PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 201, 203, 205, 207, 209, 211, 551, 553, 555, 557, 559, 561, 563, 565, 567, 569, 571 AND 573]

Health Facility Licensure

The Department of Health (Department) proposes to amend Part IV (relating to health facilities) by amending Chapters 201, 203, 205, 207, 209, 211 551, 553, 555, 557, 559, 561, 563, 565, 567, 569, 571 and 573 to read as set forth in Annex A.

Purpose of the Amendments

The amendments propose to amend the standards for the licensing and operation of long term care facilities and ambulatory surgical facilities (ASF).

On December 18, 1996, those provisions of the Health Care Facilities Act (act) (35 P. S. §§ 448.101—448.904), relevant to the Certificate of Need (CON) Program terminated. See 35 P. S. § 448.904(a). On December 14, 1996, the Department published notice that it would undertake a review of those clinically related health services covered under the CON Program. See 26 Pa.B. 6029 (December 14, 1996).

This review involved the formation of 14 work groups to review the 23 clinically related health services which were previously reviewed under the CON Program. The members of the work groups, in addition to representatives from the Department's CON, licensure and legal staff, were chosen for their expertise and knowledge of the particular service. Each work group included a physician who practiced the particular specialty under review. Additionally, representatives of Statewide organizations in the health care arena were invited to participate in the work groups. The work groups were chaired by either a Deputy Secretary or the Department's Chief Counsel.

The 14 work groups were organized to review the following services: 1) ambulatory surgical care; 2) cardiac catheterization; 3) long-term care; 4) neonatal care; 5) open heart surgery; 6) vital organ transplantation; 7) comprehensive medical rehabilitation—inpatient; 8) drug and alcohol rehabilitation—inpatient; 9) emergency department; 10) intermediate care facility/mentally retarded (ICF/MR); 11) lithotripsy—biliary and renal; 12) magnetic resonance imaging (MRI) and positron emission tomography (PET); 13) medical surgery and inpatient surgery; and 14) psychiatric inpatient—adult, child and adolescent.

The Department determined that the work groups on long term care and ambulatory surgery should begin to meet immediately. This was due to the need to address as quickly as possible any potential quality assurance gaps which could be present for these high risk health services.

The work groups met during the months of January and February, 1997. Their assigned task was to examine the criteria contained in the State Health Services Plan (SHSP) and determine if any of the criteria contained therein discussing quality assurance and patient safety should be added to existing regulations of the Department regarding licensure of health care facilities. The act provides that, in order to be issued a license, a health care provider must show that: 1) it is a responsible person; 2) the place to be used as a health care facility is adequately constructed, equipped and maintained and safely and efficiently operated; 3) it will provide safe and efficient services adequate for the care and treatment of patients or residents; and 4) it is in substantial compliance with the rules and regulations of the Department. See 35 P. S. § 448.808(a). Therefore, with the termination of the CON Program, the Department's focus is on the quality of care provided at the health care facilities which it licenses in this Commonwealth.

The long term care and ambulatory surgery work groups were comprised of representatives from the Department, the Department of Public Welfare (DPW), the Pennsylvania Medical Society (PMS), the Pennsylvania Nurses Association (PNA), the Hospital Association of Pennsylvania (HAP), the Health Law Project of the Public Interest Law Center, Legislative staff and other persons with expertise regarding these services. In addition, representatives from the Pennsylvania Association of Non-Profit Homes for the Aging (PANPHA), the Pennsylvania Health Care Association (PHCA), the Pennsylvania Association of Rehabilitation Facilities (PARF), the Pennsylvania Association of County Affiliated Homes (PACAH) and Pennsylvania Protection and Advocacy (PP&A) served on the long term care work group. The ambulatory surgery work group included representation from the Ambulatory Surgical Association, as well as input from several physicians and dentists.

At the conclusion of their review and discussion of relevant material regarding these various health care services, the work groups drafted proposed recommendations to the Secretary. The recommendations of the work groups differed depending on the service being reviewed. The recommendation of the work group that reviewed the long term care chapter of the SHSP (Chapter 14, Long Term Care), was that there was no perceivable gap between the long term care chapter of the SHSP and the current licensure regulations with regard to quality of care. However, the Department had already commenced a review of its long term care regulations for purposes of updating and to consider the effect of recently adopted Federal certification regulations. Due to this factor and the likelihood that any changes to the regulations would impact the area of quality assurance, the work group further recommended that it review the draft proposed long term care regulations. The work group met with program personnel on five separate occasions in January and February, 1997 and provided comments to the Department on the draft set of proposed amendments. The Department then revised the proposed amendments based on that input.

Similarly, the Department had published notice on December 7, 1996, in the *Pennsylvania Bulletin* that it would commence a review of the regulations pertaining to ASFs on January 10, 1997. See 26 Pa.B. 5913 (December 7, 1996). The work group which was convened in January 1997 considered amendments necessitated by changes in the delivery of care in ASFs since the enactment of the regulations and reviewed the quality assurance criteria contained in the SHSP (Chapter 5, "Surgical Services") applicable to ambulatory surgical care. The work group determined that there were gaps in quality assurance and recommended incorporating much of the criteria contained in the SHSP into the licensure regulations.

On February 1, 1997, the Department published notice that six work group recommendations were available and

that a public meeting would be held on February 11, 1997. See 27 Pa.B. 621 (February 1, 1997). These six work groups reviewed the following services: cardiac catheterization, intermediate or skilled nursing care inpatient services, ambulatory surgical care, neonatal care, open heart surgery and vital organ transplantation services. Approximately seven individuals presented testimony at the public meeting on February 11. In addition, written comments were received from various individuals and institutions.

After reviewing the recommendations and the public comments, the Department concludes that the current long term care facilities and ambulatory surgical facilities regulations should be amended, in order to reflect changes which have occurred since their enactment and to address any gaps in the area of quality assurance which may be present due to the sunset of CON.

Summary

Subpart C: Long Term Care Facilities

The Department was in the process of revising its long term care licensure regulations prior to the sunset of CON Legislation on December 18, 1996. Proposed amendments had been prepared adopting the Federal certification regulations at 42 CFR 483.1—483.75. Facilities which participate in the Medicare and Medical Assistance Programs must comply with these regulations in addition to the state licensure regulations. The great majority of Pennsylvania long term care nursing facilities participate in Medicare and Medical Assistance and are subject to both Federal and State quality assurance regulations. In many instances, the State regulations are duplicative and in a few cases, the two conflict.

The draft set of proposed licensure regulations which the Department prepared, deleted those State regulations which were either overly prescriptive or duplicative of the Federal certification regulations.

The Department felt it necessary to keep certain State licensure regulations which are not addressed in the Federal certification regulations. For example, there is no Federal counterpart to the State licensure regulation in § 211.1 (relating to reportable diseases), requiring the reporting of specific diseases or to § 201.22 (relating to prevention, control and surveillance of tuberculosis (TB)), pertaining to the protocols for tuberculosis control. There are a few proposed amendments to current regulations which are stricter in some respects than the corresponding Federal regulations. For example, the Federal regulation in 42 CFR 483.13(a), states that a restraint may not be applied for discipline or convenience. The State licensure regulation pertaining to restraints in § 211.8 (relating to use of restraints), has always been more specific than the Federal regulation and the Department now proposes to add a requirement that the need for a restraint be reviewed every 30 days by an interdisciplinary team as defined in § 201.3 (relating to definitions). Another proposed amendment in § 201.3, revises the definition of "restraint" to include chemical as well as physical restraints. This follows the Federal regulations which address chemical as well as physical restraints.

The State licensure regulation in § 201.14 (relating to responsibility of license) lists various incidents that must be reported to the appropriate Division of Nursing Care Facility's field office. The proposed amendments add deaths due to sepsis and require notification within 24 hours. Although both State and Federal regulations provide transfers and discharges in appropriate circumstances and only after adequate prior notice. However, the proposed amendment in § 201.29(d) (relating to resident rights) specifically places the responsibility for appropriate placement on the facility.

As part of the appointment of work groups to review the 21 chapters of the SHSP, a work group was assigned to look at the long term care chapter of the plan. The recommendation of the work group that reviewed the long term care chapter of the SHSP was that there was no perceivable gap between the long term care chapter of the SHSP and the current licensure regulations with regard to quality of care. However, the work group further recommended that it review the draft proposed long term care regulations. The work group met with program personnel on five separate dates in January and February 1997 and provided comments to the Department on the draft set of proposed amendments. The Department then revised the proposed amendments based on that input.

Chapter 201. General Provisions

The addition of Chapter 51 (relating to general information) covering general provisions which are common to all health care facilities necessitates the elimination of these sections which are currently located in Chapter 201. Specifically, the provisions of § 201.2 (relating to requirements) pertaining to exceptions to the long term care nursing facility licensure regulations are now addressed in §§ 51.31—51.34 (relating to exceptions). Section 205.3 is now addressed in § 51.5 (relating to building occupancy). Section 201.16, pertaining to change of ownership is now located at § 51.4 (relating to change in ownership; change in management). Section 201.28 pertaining to nondiscrimination policy is now located at §§ 51.11—51.13 (relating to civil rights).

Section 201.3 is amended to include a new definition of "abuse." The definition is taken from the guidelines to the Federal regulations. This is also the definition of "abuse" which is used by the Department when hearing appeals of nurse aides who have had a finding of abuse entered against them in the nurse aide registry. The Department kept that portion of the former definition which now appears under the subheading of "neglect."

The requirements for a charge nurse, dietician and a social worker, have been revised. The definition of "dietician" and "social worker" now reflects the Federal requirements for social workers.

The term "clinical records" is now defined and includes a resident's medical record as well as social and financial records.

The term "resident" has been added to the definitions. "Resident" replaces the term "patient" throughout the regulations. This change has been made to be consistent with Federal terminology.

A definition is now included for the term "interdisciplinary team." This definition has been taken from the Federal regulation at 42 CFR 483.20(d)(2)(ii), which lists the professionals who must take part in the preparation of residents' care plans.

The definition of "restraint" has been revised in accordance with the guidelines to the Federal regulations and now specifically includes chemical restraints. Further, the definition used to refer to a device which was applied to a resident but now includes devices which are adjacent to a resident which depending on the situation, could include side rails. This is also consistent with the Federal view of what constitutes a restraint.

The definitions of "intermediate care" and "skilled care" have been combined and a long term care nursing facility

is defined as a facility providing both skilled and intermediate care. This is in keeping with the trend toward elimination of the distinction between these two levels of care. By statement of policy dated February 17, 1996, the Department eliminated the distinction between the two levels for calculating requisite nursing hours. The new definition reflects a range of care rather than two separate levels to be provided in a long term care nursing facility.

Section 201.2

In § 201.2, the Department proposes to incorporate the Federal certification regulations at 42 CFR 483.1—483.75, pertaining to quality assurance, with the exception of various subsections listed. The subsections which the Department does not propose to incorporate primarily reference the Medicare and Medicaid Programs and are thus applicable to the facilities which participate in those programs only and not suitable as general licensure regulations.

Section 201.12 (relating to application for license)

Subsection (b), requiring the issuance of a CON as a condition of licensure, has been deleted.

