/* New York Administrative Code, part 2 of 4. */

(v) The hospital shall adopt and uniformly apply donor selection criteria and establish policies and procedures to ensure the medical suitability of organs and tissues to be transplanted, the donor selection criteria shall:

(a) be specific for each type of organ and tissue;

(b) describe those medical conditions, confirmed through the donor's medical history and appropriate clinical laboratory testing, which would make the potential donor ineligible under any circumstances, including at a minimum:

(1) For donation of kidneys, heart and liver:

(i) serologic evidence of human immunodeficiency virus (H.I.V.) or clinical history of acquired immune deficiency syndrome (AIDS);

(ii) history or evidence of a disseminated malignancy; or

(iii) evidence of a transmissible disease or infection.

(2) For bone donation:

(i) serologic evidence of H.I.V., or clinical history of AIDS;

(ii) donor death preceded availability for tissue procurement by a period exceeding 24 hours;

(iii) the presence of systemic sepsis;

(iv) evidence of a transmissible disease or infection;

(v) history or evidence of any malignancy; or

(vi) history of metabolic bone disease.

(3) For eye donation:

(i) serologic evidence of H.I.V. or clinical history of AIDS;

(ii) donor death preceded availability for tissue procurement by a period exceeding a predetermined time limit which is specified in the policies and procedures of the transplantation service;

(iii) the presence of systemic sepsis; or

(iv) evidence of a transmissible disease or infection including, but not limited to, rabies, Jacob-Creutzfeld disease, and viral hepatitis.

(4) For skin donation:

(i) serologic evidence of H.I.V. or clinical history of AIDS;

(ii) donor death preceded availability for tissue procurement by a period exceeding a predetermined time limit which is specified in the policies and procedures of the transplantation service.

(iii) the presence of systemic sepsis;

(iv) evidence of a transmissible disease or infection;

(v) the presence of diffuse dermatitis or any diseases associated with the skin;

(vi) history of any hepatic disease; or

(vii) history or evidence of any malignancy.

(5) For heart valve donation:

(I) serologic evidence of H.I.V. or clinical history of AIDS;

(ii) history or evidence of any malignancy;

(iii) the presence of systemic sepsis;

(iv) evidence of a transmissible disease or infection, including myocarditis; or

(v) the presence of congenital valve abnormalities, excluding fenestrations.

(c) describe those medical conditions, confirmed through the donor's medical history and appropriate clinical laboratory testing, for which discretion, with specified limits on that discretion, may be exercised regarding suitability, including at a minimum:

(1) unknown cause of death;

(2) history or evidence of localized malignancies not involving organ or tissues to be transplanted with the exception of bone, skin and heart valve donation for which any malignancies are absolute contraindications;

(3) localized infections not involving the organ or tissue to be transplanted;

(4) cardiovascular instability and prolonged ischemia;

(5) history of a disease of unknown etiology such as multiple

sclerosis, amyothrophic lateral scerlosis or cystic fibrosis;

(6) history of any trauma, disease process or pathology potentially compromising organ function, including but not limited to alcoholism, diabetes mellitus, longstanding hypertension, cardiovascular or peripheral vascular disease;

(7) history of prolonged drug therapy potentially affecting organ or tissue function;

(8) history or evidence of intravenous drug abuse; or

(9) history of viral hepatitis;

(d) for bone marrow donation, meet the pertinent requirements of Subpart 58-5 of this Title.

(e) be made available to the public; and

(f) be communicated to organ procurement agencies and tissue banks.

(vi) The hospital shall ensure that the transplantation service is under the direction of a qualified specialist with previous experience and training in transplantation services, The hospital shall also assure that:

(a) a staff person is designated to coordinate the procurement and transplant program including patient follow-up after discharge;

(b) nursing staff for transplantation services are commensurate with the assessed needs of the patients;

(c) supportive care, including psychiatric and social services, are made available to living donors, organ recipients and the families of these patients;

(d) all staff providing care to transplantation patients are prepared for their responsibilities through experience, demonstrated competence and completion of inservice education programs as needed;

(e) patient care evaluation, management and planning are performed by the professional health care team involved with the care of the patient, from admission to discharge, including plans for follow-up of the patient into the community;

(f) any necessary specialized facilities and equipment are available to meet the needs of the patients;

(g) clinical laboratory services are available from laboratories possessing permits issued under article 5, title 5 of the Public Health

Law, in the categories of virology, diagnostic immunology, diagnostic immunohematology, bacteriology, mycology, mycobacteriology, parasitology, cytogenetics, cellular immunology and histocompatibility;

(h) infection control policies and procedures specific to transplantation services are developed and implemented as an integral part of the hospital's infection control program;

(i) there shall be an organized follow-up program for transplant patients following discharge including data management resources to maintain records on the long-term survival of transplant patients; and

(j) as part of the hospital's quality assurance program, the hospital shall implement a system for evaluating the quality and appropriateness of patient care and patient outcomes including survival rates and any complications. Reports summarizing the outcomes from the quality assurance program for transplantation services shall be submitted to the department on an annual basis.

(2) Bone marrow transplantation service. The hospital shall:

(i) ensure that the physician director is a qualified specialist with training in immunology or hematology and advanced training and previous experience in bone marrow transplantation services;

(ii) ensure that physicians providing care in the bone marrow transplantation program have extensive experience and demonstrate expertise in the medical or surgical treatment of oncologic/ hematologic/ immunologic disease;

(iii) provide a multidisciplinary team to include qualified specialists in chemotherapy, radiation therapy, nursing, social work, infectious disease control, immunology, oncology, hematology and expertise in intensive cardiopulmonary medicine;

(iv) have clinical services with staff specialized in the care and management of bone marrow transplantation patients to include but not be limited to: pathology, immunology, anesthesiology, laboratory, radiology, renal dialysis, respiratory therapy, nutrition and pharmacology;

(v) ensure that the program is supported by a blood bank with a capacity to support four to six patients a day, and ensure the availability of a blood separator, a central blood repository, and an irradiator for blood products; and

(vi) provide or make arrangements for the harvesting of bone marrow.

(3) Liver transplantation service, The hospital shall:

(i) perform at least 20 transplants per year when fully operational to ensure quality of care and cost effectiveness;

(ii) ensure that the liver transplantation surgeon(s) is board-certified in general surgery or has equivalent training and experience and demonstrates the ability to successfully perform liver transplantation as evidenced by clinical experience in existing liver transplantation programs;

(iii) ensure that all physicians providing care in the liver transplantation program have extensive experience and demonstrate expertise in the medical and surgical treatment of hepatic disease including the immunosuppressive management of transplant recipients;

(iv) have a qualified transplantation team to include physician specialists in gastroenterology, hepatology, infectious disease, nephrology, pulmonary medicine, pediatrics, neurology, neurosurgery, immunology and hematology; and

(v) have clinical services with staff specialized in the care of liver transplant patients to include, but not be limited to: pathology, immunology, anesthesiology, laboratory, radiology, renal dialysis, respiratory therapy, nutrition and pharmacology.

(4) Renal transplantation services. The hospital shall:

(i) ensure that renal transplantation services are provided in a renal transplantation center which is a unit of a hospital approved by the department to provide transplantation and other medical and surgical services required for renal transplant patients;

(ii) ensure that the services are provided under the direction of a transplantation surgeon with previous training and experience in renal transplantation services or a physician-director who shall be responsible for planning, organizing, conducting and directing the clinical aspects of renal transplantation services and participating in the selection of a suitable treatment modality for each patient. For the purposes of this subparagraph, physician-director is defined as a licensed and currently registered physician who is board-certified in internal medicine or pediatrics or has equivalent training and experience and has at least 12 months of experience or training in the care of patients with chronic renal disease;

(iii) ensure that the surgeons performing renal transplantation are certified in general surgery or urology or have equivalent training and

experience with at least 12 months of advanced experience or training in renal transplantation;

(iv have a qualified transplantation team to include an internist with subspecialty training in nephrology and dialysis and documented experience in the management of renal transplantation patients; a physician with experience in postoperative management of transplant patients who shall be designated to ensure the availability and appropriateness of postoperative care and services; as necessary, the consultative services of physician specialists in immunology and infectious disease; and for those programs providing pediatric renal transplantation, a pediatrician whose role is specifically identified and who is trained in the subspecialty of pediatric nephrology with documented experience in the management of pediatric transplantation;

(v) have clinical services with staff specialized in the care of renal transplant patients to include, but not be limited to: radiology (including radioisotopic services), laboratory (including tissue typing), anesthesiology, nutrition, psychiatric and social services, pharmacology and renal dialysis;

(vi) provide onsite or through a formal agreement with another renal transplantation center, renal dialysis and home dialysis training. A renal transplantation center may also be a renal dialysis center; and

(vii) perform at least 20 transplants a year when fully operational to ensure quality of care and cost effectiveness.

(5) Heart transplantation service. The hospital shall:

(i) ensure compliance with all provisions of a cardiac surgery center;

(ii) develop and implement medical staff and nursing service policies and procedures which include, but are not limited to:

(a) operative procedure protocols including donor maintenance, heart removal and cardioplegia;

(b) posttransplantation treatment protocols including coordination, cardiology and infection disease/isolation protocols;

(c) Postdischarge follow-up protocols including immunosuppression and social services;

(d) commitment of appropriate support services and staffing, including but not limited to anesthesiology, cardiology, operating suite, immunology, pathology, endomycardial biopsy, dietary, nursing, social services, central supply, cardiac surgery, neurology, neurosurgery and

psychiatry; and

(e) patient data collection and reporting protocols for long-term patient follow. up; and

(iii) perform at least 14 human heart transplants per year.

