available at each examining session;

25.2.1.3 A minimum of one registered nurse with special preparation in the field of family planning. Duties of the nurse shall include, but not be limited to:

25.2.1.3.1 Supervision of all nursing activities of the family planning service;

25.2.1.3.2 Individual and group counseling in family planning methods;

25.2.1.3.3 Assessing of emotional needs of patients;

25.2.1.3.4 Interpretation of physicians' medical recommendations, and evaluation of patients' ability to follow;

25.2.1.3.5 Screening patients' records and initiation of referral to intramural services and agencies outside the facility; and

25.2.1.3.6 Initiating follow-up and broken appointment routines;

25.2.1.4 Certified nurse-midwives and family planning nurse practitioners, who may serve in the facility under medical direction.

25.2.2 Consultants shall be available to the facility. Types of consultants shall include, but not be limited to:

25.2.2.1 Public health nurse;

25.2.2.2 Dietitian or nutritionist;

25.2.2.3 Social worker; and

25.2.2.4 Medical specialists (for example, psychiatrists, internists).

25.2.2.5 The names, addresses, and telephone numbers of consultants shall be available at the facility and the policy manual shall indicate where the staff can obtain such information when needed.

25.3 Medical Procedures

25.3.1 Each new patient shall have the following services performed and data recorded:

25.3.1.1 Identifying data (see Section 10.1);

25.3.1.2 Complete health and medical history, including details of menstrual and obstetrical history and nutritional evaluation;

25.3.1.3 Physical examination, including breast and pelvic examinations, blood pressure, and weight;

25.3.1.4 Laboratory and clinical tests including:

25.3.1.4.1 Hemoglobin or hematocrit, and a sickle cell test when appropriate;

25.3.1.4.2 Complete urine analysis;

25.3.1.4.3 Serological test for syphilis;

25.3.1.4.4 Smear and culture for gonorrhea;

25.3.1.4.5 Papanicolaou smear;

25.3.1.4.6 Tuberculin test with indicated follow-up if in close contact with a diagnosed case of tuberculosis or from a high incidence area so designated by the Department;

25.3.1.4.7 Rubella titer (If negative for rubella titers, discussion with patient regarding control of conception and immunization with rubella vaccine).

25.3.1.5 Family planning orientation and education; and

25.3.1.6 Specific instruction about prescribed method of contraception, including written as well as oral instruction.

25.4 Revisits

25.4.1 At least once a year, or more often if medically indicated, the following services shall be performed and recorded for each patient:

25.4.1.1 Complete physical examination, including breast and pelvic examinations, blood pressure, and weight;

25.4.1.2 Interval health history;

25.4.1.3 Laboratory and clinical tests;

25.4.1.3.1 Hemoglobin or hematocrit;

25.4.1.3.2 Urine analysis;

25.4.1.3.3 Serological test for syphilis;

25.4.1.3.4 Smear and culture for gonorrhea;

25.4.1.3.5 Papanicolaou smear;

25.4.1.3.6 Tuberculin test (when appropriate) with indicated follow-up; and

25.4.1.3.7 Other laboratory work as indicated.

25.5 Routine for Specific Contraceptives - Revisits Schedule

25.5.1 Patients Using Oral Contraception

25.5.1.1 One to three months following initial prescription:

Interview for teaching, instruction, and to assess complaints. Blood pressure and weight shall be checked and menstrual history shall be reviewed.

25.5.1.2 The patient shall be seen at least every six months thereafter, for an interview and to assess complaints.

25.5.2 Patients Using Intrauterine Devices:

25.5.2.1 One to three months following insertion:

Repeat pelvic examination with visual inspection of the cervix at least once during the three-month period following insertion of the device.

25.5.3 Patients Using Vaginal Diaphragms

25.5.3.1 Fitting of diaphragm, and individual patient instruction for insertion.

25.5.3.2 Instruction of patient with visual aid model.

25.5.3.3 Patient shall be given an appointment for one month following original fitting to return for checkup to determine whether she has any problems, and is checked to determine whether she has any problems in actually inserting and removing diaphragm.

25.5.4 Patients Using Rhythm Method

25.5.4.1 One month following initial instruction:

Interview for instruction and assessing complaints.

25.5.4.2 At least every six months thereafter:

Interview for review of menstrual calendar and temperature charts.

25.5.5 Patients Using Other Contraceptive Devices

This would include condoms, foams, jellies, creams, etc.

25.5.5.1 Follow-up as indicated for particular device.

25.6 Physical Plant Requirements

25.6.1 All facilities shall comply with the physical plant requirements contained in Section 40.0 of this document.

FACILITIES PROVIDING A SINGLE MODALITY OF CARE

26.0 Prenatal and Postpartum Care

26.1 Where prenatal and postpartum services solely are offered by the facility, they shall be provided in accordance with Sections 1.2 through 5.7, 6.1.3, 6.3, 6.4, 6.6, 6.8, 6.9, and 7.6 through 13.2.4.5 of this document and with the following:

26.1.1 The prenatal and postpartum services provided shall include, but not be limited to:

26.1.1.1 Medical management and observation;

26.1.1.2 Laboratory (or diagnostic) procedures;

26.1.1.3 Education; and

26.1.1.4 Social and other counseling.

26.1.2 The facility shall have an agreement with one or more backup hospitals for delivery of patients and to ensure continuity of care.

26.2 Registration Policies

26.2.1 On the day of registration, every patient shall be seen by a nurse or physician for initial evaluation of her medical status.

26.2.2 Unwed mothers, pregnant minors, and other patients presenting social or emotional difficulties shall be referred to the social worker at the time of the patient's first visit.

26.2.3 As soon as possible after patient registration, arrangements for delivery of the patient shall be made and the name and address of the hospital responsible for delivery recorded in the patient's chart.

26.2.4 The facility shall refer patients found ineligible for care to another facility for prenatal care.

26.2.5 Records shall be kept of all patients including those referred elsewhere. Such records shall contain notes on follow-up and final disposition.

26.3 Staffing Patterns

26.3.1 The facility shall provide medical and ancillary staff on the premises for its operation as follows:

26.3.1.1 One administrator who has training and experience in health service administration, including at least one year of administrative or supervisory experience in a health care agency;

26.3.1.2 A minimum of one physician, board-certified or board-eligible in obstetrics and gynecology or experienced in the area to which assigned, present at every session;

26.3.1.3 A minimum of one registered professional nurse with special preparation in the area of obstetrics and gynecology. Duties of the registered nurse shall include, but not be limited to:

26.3.1.3.1 Assessing the emotional needs of the patient and her outlook toward motherhood;

26.3.1.3.2 Interpretation of physician's medical recommendations and evaluation of patient's ability to follow;

26.3.1.3.3 Screening the patient's records and initiation of referral to services and agencies outside the facility according to medical recommendation or with medical approval;

26.3.1.3.4 Acting as liaison with home care agencies; and

26.3.1.3.5 Initiating follow-up and broken appointment routines.

26.3.1.4 A nutritionist or dietitian shall be available. Duties shall include, but not be limited to:

26.3.1.4.1 Assisting in establishing the nutritional standards for patients;

26.3.1.4.2 Acting as a consultant to medical, nursing, and social service staff on patient problems relating to food and nutrition;

26.3.1.4.3 Providing nutritional counseling for problem patients referred by medical and nursing staff; and

26.3.1.4.4 Consulting with registered professional nurses, social service staff, and other community social and health agencies on home and community nutritional problems.

26.3.1.5 A social worker shall be available. Duties shall include, but not be limited to:

26.3.1.5.1 Collaborating with medical, nursing, nutritional, and other personnel, including inpatient staff, to identify patient needs, ensure necessary service and continuity of care for patients during prenatal, inpatient, and postpartum care, and promote patient awareness of available social services; and

26.3.1.5.2 Working with nursing and other community personnel in the follow-up of broken or failed appointments.

26.3.1.6 Consultants shall be available to the facility. Types of consultants shall include, but not be limited to:

26.3.1.6.1 Medical and dental;

26.3.1.6.2 Psychiatric or psychological; and

26.3.1.6.3 Public health nursing.

26.3.1.6.4 The names, addresses, and phone numbers of consultants shall be available in the facility and the policy manual shall indicate where the staff can obtain such information when needed.

26.4 Medical Procedures

26.4.1 Each patient shall have a complete medical history and physical examination performed on the first visit.

26.4.2 Each patient shall be individually counseled by a nurse at every visit and a progress note shall be recorded in the patient's chart.

26.4.3 Each patient shall be seen by the nutritionist and a report of the findings recorded in the patient's chart.

26.4.4 The patient shall be examined by the physician/nurse-midwife at least once a month during the first seven months of gestation. Thereafter, it is recommended that the patient be seen every two weeks until 36 weeks and once

a week thereafter. At each visit, the blood pressure, temperature, pulse, respiration, weight, urine analysis, uterine growth, fetal heart rate, abdominal inspection and palpation, any unusual symptoms reported by the patient, and any physical evidence of abnormality shall be recorded on the prenatal record. Other areas which should be considered during these revisits, when indicated, include evaluation of nutritional status, examination of the breast, pelvic examination, and pelvic measurements.

26.5 Laboratory Tests and Diagnostic Procedures

26.5.1 Basic laboratory services shall be provided at the facility or by written arrangement with a licensed laboratory or hospital. Each patient shall have the following laboratory tests and diagnostic procedures performed:

26.5.1.1 Complete urinalysis;

26.5.1.2 Complete blood count (hemoglobin and hematocrit) repeated at 36 weeks;

26.5.1.3 Sickle cell preparation (when appropriate);

26.5.1.4 Rh factor and blood typing. The husband of each Rh negative patient shall be tested. If he is Rh positive, the zygosity shall be determined. Each Rh negative obstetric patient with an Rh positive husband shall have an antibody determination made before the 20th week of gestation. If no antibodies are found, the test shall be repeated again at 37 weeks. If antibodies are found at any time, more frequent titrations are indicated, including specimens at least monthly during the third trimester. If there is doubt as to paternity or the husband is not available for Rh factor and blood type testing, maternal antibody determinations shall be performed as above. This data shall be available in the delivery suite when the patient is admitted in labor;

26.5.1.5 Serological test for syphilis;

26.5.1.6 Papanicolaou smear;

26.5.1.7 Smear and culture for gonorrhea (when appropriate);

26.5.1.8 Tuberculin test with indicated follow-up if in close contact with a diagnosed case of tuberculosis or from a high incidence area so designated by the Department;

26.5.1.9 Diagnostic X-rays of abdomen when indicated;

26.5.1.10 Diagnostic X-ray pelvimetry when indicated; and

26.5.1.11 Antibody titer determination for rubella (if negative, rubella vaccine with appropriate counseling regarding timing of future pregnancies shall be given to the patient after delivery prior to discharge from hospital).

26.6 Records

26.6.1 A system, approved by the Commissioner, shall be established for availability of patient records at all times to the hospital where delivery is to take place.

26.7 Infant Services

26.7.1 The facility shall arrange for pediatric care of the infant and record in the mother's chart where the infant is being cared for. Patients shall be informed of the services in the community available to them for the continuing health care of their children.

26.8 Postpartum Service

26.8.1 Provision shall be made for postpartum examinations four to six weeks after delivery. A summary of the patient's hospital course, including data on the labor and delivery or a copy of the labor and delivery record, shall be available at the patient's postpartum visit.

26.8.2 The postpartum examination shall include, but not be limited to:

26.8.2.1 Interval history;

26.8.2.2 Physical examination including blood pressure, examination of breasts, abdomen, complete pelvic examination including speculum examination, examination of extremities for varicosities;

26.8.2.3 Laboratory tests including hematocrit, complete urinalysis, repeat Papanicolaou smear if more than nine months have elapsed since the last Papanicolaou smear.