Section 201.13 (relating to issuance of license)

This section sets forth licensure fees and has been revised to reflect the statutory increase in fees which have been in effect since 1992, following amendments to the act.

Section 201.14 (relating to responsibility of license)

The Department proposes to amend subsection (c) and to add a new subsection (d) which will now require the reporting of serious incidents within 24 hours. It is proposed that reports of accidents and death due to sepsis be added to the list of reportable incidents.

Section 201.15 (relating to restrictions on license)

The reference to the former Health Care Facility Hearing Board as the appellate body to hear final licensure decisions, has been revised to reflect an amendment to The Administrative Code of 1929 (71 P. S. § 2102 (n)), in 1996, which transferred the duties of that Board to the Health Policy Board.

Section 201.16

The Department proposes to delete this section concerning change in ownership, structure or name. This requirement will now be covered under proposed § 51.4 which provides general information on change of ownership applicable to all health care facilities.

Section 201.22

The Department proposes to delete this section which requires the facility to notify the resident's attending physician and responsible person of a change in the resident's condition as this is required under the Federal regulations.

The Department proposes to add a new § 201.22 which addresses the testing of residents and staff for tuberculosis. The proposed criteria are based on CDC protocols.

Sections 201.24 and 201.25

These sections dealing with admission and discharge policies are being deleted. A new § 201.29(c) and (d) (relating to resident rights) has been proposed which sets forth the facility's responsibilities with regard to transfer and discharge of residents. The new language clarifies that 30 days advance notice must be given prior to discharge and that the facility is responsible for assuring that the resident is appropriately placed.

Chapter 203: Application of Life Safety Code for Long Term Care Nursing Facilities

Section 203.2 presently requires long term care facilities to comply with certain Life Safety Code standards. As all long term care facilities are currently required to meet Life Safety Code construction and sprinkler requirements, this section is duplicative and the Department proposes its deletion from the regulations.

Chapter 205: Physical Plant and Equipment Standards for Long Term Care Nursing Facilities

Section 205.4 (relating to building plans)

The Department proposes to amend this section which sets forth the requirements for both preliminary and final architectural plan approval. Only one set of final plans will now be required. Section 205.5 which requires preliminary plans to be filed in duplicate will be deleted.

Section 205.20 (relating to resident bedrooms)

Section 205.20 is amended to only require a flat amount of square footage for single and multibedrooms and to delete all further instructions regarding minimum space requirements. For example, a single bedroom must still have a minimum room area clearance of 100 feet but requirements that there be a minimum of 3 feet between the bed and the adjacent wall and 4 feet between the foot of the bed and the opposing wall or furniture have been deleted.

The Department had received reports that these requirements sometimes mandated bed placements which were contrary to a resident's preference.

Section 205.24 (relating to dining room)

The Department proposes to delete that portion of this section which addressed the space requirements when a facility combined a dining room and a recreation area. A new subsection (b) is added which requires tables and space to accommodate wheelchairs.

Section 205.25 (relating to kitchen)

Most of this section on requirements for a kitchen have been deleted as overly prescriptive with the exception of subsection (d), proposed (b), which requires a service pantry on each unit.

Section 205.31 (relating to storage)

The only subsection which the Department proposes to keep in this section on storage is the requirement that a minimum of 10 square feet per bed of storage space be provided for items including residents' possessions.

Section 205.33 (relating to utility room)

The Department proposes to add a new subsection (b) which requires separate bedpan flushers be provided in soiled workrooms unless a facility has them in residents' bathrooms.

Sections 205.34 and 205.35

The Department proposes to delete these regulations which require a treatment room and a telephone for resident use. The Federal regulations which are to be adopted require residents have access to a telephone.

Sections 205.36—205.40

These sections address bathrooms, toilet rooms and lavatories. The Department proposes to delete requirements as to the size of tubs and shower stalls while retaining the requirement of a minimum clearance

around bathtubs in § 205.36 (relating to bathing facilities). In § 205.38 (relating to toilet facilities), the only subsection which the Department feels is necessary to keep as a licensure regulation is (a) which requires a minimum ratio of 1/4 toilets per residents.

Sections 205.61—205.64

The Department proposes to delete several subsections from these sections which address heating requirements and plumbing and piping systems since these are for the most part covered in the NFPA 101 Life Safety Code which is already incorporated by reference in § 203.1.

Section 205.66 (relating to special ventilation requirements for new construction)

This section sets forth special ventilation requirements for new construction. Amendments have been made to the chart contained in subsection (a).

Sections 205.71 and 205.72 (relating to bed and furnishings; and futniture)

These sections address beds and furniture. The only requirement which the Department proposes to keep is that a bed be equipped with an appropriately sized mattress and that each resident have a bedside drawer or cabinet which can be locked. References to all other types of furniture such as bedside chairs, overbed tables and footstools have been deleted.

Sections 205.73 and 205.74

Sections 205.73 pertaining to sterilization requirements and § 205.74 which requires a sufficient quantity of linen are proposed to be deleted. Sterilization is covered under the general infection control provisions in the Federal regulations at 42 CFR 483.65 and § 205.75 (relating to supplies) requires that the facility have adequate supplies which would include linen.

Chapter 207: Housekeeping and Maintenance Standards for Long Term Care Nursing Facilities

Sections 207.1, 207.3 and 207.5

These sections address environmental safety, housekeeping and maintenance. The Department proposes to delete them in their entirety in light of the general requirement that the administrator be responsible for the satisfactory housekeeping and maintenance of the buildings and grounds in § 207.2(a) (relating to administrator's responsibility).

Chapter 209: Fire Protection and Safety Programs for Long Term Care Nursing Facilities

Section 209.3 (relating to smoking)

The Department proposes to keep only subsection (a) which provides that the facility must have smoking policies. The current provisions found at subsections (c)—(h), which mandate certain smoking precautions, may subsequently appear as guidelines to the regulation.

Sections 209.4, 209.5 and 209.6

These sections on fire extinguishers, the emergency lighting system and the fire alarm are being deleted as they are already addressed in the NFPA 101 Life Safety Code. The Department proposes to move subsection (f) of § 209.6, requiring personnel be instructed in the use of fire extinguishers, to a new subsection (c) in § 209.7 (relating to disaster preparedness) dealing with disaster preparedness.

Chapter 211: Program Standards for Long Term Care Nursing Facilities

Section 211.1 (relating to reportable diseases)

This section which was titled *Infection Control* has been amended and is now titled *Reportable Diseases*. The list of reportable diseases still remains but has been updated. A new subsection (c) has been added to require facilities to report cases of Methicillin Resistant S. Aureus (MRSA) to the local field office for the Division of Nursing Care Facilities.

Section 211.2 (relating to physician services)

The Department proposes to amend this section on physician services by retaining subsection (e) which states that the attending physician is responsible for the medical evaluation of a resident and for prescribing appropriate care. Subsection (l)(2) and (4) is also retained. These subsections provide that a medical director's duties include review of incidents and accidents which occur in the facility and the development of policies delineating physician responsibilities. The remainder of the paragraphs are deleted in light of the adoption of the Federal regulation on physician services and responsibilities of the medical director at 42 CFR 483.40 and 483.75(i).

Section 211.4 (relating to procedure in event of death)

Subsections (a)—(c) are proposed to be deleted. These subsections required a facility to notify a resident's treating physician upon the resident's death, to document the death in the resident's medical record and also required the physician to complete and sign the death certificate under Article V of the Vital Statistics Law of 1953 (35 P. S. §§ 450.501—450.506). The Department does not believe it is necessary to include these items in licensure regulations as they reflect standard protocol and existing law.

Section 211.5 (relating to clinical records)

The Department proposes to change the term "medical records" to "clinical records" and to delete subsections (b), (d)—(g) and (o). These subsections outlined what had to be included in nurses' notes and are not considered to be needed in a specific licensure regulation as the information should be included in nurses' notes using standard protocol. The other subsections address providing copies of records to residents upon request and maintenance of medical record facilities.

Section 211.6 (relating to dietary services)

The Department proposes to eliminate subsections (a), (b), (e)—(q) and (s). These subsections address adequate staffing, frequency of meals, substitutions and sanitary conditions. These sections are covered by the Federal regulations. The concept of a dietary services supervisor is deleted to correspond to the Federal regulation in 42 CFR 483.35(a) which requires a facility to have a qualified dietician.

Section 211.8 (relating to use of restraints)

The Department proposes to add chemical restraints to subsection (d) which requires a physician's order for the use of a restraint and to delete subsection (f) which did not require an order for a geriatric chair. Both these amendments are consistent with Federal regulations. New subsection (f) requires an interdisciplinary team to reevaluate the need for all restraints ordered by physicians.

Section 211.9 (relating to pharmacy services)

The Department proposes to eliminate the majority of subsection (a) which provides that the facility have written policies and procedures for ensuring the identity of the resident and recording of administration as these requirements are covered by the Federal regulation in 42 CFR 483.60(a) which states that the facility must assure accurate administration of all drugs.

Sections 211.10 and 211.11 (relating to resident care policies; and resident care plan)

The Department proposes to delete subsections (a) and (b) and (d)—(f) of § 211.10, pertaining to resident care policies and subsections (a)—(e) and (g) of § 211.11 pertaining to resident care plans. Federal regulations in 42 CFR 483.20, thoroughly address resident care plans. The Department intends to keep subsection (f) which specifically requires that the resident's care plan be available to staff caring for the resident's needs.

Section 211.12 (relating to nursing services)

Subsection (e) is amended to add a specific requirement that the director of nursing be responsible for nursing service objectives, job descriptions, scheduling rounds and staff development.

The Department proposes to amend the general number of nursing hours in subsection (n) to eliminate the distinctions between skilled and intermediate care. By statement of policy dated February 17, 1996, the Department set the requirement at 2.3 hours of nursing care per resident in a 24-hour period. It is now amending the regulations to reflect this policy.

Subsections (r) and (s) are proposed to be deleted as nutritional needs and restorative care are covered in the comprehensive resident assessments required by the Federal regulations in 42 CFR 483.20(b).

Section 211.13

The Department proposes to delete this section addressing rehabilitative services in its entirety as this subject is covered by the Federal regulation in 42 CFR 483.45.

Section 211.14

This section pertaining to diagnostic services is to be deleted in its entirety as the subject is addressed in the Federal regulation in 42 CFR 483.75(j) and (k).

Section 211.15 (relating to dental services)

The Department is deleting subsections (b)—(d) from this section on dental services as these are covered in the Federal regulation in 42 CFR 483.55.

Section 211.16

The Department is deleting this section addressing social services in its entirety as the subject is covered in the Federal regulation in 42 CFR 483.15(g).

Section 211.17 (relating to pet therapy)

The Department proposes to delete all subsections from this section addressing patient activities, except for subsection (f) which sets forth requirements for facilities using pet therapy. Patient activities are addressed in the Federal regulation in 42 CFR 483.15.

Subpart F: Ambulatory Surgical Facilities.

On December 7, 1996, the Department published notice in the *Pennsylvania Bulletin* that it would commence a review of the regulations pertaining to ASF on January 10, 1997. See 26 Pa.B. 5913. This review was accomplished through the convening of a work group which not only considered appropriate amendments to the ASF regulations due to the passage of time since enactment, but also, in light of the termination of the CON Program, considered the quality criteria contained in the SHSP relevant to ASFs.