(c) Burn unit/center. (1) Personnel and staffing.

(it A burn unit/center shall designate a director who is a board-certified or board-admissible general or plastic surgeon with one additional year of Specialized training in burn therapy or equivalent experience in burn patient care.

[) Staff for the burn unit/center shall include:

(a) a head nurse of the facility who is a registered professional nurse, with two years intensive care unit or equivalent training and a minimum of six months burn experience;

b) one registered professional nurse for every two intensive care patients at times;

(c) one registered professional nurse for every three nonintensive care patients at all times;

(d) on staff, or through formal arrangement, a physical therapist and occupational therapist with a minimum of three months training or six months experience in burn treatment available as needed;

(e) staff or through formal arrangement a registered dietician available as needed;

(f) on staff, or through formal arrangement, a medical social worker responsible for referral and follow-up care and individual and group counseling available as needed; and

(g) a psychologist and/or psychiatrist available as needed.

(iii) The burn unit/center shall be responsible for training facility staff and other personnel within the service area on emergency treatment procedures, assessment of total body surface area affected, and the classification of burns and triage protocols.

(2) Operation and service delivery. (i) Each burn unit/center shall have a minimum of six beds.

(ii) Each burn unit/center shall treat a minimum of 50 patients with major burn injury to moderate uncomplicated burn injury per year.

(iii) The burn unit/center shall refer patients for whom there are no available beds to another burn unit/center which can provide the care needed.

(iv) Each burn unit/center shall have available, either through direct control or through a network of clearly identified relationships, a system of land and/or air transport which will bring severe burn victims to the unit/center.

(v) Each burn unit/center shall have a designated area for providing specialized intensive care and an operating room easily accessible within the hospital.

(vi) Reviews of each patient with major burn injury or moderate uncomplicated burn injury shall be undertaken on a weekly basis by the burn care team.

(d) Cardiac surgical centers. The hospital shall not admit patients for cardiac surgery unless the facility is an approved cardiac surgical center nor shall the hospital admit patients for heart transplantation unless the facility is a cardiac surgical center approved for heart transplantation. Cardiac surgical centers shall provide both diagnostic and surgical services and shall be approved only as such a combined center.

(1) Direction. The center shall be under the direction of a qualified specialist in thoracic surgery with adequate training and concentration of practice in cardiovascular surgery.

(2) Staff. All personnel shall be prepared for their responsibilities through appropriate training and educational programs.

(i) Physicians shall all be qualified specialists in their respective specialty, and the medical staff shall at a minimum include:

(a) a pediatric cardiologist to care for patients in the pediatric age group herein defined as less than age 21;

(b) a cardiologist to care for adults;

(c) in centers doing surgery for coronary artery disease, a cardiac arteriographer with basic medical training in internal medicine or in radiology. Supplemental qualifications shall include at least two years of training or experience, including but not limited to the areas of cardiac radiology, clinical and laboratory cardiology, basic and/or clinical cardiac physiology and catheter techniques;

(d) a thoracic surgeon or surgeons whose training emphasized cardiovascular surgery;

(e) a radiologist with additional training in the cardiovascular field;

(f) an anesthesiologist with experience with cardiovascular surgical patients and open chest anesthesia;

(g) a pathologist familiar with cardiac abnormalities of all types;

(h) residents, resident fellows, physician's assistants or specialist's assistants on a full-time basis, capable of dealing with all problems that arise before, during and after surgery;

(i) consultants, readily available for consultation in additional specialties, including hematology, neurology, renal physiology and clinical pharmacology; and

(j) in centers performing transplants, the director of this service and other surgeons performing heart transplants shall be a qualified specialist in thoracic surgery and shall demonstrate adequate training and experience in performing human heart transplants.

(ii) Nursing personnel shall include:

(a) a registered professional nurse supervisor;

(b) a registered professional nurse in charge and on the unit at all times; and

(c) such registered professional nurses, licensed practical nurses, and nursing aides in such ratios that are commensurate with the type and amount of nursing needs of the patients.

(iii) Heart-lung machine (pump) operators shall have special training and experience in an active program of open heart surgery, including a thorough background in sterile techniques, perfusion physiology, and the use of monitoring equipment. The operator may be a specially trained physician, nurse, or technician, at the discretion of the director of the center.

(3) Diagnostic and surgical services. All services shall be integrated and available on an inpatient basis, but there shall also be adequately and appropriately organize outpatient services to preclude unnecessary hospitalization and ensure continuity of care. Diagnostic and surgical services shall consist of the following:

(i) a full range of diagnostic services, including but not limited to diagnostic radiology, clinical laboratory and noninvasive cardiac diagnostic capability;

(ii) medical social workers shall be available to the medical staff of the unit to assist with social problems of the patient and the family as they arise, regardless of the economic status of patient and family;

(iii) all essential therapeutic procedures, including but not limited to open and closed heart surgery;

(iv) a blood bank, that meets the requirements of Subpart 58-2 of this Title under the direction of qualified specialists in this field;

(v) intensive care, in specific units, available on a 24-hour basis to provide the special and constant care required by cardiac surgical patients. The unit shall be

staffed by personnel trained in the use of monitoring devices, respirators, pacemakers, defibrillators and other necessary equipment for cardiac resuscitation:

(vi) preoperative and postoperative care as indicated;

(vii) patient and family education, preoperative and postoperative care; and

(viii) a system of adequate patient follow-up.

(4) State Cardiac Advisory Committee. The State Cardiac Advisory Committee shall, at the request of the commissioner, consider any matter relating to cardiac surgical centers and shall advise the commissioner thereon.

(5) Approval and review, Site visits to existing and prospective new centers by members of the State Cardiac Advisory Committee, or other designees of the commissioner, shall be made as indicated, as an adjunct to initial approval and/or for maintaining approval. The public need for cardiac transplantation services shall be evaluated in accordance with section 709.9 of this Title. There shall be sufficient utilization of a cardiac surgical center or heart transplant service to insure both quality and economy of services, as determined by the commissioner. An institution seeking to maintain approval, or in applying for initial approval, shall present evidence that the annual minimum workload standards can be achieved and maintained, The following annual minimum workload standards shall be achieved within two years following initiation of the service to ensure both quality and economy of services:

(i) surgical centers performing only adult open heart surgery shall maintain an annual minimum of 100 procedures;

(ii) surgical centers performing only pediatric open heart surgery shall maintain an annual minimum of 50 procedures; and

(iii) surgical centers performing both adult and pediatric open heart procedures shall maintain an annual minimum of 100 adult and 50 pediatric open heart procedures,

(6) Waiver of minimum workload standards, The commissioner or his designee may waive the workload requirements upon a satisfactory showing by the operator and a determination by the commissioner that the quality of the service is adequate and:

(i) there are extenuating circumstances temporarily precluding compliance with the workload requirements; and/or

(ii) there is a documented unmet need in the center's geographical service area.

(e) Cardiac diagnostic centers, Cardiac diagnostic centers shall provide coronary arteriography and/or other cardiac invasive

diagnostic procedures.

(1) For purposes of this subdivision, the following terms shall have the following meanings:

(i) Combined center shall mean an adult or pediatric cardiac diagnostic center located in the same facility as a corresponding adult or pediatric cardiac surgical center,

(ii) Free-standing center shall mean an adult cardiac diagnostic center located in a separate facility from an adult cardiac surgical center,

(iii) Center shall mean an approved cardiac diagnostic facility under the direction of a qualified specialist in internal medicine (cardiovascular disease) and/or pediatrics (cardiology), depending on the age group(s) served, A center may operate more than one adult or pediatric catheterization laboratory. Each of adult and each of the pediatric catheterization laboratories must meet the card diagnostic requirements for specialized facilities, equipment, support staffing and work-load pursuant to this subdivision and section 712.11 of this Title.

(iv) Laboratory shall mean an independent unit consisting of a separate room or rooms in a facility with specialized cardiac diagnostic equipment and facilities primarily for the performance of invasive cardiovascular diagnostic procedures as referenced in paragraph (12) of this subdivision. Such laboratories shall function under the supervision of a qualified medical specialist, operate in compliance with this subdivision, and meet the construction provisions of section 712.11 of this Title.

(2) Cardiac diagnostic services may be provided at hospitals independent of cardiac surgical centers only when the following conditions have been met:

(i) these services are limited to adult cardiac diagnostic service; and

(ii) there is a written affiliation agreement, acceptable to the commissioner, between the approved cardiac diagnostic center and an approved cardiac surgical center, which provides for:

(a) the management of cardiac surgical emergencies; and

(b) regular conferences held at least once per month or more frequently if required by caseload between representatives of the cardiac surgical center and the cardiac diagnostic center in which a significant percentage of preoperative and postoperative cardiac cases of the free-standing cardiac diagnostic center are reviewed. Some of the joint conferences shall take place at the cardiac diagnostic center.