26.8.2.4 Family planning services should be made available on the premises or by referral;

26.8.2.5 Nutritional counseling;

26.8.2.6 Patient instructions regarding resumption of intercourse, activity and exercise, breast feeding, return of menses; and

26.8.2.7 Referral to appropriate community resources, if necessary.

26.9 Physical Plant Requirements

26.9.1 All facilities shall comply with the physical plant requirements contained in Section 40.0 of this document.

FACILITIES PROVIDING A SINGLE MODALITY OF CARE

27.0 Comprehensive Pediatric Services

27.1 Where comprehensive pediatric services solely are offered by the facility, they shall be provided in accordance with Sections 1.2 through 5.7, 6.2, 6.4, 6.6, 6.7, 6.8, 6.9, and 7.5 through 13.2.4.5 of this document and with the following:

27.1.1 A system for referrals and linkages shall be available for pediatric specialty services not available at the facility, such as endocrine, psychiatric, and mental health services.

27.1.2 A pediatric facility shall include well infant and child care as part of comprehensive pediatric care.

27.1.3 Consultants shall be available to the facility. Types of consultants shall include, but not be limited to:

27.1.3.1 Public health nurse;

27.1.3.2 Nutritionist; and

27.1.3.3 Social worker.

27.1.3.4 The names, addresses, and telephone numbers of available consultants shall be available in the facility and the policy manual shall indicate where the staff can obtain such information when needed.

27.2 Staffing Patterns

The facility shall provide staff necessary for its operation as follows:

27.2.1 One administrator who has training and experience in health service administration, including at least one year of administrative or supervisory experience in a health care agency;

27.2.2 A minimum of one full-time or full-time equivalent board-certified or board-eligible pediatrician or physician experienced in the area to which assigned per 10,000 annual patient visits (individuals under 17 years of age).

27.2.3 A minimum of one full-time or full-time equivalent registered nurse.

27.3 Physical Plant Requirements

27.3.1 All facilities shall comply with the physical plant requirements contained in Section 40.0 of this document.

FACILITIES PROVIDING A SINGLE MODALITY OF CARE

28.0 Surgical Services

28.1 Where surgical services solely are offered by the facility, they shall be provided in accordance with Sections 1.2 through 5.7, 6.4, 6.5, 6.8, 6.9, and 7.6 through 13.2.4.5 of this document and with the following:

28.1.1 The surgical services provided may include the following procedures:

28.1.1.1 Abortion (below 12 weeks gestation). Beyond the first trimester and within a period of gestation not exceeding 16 menstrual weeks and/or 14 gestational weeks' size as determined by a physician , termination of pregnancy using the dilation and evacuation procedure may be performed in a licensed ambulatory care facility;

28.1.1.2 Oral surgery;

28.1.1.3 Tonsillectomy and adenoidectomy;

28.1.1.4 Herniorrhaphy;

28.1.1.5 Incision and drainage;

28.1.1.6 Minor cosmetic surgery (i.e. warts, sebaceous cysts, plastic surgery, skin tumors);

28.1.1.7 Simple fractures;

28.1.1.8 Skin sutures and removal;

28.1.1.9 Repeat transfusions;

28.1.1.10 Chemotherapy; and

28.1.1.11 Treatment of first and second degree burns.

28.1.2 Any other surgical procedures shall be performed only with special written permission from the Department.

28.1.3 Surgical procedures requiring overnight care shall not be performed in the facility.

28.1.4 Written informed consent for all procedures, with a description of the specific surgical procedure, shall be obtained from each patient or person legally authorized to give consent for the patient prior to surgery.

28.1.5 The facility shall maintain records, on a monthly basis, of all unusual incidents such as post-operative complications, including infections and follow-up.

28.2 Staffing Patterns

The facility shall provide staff necessary for its operation in accordance with the following:

28.2.1 One administrator who has training and experience in health service administration, including at least one year of administrative or supervisory experience in a health care agency.

28.2.2 A minimum of one board-certified or board-eligible surgeon, gynecologist/obstetrician, dentist, or physician experienced in the service to which assigned shall be available during the hours the facility is providing service. The duties of the physician/dentist shall include, but not be limited to:

28.2.2.1 Supervision and assumption of responsibility for all surgical procedures performed in the surgical facility;

28.2.2.2 Provision of direct surgical service to patients; and

28.2.2.3 Supervision of physicians, nurses, and all other professional personnel providing direct patient care.

28.2.3 A minimum of one registered nurse with postgraduate experience in surgery shall be available at all times the facility is in operation (except for dental or other specialized procedures, as described in the program narrative, where nursing services may not be required). Duties of the registered nurse shall include, but not be limited to:

28.2.3.1 Assisting the physician/dentist before, during, and after the surgical procedure, as needed;

28.2.3.2 Providing direct patient care;

28.2.3.3 Providing patient teaching and counseling; and

28.2.3.4 Providing services for patient referral and follow-up.

28.2.4 Professional staff shall be available to observe and provide direct care to patients in a recovery area following surgery. The number and types of staff shall be dependent upon the patient census and type of surgery performed.

28.3 The facility shall develop a written policy and procedure manual including:

28.3.1 Types of procedures to be performed in the facility, and qualifications of persons performing each type of procedure;

28.3.2 Type of pre- and post-operative care for each procedure;

28.3.3 Duration of time patient will remain in the facility post-operatively; and

28.3.4 Specific types of analgesia and anesthesia which may be used for each procedure.

28.4 A complete medical history, physical examination and appropriate diagnostic and laboratory tests shall be performed and documented on all patients previously not known to the facility.

28.5 Vital signs (blood pressure, temperature, respiratory rate, and pulse) shall be performed on and recorded for all patients prior to surgery and discharge.

28.6 The facility shall have written arrangements for immediate access to an emergency room and to a hospital. Methods for emergency transportation of the patient and pertinent clinical information to the backup hospital shall be established.

28.7 The hospital with which the facility has a written agreement shall have a blood bank maintained and operated pursuant to Chapter X of the New Jersey State Sanitary Code.

28.8 Intravenous fluids and equipment shall be available at the facility in addition to the emergency equipment defined in Section 6.8.2.

28.9 All gross and microscopic tissue surgically removed shall be examined by a pathologist and a report of findings forwarded to the

29.2.5.2 Any barbiturate, central nervous system stimulant, tranquilizer or other depressant, hallucinogenic drug or derivative, any other psychotropic drug, or any other drug subject to regulation. Such dependency may include, but is not limited to, addiction as defined in these standards.

29.2.6 Direct Observation - Within immediate sight.

29.2.7 Detoxification - A process which uses a prescribed drug such as methadone for purposes of reduction of a patient's chemical dependency. Such process shall follow an approved schedule of detoxification and shall be under medical supervision.

29.2.8 Medical Director - A physician authorized to practice medicine in the State of New Jersey pursuant to N.J.S.A. 45:9-1 et seq.

29.2.9 Mental Health Professional - A person approved by the Division of Narcotic and Drug Abuse Control who, by virtue of education, training, or experience, is capable of assessing the psychological and sociological background of drug abusers to determine the treatment plan most appropriate for patients.

29.2.10 Methadone Facility - A single location at which a methadone program provides methadone to patients.

29.2.11 Methadone Detoxification - A medically supervised procedure using methadone and/or any of its derivatives to be administered in decreasing doses, over a time period not to exceed 21 days, for the purpose of detoxification from opiates.

29.2.12 Methadone Maintenance - A medically supervised procedure using methadone and/or any of its derivatives to be administered over a period of time in excess of 21 days, for the purpose of maintaining patients at a stable dosage or by slow reduction of the dosage to achieve a drug-free state.

29.2.13 Methadone Program - A person or organization or branch thereof, which is approved to utilize methadone and/or any of its derivatives for the detoxification and/or maintenance treatment for the rehabilitation of narcotic addicts.

Such a program conducts initial intake and evaluation of patients at a single specified location, and provides counseling, educational, vocational, and other approved services in the ongoing treatment of patients at the same or other specified and approved locations.

29.2.14 Patient - A person who has submitted an application for or has been given diagnosis or treatment for drug abuse at a treatment program or Central Intake Unit which provides drug treatment services.

29.2.15 Positive Tuberculin Reactor - A person who has had a positive tuberculin test, determined on the basis of either a Mantoux test with five tuberculin units of stabilized purified protein derivative, or a vesiculation following a multiple puncture tuberculin test.

29.2.16 Program Director - A person approved by the Division of Narcotics and Drug Abuse Control.

29.2.17 Social Worker - A person approved by the Division of Narcotics and Drug Abuse Control, who by virtue of education, training, or experience, is capable of providing social work services.

29.2.18 Treatment and Treatment Plan - The term "treatment" means interviewing, counseling, and any other services or activities carried on for the purpose of or as incident to diagnosis, treatment, or rehabilitation with respect to drug abuse, whether or not conducted by a member of the medical profession. The term "treatment plan" means the mode of treatment that is determined appropriate to meet the needs of the patient.

29.3 General Requirements for All Facilities

29.3.1 Where drug abuse treatment services are offered by the facility, they shall be provided in accordance with Sections 1.0 (excluding 1.1, 1.11, 1.20), 2.0, 3.0, (excluding 3.1, 3.10, 3.14.1, 3.17), 4.0, 5.0, (excluding 5.1, 5.5.1, 5.5.2, 5.6.5), 6.4.1, 6.6.1, 6.8.1, 6.9, 7.6, 7.7, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, and 15.0 (excluding 15.1, 15.2, 15.3, and 15.4) of this document and with the following:

29.3.1.1 No structure licensed as a drug abuse outpatient treatment facility and/or Central Intake Unit shall be utilized for any other purpose unless permission is granted in writing by the Department. This section shall not be retroactive; neither shall it be construed to eliminate drug treatment services conducted within licensed hospitals.

29.3.1.2 The facility shall make every effort to ensure that no patient is exposed to or instigates such behavior as might be physically, emotionally, or morally injurious to him/herself or to another person directly or indirectly related to the program. Written policies regarding the action to be taken in the control of defiant and/or criminal behavior shall be available.

29.3.1.3 Each facility shall provide notice and review of termination of treatment. In any case in which a decision is made that a patient's treatment to which these standards apply be terminated or substantially changed by the program director, the patient shall be given written notice of this fact and of the right to have such decision reviewed in accordance with procedures established for that purpose.

29.3.1.4 All patients whom the facility determines to be drug abusers shall be reported to the CODAP Project Management Section of the Division of the Confidential Client Oriented Data Acquisition Process (CODAP) form.

29.3.1.5 All patient records shall be kept confidential in accordance with the applicable federal regulations (currently 21 CFR, Part 1401, proposed to be incorporated in 42 CFR, Part 2, see 40 FR 20522, May 9, 1975).

29.3.1.6 If a patient leaves a program against the advice of administrative personnel, this fact shall be documented in the patient's medical record.

29.3.1.7 A system of pre-employment and ongoing physical examinations to include, but not be limited to, tuberculin test and/or chest X-ray, serological test for syphilis, complete blood count, urinalysis, medical and appropriate physical examination and tests. Positive tuberculin reactors shall have a chest X-ray.

29.4 Patient Admission Criteria

29.4.1 No applicant is to be processed for admission to a drug abuse treatment facility until it has been verified that he/she meets all criteria including:

29.4.1.1 Verification of the applicant's identity (name, address, date of birth, and other verified identifying data); and

29.4.1.2 Determination of opiate or other controlled dangerous substance abuse through physician examination, urinalysis for drug abuse, and verification of a history of drug abuse.

29.4.2 Patient admission criteria for all programs which use methadone for detoxification and maintenance (including maintenance build-up) shall comply with applicable Food and Drug Administration regulations and other current federal and state regulations as promulgated.

29.4.3 Each facility shall establish procedures under which a complete personal, medical (including physical and laboratory examination), and drug history for each patient shall be secured upon the patient's entry into the program and kept up-to-date throughout the patient's treatment. The intake process must be completed within ten days of the patient's date of entry. Intake information secured from a Central Intake Unit shall be acceptable if current (within 30 days of the date of admission).

29.4.4 Each facility shall provide a physical and laboratory examination not later than ten days after admission of the patient. The results of the physical and laboratory examination and their implications for the patient's treatment shall be detailed in the patient's treatment plan.