The work group recommended that the ASF regulations should apply to all freestanding or office based facilities which perform outpatient surgery on patients not requiring hospitalization, but who still need constant medical supervision for a limited period of time following the surgery. The work group recommended that the Department recognize three levels of ASFs and that these levels be distinguished by the level of anesthesia administered and by patient acuity. Class A ASFs need not be licensed but do need accreditation to be recognized as ASFs. Class B (office based) and Class C (freestanding) facilities require licensure. Operative times of up to four hours are permitted in ASFs and a recovery time of the same period is also permitted. The work group recommended that the Department be permitted to use outside National accreditating agencies to perform some or all aspects of licensure surveys. The following contains the highlights of changes proposed to the chapters discussing ASFs.

Chapter 551: General Information

Section 551.2 (relating to affected institutions) states that only facilities licensed under this subpart can provide ambulatory surgery.

Section 551.3 (relating to definitions) defines ambulatory surgery as that surgery which is performed on an outpatient basis in a facility which is not located in a hospital and upon patients who do not require hospitalization, but who do require constant medical supervision following the surgical procedure. An "ASF" is defined as a facility or portion thereof not located upon the premises of a hospital which provides specialty or multispecialty outpatient surgical treatment. These provisions clearly distinguish outpatient surgery performed in a hospital from ambulatory surgery performed at an ASF. Additionally, the definitions State that ambulatory surgery does not include individual or group practice offices of private physicians or dentists, unless these offices have a distinct part used solely for outpatient surgical treatment on a regular and organized basis. Thus, a physician's office will not generally be considered as an ASF, unless it meets the specific requirements of this subpart.

The definition divides ASFs into three classifications:

Class A—A private or group practice office of practitioners where procedures performed are limited to those requiring administration of either local or topical anesthesia or no anesthesia. Class A ASFs must receive accreditation from a Nationally recognized accrediting body such as the Accreditation Association for Ambulatory Health Care (AAAHC) or the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) in order to be identified as providing ambulatory surgery.

Class B—Single or multiple specialty facilities with a distinct part used solely for ambulatory surgical treatments involving administration of sedation analgesia or dissociative drugs wherein reflexes may be obtunded.

Class C—Single or multiple specialty facilities used exclusively for the purpose of providing ambulatory surgical treatments which involve the use of any anesthetic agents, including general anesthesia.

This classification system is based upon the types of procedures performed, the status of the patient receiving the surgery and the level of anesthesia which is used.

The patient status is covered under the definition of "physical status classification." These classifications involve an evaluation of the patient's overall health as it would influence the conduct and outcome of surgery. Five types of patient classifications are established:

Class 1—No organic, physiologic, biochemical, metabolic or psychiatric disturbance.

Class 2—These patients have a systemic disturbance which may be of mild to moderate degree but which is either controlled or has not changed in its severity for some time.

Class 3—These patients suffer from significant systemic disturbance, although the degree to which it limits the patient's functioning or causes disability may not be quantifiable.

Class 4—These patients suffer from severe systemic diseases that are already life threatening and may or may not be correctable by surgery.

Class 5—These patients are moribund and are not expected to survive without surgery.

Under the three types of ASFs, Classes A—C, the following patients may be treated: Class B ASFs may treat patients in Class 1 or 2, unless the patient's physical classification status would not be adversely affected by the surgery. Class C ASFs may treat patients in Classes 1—3 as long as the ASF complies with the regulations on anesthesia and recovery time (See § 551.21).

The classification of ASFs under Classes A—C reflects the system used under the June 17, 1994, amendments to Chapter 5 (Outpatient Surgery) of the SHSP. The patient classifications under Classes 1—5 are those established by the American Society of Anesthesiologists (ASA). Under these classifications, those entities which are the most equipped and capable of performing ambulatory surgery, will perform those surgeries requiring the higher levels of anesthesia on the more medically complex patients.

Due to the proposed addition of a general information chapter (Chapter 51) which will cover administrative matters which apply to all health care facilities, the provisions at §§ 551.11—551.13 concerning the exceptions process are proposed for deletion, as they will now be covered under §§ 51.31—51.34.

Section 551.21 (relating to criteria for ambulatory surgery) sets forth in detail the criteria for ambulatory surgery. Section 551.21(a)(1) and (2) states that ambulatory surgical procedures do not generally exceed a total of 4 hours of operating time and a total of 4 hours of directly supervised recovery. This replaces the prior limitation of 90 minutes operating time and retains the recovery time of 4 hours. Section 551.21(b)(1) and (2) states that if the surgical procedures to be performed in an ASF require anesthesia, the anesthesia must be either local or regional or general anesthesia if it is of 4 hours or less duration. Section 551.21(c)(1)—(5) states that certain types of surgical procedures may not be performed in an ASF, regardless of the classification. These surgeries are those generally associated with the risk of extreme blood loss, those which require major or prolonged invasion of body cavities, those which directly involve major blood vessels, those which are generally emergency or life threatening in nature and those surgeries which are performed on patients younger than 6 months of age or on low birth weight babies up to 1 year of age.

Section 551.31 (relating to licensure) sets forth the procedure for licensure and States that all Class B and Class C ASFs must obtain a license. The license issued by the Department will designate the facility as either Class B or Class C. For the Department to determine the appropriate classification, the applicant must provide: a list of operative procedures proposed to be performed at the facility, the highest level of anesthetic proposed to be used and highest patient classification level proposed to receive ambulatory surgery at the facility. ASFs which are classified as Class B and wish to be reclassified as Class C may not provide services to patients in Class 3 until the ASF has requested and obtained a license as a Class C ASF.

Section 551.32 discusses surveys and inspections which must be conducted by the Department prior to occupancy of the building housing the ASF. As previously stated, Chapter 51 will now address general administrative matters. Section 51.5 discusses building occupancy, thus § 551.32 is duplicative and is proposed to be deleted.

Section 551.33 (relating to survey) maintains the Department's ability to conduct onsite surveys, but adds language that the Department may designate Nationally recognized accrediting agencies to perform some or all aspects of these licensure surveys.

Section 551.34 (relating to licensure process) increases the ASF licensure fee from $50 to $250.

Sections 551.41 and 551.82 (relating to policy; and regular license) increase the period of licensure from 1 year to 2 years.

Section 551.91(b)(10) (relating to grounds) adds as a ground for refusal to renew, suspend or revoke a license a finding that the licensee is providing services exceeding the scope of the classification assigned in the license.

Sections 551.93(b) and 551.111 (relating to notice; and hearings relating to licensure) transfer the jurisdiction of hearings relating to licensure from the State Health Facilities Hearing Board to the Health Policy Board. This section tracks the statutory amendment under The Administrative Code of 1929 (71 P. S. § 2102(n)).

Sections 551.121—551.123 discuss civil rights compliance. These issues will now be covered under the general administrative chapter in §§ 51.11— 51.13. As a result, the Department proposes to delete §§ 551.121—551.123 as they are duplicative.

Chapter 553: Ownership, Governance and Management

Section 553.2(c) (relating to ownership) would be amended to define an owner of an ASF as any person who has a direct or indirect equity interest in the facility equal to or greater than 5%. Section 553.2(d) will be amended to require the ASF to notify the Department in writing within 30 days of any change in management, ownership, officers or directors. Change in ownership is specifically defined to mean any change involving 5% or more of the equity of the ASF. Change in ownership also includes the death, retirement or incapacitation of any shareholder, partner or other equity owner of an ASF. These changes are made to assure that, regardless of the corporate form of the ASF, the Department will receive the same information alerting it as to the ownership of the ASF and any change which may occur in that ownership.

Section 553.3(8)(iv) (relating to governing body responsibilities) requires the governing body of the ASF to assure compliance with the universal precautions for prevention of transmission of diseases promulgated by

OSHA. Similarly, § 553.3(8)(vi) requires the ASF to comply with all applicable Federal and State regulations, including the Americans with Disabilities Act (ADA).

Section 553.4(h) (relating to other functions) adds a requirement that the governing body appoint a medical director who shall be certified by a board recognized by the American Board of Medical Specialties or the dental, podiatric or osteopathic equivalent. The presence of a qualified medical director will assist in the functioning of the ASF and provide a medically trained individual who can deal with whatever issues might arise.

Section 553.25 (relating to discharge criteria) establishes specific physical status criteria which must be met before an individual is discharged from an ASF. The categories which must be checked are: vital signs (blood pressure, heart rate temperature and respiratory rate are within the normal range for the patient's age or at preoperative levels), activity (patient has regained preoperative mobility without assistance), mental status (patient is awake, alert or functioning at preoperative status), pain (patient's pain can be effectively controlled with medication), bleeding (patient's bleeding is controlled and consistent with that expected from the surgical procedure) and nausea/vomiting (minimal nausea or vomiting is controlled and consistent with that expected from the surgical procedure).

Chapter 555: Medical Staff

Section 555.12 (relating to oral orders) would be amended to note that oral orders for medication or treatment shall be accepted only under urgent circumstances and the relevant information must be transcribed in the patient's medical record at the time of administration and countersigned by the practitioner within 24 hours.

Section 555.13 (relating to administration of drugs) is new and requires that drugs shall be administered only upon the appropriate order of a practitioner acting within the scope of his license and according to medical staff bylaws, rules and regulations. Drugs may be administered only by: 1) the practitioner; 2) a registered professional nurse; or 3) a licensed practical nurse with pharmacy training.

Section 555.24(d) (relating to postoperative care) would be amended so as to delete the requirement that a physician be present until the patient is discharged, but requires the presence of a medical professional certified in advanced cardiac life support (ACLS). However, if general anesthesia has been administered during the operation, the anesthesiologist or anesthetist must remain present until the patient has been discharged.

Section 555.32(a) (relating to administration of anesthesia) would be amended to allow the administration of anesthetics by: 1) anesthesiologists; 2) certified registered nurse anesthetists; 3) dentist anesthetists; or 4) qualified practitioners as listed in § 551.3.

Section 555.33(c) (relating to anesthesia policies and procedures) would be amended to require that policies and procedures shall be developed by the governing body of the ASF and shall include: education, training and supervision of personnel, responsibilities of nonphysician anesthetists and responsibility of the supervising physician or dentist. Section 555.33(d)(6) and (7) would be amended to provide that certain types of intraoperative physiologic monitoring must be available and that no patient shall receive general anesthesia unless at least one other health care professional is present in addition to the professional performing the surgery.

Section 555.35 (relating to safety regulations) would be amended to add a requirement that all machines used for anesthesia shall receive at least one annual functioning test, by appropriately trained technicians.

Chapter 557: Quality Assurance and Improvement

It is proposed that the title of this section be amended to read: "quality assurance and improvement," to reflect the interest and concerns in this area. The Department expects that facilities will not only assure the quality of care delivered, but will actively seek methods to improve that quality.

Section 557.3(a) (relating to the quality assurances and improvement program) would be amended to require that the quality assurance and improvement program to monitor and evaluate specific data, including medical records, incident reports, infection control records and patient complaints. Several other areas which should be evaluated under this program are also added to this section. These additional areas reflect the standards for quality assurance and improvement programs established by the American Association for Ambulatory Health Care (AAAHC).