(3) Periodic cardiology conferences shall be. held at which the staff reviews the appropriate diagnostic studies of a statistically significant number of cases. Records of these conferences indicating attendance, cases reviewed and decisions on patient management shall be

maintained.

(4) Records of the disposition of the adult cases studied shall be maintained. The number of patients referred for surgery and the center(s) to which they are referred shall be part of these records.

(5) Criteria adopted by the cardiac diagnostic center to be used as indications for coronary arteriography and/or other cardiac invasive diagnostic procedures shall be available for review during site visits. The criteria may be developed by the center or the center may use the criteria promulgated by recognized specialty organizations, such as the American Heart Association, the Inter-Society Commission on Heart Disease, a professional standards review organization or the Society for Cardiac Angiographers.

(6) Statistics shall be kept on the number of normal invasive cardiac diagnostic studies performed, and written criteria shall be available for determining when study is to be considered abnormal.

(7) Direction. Patient services shall be under the direction of a qualified specialist internal medicine (cardiovascular disease) and/or pediatrics (cardiology), depending upon the age group(s) served.

(8) Staff. The staff of such center shall consist of the following:

(i) an internist and/or pediatrician, depending upon the age group(s) served, with special training and experience in cardiovascular diseases;

(ii) a cardiac arteriographer whose basic medical training may be in internal medicine or in radiology. Supplemental qualification shall include at least two years of training or experience, including but not limited to the areas of cardiac radiology, clinical and laboratory cardiology, basic and/or clinical cardiac physiology and catheter techniques;

(iii) anesthesiologists experienced in the management of cardiac patients shall be available to the center;

(iv) nurses or medical technicians with appropriate education and training who shall be regularly assigned to the center; and

(v) a surgeon or surgeons trained and experienced in vascular surgery shall be available to the center for consultation and management of complications.

(9) Services. All services shall be integrated and available on an inpatient basis, but there shall also be adequately and appropriately organized outpatient services, to include unnecessary hospitalization and ensure continuity of care. The following services shall be provided as a minimum:

(i) a full range of diagnostic services, including but not limited to diagnostic radiology, clinical laboratory and noninvasive cardiac

diagnostic capability;

(ii) patient and family education; and

(iii) a system of adequate follow-up.

(10) State Cardiac Advisory Committee. The State Cardiac Advisory Committee shall, at the request of the commissioner, consider any matter relating to cardiac diagnostic centers and shall advise the commissioner thereon.

(11) Approval and review. Site visits to existing and prospective new centers by members of the State Cardiac Advisory Committee, or other designees of the commissioner, shall be made as indicated, as an adjunct to initial approval, and/or for maintaining approval. There shall be sufficient utilization of a center to ensure both quality and economy of services, as determined by the commissioner. Any institution seeking to maintain approval, or in applying for initial approval, shall present evidence that the annual minimum workload standards can be achieved and maintained. The following minimum workload standards shall be achieved within two years following initiation of the service to ensure both quality and economy of services:

(i) diagnostic centers performing only adult invasive cardiovascular procedures shall maintain an annual minimum of 200 adult procedures;

(ii) a pediatric diagnostic center located in a facility approved for pediatric cardiac surgery shall maintain an annual minimum workload of 100 invasive cardiovascular procedures; and

(iii) diagnostic centers performing both adult and pediatric procedures shall maintain an annual minimum of 200 adult and 100 pediatric invasive cardiac diagnostic procedures.

(12) Waiver of minimum workload standards. The commissioner may waive the workload requirements upon a satisfactory showing by the cardiac diagnostic center that the quality of the service is adequate and:

(i) there are extenuating circumstances temporarily precluding compliance with the workload requirements; and/or

(ii) there is a documented unmet need in the center's geographical service area.

(13) Annual workload reporting. For annual reporting purposes, an invasive cardiovascular diagnostic procedure shall include left and/or right heart catheterization with or without the use of contrast visualization and with or without coronary arteriograms, excluding:

(i) placement of permanent or temporary pacemaker;

(ii) any floating type catheter;

(iii) his bundle study;

(iv) balloon septostomy;

(v) radionuclide study; and

(vi) right heart catheterization without contrast visualization in adults.

(f) Alternate level of care. (1) Organization and staffing.

(i) Patients on each service of the hospital who have been assigned alternate level of care status shall be congregated on a single care unit when there are 10 or more such persons on the service. Patients for whom discharge is anticipated with: 14 days and patients whose identified needs cannot be safely and effectively met on this unit need not be transferred to the congregate unit and shall not be counted in the 10-patient threshold.

(ii) If the hospital can demonstrate to the department that it can fully meet the needs of patients assigned alternate level of care status without congregating sue patients, it may provide such services in accordance with a plan approved by the department in lieu of meeting the requirements of subparagraph (i) of this paragraph.

(iii) The hospital shall appoint a staff person who has administrative responsibility for the delivery of patient care services to patients assigned alternate level of care status and for the supervision of the services whether or not they are provide by congregate care units.

(iv) The appointed staff person shall monitor and evaluate the quality and appropriateness of care provided to alternate level of care patients and shall ensure that identified problems are resolved and are reported, as appropriate, to the hospital-wide quality assurance program.

(2) Delivery of services. (i) The hospital shall provide each patient assigned to alternate level of care status care and services in accordance with a multidisciplinary assessment of needs in order to promote the patient's independence and health.

(a) A written individualized, comprehensive care plan based upon the patient' assessed needs shall include, but not be limited to:

(1) medical and nursing care;

(2) assistance and/or supervision, when required, with activities of daily living, such as toileting, feeding, ambulation, bathing including routine skin care, care of hair and nails, and oral hygiene;

(3) rehabilitation therapy services as the patient's needs indicate;

(4) an activities program appropriate to the needs and interests of each patient to sustain physical and psychosocial functioning; and

(5) other clinical care and supportive services to meet the needs of patients.

(b) The written individualized comprehensive care plan shall be developed and implemented by all of the qualified professionals whose services are required by the patient under the supervision and coordination of the patient's attending physician and with the involvement of the patient and the family to the extent possible, in accordance with the patient's wishes.

(c) The comprehensive care plan shall establish realistic and measurable goals for short- and long-term care needs, and shall identify the type, amount and frequency of care and services needed to maintain, restore and/or promote the patient's functioning and health within stated time frames for achievement.

(g) Acquired immune deficiency syndrome (AIDS) centers. (1) Definition. An AIDS center shall mean a hospital approved by the commissioner pursuant to Part 710 of this Title as a provider of designated, comprehensive and coordinated services for AIDS patients in accordance with the requirements of this section. These services shall include inpatient, outpatient, community and support services for the screening, diagnosis, treatment, care and follow-up of patients with AIDS.

(2) Administrative requirements. The hospital shall ensure that:

(i) integrated and comprehensive services are provided onsite to include, as a minimum, the following:

(o) a designated patient care unit for AIDS patients, except that the commissioner may waive this requirement, under a plan acceptable to the commissioner for placing patients in other than a designated unit, if the AIDS center meets all other requirements of this section and the hospital can demonstrate:

(1) that it is unable, due to structural or space limitations, to place the AIDS patients in a designated unit; or

(2) specific programmatic or operational reasons why it is preferable not to use a designated unit or not practicable to have a designated unit for AIDS patients;

(b) an outpatient clinic program for screening, diagnostic and treatment services for AIDS patients: and

(c) emergency services, available 24 hours a day, for treatment of AIDS patients;

(ii) other health care services, as appropriate, are provided directly or through contract for AIDS patients, to include at least the following:

(a) home health care, provided through a home care services agency licensed or certified under article 36 of the Public Health Law, made available 24 hours a day, 7 days a week; and

(b) personal care services;

(iii) all reasonable efforts are made to provide or arrange for the

following services and programs to meet the needs of the AIDS patients:

(a) residential health care;

(b) hospice services provided through a hospice certified under article 40 of the Public Health Law; and

(c) residential living programs;

(iv) diagnostic and therapeutic radiology services and other specialized services are made available to meet the needs of AIDS patients;

(v) inservice education programs which address the medical, psychological and social needs specific to AIDS patients are conducted for all hospital personnel caring for AIDS inpatients;

vi) infection control policies and procedures pertinent to AIDS are developed and implemented as an integral part of the hospital-wide infection control program;

(vii) a quality assurance program, which includes a review of the appropriateness of care for patients with AIDS, is developed and implemented as an integral part of the overall quality assurance program;

(viii) at the request of the department, it shall participate in clinical research programs approved by the hospital's institutional review board/human research review committee;

(ix) resource information about AIDS shall be available to the public, and educational programs are provided for particular high-risk populations in their service area; and

(x) a crisis intervention program shall be made available in coordination wit other existing community services,

(3) Patient referral, admission and discharge. The hospital shall ensure that:

(i) policies and procedures are developed and implemented which address a(mission criteria for AIDS patients, referral mechanisms and coordinated discharge planning;

(ii) only patients who meet the admission criteria for AIDS are admitted to the designated patient care unit;

(iii) services which the center provide are available to all persons regardless of age, race, color, creed, sex, sexual orientation, disability, national origin or ability to pay;

(iv) there are transfer agreements in effect with other hospitals in accordance with section 400.9 of this Title for the acceptance of referrals or the transfer of AID patients in need of specialized services available at the center; and

(v) professional staff responsible for planning patient discharges, referrals or transfers shall have available current information regarding home care programs, institutional health care providers and other support services within the hospital's primary service area.