29.4.5 The physical and laboratory examination of each patient shall include:

29.4.5.1 Investigation of the possibility of infectious disease, pulmonary, liver and cardiac abnormalities, dermatologic sequelae of addiction, and possible concurrent surgical problems;

29.4.5.2 Complete blood count and differential;

29.4.5.3 Serological test for syphilis;

29.4.5.4 Routine and microscopic urinalysis;

29.4.5.5 Urine screening for drugs (toxicology);

29.4.5.6 Multiphasic chemistry profile (SMA/12 or similar studies approved by the Division of Narcotic and Drug Abuse Control);

29.4.5.7 Mantoux test with appropriate follow-up;

29.4.5.8 Australian antigen (HbAg testing [HAA testing]) as appropriate;

29.4.5.9 Electrocardiogram and biological tests for pregnancy and sickle cell anemia, as appropriate;

29.4.5.10 Papanicolaou smear (female); and

29.4.5.11 Smear and culture for gonorrhea.

29.4.6 Each patient seeking admission or readmission for the purpose of obtaining treatment services shall be interviewed by a mental health professional having qualifications as described in Section 29.2.9 or by an intake counselor under the supervision of such mental health professional.

29.4.7 Under the supervision and guidance of the mental health professional, the staff shall obtain a complete personal history including information relating to the patient's social, economic, and family background, educational and vocational achievements, a record of past criminal conduct, and any other information which is relevant to the patient's application and which may be helpful in determining an appropriate drug-free outpatient, drug-free day care, outpatient methadone maintenance treatment plan, and/or methadone maintenance detoxification regimen. (See Section 29.4.7.3)

29.4.7.1 Each treatment plan must include documented information relating to:

29.4.7.1.1 Short- and long-term goals for treatment generated by both staff and patient;

29.4.7.1.2 The assignment of a counselor;

29.4.7.1.3 A description of the type and frequency of counseling services to be provided; and

29.4.7.1.4 A description of the supportive services determined to be needed by the individual patient.

29.4.7.2 Treatment plans shall be reexamined by the treatment team at least once in each 90-day period and altered where necessary to satisfy any needed changes. A report of each review shall be recorded in the patient's record.

29.4.7.3 All programs using methadone for detoxification shall comply with applicable Food and Drug Administration regulations and other current federal and state regulations as promulgated.

29.5 Medical Services

29.5.1 All facilities shall designate a medical director to assume responsibility for the administration of all medical services performed by the program.

29.5.2 The medical director shall be responsible for ensuring that the initial evaluation is properly performed, medical needs are periodically evaluated, and any emergency services, when needed, are provided.

29.5.3 The medical director shall also be responsible for determining what emergency medical equipment and supplies are needed to deal with possible overdoses and other medical emergencies that might arise and for making certain that such equipment and supplies are provided.

29.6 Drug Regimen

29.6.1 Each facility shall, for those patients receiving prescription medication other than methadone through the program, establish procedures under which consultation with the medical director or other program physicians will be provided at least once in every four-week period or more frequently depending upon the needs of the patient.

29.6.2 All programs providing methadone detoxification and methadone maintenance services shall, in the administration of medical services, comply with all applicable sections of the Food and Drug Administration regulations.

29.7 Staffing Patterns

29.7.1 Each facility shall provide the following minimum medical and ancillary staff on the premises for its operation including, but not limited to:

29.7.1.1 One program director who shall assume responsibility for management and supervision of the drug abuse program;

29.7.1.2 One administrator who shall assume responsibility for administration of the facility;

29.7.1.3 Drug-free outpatient and drug-free day care programs shall provide physician and nurse coverage to ensure compliance with Sections 29.5.1 through 29.6.2; and

29.7.1.4 Methadone detoxification and methadone maintenance programs shall maintain the equivalent of one full-time physician (35 hours per week) for every 300 patients. A physician not present during some of the clinic hours shall be available for consultation and emergency attendance. There shall be no less than the equivalent of two full-time registered or licensed practical nurses for up to 300 patients. Where specific approval to serve over 300 patients has been granted, there shall be one nurse for each additional 100 patients or fraction thereof. The nursing staff shall include, however, one registered nurse who shall be responsible for the general supervision of the nursing staff. The total number of nurses on the staff must be commensurate with the facility hours of operation and the number of patients to be served in order to ensure that nursing care will be provided at all times the facility is in operation. Methadone shall be administered only under direct physician or nurse observation and control.

29.8 Mental Health Consultation

29.8.1 All facilities shall provide, through a mental health professional, a minimum of five hours per week of mental health consultation for each 100 patients.

29.9 Counseling

29.9.1 All facilities shall provide counseling services performed by personnel approved by the Division of Narcotic and Drug Abuse Control, and shall utilize the individual, family, or group counseling techniques which best meet the needs of the patient.

Counseling personnel not meeting the qualifications of a mental health professional, as set forth in Section 29.2.9, shall be under the direct supervision of a qualified mental health professional.

29.9.1.1 All outpatient methadone detoxification, methadone maintenance, and outpatient drug-free programs shall have a minimum of three hours of formalized counseling per week for each patient.

29.9.1.2 Drug-free day care programs shall provide a minimum of ten hours of formalized counseling per week per patient.

29.10 Supportive Services

29.10.1 Each facility shall provide the following supportive services:

29.10.1.1 Educational;

29.10.1.2 Vocational counseling and training;

29.10.1.3 Job development and placement; and

29.10.1.4 Legal services through licensed lawyers to the extent that such services are related to the patient's treatment.

29.10.2 All facilities shall utilize community resources to provide such services.

29.10.3 If any program is unable to offer supportive services, either directly or through available community resources, a written statement of facts including alternative courses of action shall be submitted to the Department for approval.

29.11 Urine Surveillance

29.11.1 All facilities shall establish and implement written policies for the evaluation, including periodic urinalysis, of patients and staff suspected of regression to drug usage. These policies shall also include a follow-up procedure dealing with staff and patients found to be using narcotics or other dangerous substances.

29.11.2 Patients' individual urine specimens shall be collected in a manner that minimizes falsification and on a randomly scheduled basis.

29.11.3 All facilities dispensing methadone shall analyze urine specimens weekly for opiates and monthly for methadone, amphetamines, and barbiturates, as well as for other drugs as indicated.

29.11.4 In drug-free outpatient and drug-free day care programs, urine specimens or an alternate method approved by the Department from all patients shall be analyzed at least monthly for opiates, methadone, amphetamines, barbiturates, as well as for other drugs as indicated. More frequent testing shall occur when clinically indicated.

29.11.5 Laboratories used for urine testing shall comply with all applicable federal proficiency testing and licensing standards and all New Jersey State standards in conformity therewith.

29.11.6 Urine testing results shall be used as one clinical tool for the purpose of diagnosis, and in the determination of patient treatment plans. Patient medical records shall reflect the manner in which test results are utilized and shall distinguish presumptive qualitative laboratory results from those which are definitive.

29.11.7 Program and medical directors electing to rely on the results of presumptive urinalysis for patient management shall demonstrate reasonable access to definitive qualitative laboratory analysis for use when necessary, e.g. for criminal justice system records, intake urine testing on all prospective methadone clients, any loss of patient privileges based on urinalysis results, and any frequency of use of other drugs not detectable by a screening method.

29.12 Vocational Rehabilitation and Employment Program

All patients enrolled in outpatient treatment programs shall be encouraged to participate in an educational or job training program or to obtain gainful employment as soon as appropriate, but not later than 120 days from the date of enrollment. If, for any reason, a patient is not encouraged to pursue one of these alternatives, the reasons shall be recorded in the patient's record.

29.13 Program Hours for Service

29.13.1 Effort shall be made to adjust the hours of program operation to meet patient needs. Consideration should be given to the employment hours of patients, and, to the extent practicable, facility operating hours shall be scheduled at such times as will accommodate the working hours of patients. In some facilities, a 12-hour day of operation may be necessary based upon patient census.

29.13.2 Minimum hours of operation. The following minimum hours of operation shall be maintained:

29.13.2.1 Outpatient methadone maintenance. All outpatient methadone programs shall provide services seven days per week. Services provided on at least five of these seven days shall be on the basis of an eight-hour day, provided that services for a minimum of two hours of such eight-hour day shall be scheduled at a time other than the regular 9 AM to 5 PM day. Services administered during the remaining two days shall be scheduled for a period of at least four hours each day at a time most convenient to the patients;

29.13.2.2 Outpatient methadone detoxification. All outpatient methadone detoxification programs shall provide services seven days per week. Hours of operation may be flexible, but shall be consistent with agreed upon hours of service delivery;

29.13.2.3 Drug-free outpatient. All drug-free outpatient programs shall provide services at least six days per week. Services provided on at least five of these six days shall be on the basis of an eight-hour day provided that a minimum of two hours of such eight-hour day shall be scheduled at a time other than the regular 9 AM to 5 PM day. Services administered during the remaining (sixth) day shall be scheduled for a period of at least five hours; and

29.13.2.4 Drug-free day care. All drug-free day care programs shall provide services at least five days per week, ten hours per day. Services provided for the remaining two days shall be so scheduled as to accommodate the needs of the patient.

29.14 Central Intake Units

In all Central Intake Units, the following additional regulations shall apply:

29.14.1 The unit shall operate under procedures which provide:

29.14.1.1 Criteria for the admission of patients and for the termination of services rendered to them; and

29.14.1.2 Informal, standardized, initial patient orientation, multiphasic health screening, and referral to an appropriate treatment modality for new or readmitted patients.

29.14.2 Each CIU facility shall remain open at least eight hours each day, five days per week. The intake process shall not exceed a period of two days.

29.14.3 At the time of intake, an initial personal, medical, and drug history shall be obtained and a physical and laboratory examination administered by professional personnel.

29.14.4 The physical and laboratory examination of each patient shall include:

29.14.4.1 Investigation of the possibility of infectious diseases, pulmonary, liver, cardiac abnormalities, dermatologic sequelae of addiction, and possible concurrent surgical problems;

29.14.4.2 Complete blood count and differential;

29.14.4.3 Serological test for syphilis;

29.14.4.4 Routine and microscopic urinalysis;

29.14.4.5 Urine screening for drugs (toxicology);

29.14.4.6 Multiphasic chemistry profile (SMA/12 or similar studies approved by the Division of Narcotic and Drug Abuse Control);

29.14.4.7 Mantoux test with appropriate follow-up;

29.14.4.8 Australian antigen (HbAg testing [HAA testing]) as appropriate;

29.14.4.9 Electrocardiogram and biological tests for pregnancy and sickle cell anemia, as appropriate;

29.14.4.10 Papanicolaou smear (female); and

29.14.4.11 Smear and culture for gonorrhea.

29.14.5 Each CIU shall designate a medical director as specified in Section 29.5.

29.14.6 Each CIU shall conduct a pre-admission interview by a mental health professional, or by an intake counselor under the supervision of such a professional, of every patient or former patient readmitted. In the course of the interview, the staff shall obtain a complete personal history, including information relating to the patient's social, economic, and family background, his/her educational and vocational achievements, any history of past drug abuse and treatment, any record of past criminal conduct, and any other information which is relevant to his/her application and which may be helpful in determining an appropriate treatment program.

29.14.7 The staff shall discuss with the patient the various treatment modalities available. After discussing the availability of these modalities in the light of the patient's particular needs (including the results of physician's evaluation), a treatment plan shall be formulated by mutual agreement, and an appropriate referral made.

29.14.8 Each CIU shall maintain a patient file for each drug-dependent patient. This file shall be kept up-to-date by the particular agencies and all transfers to other programs and terminations noted.

29.14.9 Upon reaching an agreement as to the modality to be applied, the patient should be referred to treatment within 48 hours and his/her intake records, including results of examinations, transferred to the facility administering such treatment.

29.14.10 Each CIU shall adopt written intake procedures that will avoid the duplication of services by programs receiving patients through the central intake process.

29.14.11 Each CIU shall comply with urine surveillance procedures noted in Section 29.11.

29.14.12 Each CIU program shall establish agreements with community-based drug abuse treatment programs. Such agreements shall include the treatment program's concurrence to utilize the CIU for patient intake functions.