Chapter 559: Nursing Personnel

The only proposed changes to this chapter are in § 559.3 (relating to nursing personnel). Specifically, § 559.3(a) would be amended to provide that an adequate number of unlicensed personnel shall be present at the ASF. This section presently uses the terminology of ancillary personnel. The terminology of unlicensed personnel is a more precise description of this type of personnel. Section 559.3(b) would be amended so as to provide that at least one registered professional nurse shall be in attendance when patients are present. The current provision requires a registered professional nurse to be present at all times the facility is open, regardless if any patients are being treated. Section 559.3(c) would be amended to require that any registered professional nurse or licensed practical nurse who practices at the ASF must be appropriately licensed to practice in this Commonwealth. The current provision only requires those nurses who are employed by the ASF to be licensed.

Chapter 561: Pharmaceutical Services

Section 561.2 (relating to pharmaceutical service) would be amended to reflect National standards for ASF pharmacies. Under § 561.2(a), pharmaceutical services shall be supervised by a physician or dentist who is qualified to assume responsibility for the quality of services rendered. Section 561.2(b) would state that a pharmacy which is owned and operated by an ASF shall be supervised by a licensed pharmacist. Finally, § 561.2(c) permits the ASF to contract with a pharmacy but requires that those contracted pharmaceutical services shall be provided in accordance with the same ethical and professional practices and legal requirements that would be required if these services were provided directly by the ASF.

Section 561.21 (relating to principle) would be amended to add a sentence providing that the ASF may use drugs for experimental purposes, but the use must be approved or review waived by an Institutional Review Board (IRB).

Section 561.23 currently titled "Use of dangerous drugs" would be retitled "Use of controlled substances and other drugs." The section would be amended to provide that policies and procedures must be developed and approved by the medical staff which govern the use of controlled substances and other drugs, including sedatives, anticoagulants, antibiotics, oxytoxics and corticosteroids.

Additionally, policies shall be established regarding written orders for appropriate usage of all drugs.

Chapter 563: Medical Records

Section 563.8 (relating to automation or computerization of medical records) would be amended to state that no requirements of this subpart should be construed to prohibit the computerization of medical records. In fact, computerization of medical records is encouraged.

Chapter 565: Laboratory and Radiology Services

Section 565.15 (relating to records) would be amended to require that entries of laboratory and radiologic tests or services performed shall be made a part of the patient's medical record within 24 hours of the provision of the service. The current language requires that these entries be made in a timely manner.

Chapter 567: Environmental Services

No major changes are proposed to this chapter.

Chapter 569: Fire and Safety Services

Section 569.33(a) (relating to smoking) would be amended to ban all smoking in an ASF.

Chapter 571: Construction Standards

No major changes are proposed to this chapter.

Chapter 573: Statement of Policy

Section 573.1 is a statement of policy discussing criteria for ambulatory surgical facilities. This section would be deleted as this material is now set forth is Chapter 551. Section 573.2 is a statement of policy concerning criteria for ambulatory surgical procedures. This section would be deleted as it has been incorporated into and superseded by proposed § 551.21.

Fiscal Impact

These proposed amendments, to ensure the quality of services being provided at licensed health care facilities, will result in some additional costs to the Department. Increased staffing may be necessary to implement the expanded quality assessment process. These resources would be needed to review submitted documentation supporting the licensure requests, to conduct onsite surveys of health care facilities and process licensure applications. Additional costs may also include stipends/fees or expenses, or both, for persons not part of the Department staff who may assist the Department in the licensure and quality assurance assessment process.

The proposed amendments to the Department's licensure regulations will impose additional costs on health care providers to some degree. The proposed amendments require that medical directors of particular health care services must now receive certification from a specialty board. The employment of these individuals could increase the cost of these services. Additionally, costs may be incurred for some minor construction/renovation, equipment or supply costs to meet new requirements. However, in most instances, the standards being adopted are those which the Department expects that the vast majority of health care facilities are already meeting if they provide these services.

In reviewing the fiscal impact, it should be remembered that the reason for many of these amendments is the sunset of the CON Program. A proposal to construct either a long term care facility or an ambulatory surgical facility previously had to undergo CON review prior to commencement of their activity. This review involved expenses for the Department in the employment of an entire division to process and review CON applications. For CON applicants, the actual costs involved the preparation of the application, hiring health care consultants to assist with the CON process, a fee to the Department which could be as much as $20,000 and the time and resources of the facility's staff. Indirect costs included the time which the facility had to wait until its application went through the often lengthy CON process. Although these proposed amendments will not eliminate all of the costs which health care facilities experienced under CON, the overall effect should be a reduced fiscal impact.

Paperwork Requirements

The Department will experience some increase in paperwork related to reviews in processing licensure requests and additional regulatory requirements. In general, there will not be a significant paperwork burden on providers to comply with the expanded licensure requirements.

As with fiscal impact, most of these paperwork requirements should be compared with those previously required under the CON Program. Applicants were required to submit detailed applications which, depending on the health care service proposed to be offered, could be quite lengthy and require extensive documentation.

Effective Date/Sunset Date

The proposed amendments will become effective upon final publication in the *Pennsylvania Bulletin*.

Statutory Authority

Section 803(2) of the act (35 P. S. § 448.803(2)) authorizes the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the act. Section 801.1 of the act (35 P. S. § 448.801a) provides that a purpose of the act is to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities. The same section provides that the minimum standards are to assure safe, adequate and efficient facilities and services, and are also to promote the health, safety and adequate care of patients or residents of these facilities. These provisions, in combination with the Department's express authority under the definition of "health care facility" in section 802.1 of the act (35 P. S. § 448.802a) employ regulations to create new categories of health care facilities as may be required due to the emergence of new modes of health care, confer upon the Department the necessarily implied authority to employ regulations to restrict certain modes of health care services to specified health care facilities to ensure the health, safety and adequate care of patients.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on July 3, 1997, a copy of the proposed amendments was submitted to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed amendments, it will notify the Department by September 17, 1997 (30 days after the close of the public comment

period). The notification shall specify the regulatory review criteria which have not been met by that portion. The REgulatory Review Act specifies detailed procedures for review prior to final publication of the regulations, by the Department, the General Assembly and the Governor, of objections raised.

Contact Person

Interested persons are invited to submit written comments, suggestions or objections to or regarding the proposed amendments within 30 days of the date of publication of this notice in the *Pennsylvania Bulletin*. These comments should be directed to: James T. Steele, Jr., Assistant Counsel, Department of Health, P.O. Box 90, Harrisburg, PA 17108-0090, (717) 783-2500. If you are a person with a disability, comments, suggestions or objections regarding the proposed amendments may also be submitted to Mr. Steele in alternative formats, such as by audio tape, braille or by using TDD: (717) 783-6514. If you are a person with a disability and require an alternative format of this document (that is, large print, audio tape, braille) please contact Mr. Steele so that he can make the necessary arrangements.

DANIEL F. HOFFMANN,
Secretary

Fiscal Note: 10-149. (1) General Fund;

	Revenue Loss	*(GGO) Increased* Costs
(2) Implementing Year 1996-97 is	$750,000	$10,000
(3) 1st Succeeding Year 1997-98 is	$750,000	$10,000
2nd Succeeding Year 1998-99 is	$750,000	$10,000
3rd Succeeding Year 1999-00 is	$750,000	$10,000
4th Succeeding Year 2000-01 is	$750,000	$10,000
5th Succeeding Year 2001-02 is	$750,000	$10,000

(4) Fiscal Year 1995-96 $1.9 million; Fiscal Year 1994-95 $1.5 million; Fiscal Year 1993-94 $1.2 million;

(7) General Government Operations; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart **[B]C.** LONG TERM CARE FACILITIES

CHAPTER 201. APPLICABILITY, DEFINITIONS, OWNERSHIP AND GENERAL OPERATION ON LONG TERM CARE NURSING FACILITIES

GENERAL PROVISIONS

§ 201.1. Applicability.

[(a)] * * *

[(b) Except where minimum standards in this subpart are waived, an existing facility is required to meet the same standards as a facility or section constructed, converted or remodeled in the future.]

§ 201.2. **[Exceptions] Requirements.**

[(a) The Department may, for good reason, when the health and safety of the patients will not be endangered, grant exceptions to this subpart when the policy objective of this subpart is met. The facility shall request the exceptions in writing. The reason for granting the exceptions and the time period for the exceptions will be made in writing by the Department and incorporated as part of the permanent record of the nursing facility maintained on file in the Department. A note will be placed on the license when exceptions are granted.

(b) Exceptions may be granted to this subpart for physical plant and environment, if the facility is unable to comply because of structural features which preclude modification and if the health and safety of the patients would not be endangered.

(c) Exceptions will not be granted for a situation for which a provisional license would be appropriate or for § 201.29 (relating to patient rights).

(d) Exceptions will be granted for a fixed period of time not to exceed the expiration date of the license unless otherwise approved by the Department.]

The Department incorporates by reference Subpart B of the Federal requirements for long term care facilities, 42 CFR 483.1—483.75 (relating to requirements for long term care facilities) as licensing regulations for long term care nursing facilities with the exception of the following sections and subsections:

(1) Section 483.1 (relating to basis and scope).

(2) Section 483.5 (relating to definitions).

(3) Section 483.10(b)(5)(i)(A)(10); (c)(3)(i)(7) and (8); and (o) (relating to level A requirement: Resident rights).

(4) Section 483.12(a)(1), (b), (c)(1) and (d)(1) and (3) (relating to admission, transfer and discharge rights).

(5) Section 483.20(b)(1)(i), (4)(ii) and (iii); (c)(1)(ii), (2)—(4); and (f) (relating to resident assessment).

(6) Section 483.30(b)—(d) (relating to nursing services).

(7) Section 483.40(e) and (f) (relating to physician services).

(8) Section 483.55 (relating to dental services).

(9) Section 483.70(d)(1)(iv) and (3) (relating to physical environment).

(10) Section 483.75(e), (h) and (p) (relating to administration).

§ 201.3. Definitions.

The following words and terms, when used in this subpart, have the following meanings, unless the context clearly indicates otherwise:

***Abuse*—The willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental and psychosocial well-being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish. The term includes the following:**

(i) *Verbal abuse*—Any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their

age, ability to comprehend or disability. Examples of verbal abuse include: threats of harm; and saying things to frighten a resident, such as telling a resident that the resident will never be able to see his family again.

(ii) *Sexual abuse*—Includes sexual harassment, sexual coercion or sexual assault.

(iii) *Physical abuse*—Includes hitting, slapping, pinching and kicking. The term also includes controlling behavior through corporal punishment.

(iv) *Mental abuse*—Includes humiliation, harassment, threats of punishment or deprivation.

(v) *Involuntary seclusion*—Separation of a resident from other residents or from his room or confinement to his room (with/without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.

(vi) *Neglect*—The willful deprivation by a caretaker of goods or services which are necessary to maintain physical or mental health.

* * * * *

***Activities coordinator*—A person who meets one of the following requirements:**

(i) Is a qualified therapeutic recreation specialist.

(ii) Has 2 years of experience in a social or recreational program, within the last 5 years, 1 year of which was full-time in a resident activities program in a health care setting.