(4) Patient management plan. The hospital shall ensure that:

(i) a multidisciplinary team, whose composition reflects inpatient and outpatient care services, operating in conjunction with the attending physician:

(a) shall be responsible for each AIDS patient;

(b) shall include, as appropriate to the needs of the AIDS patient, health car professionals from nursing, nutritional, mental health and social work services and

(c) whenever practicable, the AIDS patient is assigned to the same multidisciplinary team;

(ii) a comprehensive patient management plan is developed by the multidisciplinary professional team, the patient, and when appropriate, home health care or other nonacute long-term care representatives, in consultation with the patient' family and other individuals with significant personal ties to the patients, which:

(a) shall reflect the ongoing psychological, social, functional and financial needs of the patient and is oriented to posthospital, ambulatory care and community support services;

(b) shall be based on the patient's illness, prescribed treatments and the individual patient's needs and choices;

(c) shall be reviewed and updated to reflect the patient's changing needs and current status;

(d) shall include transfer or discharge and follow-up plans coordinated by the multidisciplinary team or the case manager;

(e) shall be forwarded with the patient upon discharge or transfer for post-hospital care; and

(f) shall evaluate the extent to which the patient or patient's personal support system can provide or arrange to provide for identified care needs of that patient in the home situation;

(iii) a case manager shall he designated from the multidisciplinary team to be responsible for coordinating the health care services and plan for each AIDS patient; and

(iv) a mechanism shall he established to assure periodic reviews and updates of the patient management plan in conjunction with other agencies involved with, or responsible for, the care of the AIDS patient;

(5) Medical director. The hospital shall appoint a physician who:

(i) shall be a qualified physician with special training in infectious diseases, oncology or other appropriate subspecialty;

(ii) shall direct and coordinate all medical services provided in the AIDS center;

(iii) shall ensure the implementation of the quality assurance program specified in subparagraph (2)(vii) of this subdivision;

(iv) shall ensure that all members of the health care team participate in the quality assurance program;

(v) shall ensure that interdisciplinary rounds that include the health care professionals responsible for the patient's total care are made on a timely and sufficiently frequent basis as determined by each patient's needs;

(vi) shall ensure that other qualified physician specialists are available for consultation as indicated by the patient's condition; and

(vii) shall ensure that routine dental services are available for AIDS patients.

(6) Quality assurance monitoring. (i) The commissioner shall monitor and evaluate the quality and appropriateness of care provided to AIDS patients by the AIDS center through mechanisms which include, but are not limited to, the monitoring and evaluation of patient management plans, utilization reviews and quality assurance programs.

(ii) The department and its AIDS Institute shall develop criteria for assessing the effectiveness of AIDS centers in providing care that meets the special needs of AIDS patients.

(7) Construction requirements. The designated patient care unit shall be a discrete unit which complies with the requirements of section 712.2 of this Title, except as modified by the following:

(i) maximum patient room capacity shall be two beds, except that more than two beds per room may be allowed under a protocol based on patient diagnosis and approved by the commissioner;

(Ii) patient room temperature shall be capable of being maintained between 70 and 80 degrees F. Individual room air-conditioning units may be used; and

(iii) each patient care unit shall have at least one functional dayroom with space commensurate with the needs of the patients.

(h) Comprehensive and extended screening and monitoring services for epilepsy. (1) Definition. Comprehensive and extended screening and monitoring services for epilepsy shall mean a planned combination of services including inpatient/ outpatient care which shall include, but not be limited to: electroencephalographic monitoring, selection of appropriate anticonvulsant medication through neuropharmacological monitoring, surgical interventions, if indicated, and management of a patient's psychological and social needs through a coordinated interdisciplinary team approach. For purposes of this section, extended screening and monitoring services are considered rehabilitative care.

(2) Comprehensive and extended screening and monitoring services for epilepsy shall be provided in a hospital approved by the commissioner pursuant to Part 710 of this Title as a provider of such services.

The purpose of these services is to treat and rehabilitate patients with uncontrolled seizures in order to restore and promote them to their optimal level of functioning.

(3) Administrative requirements. The hospital shall ensure that:

(i) policies and procedures be developed and implemented which address provision and coordination of care between the inpatient unit and the outpatient unit for comprehensive and extended screening and monitoring services for patients with epilepsy;

(ii) a physician is appointed to direct the service, who is a qualified neurologist and who has demonstrated competence in the services and care provided to patients with epilepsy;

(iii) an interdisciplinary team of health care professionals with training and experience in the treatment of epilepsy shall be responsible for assessing patients and planning, providing and coordinating care. The interdisciplinary team shall include as a minimum the following types of health care professionals: neurologist, neurosurgeon, registered professional nurse, pharmacist, psychiatrist with training in neuropsychiatry, psychologist with training in neuropsychology, social worker, dietician, physical therapy, occupational therapist, and dentist;

(iv) consultative services of a neurologist with experience in pediatrics shall be made available as needed;

(v) the service shall provide or make formal arrangement for vocational rehabilitation services and special education services for patients who can benefit from such services;

(vi) comprehensive and extended screening and monitoring services for epilepsy shall include clinical services with staff specialized in electroencephalography, cable telemetry and neuropharmacological monitoring of anticonvulsant drugs; and

(vii) as part of the hospital's quality assurance program, the comprehensive epilepsy service shall implement a system for evaluating the quality and appropriateness of patient care and patient outcomes. Reports summarizing the outcomes from the quality assurance program for these services shall be submitted to the department on an annual basis.

(i) Pediatric and maternal human immunodeficiency virus (HIV) services.

(1) Applicability. (i) AIDS centers designated in accordance with subdivision (g) of this section which have pediatric and/or maternity services shall provide

specialized services for infants, children, adolescents, and pregnant women who are infected with human immunodeficiency virus (HIV) or who are HIV antibody positive and comply with the pertinent provisions of this subdivision as well as those in subdivision (g).

(ii) Hospitals not designated as AIDS centers in accordance with subdivision (g) may be approved to provide specialized services for infants, children, adolescents and pregnant women who are infected with human immunodeficiency virus or who are antibody positive, if the hospital:

(a) is in an area of high prevalence of HIV infection in children and women as evidenced by the hospital's newborn HIV seropositivity rate and the hospital's discharge rate for pediatric and maternal HIV related disorders;

(b) provided care in the past to pediatric and maternal HIV patients;

(c) demonstrates that it is unable to meet the requirements for full designation under subdivision (g) of this section; and

(d) complies with the requirements of this subdivision and subdivision (g) of this section, except for the definition of AIDS center in paragraph (g)(1) and except for the administrative requirement regarding designated patient care units in clause (g)(2)(l)(a).

(iii) A patient shall be eligible for services if the patient is an infant, child, adolescent or a pregnant woman who is infected with HIV or is HIV antibody positive, whether or not the patient has progressed to symptomatic HIV related illness.

(iv) For purposes of these regulations, family shall include the patient's immediate kin, legal guardian or anyone with significant personal ties to and who resides with the patient.

(2) Organization of services. The hospital shall ensure that:

(i) patients who require HIV related services are identified and referred for care by the pediatric and maternal HIV services;

(ii) obstetrical, pediatric and medical services develop and implement procedures to coordinate the clinical care of pediatric and maternal HIV patients to ensure the voluntary identification of potentially affected patients and family members and the delivery of appropriate services;

(iii) an organizational plan and policies and procedures are developed and implemented which address interdepartmental relationships and communications between the pediatric and maternal HIV services;

(iv) patient care services are provided through a coordinated interdisciplinary team approach, Inpatient and outpatient services shall be organized to preclude unnecessary hospitalization and to ensure continuity of care. A member of the interdisciplinary team managing the patient shall be designated as the individual patient's and family's case manager and shall be responsible for serving as a liaison among patient, family, staff and resources in the community and responsible for coordinating the comprehensive family management plan;

(v) services are family-centered and, in addition to the inpatient services, include the following ambulatory care and community support services: dental, substance abuse treatment, family planning, infusion therapy, mental health, neurodevelopmental evaluation, nutrition, rehabilitation therapies, prenatal care and primary care services;

(vi) other health and related human services are provided or arranged for as appropriate to meet the personal, social, educational, developmental and financial needs of these patients, including as a minimum:

(a) personal services such as caregiver support, day care, homemaker, housekeeper, transitional residential living programs, respite and transportation to and from needed services;

(b) referral for legal services as appropriate to the needs of the patient;

(c) identification and referral of children and adolescents in need of foster care and adoption services;

(d) financial services such as emergency support, food stamps, housing assistance, medical assistance, public assistance, Social Security Disability, Supplemental Security Income and Special Supplemental Food Program for Women, Infants and Children; and

(e) education and developmental services such as early intervention and therapeutic day care services.

(vii) a comprehensive family management plan is developed and implemented to address the medical, nursing, nutritional, functional, developmental, educational, psychological, social and financial needs of the patient and family, which plan:

(a) integrates the patient management plans as specified in subdivision (g) of this section with plans addressing the needs of the family; and

(b) documents the assessment and the monitoring of the patient's and family's needs with reassessment as necessary.