It shall also provide for the acceptance of only those patients who have been processed through the CIU.

29.14.13 Each CIU program shall adopt procedures relating to the following:

29.14.13.1 Orientation of patients with instructions on the available treatment options and the specific treatment program recommended to meet the needs of the patient;

29.14.13.2 Consideration and determination of the method to be followed for referral to treatment;

29.14.13.3 Negotiation of an agreement with the patient covering the terms and conditions of referral to treatment; and

29.14.13.4 Establishment of standards for meeting the needs of patients referred to CIU for rescreening and for referral to a modality or program determined to be more suitable for their needs.

29.14.14 Each CIU program shall submit reports to CODAP on appropriate forms provided by the Department.

29.15 Physical Plant Requirements

All drug abuse outpatient treatment facilities and/or Central Intake Units shall comply with the physical plant requirements contained in Section 40.0 of this document.

29.16 Infection Control

All drug abuse outpatient treatment facilities and/or Central Intake Units shall comply with Section 15 of this document (excluding 15.1, 15.2, 15.3, and 15.4), and the following:

29.16.1 The administrator shall be responsible for the duties as specified in Section 15;

29.16.2 Each service in the facility shall develop written infection control policies and procedures for that service, based upon those developed by the administrator;

29.16.3 The occurrence of a reportable disease shall be reported in conformance with Chapter 2 of the New Jersey Sanitary Code. The facility shall also have written policies and procedures, developed by the administrator for reporting other diseases, according to Regulations 2 and 3 of Chapter 2. The administrator shall develop policies and procedures for exclusion from work, and authorization to return to work, of employees with communicable diseases; and

29.16.4 Written reports of state and local sanitary inspections, including cultures taken on food, equipment, and personnel, shall be sent to the administrator for evaluation and corrective action.

FACILITIES PROVIDING A SINGLE MODALITY OF CARE

30.0 Intermediate Dialysis Services

30.1 Definitions

30.1.1 Anticoagulation - The prevention of clotting. When blood comes in contact with foreign surfaces it tends to clot. Therefore, when the patient's blood passes through the lines and coil of the kidney machine,it will clot unless measures are taken to prevent clotting. Since dialysis lasts only a brief time, a short-acting anticoagulation method called heparinization is used.

30.1.2 Artificial Kidney or Kidney Machine - The apparatus which permits the cleansing of body waste from the blood by a mechanical method substituting for the human kidney. The dialyzer and dialysate delivery system make up the total system used for hemodialysis.

30.1.3 Backup Dialysis - Dialysis given patients trained for self-care who, under special circumstances, are unable to perform dialysis without additional assistance; also, pre- and post-operative dialysis provided to transplantation patients, particularly when the newly grafted organ is unable to assume its full function immediately.

30.1.4 Belzer Machine - A special type of perfusion equipment developed by Dr. F. Belzer. There are others, some devised by local hospitals. Perfusion machines preserve harvested cadaver kidneys in a viable condition for periods of up to 48 hours.

30.1.5 Cannula - A surgically prepared, exposed connection made with silastic tubing between an artery and a vein. (Does not apply to peritoneal dialysis.)

30.1.6 Dialysate - The solution used in an artificial kidney to rid the body of accumulated waste products in the blood.

30.1.7 Dialysate Delivery System - That part of the artificial kidney which supplies the dialysate and regulates such critical items as rate of flow, temperature, and concentration of dialysate.

30.1.8 Dialysis (Hemodialysis) - A process by which waste products are removed from the blood by diffusion from one fluid compartment to another across a semipermeable membrane. In kidney dialysis, blood and the bath solution or dialysate are the two fluids.

30.1.9 Dialysis Technician - A paramedical person not currently licensed or certified, but who has had special training in dialysis techniques in a licensed facility and is experienced in the dialysis procedure.

30.1.10 Dialyzer - That part of the artificial kidney through which waste products pass from the blood to the bath solution or dialysate.

30.1.11 Diffusion - The passage of particles through a semipermeable membrane from an area of greater concentration to an area of lesser concentration.

30.1.12 End-Stage (Renal) Disease - That stage of renal impairment which cannot be favorably influenced by medical treatment and which requires dialysis and/or kidney transplantation to maintain life and health.

30.1.13 End-Stage (Renal) Treatment - Refers to dialysis or kidney transplantation or both forms of therapy.

30.1.14 Fistula - A surgically prepared inner connection made directly between an artery and a vein, permitting direct arterial flow from the artery into the vein.

30.1.15 Functions of the Kidney - The normal kidney functions include, but are not limited to: (1) control of electrolyte concentration in the body; (2) maintenance of proper water balance; (3) maintenance of the body buffer system; (4) excretion of the by-products of protein metabolism (urea, creatinine, and uric acid).

30.1.16 Hemolysis - The destruction of red blood cells with the liberation of hemoglobin which diffuses into the extracellular fluid surrounding the blood cells.

30.1.17 Heparin - A short-acting anticoagulant (agent used to prevent clotting), gradually inactivated by the body.

30.1.18 Intermediate Dialysis Facility - A profit or non-profit, official or voluntary health care agency, either within or outside of a hospital facility, established to serve the people of a specific community or geographic area, with organized medical staffs and permanent facilities to provide dialysis services only. The intermediate dialysis facility shall have a written patient transfer agreement with at least one hospital having a chronic renal dialysis center approved by the New Jersey State Department of Health.

30.1.19 Kidney Disease - A spectrum of conditions which directly or indirectly affect the kidneys and impair their functioning. (Occasionally, the entire urinary tract is involved.)

30.1.20 Medical Director - A physician licensed to practice medicine and surgery in the State of New Jersey who:

30.1.20.1 Has a minimum of one year of training in internal medicine in an approved residency training program;

30.1.20.2 Has at least one year of continued training (fellowship) in nephrology under the guidance of an approved program recognized by the American Board of Internal Medicine. The fellowship may be waived for a person who graduated from medical school prior to 1960;

30.1.20.3 Has a major continuing interest in the field of nephrology, as demonstrated by the nature of his/her practice; and

30.1.20.4 Is board-certified or board-eligible in internal medicine with a subspecialty in nephrology.

30.1.21 Organ Preservation - Maintenance of the kidney after it has been removed from the donor and until it has been transplanted into a recipient. Organ preservation is an integral part of a kidney transplantation program.

30.1.22 Organ Procurement - The method(s) used to obtain a viable, functioning human or animal organ from a body (donor) preparatory to its anticipated transfer to another body (recipient).

30.1.23 Peritoneal Dialysis - An alternative to hemodialysis. A process by which the dialysate is introduced into the abdominal cavity, using the peritoneum as the semipermeable membrane.

30.1.24 Shunt (noun) - The means by which blood is passed through other than the usual channels. Two types of shunts are used in dialysis: (1) the channels; (2) the fistula.

30.1.25 Sphygmomanometer - An apparatus used to measure blood pressure.

30.1.26 Tissue Typing - A laboratory procedure used to determine the degree of compatability between the donor organ and the recipient of a kidney transplant.

30.1.27 Urinary Tract - Collective term referring to the kidneys, ureters, bladder, and urethra.

30.2 General Requirements for All Facilities

30.2.1 Where intermediate renal dialysis services solely are offered by the facility, they shall be provided in accordance with Sections 1.0 (excluding 1.16 and 1.17),2.0, 3.0 (excluding 3.1 and 3.10), 4.0,5.0 (excluding 5.1, 5.5.1, and 5.5.2), 6.1.1, 6.4, 6.6 (excluding 6.6.3 through 6.6.3.3), 6.8, 6.9,7.6 through 7.8, 8.0 (excluding 8.6), and 9.0 through 13.2.4.5 of this document and with the following:

30.2.2 Written patient care policies governing hemodialysis prodecures shall be developed and implemented.

30.2.3 The facility shall have written policies concerning staff qualifications, privileges, duties, and responsibilities of physicians.

30.2.4 A social service evaluation, medical history, results of physical examination, specified dialysis orders, dietary regimen, and drug therapy, all in written form, must accompany the patient prior to initiation of care in the facility.

30.2.5 An ongoing written evaluation shall be prepared for each patient, including identification of immediate and long-term goals, a regimen planned for medical and dialysis care, treatments, nursing needs, medications, diet, and other supportive or special services. The patient evaluation shall include the medical decision, based on all possible clinical record information, as to the patient's potential for transplantation.

30.2.6 Each time a patient visits the facility, he/she shall be seen by a physician.

30.2.7 Information describing the care and services offered by the facility shall be provided before the patient is accepted for care.

30.2.8 Written policies and procedures shall be established relating to notification of the patient, next of kin and/or sponsor in the event of significant change in patient status or in patient charges, billings, and other related administrative matters.

30.2.8.1 Any change in patient status or cost of services shall be discussed with the patient, next of kin and/or sponsor before implementation.

30.2.9 Written policies regarding visitors shall be established and made known to all patients and physicians.

30.3 Staffing Patterns

30.3.1 The facility shall provide staff necessary for its operation as follows:

30.3.1.1 A full-time administrator responsible to the medical director for decisions bearing upon any aspect of patient care;

30.3.1.2 A medical director available for service to the hemodialysis facility for a minimum of 50 percent of his/her usual work day;

30.3.1.3 A minimum of one physician, board-certified or board-eligible in internal medicine with a subspecialty in nephrology, available during the hours the facility is providing service;

30.3.1.4 A minimum of one registered professional nurse assigned to each shift, with an additional registered professional nurse available for backup. The registered professional nurses shall be currently licensed to practice in New Jersey and trained in hemodialysis techniques, with a minimum of three months of experience within the past year in a licensed New Jersey renal dialysis center or with approval of the Department. The registered nurse designated as charge nurse shall be responsible for the following activities:

30.3.1.4.1 Assisting in the development of nursing procedures and manuals and written job descriptions for each level of nursing personnel;

30.3.1.4.2 Recommending to administrator the number and levels of nursing personnel to be employed, participating in their recruitment and selection, and recommending termination of employment when necessary;

30.3.1.4.3 Assigning and supervising onsite all levels of nursing personnel, including registered professional nurses, licensed practical nurses, and dialysis technicians;

30.3.1.4.4 Maintaining written work schedules for all nursing staff members on all shifts;

30.3.1.4.5 Participating in planning and budgeting for nursing care;

30.3.1.4.6 Ensuring that a nursing care plan is established for each patient and reviewed and modified as necessary;

30.3.1.4.7 Providing nursing services, treatment, diagnostic and preventive sanitary procedures, and adequately documenting the care given;

30.3.1.4.8 Assisting in the development and implementation of a continuous in-service educational program for all nursing personnel. The in-service educational program shall include:

30.3.1.4.8.1 Instruction and supervision of all patient care personnel in the care of hemodialysis patients, including the social aspects of patient care;

30.3.1.4.8.2 Orientation of new personnel, including a review of emergency procedures for patients and equipment; and

30.3.1.4.8.3 Opportunities for nursing personnel to attend training courses in hemodialysis nursing and other educational programs related to the care of long-term kidney patients.

30.3.1.5 A ratio of one nursing service staff member to three patients receiving treatment shall be maintained at all times the facility is in operation.

30.4 Pharmaceutical Services

30.4.1 The facility shall have written pharmacy policies and procedures for obtaining, dispensing, storing, and administering medications

and biologicals, developed with the advice of a group of physicians and pharmacists in accordance with state and federal regulations. The group shall meet at least annually and minutes of each meeting shall be recorded and made available to the Department upon request.

30.4.2 If the facility maintains a pharmacy department, it shall employ a registered pharmacist licensed by the New Jersey State Board of Pharmacy.

30.4.3 In the event the facility does not have a licensed pharmacy department, the facility shall have methods and procedures for obtaining prescribed medication and biologicals from a pharmacy licensed by the New Jersey State Board of Pharmacy.

30.4.4 If the facility does not have a pharmacy department, the facility shall provide for a consultant pharmacist who shall advise on and be responsible for the control of all drugs according to the facility's established policies, procedures, and methods.