* * * * *

Administrator—An individual who is charged with the general administration of a **[nursing]** facility, whether or not the individual has an ownership interest in the home and whether or not the individual's functions and duties are shared with one or more other individuals. **[The term applies to skilled and intermediate care facilities.]** The administrator **[of an intermediate care facility, a skilled nursing facility or a dual facility]** shall be currently licensed and registered by the Department of State under the Nursing Home Administrators License Act (63 P. S. §§ 1101—1114.2).

* * * * *

Ambulatory **[*patient*] *resident***—* * *

* * * * *

Authorized person to administer drugs and medications—Persons qualified to administer drugs and medications in **[long term care]** facilities are as follows:

* * * * *

Certified ***Registered*** *Nurse Practitioner (CRNP)*—* * *

Charge nurse—A person **designated by the facility** who is experienced in nursing service administration and supervision and in areas such as rehabilitative or geriatric nursing or who acquires the preparation through formal staff development programs and who is licensed by the Commonwealth as one of the following:

* * * * *

[(ii) A practical nurse who is a graduate of a Commonwealth recognized school of practical nursing or who has 2 years of appropriate experience following licensure by waiver as a practical nurse and who has achieved a satisfactory grade on a proficiency examination conducted, approved or sponsored by the United States Public Health Service. The determinations of proficiency will not apply with respect to persons initially licensed by a state or seeking initial qualifications as a practical nurse after December 31, 1977.]

[(iii)] (ii) * * *

(iii) A practical nurse who is a graduate of a Commonwealth recognized school of practical nursing or who has 2 years of appropriate experience following licensure by waiver as a practical nurse.

(iv) A practical nurse shall be designated by the facility as a charge nurse only on the night tour of duty in a facility with a census of 59 or less.

Clinical laboratory—A place, establishment or institution, organized and operated primarily for the performance of bacteriological, biochemical, hematological, microscopical, serological or parasitological or other tests by the practical application of one or more of the fundamental sciences to material originating from the human body**, by the use of specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health**. The tests are conducted using specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health. **[The term includes, but is not limited to, independent, hospital, industrial, state, county and municipal laboratories and laboratory facilities operated in private offices and clinics of practitioners of the healing arts except for those issued a Certificate of Exemption.]**

***Clinical records*—All facility records, whether or not automated, pertaining to a resident, including medical records, social records and records dealing with resident fund accounts.**

* * * * *

Dietitian—A person who **[meets one of the following requirements:**

(i) Is eligible for registration by the American Dietetic Association. To be eligible, one of the following shall be met:

(A) *Coordinated undergraduate program*—Completion of clinical and didactic area—Plan III or IV—conferral of the baccalaureate and endorsement of the Program Director.

(B) *Dietetic internship*—Baccalaureate, completion of Plan III or IV requirements, successful completion of the internship and the endorsement of the Program Director.

(C) *Three year preplanned associate membership*—Baccalaureate, completion of Plan III or IV requirements, two endorsements and completion of 3 years of approved experience.

(D) *Master's degree*—Baccalaureate and master's in dietetics or a related field, plus the completion of Plan III or IV requirements, two endorsements and 6 months' full-time—12 months' half-time—experience in the area of dietetics. A half-time graduate

assistantship which includes a variety of experiences related to the practice of dietetics and which has been reviewed by the membership department will also be accepted.

(E) *Doctorate*—Specific requirements are available from the membership department.

(ii) Has a baccalaureate degree with major studies in food and nutrition, dietetics or food service management, has 1 year of supervisory experience in the dietetic service of a health care institution and participates annually in continuing dietetic education. An individual retaining an Associate Membership in ADA meets the educational requirements and shall have 1 year of supervisory experience. A major in food studies means that the person has at least 25 credit hours in food and nutrition, dietetics or food service management.] is either:

(i) Registered by the Commission on Dietetic Registration of the American Dietetic Association.

(ii) Has appropriate education, training or experience in identification of dietary needs, planning and implementation of dietary programs.

* * * * *

[*Dispenser*—A practitioner or a person who is licensed in this Commonwealth to dispense drugs under the Pharmacy Act (63 P. S. §§ 390-1—390-13).]

* * * * *

Drug dispensing—An act **by a practitioner or a person who is licensed in this Commonwealth to dispense drugs under the Pharmacy Act (63 P. S. §§ 390-1—390-13)** entailing the interpretation of an order for a drug or biological and, under that order, the proper selecting, measuring, labeling, packaging and issuance of the drug or biological for a patient or for a service unit of the facility.

[*Drugs*] *Drug or medication*—* * *

Existing facility—A long term care nursing facility or section **[of a facility] thereof** which was constructed and licensed as **[a skilled or intermediate care facility or has been approved and is in the process of construction] such** on **or before** July 1, 1987.

* * * * *

Facility—A **licensed long term care nursing** facility **[that provides either skilled or intermediate nursing care or both levels of care to two or more patients, who are unrelated to the nursing home administrator, for a period exceeding 24 hours] as defined in Chapter 8 of the Health Care Facilities Act (35 P. S. §§ 448.801—448.821).**

* * * * *

[*Intermediate care*—Health related care and services, above the level of room and board, provided on a regular basis to resident individuals who do not require hospital or skilled nursing care, but who, because of mental or physical condition, require the services under a plan of care supervised by licensed and qualified personnel.]

***Interdisciplinary team*—A team including the resident's attending physician, a registered nurse with responsibility for the resident and other appropriate staff in disciplines as determined by the resident's needs, and to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative.**

* * * * *

[*Long term care nursing facility*—A facility that provides either skilled or intermediate nursing care or both levels of care to two or more patients, who are unrelated to the nursing home administrator, for a period exceeding 24 hours.]

Mantoux ***tuberculin skin*** *test* **[*(intermediate strength)*—Intracutaneous] The intradermal** injection of 0.1 ml **of** PPD—tuberculin containing 5 tuberculin units (TU), using a **[26 or 27 gauge needle with a] disposable** tuberculin syringe.

[*Medical record practitioner*—A person who meets one of the following requirements:

(i) Is eligible for certification as a registered record administrator (RRA), or an accredited record technician (ART), by the American Medical Record Association under its requirements in effect January 4, 1975.

(ii) Is a graduate of a school of medical record science that is accredited jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association.

***Medication*—A substance meeting one of the following qualifications:**

(i) Is recognized in the official United States Pharmacopeia, or official National Formulary or a supplement to either of them.

(ii) Is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.

(iii) Is other than food and intended to affect the structure or a function of the human body or other animal body.

(iv) Is intended for use as a component of an article specified in subparagraphs (i), (ii) or (iii), but not including devices or their components, parts or accessories.]

* * * * *

Nonambulatory **[*patient*] *resident***—A **[patient] resident** who is not physically **[and] or** mentally capable of getting in and out of bed and walking a normal path to safety in a reasonable period of time, including the ascent and descent of stairs, without the aid of another person.

* * * * *

Nurse aide—A person who does not possess a license to practice professional or practical nursing in this Commonwealth, but has received training on the job or through other planned nursing programs **[to enable him]** to perform nursing care functions which do not require the skills and judgment of a professional or practical nurse**[, or both]**.

* * * * *

Nursing service personnel—Registered nurses, licensed practical nurses**[,] and nurse** aides **[and orderlies]**.

* * * * *

[*Patient abuse*—The occurrence of any of the following acts:

(i) The infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain or mental anguish.

(ii) The willful deprivation by a caretaker of goods or services which are necessary to maintain physical or mental health.

(iii) Sexual harassment, rape or abuse as defined in section 2 of the Protection from Abuse Act (35 P. S. § 10182) (Repealed).

***Patient activities coordinator*—A person who meets one of the following requirements:**

(i) Is a qualified therapeutic recreation specialist.

(ii) Has 2 years of experience in a social or recreational program, within the last 5 years, 1 year of which was full-time in a patient activities program in a health care setting.

***Patient or resident*—A person who is admitted to a long term care nursing facility for observation, treatment or care for illness, disease, injury or other disability.]**

* * * * *

Prescription—A written or verbal order for drugs issued by a licensed medical practitioner in the course of his professional practice.

* * * * *

***Resident*—A person who is admitted to a licensed long term care nursing facility for observation, treatment, or care for illness, disease, injury or other disability.**

Residential unit—A section or area where persons **[not requiring nursing care or nursing supervision are residing] reside who do not require long term nursing facility care.**

Responsible person—A person who is not an employe of the facility and is responsible for making decisions on behalf of the **[patient] resident**. The person shall be so designated by the **[patient] resident** or the court and documentation shall be available on the **[patient's medicine] resident's clinical** record to this effect. An employe of the facility will be permitted to be a responsible person only if appointed the **[patient's] resident's** legal guardian by the court.

Restraint—**[An apparatus, article, device or garment applied to a patient which interferes with the free movement of the patient and which cannot easily be removed by the patient.] A restraint can be physical or chemical. A physical restraint includes any apparatus, appliance, device or garment applied to or adjacent to a resident's body, which restricts or diminishes the resident's level of independence or freedom. A chemical restraint includes psychopharmacologic drugs that are used for discipline or convenience and not required to treat medical symptoms.**

[*Serious violation*—An action which poses a significant threat to the health of patients.]

Skilled ***or intermediate nursing*** *care*—Professionally supervised nursing care and related medical and other health services provided for a period exceeding 24 hours to an individual not in need of hospitalization, but whose needs are **[such that they] above the level of room and board and** can only be met in a long term care **nursing** facility on an inpatient basis**[, and who needs the care]** because of age, illness, disease, injury, convalescence or physical or mental infirmity. The term includes the provision of **[daily]** inpatient services that are needed on a daily basis by the **[patient] resident**, ordered by **and provided under the direction of** a physician, **and** which require the skills of **[and are furnished directly by or under the supervision of technical or]** professional personnel, such as, **[but not limited to,]** registered nurses, licensed practical nurses, physical therapists, occupational therapists, speech pathologists or audiologists. **[The care would include skilled nursing, skilled rehabilitation or a personal care service that because of a special medical complication of the patient require that the personal care services be performed by or under the direct supervision of skilled nursing or rehabilitative personnel.]**

Social worker—**[A graduate of a school of social work approved by the Council on Social Work Education prior to July 1, 1975 or accredited by the Council on Social Work Education who has 1 year of social work experience in a health care setting] An individual with the following qualifications:**

(i) A bachelor's degree in social work or a bachelor's degree in a human services field including sociology, special education, rehabilitation counseling and psychology.

(ii) One year of supervised social work experience in a health care setting working directly with individuals.

* * * * *

[*Therapeutic recreation specialists*—A person licensed or registered, if applicable, by the state in which practicing, and eligible for registration as a therapeutic recreation specialist by the National Therapeutic Recreation Society—Branch of National Recreation and Park Association—under its requirements in effect on January 4, 1975.]

OWNERSHIP AND MANAGEMENT

§ 201.12. Application for license.

* * * * *

(b) **[If required by the Department, Division of Need Review, the facility shall have an approved certificate of need.**

(c)] * * *

* * * * *

§ 201.13. Issuance of license.

(a) No person may maintain or operate a facility for skilled or intermediate care **[patients] residents** without first obtaining a license issued by the Department.