(3) Patient referral, admission and discharge. The hospital shall ensure that:

(i) services begin at the home of the patient's entry into the pediatric and maternal HIV service program and continue until the patient chooses not to participate in the pediatric and maternal HIV service; or relocates outside the pediatric and maternal HIV service catchment area; or transfers to another AIDS center for pediatric and maternal HIV service; or expires;

(ii) admission criteria include provisions for the assignment of pediatric and adolescent patients to a unit appropriate for the developmental needs of the patient; and

(iii) written policies and procedures are established and implemented for the pediatric and maternal HIV service to include voluntary HIV counseling and testing.

(j) Secure units for tuberculosis patients including detainees. (1) Definition. Secure unit for tuberculosis patients including detainees shall mean a designated patient care unit specifically designed to accommodate patients who have been diagnosed with active tuberculosis patients eligible for admission to such units shall include

(i) patients who have been found to be noncompliant with medical regimens and legally remanded to such unit shall receive priority admission to and retention in such unit; and

(ii) other patients requiring acute care for active tuberculosis but not legally remanded for treatment. Hospitals shall provide such patients with safe and adequate care within such secure unit in accordance with procedures approved by he commissioner.

(2) Staffing and operation. A secure unit for tuberculosis patients including detainees shall:

(i) maintain staff that are adequate in number and trained, including continuing education and inservice training, to perform all necessary activities related to the care of such patients with tuberculosis;

(ii) implement procedures to identify, diagnose and treat patients who exhibit signs and symptoms of infectious disease including the use of appropriate isolation practices;

(iii) consist of an environmentally sound physical plant in accordance with current, generally accepted standards of infection control practices specifically relating to tuberculosis, Such practices shall address ventilation, air dilution, and the provision of adequate and appropriate isolation facilities; and

(iv) provide adequate and effective personal protective devices to any persons at risk of exposure to an infectious tuberculosis patient. Such protective devices shall be utilized and monitored through a respiratory program which shall ensure training, proper use and/or fit of such appropriate devices in accordance with generally accepted standards of practice.

(3) Approval. Hospitals wishing to operate secure units for tuberculosis patients including detainees, for which construction approval pursuant to Part 710 of this Title is not otherwise required, shall apply to the Commissioner of Health for approval to operate such units pursuant to such Part.

NEW YORK ADMINISTRATIVE CODE, part 6

CHAPTER V MEDICAL FACILITIES

PART 422

HEALTH-RELATED FACILITIES FOR PERSONS WITH ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Section 422.1 Applicability. (a) This Part shall apply to a free-standing health-related facility (HRF) of 40 beds or less, approved by the commissioner pursuant to Part 710 of this Title, which is designated solely for the care and management of persons with AIDS.

(b) For purposes of this Part, AIDS shall mean acquired immune

deficiency syndrome and other human immunodeficiency virus (HIV) related illness.

422.2 Administrative requirements. The operator shall ensure that:

(a) a health-related facility for persons with AIDS shall comply with the rules and regulations set forth in Parts 400, 401 and 414 of this Title, and other regulations specified in this Part, unless a contrary requirement is stated;

(b) only persons diagnosed by a physician as having AIDS, who are ambulant and who would benefit from the support and clinical services provided in the HRF, shall be admitted;

(c) a written agreement exists between the HRF and at least one designated AIDS center for the provision of case management services for each resident. The commissioner may waive the requirement that case management services be provided by a designated AIDS center if the facility presents an alternative plan to the department which adequately meets the case management of its residents;

(d) outpatient, emergency and acute inpatient health-care services are to be provided by a designated AIDS center or other hospital. The facility shall provide directly or make formal arrangements for special services to residents in need thereof. These services must include, as a minimum, medical, substance abuse, mental health, dental, rehabilitative and pastoral counseling;

(e) a written transfer agreement exists with the designated AIDS center or other hospital for the transfer of residents requiring emergency care and acute inpatient care services;

(f) all resident transfers and discharges are coordinated with the resident's case manager and the resident, or the resident's legal representative, and the attending physician. Such persons shall be informed of the transfer or discharge at least five days before the transfer or discharge occurs, except in an emergency;

(g) in-service and continuing educational programs which address the medical, psychological, social problems and care needs specific to persons with AIDS are conducted for all staff on a regular basis, but no less than every three months. A record of programs attended shall be maintained for each employee;

(h) staff counseling and supportive services are made available to staff to address problems related to the care of patients with AIDS;

(i) infection control policies and procedures specific to AIDS are developed and implemented;

(j) written policies and procedures, including admission and discharge criteria, are developed and implemented. The HRF shall admit and retain only persons with AIDS whose needs can be met by this type of facility;

(k) written policies and related procedures that govern each service furnish onsite by the facility are developed and implemented. The policies and procedures must be available to the staff, residents, members of the family and legal representatives of the residents, and the public; and

(l) security services sufficient to safeguard staff and residents are provided 24 hours a day.

422.3 Physician services. The operator shall ensure that:

(a) the health care of each resident is under the continuing supervision of an attending physician;

(b) the attending physician sees and evaluates the resident whenever necessary, but at least once every 30 days, and participates in interdisciplinary resident care planning; and

(c) a physician experienced in the care and clinical management of persons with AIDS is designated as medical director. This individual shall provide medical consultation as needed to the attending physicians and assist with the development of policies and procedures for the facility.

422.4 Administrative and health-care staff. There shall be sufficient numbers of qualified staff on duty 24 hours a day to carry out the responsibilities and the programs of the HRF to include, as a minimum:

(a) a currently licensed nursing home administrator full-time or part-time depending on the number of beds and the type of program in accordance with section 420.2(a) through (d) of this Title;

(b) a resident services director, who may be the administrator or a licensed or certified health professional, and who is responsible for coordinating and monitoring the resident's plan of care;

(c) a registered professional nurse who is responsible for the supervision of the HRF's health services and nursing care seven days a

week for at least one shift each day;

(d) nurse aids employed on each shift, seven days a week, in sufficient numbers to meet the health-care needs of the residents; and

(e) a substance abuse specialist with experience in the direct treatment of drug abuse, who is responsible for substance abuse counseling and referral of the resident to other programs as needed.

422.5 Social services. The operator shall ensure that:

(a) social services are provided for each resident as needed;

(b) the facility either provides these services directly or arranges for them with qualified outside resources; and

(c) the facility designates one staff member, qualified by training or experience, to be responsible for arranging for social services and integrating plans for social services into the resident's plan of care.

422.6 Pharmaceutical services. The operator shall ensure that:

(a) a formal agreement exists with a registered pharmacist to assist with the development and implementation of written policies and procedures for the ordering, storage, dispensing, administration, disposal, and recordkeeping of drugs and biologicals, in accordance with current standards of professional practice;

(b) verbal orders made by a physician are given to only a licensed nurse, pharmacist or another physician. Such orders must be reduced to writing, signed by the nurse and countersigned by the physician within 48 hours;

(c) only physicians and licensed nurses administer medications, except that residents be allowed to administer their own medications if the attending physician gives permission in writing: and

(d) a pharmacist reviews each resident's medications as needed, but at least every month, and notifies the physician if changes are needed.

422.7 Dietary services. The operator shall ensure that:

(a) dietary services are under the supervision of a staff person trained or experienced in food management and nutrition;

(b) the dietary supervisor is responsible for planning menus that meet the nutritional needs of each resident in accordance with medical orders and current professional nutritional standards.

(c) medically prescribed, therapeutic diets are planned by a dietitian;

(d) at least three meals or their equivalent are served each day at regular times, with more than 14 hours between the evening meal and breakfast;

(e) menus are kept for at least 30 days;

(f) appropriate eating equipment and utensils are provided as needed for residents; and

(g) the facility complies with the sanitary requirements of Part 14 of this Title.

422.8 Activities and recreational programs. The operator shall:

(a) designate a staff member, qualified by training or experience in activity and recreational programming, to be responsible for planning individual and group activities and recreation; and

(b) ensure that there are ongoing programs of activities appropriate to the residents needs and interests.

422.9 Comprehensive care plans. The operator shall ensure that:

(a) a written, comprehensive care plan is developed and implemented for each resident in coordination with the case manager and in consultation with the resident or the resident's authorized representative. The care plan is developed by an interdisciplinary team of health-care professionals as appropriate to the needs of the resident, to include, as a minimum, the attending physician, a registered professional nurse and a social worker; and

(b) the care plan is reviewed and modified as necessary, but at least monthly, by the interdisciplinary team.

422.10 Medical record system. The operator shall ensure that:

(a) the facility maintains a medical record system that contains a

record of each resident in accordance with accepted professional standards of practice. Each resident's medical record shall contain, as a minimum:

(1) identification and admission information;

(2) a current comprehensive care plan;

(3) documentation of medical examinations, progress notes and discharge summaries; and

(4) all other pertinent information related to the resident's care;

(b) the facility shall develop and implement policies and procedures to ensure the confidentiality of all medical records.

422.11 Utilization control. The operator shall ensure that:

(a) the utilization control program of the facility conforms to the regulations set forth in sections 86-2.30(i), 400.12 and 421.13 of this Title; and

(b) each resident is reviewed every 30 days in accordance with a utilization review plan approved by the department.

REPORTS

455.44 Acquired Immune Deficiency Syndrome. This functional reporting center must contain all the expenses associated with the care of individuals with AIDS, AIDS-related complex, and those diagnosed with other human immunodeficiency virus-related illnesses in a discrete AIDS unit within a residential health care facility or in a free-standing designated AIDS center. Costs associated with AIDS patients in designated or undesignated AIDS beds in an existing non-AIDS unit will remain a part of that unit's costs.