30.4.5 The control of drugs subject to the Controlled Substances Act of 1970 shall be in full compliance with all federal and state laws and regulations concerning procurement, storage, dispensing, administration, and disposition.

30.4.5.1 An individual record shall be maintained for each type and strength of medication subject to the aforementioned Act. The following shall be recorded: the name of the patient, the name and strength of the drug, date of administration, dosage administered, amount of medication wasted (when appropriate), route of administration, physician's name, signature of the licensed nurse administering the drug, the balance of the medication remaining, and the signature of the nurse witnessing the destruction of the amount of medication wasted (when appropriate).

30.4.5.2 A record of the verification of the inventories of the controlled substances shall be made at the termination of each tour of duty. At that time, the record shall be signed by both the in-coming and out-going licensed nurses. The facility shall have a written procedure to be followed in the event that the inventories cannot be verified. A report of all such incidents shall be written and signed by both

licensed nurses and further investigation shall be made by the pharmacist and/or the charge nurse. A record of the verification of the inventories of the controlled substances need not be maintained when a single unit dose packaging drug distribution system is in effect.

30.4.5.3 Written policies and procedures shall be established for controlled substances which are lost, contaminated, or destroyed. Such incidents shall be documented by the nurses involved and those witnesses present. A follow-up investigation shall be made and documented by the pharmacist and the charge nurse.

30.4.5.4 The stock supplies of controlled substances shall be stored in the pharmacy service and accessible to the pharmacist only.

30.4.5.5 Medications subject to the Controlled Substances Act of 1970, Class II, shall be stored in a separately locked, securely fastened box (or drawer) within the medication cabinet, medication room, or mobile medication cart. A separate area and securely fastened boxes (or drawers) within the medication cabinet, medication room, or mobile medication cart shall be provided for the storage of medications affected by the Controlled Substances Act of 1970, Classes III, IV, and V. Exceptions may be made to the storage requirements of medications subject to the Controlled Substances Act of 1970 if the facility uses a single unit dose packaging drug distribution system in which the quantity of medication stored is minimal and a missing dose can be readily detected.

30.4.6 A system of records, bookkeeping, and periodic physical inventories shall be established for maintaining controls over the requisitioning and dispensing of all drugs and pharmaceutical supplies within the pharmacy service.

30.4.6.1 Records of all prescription drugs dispensed from the pharmacy service to each patient (inpatient and outpatient) shall be maintained and correlated with each patient's clinical record.

30.4.7 Emergency medication kits or carts approved by the advisory group of physicians and pharmacists shall be kept at each nurses' station.

30.4.8 All medications administered to patients shall be ordered in writing by the patient's physician. The facility shall develop written policies acceptable to the Department concerning the handling of verbal orders.

30.4.9 Medications which the physician's written order does not specifically limit as to time or number of doses shall be automatically stopped, in accordance with the facility's written pharmaceutical policy as approved by the physician or physicians responsible for advising on the facility's medical administrative policies.

30.4.9.1 Every 30 days, the charge nurse and the prescribing physician together shall review each patient's medications and written renewals for all drugs to be continued;

30.4.9.2 The patient's attending physician shall be notified of stop order policies and contacted promptly for renewal of such orders so that continuity of the patient's therapeutic regimen is not interrupted.

30.4.10 Medications shall be released to patients on discharge only on the written authorization of the physician, and medications for patients discharged without such authorization or by reason of death shall be disposed of in accordance with state and federal laws, rules, and regulations.

30.4.11 The facility shall ensure that:

30.4.11.1 All medications are administered by licensed or authorized medical or nursing personnel in accordance with the New Jersey State Medical and Nurse Practice Acts, and each dose administered is recorded in the patient's record;

30.4.11.2 The nurses' station has available items necessary for the administration of medication;

30.4.11.3 In administering medication, medication cards or other systems acceptable to the Department are used and checked daily against the physician's orders;

30.4.11.4 Medications prescribed for one patient are not administered to any other patient;

30.4.11.5 Self-administration of medications by patients is not permitted except on special order of the patient's physician;

30.4.11.6 Medication errors and drug reactions are immediately reported to the patient's physician and to the pharmacist and an entry thereof made in the patient's clinical record as well as on an incident report; and

30.4.11.7 An up-to-date medication reference index and sources of information, such as the American Hospital Formulary Service of the American Society of Hospital Pharmacists or other suitable and acceptable references, are provided for each nurses' station.

30.4.12 The facility and the registered pharmacist shall ensure that:

30.4.12.1 Patients' medications are properly labeled, stored, and locked at each nurses' station or in the medicine room;

30.4.12.2 The label of each patient's individual medication container clearly indicates the patient's full name, physician's name, prescription number, name and strength of drug, date of issue, expiration date of all time-dated medications, and name, address, and telephone number of the pharmacy issuing the drug, except for non-legend drugs containing the seven-point label as stipulated by the Federal Food and Drug Administration;

30.4.12.3 Medication containers having soiled, damaged, incomplete, illegible, or makeshift labels are returned to the issuing pharmacist or pharmacy for relabeling or disposal, and containers having no labels are destroyed in accordance with state and federal laws;

30.4.12.4 Medications for individual patients are kept and stored in the original prescription container, and there is no transferring between containers;

30.4.12.5 Medications requiring refrigeration are kept in a separate locked box securely fastened within the refrigerator or in a separate locked refrigerator at or near the nurses' station;

30.4.12.6 Poisons and medications for "external use only" are kept in a locked cabinet and separate from other medication;

30.4.12.7 Medications no longer in use are disposed of or destroyed in accordance with state and federal laws and regulations; and

30.4.12.8 Medications and intravenous solutions having an expiration date are removed from use and disposed of after such date as prescribed by law.

30.4.13 The staff or consultant pharmacist shall review in writing the drug regimen of each patient at least monthly, and report any irregularities to the medical director and administrator. The staff or consultant pharmacist shall submit a written report at least quarterly to the pharmacy advisory group on the status of the facility's pharmaceutical service and staff performance.

30.4.14 The staff or consultant pharmacist shall document all participation in staff development and orientation programs presented.

30.5 Dietary Services

30.5.1 Written policies shall be established and implemented regarding dietary services, food, and meals provided for patients and staff. If no food is provided, this shall be clearly stated.

30.5.2 No food production or preparation shall take place in the dialysis area of the facility. If food is prepared on the premises, it shall be prepared in an area completely separated from the dialysis area, and in compliance with Chapter 12 of the New Jersey State Sanitary Code and with any applicable codes or regulations of the local municipality.

30.5.3 Food prepared in the facility,delivered to it, or brought in by patients or family members may be eaten in the dialysis area by patients only. Staff members shall not eat or drink in the dialysis area.

30.5.4 If food, meals, or tray service is purchased from an outside source or hospital, it shall be supplied in disposable equipment or trays and handled in compliance with Chapter 12 of the State Sanitary Code.

30.5.5 Written policies shall be established and implemented regarding therapeutic diets and modified diet foods provided by the facility. These policies shall be made known to all patients and physicians.

30.5.5.1 Therapeutic or modified diets prepared in the facility or purchased or contracted for from an outside source shall be planned and prepared under the supervison of or with consultation from a dietitian registered (RD) by the American Dietetic Association.

30.5.6 Waste materials, food, or disposable storage or serving equipment shall be disposed of in accordance with applicable chapters of the State Sanitary Code.

30.6 Records

30.6.1 A clinical record shall be maintained for each patient, including the information in Section 10.0 and the following:

30.6.1.1 Patient identification and summary sheet(s), including social security number, Medicaid number (if appropriate), marital status, religion (optional), name of hospital dialysis unit from which patient is referred, addresses and telephone numbers of personal physician, dentist, and next of kin and/or sponsor, primary diagnosis related to dialysis and secondary diagnoses.

30.6.1.2 Hospital or other discharge summary sheets, and summary of previous dialysis orders and procedures; and

30.6.1.3 Patient's dental status.

30.7 Transfer Agreement

30.7.1 The facility shall have in effect a written, signed transfer agreement with one or more hospitals having licensed chronic renal dialysis centers.

30.7.1.1 The transfer agreement shall provide for transfer of patients between the hospital and the facility whenever medically required as determined by the attending nephrologist.

30.7.1.2 The institutions shall provide to each other operational information to determine whether the care needed by a patient is available.

30.7.1.3 The agreement shall establish responsibility for the prompt exchange of patient information to enable each institution to determine whether it can care for the patient and to ensure continuity of care.

30.8 Infection Control

30.8.1 The facility shall establish an Infection Control Committee which shall consist of the administrator and a member of each service. The Committee shall establish policies and procedures in accordance with applicable chapters of the State Sanitary Code for investigating, controlling, and preventing infections in the facility, and monitor staff performance to ensure that the policies and procedures are executed.

30.8.2 The facility shall maintain written procedures for aseptic and isolation techniques which shall be reviewed and followed by all personnel. The procedures shall be reviewed and revised annually by the Infection Control Committee.

30.8.3 The administrator of the facility shall provide housekeeping services so as to maintain clean, safe, and orderly surroundings for patients and personnel. To this end:

30.8.3.1 A work plan for cleaning operations shall be categorized as to daily, weekly, monthly, or annual assignment for each room space, windows, etc.;

30.8.3.2 A full-time employee shall be designated responsible for supervision and training of personnel;

30.8.3.3 Housekeeping personnel shall be trained in procedures of cleaning;

30.8.3.4 Safety aspects of housekeeping procedures shall be followed by all personnel; and

30.8.3.5 Cleaning equipment and compounds shall be provided for all housekeeping procedures required within the facility.

30.8.4 "No-Pest Strips" shall not be used in any area of the facility.

30.8.5 There shall be linen three times the census so that at least one set of clean linens remains on the shelves for each patient; and

30.8.6 Lounges or beds shall be thoroughly sanitized between patient use. Linen shall be completely changed and mattresses sanitized by a "one wipe" or sanitizing material. All beds or lounge frames must be sanitized at least weekly.

30.8.7 Dialysis machines shall be cleaned and sanitized between patient use, in accordance with policies incorporated into the dialysis procedure manual adopted by the facility.

30.8.8 Floors and walls in the dialysis area shall be washed and sanitized daily.

30.8.9 Garbage and contaminated waste materials (blood products) shall be stored separately.

30.8.9.1 Blood products and any other contaminated waste shall be sealed and disposed of according to applicable chapters of the State Sanitary Code and to the standards developed by the Infection Control Committee.

30.9 Emergency Procedures (Including Equipment Breakdown), Disaster, and Fire Plan

30.9.1 The facility shall have written procedures to be followed in case of medical emergencies, equipment breakdown, fire, or other disaster.

30.9.2 Procedures for medical emergencies shall specify persons to be notified, location of emergency equipment, who shall use it, and specific tasks and responsibilities of all personnel.

30.9.2.1 The facility shall maintain medical/surgical equipment used in cardiac arrest and/or shock.

30.9.2.2 Location of emergency equipment, such as electrocardiogram machines, oxygen, aspirator, other equipment, and emergency medications shall be clearly marked, and all staff instructed as to its location.

30.9.3 Procedures to be followed in case of fire, loss of electricity or other sources of power, explosion, or other emergency shall specify persons to be notified, locations of alarm signals and fire extinguishers, evacuation routes, procedures for evacuating patients, and assignment of specific tasks and responsibilities to the personnel of each shift. The plan shall be developed with the assistance of local fire and safety authorities.

30.9.4 All employees shall be trained to perform their assigned tasks.

30.9.5 Simulated drills of all plans shall be conducted a minimum of four times a year on each shift to include at least these types of emergency:

30.9.5.1 Medical emergency;

30.9.5.2 Equipment failure or power loss;

30.9.5.3 Fire; and

30.9.5.4 Other disaster (storm, flood, other natural disaster, or military alert).

30.9.6 All plans shall be posted throughout the facility.

30.10 Physical Plant

30.10.1 All intermediate renal dialysis facilities shall comply with the National Fire Protection Association Code, the Occupational Safety and Hazards Act, the physical plant requirements in Section 40.0 of this document, and the following:

30.10.2 Open planned treatment areas shall not exceed 3,000 square feet in area. The travel distance from open planned area to an approved exterior exit facility shall not exceed 100 feet along the line of travel. Each machine or lounge shall have a privacy curtain and the open planned areas shall have at least two clear means of egress for compliance with the National Fire Protection Association Code 101.