* * * * *

(c) The required fee for a license is:

Regular Licenses (new or renewal) ..... **[$100]$250**

Each inpatient bed **in excess of 75 beds** .... $2**[.00]**

[First] Provisional **I** License ..... **[100]$400**

Each inpatient bed ..... **[2.00]$4**

[Second] Provisional **II** License ..... **[200]$600**

Each inpatient bed ..... **[2.00]$6**

[Third] Provisional **III** License ..... **[300]$800**

Each inpatient bed ..... **[2.00]$8**

[Fourth] Provisional **IV** License ..... **[400]$1,000**

Each inpatient bed ..... **[2.00]$10**

* * * * *

§ 201.14. Responsibility of licensee.

* * * * *

(c) The licensee **[or] through** the administrator shall **[immediately]** report **[in writing]** to the **[Department's Long Term Care Field Office] appropriate Nursing Care Facilities field office** serious incidents involving **[patients] residents**, including **[but not limited to]** the following:

(1) Deaths due to injuries**, accidents** or suicide.

(2) Deaths **occurring in the facility or following a hospital admission,** due to malnutrition **[or],** dehydration **or sepsis.**

(3) Elopements**[, that is, when a patient leaves the facility without the knowledge of the facility]**.

(4) Transfers **or admissions** to hospitals as a result of injuries or accidents.

(5) Complaints of **[patient] resident** abuse whether or not confirmed by the facility.

(6) Temporary disruptions of services due to a disaster such as a fire, storm, flood or other interruption of services which affect the health and safety of residents. Fires, regardless of whether services are disrupted, shall be reported to the appropriate Division of Nursing Care Facilities field office.

(d) **[The Department's Long Term Care Field Office shall be notified if services in the facility are temporarily disrupted due to a disaster, such as fire, storm, flood or other interruption of services which affect the health and safety of the patients. Fires, regardless of whether services are disrupted, shall be reported to the Department's Long Term Care Field Office] The administrator shall notify the Department as soon as possible within 24 hours of the incidents listed in subsection (c).**

(e) Upon receipt of a strike notice, the licensee or administrator shall promptly notify the **[Department's Long Term] appropriate Division of Nursing** Care **[Field Office] Facilities field office** and keep the Department apprised of the strike status and the measures being taken to provide **[patient] resident** care during the strike.

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§ 201.15. Restrictions on license.

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(c) **[A serious violation of this subpart may result in the nonissuance, nonrenewal or revocation of a license.**

(d)] A final order or determination by the Department relating to licensure may be appealed by the provider of services to the **[State Health Facility Hearing Board under section 805 of the act (35 P. S. § 448.805). The issuance of a provisional license may also be appealed] Health Policy Board under section 2102(n) of The Administrative Code of 1929 (71 P. S. § 532(n)).**

§ 201.16 **[Change in ownership, structure or name] (Reserved).**

[(a) The Department shall be notified in writing at least 90 days in advance of a potential change in ownership, licensee or name of the facility. The license is not transferable without prior approval of the Department.

(b) If a license is issued to a partnership and one or more of the partners dies, the executor or administrator of the deceased's estate, together with the surviving partner, may apply for a license. A complete list of names and addresses of the administrator and partners responsible for the management of the facility shall be submitted with the application.

(c) If a person dies who was the sole owner of a facility, the executor or administrator of the estate may apply for, and the Department may grant, a license for the facility.

(d) The terms "hospital," "medicare," "Medicaid," "extended care," "intensive care," "convalescent home," "skilled nursing home," "intermediate care facility" or "long term care nursing facility" may not be used as a part of, or within the name of the facility, unless the facility has had prior approval by the Department that the facility is in fact providing the care.

(e) The Department shall be notified in writing if there is a transfer of stock of 5% or more. This notification shall be made within 30 days of the effective date of the change.

(f) A corporation shall file an exact copy of the articles of incorporation with the Division of Long Term Care.

(g) Copies of a fictitious name approval and a charter approval, if applicable, shall be filed with the Division of Long Term Care.]

§ 201.18. Management.

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(b) The governing body shall adopt and enforce rules relative to:

(1) The health care and safety of the **[patients] residents.**

(2) Protection of personal and property rights of the **[patients] residents,** while in the facility, and upon discharge or after death.

* * * * *

(e) **[The governing body shall cooperate in an effective program which provides for a regular evaluation of the patients in the facility by person-**

nel of the Department to the extent required by the programs in which the facility participates.

(f)] The governing body shall appoint a full-time administrator who is currently licensed and registered in this Commonwealth and who is responsible for the overall management of the facility. The Department may, by exception, permit a long term care facility of 25 beds or less to share the services of an administrator in keeping with section 3(b) of the Nursing Home Administrators License Act (63 P. S. § 1103(b)). The sharing of an administrator shall be limited to two facilities. The schedule of the currently licensed administrator shall be publicly posted in each facility. The administrator's responsibilities shall include, **[but not be limited to,]** the following:

(1) Enforcing the regulations relative to the level of health care and safety of **[patients] residents** and to the protection of their personal and property rights.

* * * * *

(7) Developing a written plan to assure the continuity of **[patient] resident** care and services in the event of a strike.

[(g) The governing body shall develop a written institutional plan that reflects the operating budget and capital expenditures plan that meets the following requirements:

(1) Provides for an annual operating budget which includes anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items. Nothing in this paragraph requires that there be prepared, in connection with a budget, an item-by-item identification of the components of each type of anticipated expenditure or income.

(2) Provides for an annual capital expenditure plan which includes and identifies in detail the anticipated sources of financing for the objectives of each anticipated expenditures related to the acquisition of land; the improvement of land, buildings and equipment; and the replacement, modernization and expansion of the buildings and equipment which would, under generally accepted accounting principles, be considered capital items.

(3) Is prepared, under the direction of the governing body of the institution, by a committee consisting of representatives of the governing body, the administrative staff and the organized medical staff of the institution, if any.

(h)] (f) A written record shall be maintained on a current basis for each **[patient] resident** with written receipts for personal possessions and funds received or deposited with the facility and for expenditures and disbursements made on behalf of the patient. The record shall be available for review by the patient or patient's responsible person upon request.

[(i)] (g) The governing body shall disclose, upon request, to be made available to the public, the licensee's current daily **[cost]** reimbursement under Blue Cross, Medical Assistance and Medicare as well as the average daily charge to other insured and noninsured private pay **[patients] residents.**

[(j) If] (h) When the facility accepts the responsibility for the **[patient's] resident's** financial affairs, the **[patient] resident** or **[patient's] resident's** responsible person shall designate, in writing, the transfer of the responsibility. **[Further, the] The** facility shall **[establish and maintain policies and procedures that:**

(1) Assure a complete written account of each patient's personal funds is given to the patient or patient's responsible person at least quarterly. A current accounting report shall be available for review upon reasonable request of the patient or patient's responsible person.

(2) Prohibit the commingling of patient funds with facility funds.

(3) Allocate investment income, if any is earned on patients' funds, to the patients' accounts.

(4) Transfer the patient's funds, in the event of the patient's death, to the patient's estate or person designated in writing by the patient.

(5) Notify the patient of the location and account number of the account; designate this account as the patient fund account at the financial institution, if one is used.

(6) Provide] provide the **[patients] residents** with access to their money within **[7] 3** bank business days of the request and in the form—cash or check—requested by the **[patient] resident**.

§ 201.19. Personnel policies and procedures.

[(a) The governing body, through the administrator, is responsible for implementing and maintaining written personnel policies, procedures and job descriptions that support sound patient care and personnel practices.

(b)] Personnel records shall be kept current and available for each employe and contain sufficient information to support placement in the position to which assigned.

[(c) Written policies for control of communicable disease shall be in effect to ensure that employes with symptoms of communicable disease or infected skin lesions are not permitted to work.

(d) Incidents and accidents to patients, personnel and visitors shall be reviewed by the administrator to identify health and safety hazards and to correct or eliminate the hazards as quickly as possible.

(e) A potential employe who will work in the facility shall have a pre-employment examination to determine that the employe is free of communicable diseases in the communicable stage and is able to function in the capacity in which application is made. The physical examination shall be completed and the report shall be available within 48 hours after the employe reports for work. If the information required in this subsection was completed by a physician within the 30 days prior to the employment date, it shall be acceptable.

(f) The pre-employment physical examination shall be completed by a physician currently licensed to practice in this Commonwealth.

(g) An employe shall be in acceptable physical condition as certified by a written statement issued by the examining physician. The statement shall indicate that the individual is free from communicable diseases in the communicable state and from

health handicaps which might disqualify the employe from the position which is being sought for employment.

(h) The employe shall have a pre-employment intermediate strength tuberculin skin test—Mantoux. Mantoux positive reactors shall have a pre-employment X-ray and evaluation for appropriate therapy. Persons with a history of a positive Mantoux reaction may have a chest X-ray instead of Mantoux test.

(i) A written report issued by a physician, hospital or agency, of a tuberculin skin test is required. If the test is positive, a chest X-ray, completed within the past 60 days, shall be considered as meeting the requirement as stated in this section. The report shall be available in the facility before employment.

(j) An employe shall be treated or referred for treatment as necessary.

(k) There shall be written policies that provide for registration of employe complaints with the Department or other agencies without threat of reprisal.]

§ 201.20. Staff development.

(a) There shall be an ongoing coordinated educational program which is planned and conducted for the development and improvement of skills of the facility's personnel, including training related to problems **[and],** needs **and rights** of the **[patients] residents.**

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(c) There shall be at least annual inservice training which includes at least infection prevention and control, fire prevention and safety, accident prevention, disaster preparedness, **[patient] resident** confidential information, **[patient] resident** psychosocial needs, restorative nursing techniques and **[patient] resident** dignity preservation, including the **[patient's] resident's** protection of privacy and personal property rights.

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§ 201.21. Use of outside resources.

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(b) If the facility does not employ a qualified professional person to render a specific service to be provided by the facility, it shall make arrangements to have the service provided by an outside resource, a person or agency that will render direct service to **[patients] residents** or act as a consultant to the facility.

* * * * *

(d) **[The outside resource, when acting as a consultant, shall apprise the administrator of recommendations, plans for implementation and continuing assessment through dated, signed reports which are retained by the administrator for follow-up action and evaluation of performance.**

(e)] Outside resources supplying temporary employes to a facility shall provide the facility with documentation of an employe's health status as required under § **[201.19(e)—(j)] 201.22(c)—(j) and (l)—(m)** (relating to **[personnel policies and procedures] prevention, control and surveillance of tuberculosis (TB)).**

§ 201.22. **[Notification of change in patient status] Prevention, control and surveillance of tuberculosis (TB).**

(a) **[The facility shall have written policies and procedures which relate to notification of the patient's attending physician and other responsible persons in the event of significant changes in the patient's physical, mental or emotional status, or patient's charges, billing and related administrative matters.] The facility shall have a written TB infection control plan with established protocols which address risk assessment and management, screening and surveillance methods, identification, evaluation and treatment of residents who have a possible TB infection or active TB.**

(b) **[Except in a medical emergency, a patient may not be transferred or discharged nor shall treatment be altered radically without consultation with the patient, or if the patient appears to be mentally incapacitated, without prior notification of the patient's responsible person.] Recommendations of the Centers for Disease Control (CDC), United States Department of Health and Human Services (HHS) shall be followed in treating and managing persons with confirmed or suspected TB.**

(c) A baseline TB status shall be obtained on the residents and employes in the facility.