(a) Standard unit of measure: number of patient days of care for all patients admitted to this unit. Include the day of admission, but not the day of discharge or death. If both admission and discharge or death occur on the same day, the day is considered a day of admission and counts as one patient day.

(b) Data source. The number of patient days shall be taken from dally census counts.

714.20 Health-related facilities-AIDS patients; general. New free-standing health-related facilities to be constructed and designed specifically for persons suffering with acquired immune deficiency syndrome (AIDS) need not comply with any other provision of this Part but shall be subject to sections 711.1-711.3 and 711.9 of this Title and to the following:

(a) The residential board and care occupancies provisions of the National Fire Protection Association's Life Safety Code 101. Further details concerning this referenced material are contained in section 711.2(a) of this Title.

(b) To the extent permitted by section 2812 of the Public Health Law, local laws, rules and regulations relating to fire and safety, sanitation and other health requirements, where such local laws impose standards in addition to those required by this section.

(c) Applicable requirements of American National Standards Institute (ANSI) Standard No. A117.1, for building and facilities providing accessibility and usability for physically handicapped people. Further details concerning this referenced material are contained in section 711.2(b) of this Title.

(d) Resident rooms. Each resident room shall meet the following requirements:

(1) The maximum room capacity shall be two residents. At least two single-occupancy rooms shall be provided.

(2) Minimum room area, exclusive of toilet rooms, closets, lockers, wardrobes, alcoves or vestibules, shall be 100 square feet in single rooms and 80 square feet per bed in double rooms.

(3) Each room shall be at or above grade level.

(4) Each room shall be equipped with a device for calling the staff member on duty.

(5) Each room shall be equipped with closet or wardrobe space, at least 18 inches by 60 inches high, that provides security and privacy for the clothing and personal belongings of each resident.

(6) Each room shall be equipped with or conveniently located near toilet and bathing facilities.

(7) Each room shall contain a suitable bed and appropriate furniture

for each resident.

(8) Each resident sleeping room shall be protected by an automatic smoke and heat detector interconnected with the fire alarm system.

(e) Bathroom facilities. Toilet and bathing facilities shall be appropriate in number, size and design to meet the needs of the residents. In no case shall the facility provide less than one toilet, lavatory and bathing fixture for every six or fewer number of residents. Toilet and bathing facilities shall be provided on the same floor as the resident bedrooms served.

(f) Lounge facilities. Each facility shall provide adequate lounge area(s) to meet the residents' recreational and social needs. In addition to the dining area(s) required in this section, each facility shall provide at least one lounge area of 200 square feet or e square feet per resident, whichever is greater.

(g) Dining area. Each facility shall provide adequate dining facilities to meet the needs of the residents at the rate of 15 square feet per resident.

(h) Service areas. (1) An office for staff use must be provided onsite to provide for administrative and records storage area.

(2) Drug distribution station. Provision shall be made for convenient and prompt 24-hour distribution of drugs. This may be a medicine preparation room or unit, or a self-contained medicine dispensing unit. If used, a medicine preparation room or unit shall be under the staff's visual control and contain a work counter, refrigerator, and locked storage for drugs.

(3) At least one toilet and lavatory shall be provided for staff and visitor use.

(4) Janitor's closet. At least one janitor's closet shall be provided.

(5) Soiled linen. An enclosed space shall be provided for the storage and/or treatment of soiled linens.

(6) Clean linen. Separate closet(s) or designated area(s) for the storage of clean linens shall be provided. Adequate linen shall he available at all times for the proper care and comfort of the residents.

(7) Waste disposal. An enclosed space shall be provided for the proper storage and removal of waste materials.

(8) Therapy space. Therapy areas must be properly designed in terms of size and equipment to support all program functions.

(9) Dietary. Adequate space and equipment for the storage, preparation and service of meals shall be provided.

PART 759

ADULT DAY HEALTH CARE SERVICES FOR PATIENTS WITH AIDS

Section 759.1 Definitions. As used in this Part, unless the context otherwise requires:

(a) For purposes of this Part, AIDS shall mean acquired immune deficiency syndrome and other human immunodeficiency (HIV) related illnesses.

(b) Registrant means a person who has AIDS or HIV illness:

(1) who is not a resident of a residential health care facility, is functionally impaired and not homebound, and requires certain preventive, diagnostic, therapeutic, rehabilitative or palliative items or services but does not require the continuous 24-hour-a-day inpatient care and services provided by a general hospital, or residential health care facility; and

(2) whose assessed social and health care needs, in the professional judgment of the physician of record, nursing staff, social services and other professional personnel of the adult day health care program can be met satisfactorily in whole or in part by delivery of appropriate services in such program.

(c) Adult day health care means care and services provided to a registrant in a diagnostic and treatment center or approved extension site under the medical direction of a physician by personnel of the adult day health care program in accord with a comprehensive assessment of care needs and individualized health care plan, ongoing implementation and coordination of the health care plan, and transportation.

759.2 Applicability.

(a) (1) The operator of a diagnostic and treatment center may provide adult day health care services to registrants when approved pursuant to Part 710 of this Title -

(2) A diagnostic and treatment center which has been approved by

the department to operate an adult day health care program at its primary site may provide adult day health care services at an extension site approved by the department under the provisions of section 710.1 of this Title.

(3) A diagnostic and treatment center which does not operate an adult day health care program at its primary site may provide such a program at an extension site approved by the department in accordance with section 710.1 of this Title if there is not sufficient suitable space within the center to accommodate a full range of adult day health care program activities and services. The department may conduct an onsite survey of the center to determine whether the facility space and/or location is suitable for an adult day health care program.

(b) Prior to operation of the facility's adult day health care services program, the operator shall apply to the department for approval in accordance with Part 710 of this Title and shall submit a description of the proposed program, including but not limited to:

(1) need for the program, including statements on philosophy and objectives of the program;

(2) range of services provided;

(3) methods of delivery of services;

(4) transportation arrangements for registrants;

(5) physical space and use thereof;

(6) number and expected characteristics of registrants to be served;

(7) personnel participating in the program, including qualifications;

(8) case management services and use of and coordination with existing community resources, including AIDS centers, alcohol and substance abuse programs and rehabilitation facilities as appropriate;

(9) financial policies and procedures;

(10) program budget;

(11) methods for program evaluation; and

(12) proximity to an identified number of potential registrants.

759.3 General requirements. The operator shall have and implement

written policies and procedures which shall provide for:

(a) a written transfer agreement with a designated AIDS center or other hospital for the transfer of registrants requiring emergency care and acute inpatient care services;

(b) the appropriate transfer of registrants when applicable, to the care or supervision of other health facilities in accordance with the provisions for transfer and affiliation under section 400.9 of this Title;

(c) staff experienced in the care and management of persons with AIDS or HIV related illness, equipment and space sufficient to meet the assessed needs of registrants, including sufficient bath and toilet facilities pursuant to section 713-2.12 of this Title; and

(d) the development and implementation of in-service and continuing educational programs, staff counseling and supportive services, and infection control specific AIDS and HIV illness.

759.4 Admission and patient assessment. (a) The operator shall:

(1) select and admit to the adult day health care program only those persons for whom adequate care and needed services can be provided and who, according to the needs assessment, can benefit from the services and require a minimum of three hours of health care services provided on the basis of at least one visit per week to the program;

(2) assess each applicant, utilizing an assessment instrument provided by the department as part of the admission review process, which assessment shall include at a minimum the following:

(i) medical needs, including the determination that the applicant is expected to need continued service for a period of 60 or more days;

(ii) use of medication and required treatment;

(iii) nursing care needs;

(iv) functional status;

(v) mental status;

(vi) sensory impairments;

(vii) rehabilitation therapy needs, including a determination regarding the specific need for physical therapy, occupational therapy, and speech language pathology services;

(viii) family and other informal supports;

(ix) home environment;

(x) psycho-social needs;

(xi) financial status;

(xii) nutritional status;

(xiii) ability to tolerate the duration and method of transportation to the program;

(xiv) evidence of any substance abuse problem; and

(xv) need for HIV risk reduction counseling.

(3) register each applicant only upon recommendation from the applicant's physician and after completion of a personal interview by qualified personnel with the applicant, next of kin and/or sponsor;

(4) register each applicant only after determining that the applicant is not receiving the same services from any other facility or agency;

(5) admit an applicant to the service only after execution of a written agreement which shall include but not be limited to a requirement that:

(i) the applicant agrees to a medical examination at a physician's office, the facility or other appropriate site, within six weeks prior to or seven days after admission and as indicated in the physician's plan of care, HIV comprehensive care protocols or by medical necessity; and

(ii) the operator provides to the applicant, next of kin and/or sponsor a written list of basic services furnished by the facility to registrants and paid for as part of the registrant visit at daily, weekly or monthly rates;

(6) record all financial arrangements with the applicant or designated representative, with copies executed by and furnished to each party;

(7) make no arrangement for prepayment for basic services exceeding one month;

(8) comply with the provision of financial policies as set forth in the applicable section of this Title; and

(9) register applicants in an adult day health care program only if the pre-registration evaluation determines that the program can adequately and appropriately care for the applicants.