30.10.3 The space allocated for each machine shall be at least 100 square feet, and 30 inches clear around the machine and lounge shall be maintained. Machines may be installed flush against the wall on one side only. There shall be a four-foot space between beds or lounges.

30.10.4 Separate clean and soiled work or utility rooms are required. Soiled and clean utility rooms shall contain a minimum of 80 square feet each.

30.10.5 A soiled utility room shall contain:

30.10.5.1 Handwashing facilities;

30.10.5.2 A bedpan washer; and

30.10.5.3 A compactor for compaction of renal waste. The size of the compactor shall be in proportion to the number of dialysis stations.

30.10.6 A sterilizer shall be provided in the facility for control of hepatitis and other infectious diseases.

30.10.7 A separate janitor's closet and storage area shall be provided, with a safe area for storage of cleaning chemicals.

30.10.8 Separate clean and soiled linen rooms are required. Clean and soiled linen rooms shall contain a minimum of 80 square feet each.

30.10.9 A laundry area, if provided, shall be treated as a hazardous area.

30.10.10 Separate sanitary facilities shall be provided for patients and employees.

30.10.11 If a kitchen is provided, it shall be separate from the dining area. Employee dining is not permitted in the dialysis area, but a separate dining area for employees shall be provided.

30.10.11.1 If a patient brings food to the facility, it shall be confined to his/her dialysis area, which shall be sanitized after the food is consumed.

30.10.12 Trash and garbage from the kitchen area shall be separate from that of the renal dialysis area. All renal dialysis material shall be disposed of daily. Renal waste shall be double-bagged and local public health officials notified of potentially infectious material.

30.10.13 For each bed or lounge, the net usable square foot area shall be 80 square feet with 100 square feet gross area. A minimum of 48 inches between beds or lounges is required.

30.10.14 A nurses' station is required in or adjacent to the dialysis area. A maximum of one day's supplies may be stored at the nurses' station. Such storage shall be off the floor to permit cleaning underneath.

30.10.15 All doors to patient's toilet rooms shall be equipped with hardware which will permit access in any emergency.

30.10.16 If home training rooms/areas are provided, each such room/area shall be equipped with a sink for handwashing.

30.10.17 If disposable equipment is used, the clean linen and clean utility room may be combined. This combination shall contain a minimum of 120 square feet.

30.10.18 If disposable equipment is used, the soiled linen and soiled utility room may be combined. This combination shall contain a minimum of 120 square feet.

30.10.19 Adequate and proper storage will be required for at least five or six days' (one operational week) operating supplies in a separate room adjacent to the dialysis area. Sixty to seventy square feet of storage space per dialysis machine is recommended.

30.10.19.1 Storage space shall be provided for wheelchairs and stretchers.

30.10.19.2 All gas storage and gas piping shall be in compliance with the National Fire Protection Association rules and regulations.

30.10.20 A treatment and/or examination room shall be provided with a minimum of 80 square feet and shall have a work counter and lavatory for handwashing.

30.10.21 Building construction shall comply with the following:

30.10.21.1 A building of frame or ordinary construction shall be one story in height and have a one-hour fire rating;

30.10.21.2 A noncombustible building with a two-hour fire rating may be two stories in height;

30.10.21.3 A noncombustible building of one story in height shall be built of one-hour protected, noncombustible construction; and

30.10.21.4 A noncombustible building with a two-hour fire rating or a fire-resistive building may be multi-story, provided it is in compliance with the National Fire Protection Association (N.F.P.A.) Codes 101 and 220.

30.10.22 Smoking shall be permitted only in special areas approved for smoking by the New Jersey State Fire Marshall's Office with proper mechanical power exhaust. Signs designating smoking areas shall be posted.

30.10.23 All machines shall be on an emergency generator so that all life support machines will operate for at least four hours. The emergency generator shall be in a separate room which has a one-hour fire rating with an approved fresh air intake and an explosion release.

40.0 Physical Plant Requirements

40.1 General Considerations

40.1.1 Narrative program

The sponsor for each project shall provide a narrative program which describes the functional space requirements, staffing patterns, departmental relationships, and other information relating to the fulfillment of the facility's objectives, so that the Department may determine the applicability of these standards to the facility.

40.1.2 Services

Ambulatory care facilities shall contain, but not be limited to, the elements described herein, or the narrative program shall indicate the manner in which the services required shall be made available. When services are shared or purchased, appropriate modifications or deletions in space and equipment requirements shall be made to avoid duplication. Each element provided in the facility must, as a minimum, meet the requirements outlined herein so as to fulfill the program requirements.

40.1.3 Size

The extent (number and types) of the diagnostic, clinical, and administrative facilities to be provided will be determined by the services contemplated and the estimated patient load as described in the narrative program.

40.1.4 Provisions for handicapped

Facilities shall be available and accessible to the physically handicapped (public, staff, and patients). (New Jersey Laws of 1975, Chapters 221 and 225)

40.1.5 Privacy for patient

The planning of ambulatory services shall provide for the privacy and dignity of the patient during interview, examination, and treatment.

40.1.6 Parking

Each facility shall have parking space to satisfy the minimum needs of patients and

employees. In the absence of a formal parking study, each facility shall provide not less than one space for each employee plus one space for each examination room. This ratio may be reduced in an area convenient to a public transportation system or to public parking facilities if proper justification is included in the narrative program. Space shall be provided for emergency and delivery vehicles.

40.2 Administration and Public Areas

40.2.1 Entrance

The entrance shall be located at grade level, sheltered from the weather, and able to accommodate wheelchairs.

40.2.2 Reception area

This shall include:

40.2.2.1 Wheelchair storage space(s);

40.2.2.2 Reception and information counter or desk;

40.2.2.3 Waiting space(s);

40.2.2.4 Access to public toilet facilities from a public corridor;

40.2.2.5 Access to public telephone(s) from a public corridor; and

40.2.2.6 Access to drinking fountain(s) from a public corridor.

40.2.3 Interview space(s)

These shall be provided for private interviews relating to social service, credit, and admissions.

40.2.4 General or individual office(s)

These shall be provided for business transactions, records, and administrative and professional staffs.

40.2.5 Multipurpose room(s)

Access to multipurpose rooms shall be provided for conferences, meetings, and health education purposes, and shall be equipped for showing visual aids.

40.2.6 Special storage

Space shall be provided for employees' personal effects.

40.2.7 General storage facilities

These shall be provided for office supplies, sterile supplies, pharmaceutical supplies, splints and other orthopedic supplies, and housekeeping supplies and equipment.

40.3 Clinical Facilities

40.3.1 General purpose examination room(s)

These shall have a minimum floor area of 80 square feet (7.43 square meters), excluding such spaces as vestibule, toilet, and closet. Arrangement shall permit at least 2'6" (76cm) clearance at each side and at the foot of the examination table. A lavatory or sink equipped for handwashing and a counter or shelf space for writing shall be provided.

40.3.2 Special purpose examination room(s)

Room sizes for special clinics such as eye, dental, and ear, nose, and throat examinations shall be determined by types of equipment used but shall be not less than 80 square feet (7.43 square meters) excluding such spaces as vestibule, toilet, and closet. A lavatory or sink equipped for handwashing and a counter or shelf space for writing shall be provided.

40.3.3 Treatment room(s) for minor surgical procedures and cast procedures

These shall have a minimum floor area of 120 square feet (11.15 square meters), excluding such spaces as vestibule, toilet, closet, and work counter (whether fixed or movable). The minimum room dimension shall be ten feet (3.05 m). A lavatory or sink equipped for handwashing and a counter or shelf space for writing shall be provided.

40.3.4 Observation room(s)

Observation rooms shall be provided for handling isolation, suspect, or disturbed patients and shall be conveniently located near the nurses' station or other control station to permit close

observation of patients and to minimize their hiding, escape, injury, or suicide. Patients shall have access to a toilet room without entering the general corridor area. In facilities having an annual patient visit load of 20,000 or less, a separate room is not required if an examination room is modified to accommodate this function.

40.3.5 Facilities for charting and for clinical records or nurses' station(s)

Work counter, communication system, and a space for supplies shall be provided. A separate space may be omitted if these functions are accommodated in each examination room and each treatment room.

40.3.6 Drug distribution station

This may be a medicine preparation room or unit, a self-contained medicine dispensing unit, or another approved system. If used, a medicine preparation room or unit shall be under nursing staff's visual control and contain a work counter, refrigerator, and locked storage for biologicals and drugs. A medicine dispensing unit may be located at the nurses' station, in the clean workroom, or in an alcove or other space under direct control of nursing or pharmacy staff.

40.3.7 Clean workroom or clean holding room

The clean workroom shall contain a work counter and handwashing and storage facilities. The clean holding room shall be part of a system for storage and distribution of clean and sterile supply materials and shall be similar to the clean workroom except that the work counter and handwashing facilities may be omitted.

40.3.8 Soiled workroom or soiled holding room

The soiled workroom shall contain a clinical sink or equivalent flushing rim fixture, sink equipped for handwashing, work counter, waste receptacle, and linen receptacle. A soiled holding room shall be part of a system for the collection and disposal of soiled materials and shall be similar to the soiled workroom except that the clinical sink and the work counter may be omitted.

40.3.9 Sterilizing facilities

A system for the sterilization of equipment and supplies shall be provided.

40.4 Diagnostic Facilities

40.4.1 Radiology suite

Equipment shall be provided for diagnostic purposes or shall be available through an effective contract arrangement with a nearby hospital or radiographic service. Therapeutic equipment may also be included. The suite shall contain:

40.4.1.1 Radiographic room(s). (See Section 40.8.1.16 for special requirements);

40.4.1.2 Film processing facilities;

40.4.1.3 Viewing and administration area(s);

40.4.1.4 Film storage facilities;

40.4.1.5 Toilet room with handwashing facilities directly accessible from each fluoroscopy room without entering the general corridor area; and

40.4.1.6 Dressing area(s), with convenient access to public toilets.

40.4.2 Laboratory

Laboratory facilities shall be provided in the ambulatory care facility or through an effective contract arrangement with a nearby hospital or laboratory service for hematology, clinical chemistry, urinalysis, cytology, pathology, and bacteriology. If these are provided through such a contract, then the following laboratory facilities, at a minimum, shall be provided in the ambulatory care facility:

40.4.2.1 Laboratory work counter(s), with sink and vacuum, gas, and electric services;

40.4.2.2 Lavatory(ies) or counter sink(s), equipped for handwashing;

40.4.2.3 Storage cabinet(s) or closet(s); and

40.4.2.4 Specimen collection facilities. Urine collection rooms shall be equipped with a water closet and lavatory. Blood collection facilities shall have space for a chair and work counter.

40.5 Janitors' Closet(s)

This room shall contain a floor receptor or service sink and storage for housekeeping

supplies and equipment. At least one janitors' closet shall be provided per floor.

40.6 Employees' Facilities

Locker rooms, lounges, toilets, or shower facilities, as required, shall be provided to accommodate the needs of all personnel and volunteers.

40.7 Engineering Service and Equipment Areas

The following shall be provided:

40.7.1 Equipment room(s)

These shall contain boilers, mechanical equipment, and electrical equipment.

40.7.2 Storage room(s)

These shall contain building maintenance supplies and yard equipment.

40.7.3 Waste processing services

40.7.3.1 Space and facilities shall be provided for the sanitary storage and disposal of waste by mechanical destruction, compaction, containerization, or removal, or by a combination of these techniques.

40.7.3.2 If provided, design and construction of trash chutes shall be in accordance with N.F.P.A. (National Fire Protection Association) Standard 82.

40.8 Details and Finishes

All details and finishes shall meet the following requirements:

40.8.1 Details

40.8.1.1 Minimum public corridor width shall be 5 feet (1.52m) and sub-corridor width shall be 3'8" (1.12m). For a facility providing family planning services, minimum width for all corridors shall be 3'8" (1.12m).