(d) The Mantoux tuberculin skin test is to be used whenever skin testing is done. This consists of an intradermal injection of 0.1 ml of purified protein derivative (PPD) tuberculin containing 5 tuberculin units (TU) using a disposable tuberculin syringe.

(e) The 2-step Mantoux tuberculin skin test shall be the method used for initial testing of residents and employes. If the first test is positive, consider the person infected. If the first test is negative, a second test should be administered in 1—3 weeks. If the second test is positive, consider the person previously infected. If the second test result is negative, the person is to be classified as uninfected.

(f) Persons with reactions of $\geq$ 10 mm or persons with symptoms suggestive of TB regardless of the size of the test reaction, shall be referred for further diagnostic studies in accordance with CDC recommendations.

(g) A written report of test results shall be maintained in the facility for each individual, irrespective of where the test is performed. Reactions shall be recorded in millimeters of induration, even those classified as negative. If no induration is found, "0 mm" is to be recorded.

(h) Skin test negative employes and volunteers having regular contact of 10 or more hours with residents shall have repeat Mantoux tuberculin skin tests at intervals determined by the risk of transmission in the facility. The existing CDC protocol for conducting a TB risk assessment in a health care facility shall be used to establish the risk of transmission.

(i) Repeat skin tests shall be required for tuberculin-negative employes and residents after any suspected exposure to a documented case of active TB.

(j) New employes shall have the Mantoux skin test before beginning employment unless there is

documentation of a previous positive skin reaction. Test results shall be made available prior to assumption of job responsibilities.

(k) The Mantoux tuberculin skin test shall be administered to new residents upon admission, unless there is documentation of a previous positive Mantoux test.

(l) New Mantoux positive reactors (converters) and persons with documentation of a previous positive reaction, shall be referred for further diagnostic testing and treatment in accordance with current standards of practice.

(m) If a chest X-ray is compatible with active TB, the individual shall be excluded from the workplace until a diagnosis of active TB is ruled out or a diagnosis of active TB is established and a determination made that the individual is considered to be noninfectious. A statement from a physician stating the individual is noninfectious shall be required.

(n) A resident with a diagnosis of TB may be admitted to the facility if:

(1) Three consecutive daily sputum smears have been negative for acid-fast bacilli.

(2) The individual has received appropriate treatment for at least 2—3 weeks.

(3) Clinical response to therapy, as documented by a physician, has been favorable.

§ 201.23. Closure of facility.

(a) The administrator or owner shall notify the **[Long Term] appropriate Division of Nursing** Care **Facilities [Field Office] field office** at least 90 days prior to closure.

(b) If the facility is to be closed, the licensee shall notify the **[patient] resident** or the **[patient's] resident's** responsible person in writing.

(c) Sufficient time shall be given to the **[patient] resident** or the **[patient's] resident's** responsible person to effect an orderly transfer **[as required in § 201.25(b) (relating to discharge policy)]**.

(d) No **[patient] resident** in a facility may be required to leave the facility prior to 30 days following receipt of a written notice from the licensee of the intent to close the facility, except in cases where the Department determines that removal of the **[patient] resident** at an earlier time is necessary for health and safety.

(e) If an orderly transfer of the **[patients] residents** cannot be safely effected within 30 days, the Department may require the facility to remain open an additional 30 days.

(f) The Department is permitted to monitor the transfer of **[patients] residents**.

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§ 201.24. **[Admission policy] (Reserved).**

[(a) The patient may be permitted to name a responsible person; however, the patient is not required to name a responsible person if the patient is capable of managing his own affairs. The patient's responsible person may not be named the patient's financial guarantor unless this is specifically agreed upon in writing.

(b) A long term care facility may not obtain from or on behalf of patients a release from liabilities or duties imposed by law or this chapter and Chapters 203—211 except as part of formal settlement in litigation.

(c) A long term care facility shall admit only patients whose nursing care and physical needs can be provided by the staff and facility.

(d) A patient with a disease in the communicable stage may not be admitted to the facility unless it is deemed advisable by the attending physician—medical director, if applicable—and administrator and unless the facility has the capability to care for the needs of the patient.

(e) A patient who in the opinion of a qualified physician, is not infectious and is receiving appropriate antituberculosis chemotherapy may be admitted to the facility.]

§ 201.25. **[Discharge policy] (Reserved).**

[(a) There shall be a centralized coordinated discharge plan to ensure that the patient has a program of needed continuing care after discharge from the facility. The plan shall be developed within 7 days of admission and shall be an integral part of the patient care plan.

(b) Except in an emergency, a patient may not be transferred or discharged from the facility without prior notification. The patient and the patient's responsible person shall receive written notification in reasonable advance of the impending discharge. Reasonable advance notice shall be interpreted to mean 30 days unless appropriate plans can be implemented. The actions shall be documented on the patient record. Suitable clinical notes, list of orders and medications as directed by the attending physician shall accompany the patient if the patient is sent to another medical facility.

(c) Unless the discharge is initiated by the patient or patient's responsible person, the facility is responsible to assure that appropriate arrangements are made for a safe and orderly transfer and that the patient is transferred to an appropriate place that is capable of meeting the patient's needs.

(d) Discharges shall be consistent with the requirements of § 201.29(h) (relating to patient rights).

(e) A patient who becomes mentally disturbed after admission and exhibits behavior which may cause injury to himself or others may be treated in the facility by appropriate medical management and supervision. If, in the opinion of the attending physician, the patient cannot be managed, immediate arrangements shall be made by the attending physician for the transfer of the patient to an appropriate facility at the earliest practical time. The current facility is responsible for the health and safety of the patient and for arranging the safe and orderly transfer of the patient.

(f) If, in the opinion of the attending physician, changes occur in the patient's condition, which require services or a level of care that the facility is not presently providing to its patients, arrangements shall be made to have the patient transferred as soon as possible to another appropriate facility

which can care for the patient. The current facility shall maintain the patient with adequate care until appropriate arrangements can be made. The patient and patient's responsible person shall be notified of the need for transfer.

(g) When a patient's condition changes, it is not necessary to transfer a patient within or between facilities when, in the opinion of the attending physician, the transfer may be harmful to the physical and mental health of the patient. The physical shall document accordingly on the patient's record.]

§ 201.26. Power of attorney.

Power of attorney may not be assumed for a **[patient] resident** by the licensee, owner/operator, members of the governing body, an employe or anyone having a financial interest in the facility unless ordered by a court of competent jurisdiction.

§ 201.27. **[Advertisement of special services] (Reserved).**

[A facility may not advertise special services offered unless the service is under the direction and supervision of personnel trained or educated in that particular special service, such as, rehabilitation or physical therapy by a registered physical therapist; occupational therapy by a registered occupational therapist; skilled nursing care by registered nurses; special diets by a dietitian; or special foods.]

§ 201.28. **[Nondiscriminatory policy] (Reserved).**

[(a) Title VI of the Civil Rights Act of 1964 (42 U.S.C.A. §§ 2000e—2000e-17) and the Pennsylvania Human Relations Act (43 P. S. §§ 951—962.2) apply in the following manner:

(1) There shall be a nondiscriminatory policy of the institution which shall apply to patients, physicians and employes. Under no circumstances will the application of this policy result in the segregation or resegregation of buildings, wings, floors and rooms for reasons of race, color, national origin, ancestry, age, sex, religious creed, or handicap or disability.

(2) Specifically, the nondiscriminatory policy shall include, but not be limited to, the following:

(i) Inpatient or outpatient admission or care.

(ii) Assigning patients to rooms, floors and sections.

(iii) Asking patients about roommate preferences.

(iv) Assigning employes to patient services.

(v) Staff privileges of professionally qualified personnel.

(vi) Utilization of facilities of the institution.

(vii) Transfer of patients from the rooms assigned or selected. A patient may request to upgrade the room assigned or selected for any reason if the room requested is readily available and the patient is financially able to pay for the requested room.

(3) Under the Civil Rights Act of 1964 (42 U.S.C.A. §§ 1971—2000h-6) and the Pennsylvania Human Relations Act, a facility is required to comply with and sign the following statement:

"This facility has agreed to comply with the provisions of the Federal Civil Rights Act of 1964, and the Pennsylvania Human Relations Act, (43 P. S. §§ 951—962.2) and all requirements imposed pursuant thereto, to the end that no person shall, on the grounds of race, color, national origin, ancestry, age, sex, or religious creed, or handicap or disability, be excluded from participation in, be denied benefits of, or otherwise be subject to discrimination in the provision of any care or service."

(4) This subsection is subject to § 201.24 (relating to admission policy).

(5) A facility which is operated, supervised or controlled by a religious organization may delete references relating to religious creed.

(b) Segregation of patients is not permitted based on source of payment except as necessary to obtain third party reimbursement or when optional services are being purchased by the patient.

(c) The following records shall be maintained by a facility to show compliance with the statutes cited in subsection (a). These records shall be available for review by the Department:

(1) A signed and dated copy of the facility's admission policy, including the date of its adoption, which shall set forth in clear terms nondiscriminatory practices with regard to race, color, creed, ancestry, age, sex, national origin or handicap or disability, subject to § 201.24.

(2) Copies of a signed and dated annual notification to referral agencies, such as physicians, social workers, hospitals and minority groups, who have been advised of the admission policy.

(3) A copy of a signed and dated annual notification and description of the continuing method used to inform employes of the nondiscriminatory policies.

(4) Evidence that the nondiscriminatory practices of the facility have been publicized in the community at least once every 3 years by one of the following methods:

(i) Newspapers.

(ii) Radio.

(iii) Television.

(iv) Yellow pages.

(v) Brochure.

(5) Other records or reports as may be required by the Department.

(d) Copies of the facility's nondiscriminatory policy shall be posted in locations accessible to the facility's staff and the general public.

(e) The administrator shall forward to the Department a signed and dated copy of nondiscriminatory policy changes within 30 days of the effective date of the changes.]

§ 201.29. **[Patient] Resident** rights.

(a) **[The governing body of the facility shall establish written policies regarding the rights and responsibilities of patients and, through the administrator, shall be responsible for development of and adherence to procedures implementing the policies.**

(b) The policies and procedures shall be made available to patients, guardians, next of kin, a sponsoring agency or a responsible person.

(c) Policies of the facility shall be available to staff, patients, consumer groups and the interested public, including a written outline of the facility's objectives and a statement of the rights of its patients. The policies shall set forth the rights of the patient and prohibit mistreatment and abuse of the patient.

(d)] The staff of the facility shall be trained and involved in the implementation of the policies and procedures.

[(e)] (b) The **[patient] resident** and **[patient's] resident's** responsible person, or in the case of a Medical Assistance recipient, the recipient **[and the relevant County Board of Assistance]** in the absence of a **[patient's] resident's** responsible person, shall be informed verbally and in writing prior to, or at the time of admission, of services available in the facility and of charges. If changes in the charges occur during the patient's stay, the patient shall be advised verbally and in writing reasonably in advance of the change. "Reasonably in advance" shall be interpreted to be 30 days unless circumstances dictate otherwise. If a facility requires a security deposit, the written procedure or contract that is given to the patient or patient's responsible person shall indicate how the deposit will be used and the terms for the return of the money. A security deposit is not required for a patient receiving Medical Assistance.