(b) No applicant suffering from the infectious stages of tuberculosis may be registered or retained for services on the premises unless a physician certifies that the registrant presents no significant risk to any person.

759.5 Comprehensive care planning. (a) The operator shall:

(1) develop a comprehensive care plan and, when applicable, a transfer or discharge plan, for each registrant within five visits, not to exceed 30 days, from registration;

(2) designate staff members to ensure the completion of the comprehensive care plan with the participation of consultants in the medical, social, paramedical and related fields as appropriate;

(3) ensure that the comprehensive registrant care plan includes for each registrant:

(i) the medical and nursing goals and limitations anticipated for each registrant and, as appropriate, the nutritional, social, rehabilitative and leisure time goals and limitations;

(ii) the registrant's potential for remaining in the community; and

(iii) transportation arrangements;

(4) ensure that development and modification of the comprehensive care plan is coordinated with other health care providers outside the program who are involved in the registrant's care.

(b) Designated staff members, with the participation of consultants in the medical, social, paramedical and related fields, as appropriate, shall:

(1) record changes in the registrant's status which require alterations in the registrant comprehensive care plan;

(2) modify the plan accordingly; and

(3) review the plan at least quarterly.

759.6 Registrant services. Registrant services shall be provided and/or arranged for in accord with the multidisciplinary assessment of needs and comprehensive care plan which include but are not limited to:

(a) medical services and HIV primary care services including

gynecologic services as appropriate;

(b) case management services;

(c) food and nutrition services;

(d) social services as the registrant's medically related social and emotional needs indicate;

(e) assistance and/or supervision, when required, with activities of daily living, such as toileting, feeding, ambulation, bathing including routine skin care, care of hair and nails, and oral hygiene;

(f) rehabilitation therapy services as the registrant's needs indicate;

(g) an activities program involving community, interpersonal and self-care functions appropriate and sufficient in scope to the needs and interests of each registrant to sustain physical and psychosocial functioning;

(h) nursing services;

(i) religious services and pastoral counseling and counseling for HIV risk reduction for any registrants requesting such services;

(j) pharmaceutical services;

(k) substance abuse treatment, if appropriate; and

(1) dental services as the registrant's needs indicate.

759.7 Medical record system. The operator shall ensure that:

(a) the facility maintains a medical record system that contains a record, including current comprehensive care plan for each registrant, in accordance with accepted professional standards of practice and the medical records system section of this Title. Each registrant's medical record shall contain, as a minimum:

(1) identification and admission information;

(2) documentation of medical examinations, progress notes and discharge summaries; and

(3) all other pertinent information related to the resident's care including record of attendance;

(b) the facility shall develop and implement policies and procedures to ensure the confidentiality of all medical records.

759.8 Utilization control and quality assurance. The operator shall ensure that the utilization control and quality assurance program of the

facility conforms to the regulations set forth in section 751.8 of this Title.

759.9 Evaluation. The operator shall develop and implement procedures which provide for at least an annual written evaluation of the adult day health care program to include, at a minimum, a profile of the characteristics of the registrants admitted to the program, the services and degree of services most utilized, the length of stay and use rate, registrant need for care and services and disposition upon discharge. The evaluation shall also include such data items as are available to the operator and are identified and set forth on forms provided by the department.

PART 772

AIDS HOME CARE PROGRAMS PROVIDED BY AIDS CENTERS

Section 772.1 Definition. An AIDS home care program provided by an AIDS center shall mean, for purposes of this Part, a long term home health care program as defined in Part 700 of this Title which is authorized only to provide an AIDS home care program as defined in Part 700 of this Title.

772.2 General. (a) No AIDS center shall provide an AIDS home care program without the written authorization of the commissioner pursuant to Part 770 of this Title to provide such a program.

(b) An AIDS home care program provided by an AIDS center shall comply with the standards of organization and administration for a long term home health care program as set forth in Part 771 of this Title.

NEW YORK ADMINISTRATIVE CODE, PART 7

SUBPART 43.2

AIDS DRUG ASSISTANCE PROGRAM

Section 43.2.1 Scope. These regulations govern the application and eligibility determination process for the AIDS Drug Assistance Program and establish the rights and responsibilities of applicants, participants, medical providers, and the contractor in that process.

43.2.2 Definitions. (a) An applicant is a person who has directly or by a representative applied in writing to the New York State Department of Health.

(b) An application is the process by which a person indicates, in writing on a Department of Health approved form, his/her desire to receive assistance.

(c) Resident means a person domiciled within the State.

(d) Authorized representative means any person authorized by an applicant or participant to act on his/her behalf.

(e) Period of coverage. Coverage for assistance is effective on the first date a drug is dispensed to an individual who is determined to be eligible for participation in the program. Coverage will terminate under the following circumstances:

(1) the applicant indicates in writing that he/she no longer needs or desires assistance;

(2) the department determines that a change in the participant's circumstances or residence has affected his/her eligibility;

(3) the participant has died or cannot be located; and

(4) funding for the AIDS Drug Assistance Program is exhausted.

(f) Program means the AIDS Drug Assistance Program.

(g) Household. The applicant, and persons legally responsible for the applicant, and persons for whom the applicant is legally responsible, shall be considered part of the household.

(h) Income means total gross income of the household. Income shall include: monetary compensation for services, including wages, salary, commissions, or fees; net income from self-employment; unemployment insurance compensation; government civilian employee or military retirement or pension, including veteran's payments; pensions or annuities; alimony or child support payments; regular contributions from persons not living in the household; net royalties; social security benefits; dividends or interest on savings or bonds; income from estates or trusts; net rental income; public assistance or welfare payments; cash or any other income resource.

(I) Contractor means any corporation which has entered into a contract with the department to assist in carrying out the provisions of the program.

43-2.3 Confidentiality. All information which may identify an applicant which is received by the program will be confidential and can only be used when necessary for supervision, monitoring or administration of the program. Information received by any contractor, his agents, employees, or by any other person or agency concerning applicants or participants in the program is confidential and may not be disclosed without the written approval of the AIDS Drug Assistance Program director, who shall approve disclosure only in conformance with article 27-F of the Public Health Law.

43-2.4 Use of the application form. (a) The State-approved application form must be completed:

(1) for each applicant upon initial application and recertification, if required; and

(2) when there is a change in status affecting eligibility.

(b) The signature of the individual applying for assistance is required on the State-approved application form. In any case where the applicant is incapable of signing the application because of physical incapability, or mental incompetency, application shall be signed on behalf of such a person by his/her authorized representative.

(c) The State-approved form shall contain the following information, in addition to any other information which the Department of Health may require for the proper administration of the program:

(1) name, sex, date of birth, social security number, marital status, address and telephone number of the applicant;

(2) name and relationship to applicant for applicant's household members;

(3) income information for the applicant and members of the applicant's household; and

(4) information regarding any other health benefits or insurance coverage that is available to the applicant.

43-2.5 Eligibility for coverage. (a) An applicant must be confirmed as medically eligible to participate in the program. The Department of Health will confirm medical eligibility based upon information received from the applicant or the applicant's physician or the physician's

designee. The applicant's physician or the physician's designee will be required to submit information regarding an applicant's medical condition on a State-approved form.

(b) Financial eligibility will be based upon the total gross income available to the applicant's household.

(1) In order to be eligible, an applicant's household income must be equal to or less than the income guideline for the applicant's family size as specified below:

Schedule-Statewide Standard of Need (Annual)

Number of Persons in Household

One	Two	Three +
44,000	59,200	74,400

(2) Applicants must provide income information for a reasonable period prior to application. Applicants who are self-employed must provide business records for the three months prior to application indicating type of business, gross income and net income.

(c) Liquid resources shall be reviewed to determine their availability in determining eligibility for the program. In order to be eligible, an applicant's liquid resources must be less than $25,000.

(1) Liquid resources are cash or those assets which can be readily converted to cash such as bank accounts, lump sum payments, i.e., stocks, bonds and mutual fund shares. Resources in an individual retirement account (IRA) or other tax deferred compensation plan will be calculated at the rate of 50 percent for purposes of determining liquid assets.

(d) Full and proper use shall be made of existing public and private medical and health services and facilities for obtaining therapeutic drugs for the treatment of AIDS.

(e) An applicant or recipient of assistance may be required as a condition of eligibility or continued eligibility to assign any rights he/she may have for drug coverage benefits under any health insurance policy or group health plan to the department.

(f) The department may employ a contractor to determine eligibility consistent with the requirements and responsibilities of Subpart 43-2 of this Part. Eligibility determinations are subject to department review and adjustment.

43-2.6 Decision on eligibility. (a) The department shall make one of the following decisions, based upon the application information:

(1) Accepted for coverage. This means that eligibility has been established through review and verification to the satisfaction of the department; or

(2) Not accepted for coverage. Applications are denied when the information given by the applicant establishes that the applicant is ineligible, or when the applicant refuses to comply with any requirement essential to the determination of eligibility.

(b) No decision is required when:

(1) an application is withdrawn by the applicant; or

(2) the department documents that the applicant has died, cannot be located, or has left the State prior to the completion of the review and verification.

43-2.7 Responsibility for prompt determination of eligibility. The decision to accept or deny the application shall be made as soon as sufficient information to make a determination about eligibility is obtained.