40.8.1.2 Each building shall have at least two exits remote from each other. Other details relating to exits and fire safety shall be in accordance with Section 13 of N.F.P.A. Standard 101 and the requirements outlined herein. Sections 13-1132, 13-1253, 13-13I2, 13-1331, 13-1262, and 13-2111 shall not apply to ambulatory care facilities.

40.8.1.3 Items such as drinking fountains, telephone booths, vending machines, and portable equipment shall be located so as not to restrict corridor traffic or reduce the corridor width below the required minimum.

40.8.1.4 Toilet rooms which may be used by patients shall be equipped with doors and hardware which will permit access from the outside in any emergency. When such rooms have only one opening, or are small, the doors shall be capable of opening outwards, or be otherwise designed to be opened without need to push against a patient who may have collapsed within the room.

40.8.1.5 The minimum width of doors for patient access to examination and treatment rooms shall be 2'10" (86.3cm).

40.8.1.6 Doors on all openings between corridors and rooms or spaces subject to occupancy, except elevator doors, shall be swing-type.

40.8.1.7 Doors, except doors to spaces such as small closets which are not subject to occupancy, shall not swing into corridors in a manner that might obstruct traffic flow or reduce the required corridor width. (Large walk-in type closets are considered occupiable spaces.)

40.8.1.8 Doors between all rooms and corridors (except those exempt from swing-type requirements) shall be of not less than 1 3/4 inches thick, solid core, wood, flush doors of 30-minute fire-resistive construction except for doors to hazardous areas which are specifically identified elsewhere. Fire door hardware is not required on 30-minute fire-resistive doors.

40.8.1.9 Doors, sidelights, borrowed lights, and windows in which the glazing extends down to within 18 inches (46cm) of the floor (thereby creating possibility of accidental breakage by pedestrian traffic) shall be glazed with safety glass, wire glass, or plastic glazing material that will resist breaking and will not create dangerous cutting edges when broken. Similar materials shall be used in wall openings of playrooms and exercise rooms unless required otherwise for fire safety. Safety glass or plastic glazing materials shall be used for shower doors and bath enclosures.

40.8.1.10 Threshold and expansion joint covers shall be made flush with the floor surface to facilitate use of wheelchairs and carts.

40.8.1.11 The location and arrangements of handwashing facilities shall permit their proper use and operation. Particular care shall be given to the clearances required for blade-type operating handles. (See Section 40.11.5.1.2)

40.8.1.12 Paper towel dispensers and waste receptacles shall be provided at all handwashing fixtures. Hot air hand dryers may be used if they comply with Underwriters' Laboratories, Inc. and the National Electrical Code.

40.8.1.13 Where labeled fire doors are required, these shall be certified by an independent testing laboratory as meeting the construction requirements equal to those for fire doors in N.F.P.A. Standard 80. A labeled fire door shall be construed to mean labeled frame and hardware.

40.8.1.14 Dumbwaiters, conveyors, and material handling systems shall not open into a corridor or exitway but shall open into a room enclosed by construction having a fire-resistance of not less than one hour and provided with Class "C" three-quarters-hour labeled fire doors. Service entrance doors to vertical shafts containing dumbwaiters, conveyors, and material handling systems shall be not less than Class "B" one and one-half-hour labeled fire doors. Where horizontal conveyors and material handling systems penetrate fire-rated walls or smoke partitions, the opening thereto must be provided with a Class "B" one and one-half hour labeled fire door for two-hour walls and a Class "C" three-quarters-hour labeled fire door for one-hour walls or partitions.

40.8.1.15 Elevator shaft openings shall have Class "B" one and one-half-hour labeled fire doors.

40.8.1.16 Radiation protection requirements of X-ray and gamma ray installations shall conform with N.C.R.P. Reports Nos. 33 and 34. Provisions shall be made for testing the completed installation before use and all defects must be corrected before acceptance.

40.8.1.17 Ceiling heights shall be as follows:

40.8.1.17.1 Boiler rooms shall have ceiling clearances not less than 2'6" (76cm) above the main boiler header and connecting piping;

40.8.1.17.2 Radiographic and other rooms containing ceiling-mounted equipment and those having ceiling-mounted surgical light fixtures shall have height required to accommodate the equipment or fixtures; and

40.8.1.17.3 All other rooms shall have not less than 8 feet (2.44m) ceilings except that corridors, storage rooms, toilet rooms, and other minor rooms may be not less than 7'8" (2.34m). Suspended tracks, rails, and pipes located in the path of normal traffic shall be not less than 6'8" (2.03m) above the floor.

40.8.1.18 Rooms containing heat producing equipment (such as boiler or heater rooms) shall be insulated and ventilated to prevent any floor surface above from exceeding a temperature of ten degrees F. (six degrees C.) above the ambient room temperature.

40.8.1.19 Approved fire extinguishers shall be provided throughout the building in accordance with N.F.P.A. Standard No. 10.

40.8.1.20 Protected openings. Except where specifically indicated otherwise, doors in two-hour fire-resistive walls shall be Class "B" one and one-half-hour labeled fire doors and in one-hour fire-resistive walls shall be Class "C" three-quarters-hour labeled fire doors.

40.8.2 Finishes

40.8.2.1 Cubicle curtains, draperies, etc. shall be noncombustible or rendered flame retardant and shall pass both the large and small scale tests of N.F.P.A. Standard No. 701. A dressing area shall be available in examination rooms.

40.8.2.2 Flame spread and smoke developed ratings of finishes are covered under Section 40.9.2.7.

40.8.2.3 Floor materials shall be easily cleanable and have wear-resistance appropriate for the location involved. In all areas frequently subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions. Floors that are subject to traffic while wet, such as shower and bath areas and certain work areas, shall have a nonslip surface.

40.8.2.4 Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth and moisture-resistant.

40.8.2.5 Wall bases in soiled workrooms and other areas which are frequently subject to wet cleaning methods shall be made integral and coved with the floor, tightly sealed within the wall, and constructed without voids that can harbor insects.

40.8.2.6 Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

40.8.2.7 The sound transmission for ceiling and walls in corridors, multipurpose rooms, and waiting areas shall be between 45-55 decibel rating.

40.9 Construction

40.9.1 Existing construction shall refer to any building in operation as an ambulatory care facility prior to adoption of these standards and shall meet these minimum requirements. Such a facility shall comply with the regulations for new construction if it undergoes any expansion or major renovation.

40.9.1.1 A comprehensive, closed circuit, fully supervised, automatic and manual fire alarm system to comply with N.F.P.A. Standard No. 72 shall be provided in an existing facility of up to three stories in height which is not of fire-resistive construction.

40.9.1.2 An elevator shall be provided in an existing facility of three or more stories in height which is not of fire-resistive construction, if any floor above the second floor is utilized by patients.

40.9.1.3 A comprehensive, automatic sprinkler system to comply with N.F.P.A. Standard No. 13 shall be provided in an existing facility of four or more stories in height which is not of fire-resistive construction, if any floor above the second floor is utilized by patients or employees.

40.9.1.4 Corridor widths in an existing facility shall be a minimum of 36 inches in the clear.

40.9.1.5 No door in an existing facility shall be less than 30 inches in width except doors to toilet rooms or small closets, which shall be no less than 26 inches in width.

40.9.1.6 The existing facility shall provide emergency lighting and exit lights illuminated by either battery pack or emergency generator. The exit signs shall be illuminated at all times when the facility is occupied.

40.9.1.7 Patient treatment rooms in an existing facility shall be provided with mechanical power exhaust ventilation. Interior rooms which have no natural light shall have outdoor-tempered air.

40.9.1.8 Electrical systems in an existing facility shall comply with the National Electrical Code and shall provide sufficient power for the full operation of the facility.

40.9.2 New construction shall refer to new buildings, additions or major renovations or alterations to existing buildings, and buildings not presently utilized as ambulatory care facilities.

40.9.2.1 Construction of ambulatory care facilities shall generally be similar to recognized national model building code requirements applicable to office occupancies and to the minimum requirements contained herein.

40.9.2.2 Foundation shall rest on natural solid ground if a satisfactory soil is available at reasonable depths. Proper soil-bearing values shall be established in accordance with recognized standards. If solid ground is not encountered at practical depths, the structure shall be supported on driven piles or drilled piers designed to support the intended load without detrimental settlement, except that one-story buildings may rest on a fill designed by a soils engineer. When engineered fill is used, site preparation and all grading shall be done under the direct full-time supervision of the soils engineer. The soils engineer shall issue a final report on the grading operation and a certification of compliance with the job specifications. Special review and approval by this Department shall be required for foundations supported on engineered fill. All footings shall extend to a depth of not less than one foot below the estimated maximum frost line.

40.9.2.3 Corridor partitions shall be of construction having a fire-resistance of not less than one-hour or shall be of noncombustible non-rated construction extending from the floor slab to the underside of the floor slab above.

40.9.2.4 Floor finish materials may also be considered acceptable if they have a flame spread index of not more than 4.0 when tested by an independent testing laboratory in accordance with Underwriters' Laboratories, Inc. Standard No. 992.

40.9.2.5 If a separate underlayment is used with any floor finish material, the flame spread test assembly shall include the underlayment, or otherwise make equivalent provision for its effect on the flammability characteristics of the floor finish material.

40.9.2.6 Building insulation. Building insulation materials shall be noncombustible. Exposed vapor barriers and coverings on building insulation shall be noncombustible or fire retardent.

40.9.2.7 Interior finish

Interior finish materials shall comply with the flame spread limitations and the smoke production limitations shown in Table 1. If a separate underlayment is used with any floor finish materials, the underlayment and the finish material shall be tested as a unit, or equivalent provisions shall be made to determine the effect of the underlayment on the flammability characteristics of the floor finish material. Tests shall be performed by an independent testing laboratory.

Table 1. FLAME SPREAD AND SMOKE PRODUCTION LIMITATIONS ON INTERIOR FINISHES IN AMBULATORY CARE FACILITIES

		Flame Spread Rating	Smoke Production Rating
Walls and Ceilings	Exitways, storage rooms, and areas of unusual fire hazard	A.S.T.M. Standard E 84 25 or less	Appendix II NBS Technical Notes 708 450 or less*
	All other areas	A.S.T.M. Standard E 84 75 or less	
Floors		A.S.T.M. Standard E 84 75 or less	

*Average of flaming and nonflaming values.

40.9.2.8 Insulation materials

Building insulation materials, unless sealed on all sides and edges, shall have a flame spread rating of 25 or less and a smoke developed rating of 150 or less when tested in accordance with A.S.T.M. Standard E 84.

40.9.8 Special provisions shall be made in the design of buildings in regions where local experience shows loss of life or damage to building resulting from hurricanes, tornadoes, floods, or other natural disasters.

40.10 Elevators

40.10.1 General

All buildings having examination rooms, treatment rooms, or diagnostic services located on other than the main entrance floor shall have electric or electro-hydraulic elevators. The elevators shall be installed in sufficient quantity, capacity, and speed so that the average interval of dispatch time will not exceed one minute, and average peak loading can be accommodated.

40.10.1.1 Cars and platforms. Cars shall have a minimum inside floor dimension of not less than 5 feet (1.52m). The car door shall have a clear opening of not less than 3 feet (91cm).

40.10.1.2 Leveling. Elevators shall be equipped with an automatic leveling device of the two-way automatic maintaining type with an accuracy of ± one-half inch (± 1.3cm).

40.10.1.3 Operation. Elevators, except freight elevators, shall be equipped with a two-way special service switch to permit cars to bypass all landing button calls and be dispatched directly to any floor.

40.10.1.4 Elevator controls, alarm buttons, and telephones shall be accessible to wheelchair occupants.

40.10.1.5 Elevator call buttons, controls, and door safety stops shall be of a type that will not be activated by heat or smoke.

40.10.2 Field inspections and tests

Field inspections and tests shall be made and the owner shall be furnished written certification that the installation meets the requirements set forth in this section and all applicable safety regulations and codes.

40.11 Mechanical Requirements

40.11.1 General

40.11.1.1 Prior to completion and acceptance of the facility, all mechanical systems shall be tested, balanced, and operated to demonstrate to the owner or his/her representative that the installation and performance of these systems conform to the requirements of the plans and specifications.

40.11.1.2 Upon completion of the contract, the owner shall be furnished with a complete set of manufacturers' operating, maintenance, and preventive maintenance instructions, a parts list with numbers and description for each piece of equipment, and shall be provided with instruction in the operational use of systems and equipment, as required.

40.11.2 Thermal and acoustical insulation

40.11.2.1 The following shall be insulated within the building:

40.11.2.1.1 Boilers, smoke breeching and stacks;

40.11.2.1.2 Steam supply and condensate return piping;

40.11.2.1.3 Hot water piping above 180 degrees F. (82 degrees C.)and all hot water heaters, generators and convertors;

40.11.2.1.4 Hot water piping exposed to patient contact operating above 125 degrees F. (52 degrees C.);

40.11.2.1.5 Chilled water, refrigerant, other process piping and equipment operating with fluid temperatures below ambient dew point;

40.11.2.1.6 Water supply and drainage piping on which condensation may occur; and

40.11.2.1.7 Air ducts and casings with outside surface temperature below ambient dew point.

40.11.2.2 Insulation may be omitted from hot water and steam condensate piping when such insulation is unnecessary for preventing excessive system heat loss, excessive space heat gain, or accidental contact.

40.11.2.3 Insulation on cold surfaces shall include an exterior vapor barrier.

40.11.2.4 Insulation including finishes and adhesives on the exterior surfaces of ducts, pipes, and equipment shall have a flame spread rating of 25 or less and a smoke developed rating of 150 or less as determined by an independent testing laboratory in accordance with the American Society for Testing and Materials (A.S.T.M.) Standard E 84.

40.11.2.5 Linings in air ducts and equipment shall meet the Erosion Test Method described in Underwriters' Laboratories, Inc. Publication No. 181. The linings and insulation, including coatings and adhesive on the exterior surfaces of ducts, pipes, and equipment located in air plenums shall have a flame spread rating of 25 or less and a smoke developed rating of 50 or less as determined by an independent testing laboratory in accordance with the A.S.T.M. Standard E 84.

40.11.3 Steam and hot water systems

40.11.3.1 Boilers. Boilers shall have the capacity, based upon the published Steel Boiler Institute or Institute of Boiler and Radiator Manufacturers' net ratings, to supply the normal requirements of all systems and equipment. The heat source may be an integral part of the facility or from a remote facility. An electrical emergency switch for the oil burner shall be provided on the first floor.

40.11.3.2 Valves. Supply and return mains and risers of space heating and process steam systems shall be valved to isolate the various sections of each system. Each piece of equipment shall be valved at the supply and return end.

40.11.4 Heating, ventilating, and filtering systems

40.11.4.1 Temperatures. The heating system shall be designed on the basis of 75 degrees F. (24 degrees C.) for all occupied areas at winter design conditions.

40.11.4.2 Ventilation system details. All air supply and air exhaust systems shall be mechanically operated. All fans serving exhaust systems shall be located at or near the point of discharge from the building. The ventilation rates shown in Table 2 shall be considered as minimal acceptable rates and shall not be construed as precluding higher ventilation rates. Except as noted below, the requirements of N.F.P.A. Standard 90 A shall be followed.

40.11.4.2.1 Outdoor air intakes, other than for individual room units, shall be located as far as practicable but not less than 25 feet (7.62m) from the exhausts from any ventilating system, plumbing stack, combustion equipment, or areas that may collect noxious fumes. The bottom of outdoor air intakes shall be located as high as practicable but not less than 6 feet (1.83m) above the ground level or, if installed through the roof, 3 feet (91cm) above roof level or parapets.

40.11.4.2.2 The ventilating systems shall be designed and balanced to provide the general pressure relationships shown in Table 2, and areas not shown shall be balanced. All occupied rooms not listed shall be adequately ventilated by natural and mechanical means.

40.11.4.2.3 Room supply air inlets, recirculation and exhaust air outlets shall be located not less than 3 inches (7.6cm) above the floor.

40.11.4.2.4 Central systems shall be equipped with filter or filters with a minimum filtering efficiency of 80 percent for treatment areas and 25 percent for all other areas, certified by an independent testing agency based on the atmospheric dust spot efficiency determination in accordance with the American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE) Standard No. 52-68.

40.11.4.2.5 The exhausts from all hoods in which infectious or radioactive materials are processed shall be equipped with filters having a 99 percent filtering efficiency based on the DOP (dioctylphthalate) test method and there shall be equipment and/or procedures for the safe removal and replacement of contaminated filters.

40.11.4.2.6 Filterframes, enclosing duct work and filter segments, shall be sealed or gasketed to provide positive seal against air leakage.

40.11.4.2.7 A manometer shall be installed across each filter bed serving central air systems.

40.11.4.2.8 Duct installation, material and duct linings shall meet or exceed the requirements of N.F.P.A. Standard No. 90 A.

40.11.4.2.9 Ducts which penetrate construction intended for X-ray and other ray protection shall not impair the effectiveness of the protection.

40.11.4.2.10 Laboratory hoods for general use shall have a minimum coverage face velocity of 75 feet per minute.

Hoods in which infectious or radioactive materials are processed shall have a face velocity of 100 feet per minute and each shall have an independent exhaust system with the fan at the discharge point of the system. Hoods for processing infectious material shall be equipped with means for disinfection. Duct systems serving these hoods shall be constructed of corrosion-resistant material.

Table 2. PRESSURE RELATIONSHIPS AND VENTILATION OF CERTAIN AREAS OF AMBULATORY CARE

Area Designation	Pressure Relationships to Adjacent Areas	Minimum Air Changes of Outdoor Air per Hour	Minimum Total Air Changes per Hour	All Air Exhausted Directly to Outdoors
Dental room	-	2	6	Yes
Treatment room	0	2	6	--
Laboratory, gen.	-	2	6	--
X-ray and film processing	-	2	6	Yes
Clean workroom	+	2	4	--
Soiled workroom	-	2	10	Yes
Waiting room	0	2	6	--
Corridors	0	2	6	--
Examination room	0	2	6	--
Observation room	-	2	6	Yes
Janitor's closet	-	--	10	Yes
Soiled storage	-	--	10	Yes
Toilet room	-	--	10	Yes

\+ = Positive
\- = Negative
0 = Equal
-- = Optional

40.11.4.2.11 Fire dampers shall be located in accordance with the N.F.P.A. Standard No. 90 A. The location of all dampers shall be shown on the plans.

40.11.4.2.12 Plenum systems shall conform to N.F.P.A. Standard No. 90 A for tested systems.

40.11.5 Plumbing and other piping systems. All plumbing systems shall be installed in accordance with the requirements of Chapter 14, "Medical Care Facility Plumbing Equipment," in the National Standard Plumbing Code and the New Jersey Plumbing Code.

40.11.5.1 Plumbing fixtures

40.11.5.1.1 The material used for plumbing fixtures shall be nonabsorptive acid-resistant.

40.11.5.1.2 Lavatories and sinks required in patient care areas shall have the water supply spout mounted so that its discharge point is a minimum distance of 5 inches (12.7cm) above the rim of the fixture. All fixtures used by medical and nursing staff and all lavatories used by patients shall be trimmed with valves which can be operated without the use of hands. Where blade handles are used for this purpose, they shall not exceed 4½ inches (11.4cm) in length, except that handles on clinical sinks shall be not less than 6 inches (15.2cm) long.

40.11.5.1.3 Clinical sinks shall have an integral trap in which the upper portion of a visible trap seal provides a water surface.

40.11.5.2 Water supply systems

40.11.5.2.1 Systems shall be designed to supply water to the fixtures and equipment on the upper floors at a minimum pressure of 15 pounds per square inch during maximum demand periods.

40.11.5.2.2 Each water service main, branch main, riser, and branch to a group of fixtures shall be valved. Stop valves shall be provided at each fixture.

40.11.5.2.3 Backflow preventers (vacuum breakers) shall be installed on hose bibbs and on all fixtures to which hoses or tubing can be attached, such as janitors' sinks and bedpan flushing attachments.

40.11.5.2.4 Flush valves installed on plumbing fixtures shall be of a quiet operating type, equipped with silencers.

40.11.5.2.5 Hot water distribution systems shall be arranged to provide hot water at each hot water outlet at all times. Hot water to handwashing facilities and showers shall not exceed 110 degrees F. (43 degrees C.).

40.11.5.3 Drainage system. Building sewers shall discharge into a community sewage system. Where such a system is not available, a facility providing sewage treatment which conforms to applicable local and state regulations shall be required.

40.11.5.4 Fire extinguishing system. Automatic fire extinguishing systems in accordance with N.F.P.A. requirements shall be installed in trash rooms, bulk storage rooms, attic spaces, and crawl spaces used for storage, and any other hazardous area. Storage rooms of less than 100 square feet (9.29 square meters) are excluded from this requirement.

40.11.5.5 Non-flammable medical gas system. Non-flammable medical gas system installation shall be in accordance with the requirements of N.F.P.A. Standard No. 56 A.

40.12 Electrical Requirements

40.12.1 General

40.12.1.1 All material including equipment, conductors, controls, and signaling devices shall be installed to provide a complete electrical system with the necessary characteristics and capacity to supply the electrical facilities shown in the specifications or indicated on the plans. All materials shall be listed as complying with applicable standards of Underwriters' Laboratories, Inc., or other similarly established standards.

40.12.1.2 The project contract shall require testing of all electrical installations and systems and shall show that the equipment is correctly installed and operates as planned or specified.

40.12.2 Switchboard and power panels. Circuit breakers or fusible switches that provide disconnecting means and overcurrent protection for conductors connected to switchboards and distribution panelboards shall be enclosed or guarded to provide a deadfront type of assembly. The main switchboard shall be convenient for use, readily accessible for maintenance, clear of traffic lanes, and in a dry, ventilated space free of corrosive fumes or gases. Overload protective devices shall be suitable for operating properly in the ambient temperature conditions.

40.12.3 Distribution panelboards. Lighting and appliance panelboards shall be located on the same floor as the circuits they serve.

40.12.4 Lighting. All spaces occupied by people, machinery, and equipment within buildings, the approaches to the buildings, and parking lots shall have lighting. Exit lighting shall be provided in each corridor such that two lights are visible from any point within any corridor. A portable or fixed examination light shall be provided in each examination and treatment room.

40.12.5 Receptacles (convenience outlets)

40.12.5.1 Rooms. Duplex grounding type receptacles shall be installed in all areas in sufficient quantities for the tasks to be performed. A minimum of one duplex receptacle for each wall shall be installed in each work area or room other than storage or lockers. Each examination or work table shall have access to a minimum of two duplex receptacles.

40.12.5.2 Corridors. Duplex receptacles for cleaning equipment and general use shall be installed approximately 50 feet (15.24m) apart in all corridors and within 25 feet (7.62m) of ends of corridors.

40.12.6 Equipment installation in special areas

40.12.6.1 X-ray and gamma-ray installation. X-ray stationary installations and mobile equipment shall conform to Article 660 of N.F.P.A. Standard No. 70.

40.12.6.2 X-ray film illuminator. At least two viewing panels shall be installed in each X-ray viewing room.

40.12.7 Fire alarms. A manually-operated, electrically supervised, fire alarm system shall be installed in each building having an area exceeding 5,000 square feet (464.52 square meters). In multi-story buildings or in multi-story facilities, the total floor area signal shall be coded or otherwise arranged to indicate the location of the station operated. Pre-signal system will not be permitted.

40.12.8 Emergency lighting. Automatic emergency lighting to provide safe egress from the building in the event of power failure shall be provided. Emergency lighting in treatment rooms shall also be provided.

40.12.9 Emergency generator. In facilities where life-support equipment is required, an emergency generator shall be connected for use by this equipment. The emergency system shall be so controlled that after interruption of the normal power supply, the generator is brought to full voltage and frequency within ten seconds.