43-2.8 Notification. Written notification shall be given of the decision to accept or deny an application. Notification of denial shall clearly set forth the specific reason why the application was denied.

43-2.9 Issuance of program eligibility cards. (a) The department or authorized parties shall issue a program eligibility card to each person determined eligible for benefits.

(b) The card shall include the following information:

(1) participant's full name;

(2) participant's identification number;

(3) participant's effective date of coverage;

(4) category of drugs for which the participant is eligible; and

(5) the effective date of coverage for each category.

43-2.10 Investigation. The department official shall review and verify information received on applications, as required. Documents, personal observation, personal and collateral interviews and contacts, reports, correspondence and conferences are means of verification of information supplied. When information is sought from collateral sources other than public records because the applicant or participant cannot provide verification, the department will inform the applicant/ participant or his/her representative of what information is desired, why it is needed and how it will be used.

43-2.11 Fraud and abuse. (a) The commissioner, his agents or designees, shall investigate and refer for prosecution any violations of State laws pertaining to fraud or abuse in the program.

(b) Where review indicates substantial evidence of abuse of the program, the participant may be removed from the program or restricted to a single provider.

(c) If the recipient did not provide accurate information regarding his income and expenses, the commissioner may summarily suspend an enrollee's participation in the program, and the department can recover the amount of assistance granted, to which the recipient is not entitled.

43-2.12 Appeals. (a) An applicant may request a reconsideration of an adverse decision within 60 days of a decision.

(b) The department shall review any additional submissions and issue a written decision within 30 days of an applicant's request and submission of additional documents.

43-2.13 Continuing eligibility. (a) Participants may be required to establish periodically that they remain eligible for the program.

(b) The applicant/participant must notify the department immediately of any changes in circumstances that may affect eligibility.

43.2.14 Enrollment of providers. The department will contract with pharmacies and health care providers which demonstrate that they are

qualified to provide prescription drugs.

43.2.15 Audit and claim review. (a) Providers shall be subject to audit by the commissioner, his agents or designees. With respect to such audits, the provider may be required:

(1) to reimburse the department for overpayments discovered by audits; and

(2) to pay restitution for any direct or indirect monetary damage to the program resulting from their improperly or inappropriately furnishing covered drugs.

(b) The commissioner, his agents or designees, may conduct audits and claim reviews, and investigate potential fraud or abuse in a provider's conduct.

(c) The commissioner, his agents or designees, may pay or deny claims, or delay claims for audit review.

(d) When audit findings indicate that a provider has provided covered drugs in a manner which may be inconsistent with regulations governing the program, or with established standards for quality, or in an otherwise unauthorized manner, the commissioner may summarily suspend a provider's participation in the program and/or payment of all claims submitted and of all future claims may be delayed or suspended. When claims are delayed or suspended, a notice of withholding payment or recoupment shall be sent to the provider by the department. This notice shall inform the provider that within 30 days he/she may request in writing an administrative review of the audit determination before a designee of the commissioner. The review must occur and a decision rendered within a reasonable time after a request for recoupment is warranted, or if no request for review is made by the provider within the 30 days provided, the department shall continue to recoup or withhold funds pursuant to the audit determination.

(e) Where investigation indicates evidence of abuse by a provider, the provider may be fined, suspended, restricted or terminated from the program.

43-2.16 Audits and recovery of overpayments. (a) Recovery of overpayments shall be made only upon a determination by the commissioner, his agents or designees, at such overpayments have been made, and recovery shall be made of all money paid to the

provider to which it has no lawful right or entitlement.

(b) Recovery of overpayments pursuant to this subject shall not preclude the commissioner or any other authorized governmental body or agency from taking any other action with respect to the provider, including auditing or reviewing other payments or claims for payment for the same or similar periods, imposing program sanctions, or taking any other action authorized by law.

(c) The commissioner may utilize any lawful means to recover overpayments, including civil lawsuit, participation in a proceeding in bankruptcy, common law set-off, or such other actions or proceedings authorized or recognized by law.

(d) All fiscal and statistical records and reports of providers and prescriptions filled or refilled which are used for the purpose of establishing the provider's right to payment under the program and any underlying books, records, documentation which formed the basis for such fiscal and statistical records and reports shall be subject to audit. All underlying books, records and documentation including all prescriptions filled or refilled shall be kept and maintained by the provider for a period of not less than three years from the date of completion of such reports, or the date upon which the fiscal and statistical records were required to be filed, whichever is later, or the date the prescription was filled or refilled.

(e) All claims made under the program shall be subject to audit by the Commissioner, his agents or designees, for a period of three years from the date of their filing this limitation shall not apply to situations in which fraud may be involved or where the provider or an agent thereof prevents or obstructs the performance of an audit pursuant to this Part.

43.2.17 Recoupment of overpayments. Overpayments determined to have been made pursuant to this section and section 43-2.16 of this Subpart shall be recovered by withholding the provider's current or future payments on claims submitted or a percentage of payments otherwise payable on such claims, or such other remedies as may be available through a court of law.

CHAPTER II ADMINISTRATIVE RULES AND REGULATIONS

SUBCHAPTER G

AIDS Testing, Communicable Diseases and Poisoning

PART 63

AIDS TESTING AND CONFIDENTIALITY OF HIV-RELATED INFORMATION

Section 63.1 Definitions. (a) HIV-infection means infection with the human immunodeficiency virus or any other agent identified as a probable cause of AIDS.

(b) AIDS means acquired immune deficiency syndrome, as may be defined from time to time by the centers for disease control of the United States Public Health Services.

(c) HIV-related illness means any clinical illness that may result from or be associated with HIV infection.

(d) HIV- related test means any laboratory test or series of tests for any virus, antibody, antigen or etiologic agent whatsoever, thought to cause or to indicate the presence of HIV infection.

(e) Capacity to consent means an individual's ability, determined without regard to the individual's age, to understand and appreciate the nature and consequences of proposed health care service, treatment, or procedure, or of a proposed disclosure of confidential HIV-related information, and to make an informed decision concerning the service, treatment, procedure or disclosure.

(f) Protected individual means a person who is the subject of an HIV-related test or who has been diagnosed as having HIV infection, AIDS or HIV-related illness.

(g) Confidential HIV-related information means any information, in the possession of a person who provides health or social services or who obtains the information pursuant to a release of confidential HIV-related information, concerning whether an individual has been the subject of an HIV-related test, or has HIV infection, HIV-related illnesses or AIDS, or information which identifies or reasonably could identify an individual as having one or more of such conditions, including information pertaining to such individual's contacts.

(h) Health or social service means any care, treatment, clinical laboratory test, counseling or educational service for adults or children, and acute, chronic, custodial, residential, outpatient, home or other health care; public assistance, including disability payments available pursuant to the Social Security Act; employment-related services, housing services, foster care, shelter, protective services, day care or preventive services; services for the mentally disabled; probation services; parole services; correctional services; detention and rehabilitative services; and the activities of the Health Care Worker

HIV/HBV Advisory Panel (see Public Health Law article 27-DD), all as defined in section 2780(8) of the Public Health Law.

(i) Health facility means a hospital as defined in section 2801 of the Public Health Law, blood bank, blood center, sperm bank, organ or tissue bank, clinical laboratory, or facility providing care or treatment to persons with a mental disability.

(j) Health care provider means any physician, nurse, provider of services for the mentally disabled or other person involved in providing medical, nursing, counseling, or other health care or mental health service, including those associated with, or under contract to, a health maintenance organization or medical services plan.

(k) Contact means an identified spouse or sex partner of the protected individual or a person identified as having shared hypodermic needles or syringes with protected individual.

(1) Person includes any natural person, partnership, association, joint venture, trust, public or private corporation or State or local government agency.

(m) Release of confidential HIV- related information means a written authorization for disclosure of confidential HIV-related information which is signed by the protected individual, or if the protected individual lacks capacity to consent, a person authorized pursuant to law to consent to health care for the individual. Such release shall be dated and shall specify to whom disclosure is authorized, the purpose for such disclosure and the time period during which the release is to be effective. A general authorization for the release of medical or other information shall not be construed as a release of confidential HIV-related information, unless such authorization specifically indicates its dual purpose as a general authorization and an authorization for the release of confidential HIV-related information and complies with this definition.

(n) Insurance institution means any corporation, association, partnership, reciprocal exchange, interinsurer, fraternal benefits society, agent, broker or other entity in the business of providing health, life and disability coverage including, but not limited to, any health maintenance organization, medical service plan, or hospital plan which:

(1) is engaged in the business of insurance;

(2) provides health services coverage plans; or

(3) provides benefits under, administers, or provides services for, an

employee welfare benefit as defined in 29 USC 1002(1).

63.2 Application. These regulations apply to persons who order an HIV-related test, to persons who receive confidential HIV-related information in the course of providing any health or social service or who receive confidential HIV-related information pursuant to a release. All disclosures of confidential HIV-related information made on or after February 1, 1989 are subject to such regulations. These regulations do not apply to information which is received by the commissioner under Subpart 24-1 of this Title and protected from disclosure pursuant to Public Health Law, section 206(1)(j). These regulations do not apply to insurance institutions and insurance support organizations, except as noted in section 63.5(a)(9), (10) and (12) of this Part. Health care providers associated with or under contract to a health maintenance organization or other medical services plan are subject to these regulations.