[(f) The patient shall be fully informed, as evidenced by the patient's written acknowledgment, prior to or at the time of admission and during stay of the rights and of regulations governing patient conduct and responsibilities.

(g) The physician shall inform the patient of his medical condition unless it is medically contraindicated, as documented in the medical record. The patient shall be afforded the opportunity to participate in the planning of his medical treatment. The patient has the right to refuse treatment, to the extent permitted by law.

(h)] (c) The **[patient] resident** shall be transferred or discharged only for medical reasons, for his welfare or that of other **[patients] residents** or for nonpayment of stay if the facility has demonstrated reasonable effort to collect the debt. **Except in an emergency, a resident may not be transferred or discharged from the facility without prior notification. The resident and the resident's responsible person shall receive written notification in reasonable advance of the impending transfer or discharge. Reasonable advance notice shall be interpreted to mean 30 days unless appropriate plans can be implemented. The actions shall be documented on the resident record. Suitable clinical notes, list of orders and medications as directed by the attending physician shall accompany the resident if the resident is sent to another medical facility.**

(d) Unless the discharge is initiated by the resident or resident's responsible person, the facility is responsible to assure that appropriate arrangements are made for a safe and orderly transfer and that the resident is transferred to an appropriate place that is capable of meeting the resident's needs.

[(i) The patient shall be encouraged and assisted throughout the period of stay to exercise his rights as a patient and as a citizen and may voice grievances and recommend changes in policies and services to the facility staff or to outside representatives of his choice. The patient or patient's responsible person shall be made aware of the Governor's Action Line (toll free (800) 932-0784) and the Department's Hot Line (800) 692-7254), and the telephone number of the Long Term Care Ombudsman Program located within the Local Area Agency on Aging, and the local Legal Services Program to which the patient may address grievances. A facility is required to post the ombudsman poster in a prominent location.

(j) The patient shall be free from interference, coercion, discrimination or reprisal.

(k) A patient may manage his personal financial affairs.

(l) If the facility accepts the responsibility for the financial affairs of the patient, the patient or responsible person shall designate the transfer of responsibility in writing. The facility shall establish and maintain written policies and procedures that:

(1) Assure that a full accounting of a patient's personal funds is given in writing to the patient or the responsible person at least quarterly.

(2) Prohibit the commingling of a patient's funds with facility funds.

(m) The patient shall be free from mental and physical abuse and free from chemical and, except in emergencies, physical restraints except as authorized in writing by a physician for a specified and limited period of time or when it is necessary to protect the patient from injury to the patient or to others.

(n) The patient shall be assured confidential treatment of the personal and medical records and may approve or refuse their release to an individual outside the facility, except in case of a transfer to another health care institution or as required by statute or third party payment contract.

(o) The patient shall be treated with consideration, respect and full recognition of dignity and individuality, including privacy in treatment and in care for the necessary personal and social needs.

(p) The patient may not be required to perform services for the facility that are not included for therapeutic purposes in the plan of care and agreed to by the patient.

(q) The patient shall be permitted to associate and communicate privately with persons of choice. The patient shall be permitted to send and receive personal mail unopened. Facility staff may assist the patient in sending or receiving personal mail if the patient requests assistance.

(r) The patient shall be permitted, unless medically contraindicated, to participate in social and religious activities without interference from the administrator or the facility staff except as noted in § 201.30 (relating to access requirements).

(s) The patient shall be permitted to meet with community groups unless medically contraindicated, as documented by the physician in the medical record.

(t) The patient shall be permitted to retain and use personal clothing and possessions as space permits unless to do so would infringe upon rights of other patients and unless medically contraindicated, as documented by his physician in the medical record. Reasonable provisions shall be made for the proper handling of personal clothing and possessions that are retained in the facility. The patient shall have access and use of these belongings.

(u) A patient shall be afforded an opportunity to meet in private with visitors or persons of choice.

(v) The rights and responsibilities specified in subsections (f)—(i) and (k) devolve to the patient's responsible person in the following instances:

(1) A patient adjudicated incompetent under Commonwealth statutes.

(2) A patient found by his physician to be medically incapable of understanding his rights.

(3) A patient who is unable to communicate in any way.

(w)] **(e)** The **[patient] resident** rights in this section shall be reflected in the policies and procedures of the facility.

[(x) This section shall be posted in a conspicuous place near the entrances and on each floor of the facility. The facility shall post in a conspicuous place near the entrances and on each floor of the facility a notice which sets forth the policy intent of this section. The facility shall on admission provide a patient or patient's responsible person with a personal copy of the notice. In the case of a patient who cannot read, write or understand English, arrangements shall be made to communicate this policy to the patient. A certificate of the provision of personal notice as required in this section shall be entered in the patient's medical record.

(y) No experimental research or treatment in a nursing home shall be carried out without the approval of the Department and without the written approval of the patient after full disclosure. For the purposes of this subsection, "experimental research" means an experimental treatment or procedure that:

(1) Is not a generally accepted practice in the medical community.

(2) Exposes the patients to pain, injury, invasion of privacy or asks the patient to surrender their autonomy, such as a drug study.]

§ 201.30. Access requirements.

(a) **[Areas of the facility are subject to inspection and review by authorized representatives of the Department.**

(b) Visiting hours shall consist of a minimum of 8 hours per day during the period between 8 a.m. and 8 p.m.

(c) A notice listing the visiting hours shall be posted in a conspicuous and public place.

(d) The facility shall permit members of recognized community organizations, representatives of community legal service programs and representatives of the Department of Aging Ombudsman Program, whose purpose includes rendering assistance without charge to patients to have access to the facility. Ombudsman or advocate representatives shall be permitted freedom to see and talk with patients in private if the patients so desire. The purpose of the visits may be to:

(1) Visit, talk with and make personal, social and legal services available to patients.

(2) Inform patients of their rights and entitlements and corresponding obligations, under Federal and State statutes by means of distribution of educational materials and discussion in groups and with individual patients.

(3) Assist patients in asserting their legal rights regarding claims for public assistance, medical assistance and Social Security benefits, as well as in other matters in which patients are aggrieved. Assistance may be provided individually, as well as on a group basis, and may include organizational activity as well as counseling and litigation.

(4) Engage in other methods of assisting, advising and representing patients so as to extend to them the opportunity to fully exercise their rights.

(e) The facility may limit access where it may be a detriment to the care and well-being of the patient in the facility. The facility may not restrict the right of the patient to have legal representation or to visit the representatives of the Department of Aging Ombudsman Program.

(f)] A person entering a facility who has not been invited by **[patients] residents** or **[patients'] residents'** responsible persons under **[subsection (d)]** shall promptly advise the administrator or other available agent of the facility of his presence. The person may not enter the living area of a **[patient] resident** without identifying themselves to the **[patient] resident** and without receiving the **[patient's] resident's** permission to enter.

[(g) An individual patient has the right to terminate a visit by persons having access under subsection (d). Communication between a patient and the person shall be confidential unless the patient authorizes the release of information.

(h)] **(b)** The facility shall post in a conspicuous place near the entrances and on each floor of the facility a notice **[which sets forth the policy intent of § 201.29 (relating to patient rights)] informing residents of their rights.** The facility shall on admission provide a **[patient] resident** or **[patient's] resident's** responsible person with a personal copy of the notice. If a **[patient] resident** cannot read, write or understand English, arrangements shall be made to communicate this policy to the **[patient] resident.** A certificate of the provision of personal notice as required in this section shall be entered in the **[patient's medical] resident's clinical** record.

[(i) This section may not be construed to restrict a right or privilege of a nursing home patient to receive visitors who are not representative of community organizations or legal services programs.

(j) A patient shall be permitted to meet in private with clergy or with a representative of the clergy during the normal visiting hours. Upon request of the patient or patient's family, the patient shall be

permitted to meet with clergy or a representative of the clergy at any time.]

§ 201.31. Transfer agreement.

(a) **[The nursing facility shall have in effect a transfer agreement with one or more hospitals, reasonably close, which provides the basis for effective working arrangements. Under the agreement, inpatient hospital care or other hospital services shall be promptly available to the facility's patients when needed.**

(b)] A hospital and a facility are considered to have a transfer agreement in effect if, by reason of a written agreement between them or, in the case of two institutions under common control, by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that**[:**

(1) A transfer of patients will be effected between the other health facility and the nursing facility, ensuring timely admission, whenever the transfer is medically appropriate as determined by the attending physician.

(2) There will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between the institutions, or in determining whether the individuals can be adequately cared for other than in either of the institutions.

(3) There] there will be arrangements made for the transfer of personal effects, particularly money and valuables, and for the transfer of information related to these items when necessary.

[(c) A nursing facility which does not have an agreement in effect, but which is found by the Department to have attempted in good faith to enter into an agreement with a hospital or other related health care facility located sufficiently close to the facility to make feasible the transfer of patients and the information referred to in subsection (b), is considered to have an agreement in effect if, and for so long as, the Department finds that to do so is in the public interest and essential to assuring nursing facility services for persons in the community.]

§ 201.32. **[Room placements] (Reserved).**

[A husband and wife may occupy the same room if they so desire unless it is medically contraindicated as documented in the medical record by a physician. The room shall comply with standards for a multi-bed room.]

CHAPTER 203. APPLICATION OF LIFE SAFETY CODE FOR LONG TERM CARE NURSING FACILITIES

§ 203.2. **[Restrictions] (Reserved).**

[Blind, nonambulatory or physically-handicapped patients may not be housed above the street-level floor unless the facility is constructed of 1-hour protected noncombustible construction (as defined in National Fire Protection Association Standard No. 220); fully-sprinklered, 1-hour protected ordinary construction; or fully-sprinklered, 1-hour protected wood-frame construction.]

CHAPTER 205. PHYSICAL PLANT AND EQUIPMENT STANDARDS FOR LONG TERM CARE NURSING FACILITIES

BUILDINGS AND GROUNDS

§ 205.1. Location or site.

A building to be used for and by **[patients] residents** shall be located in areas conducive to the health and safety of the **[patients] residents**.

§ 205.2. Grounds.

(a) Grounds shall be adequate to provide necessary service areas and outdoor areas for **[patients] residents**. A facility with site limitations may provide rooftop or balcony areas if adequate protective enclosures are provided.

(b) Delivery areas, service yards or parking area shall be located so that traffic does not cross areas commonly used by **[patients] residents**.

§ 205.3. **[Building approval] (Reserved).**

[A building intended to be used for and by patients shall be approved by the Department before occupancy, construction, conversion, alterations or additions are started.]

§ 205.4. Buildings plans.

(a) **[Architectural plans shall be submitted to the Department for preliminary approval prior to the development of final plans.**

(b)] * * *

[(c)] (b) * * *

[(d)] (c) The licensee or prospective licensee shall have the opportunity to present and discuss purposes and plans concerning the requested changes indicated on the architectural plans with the Department. If differences occur and cannot be resolved, an administrative hearing may be sought under **[§ 8.1] 1 Pa. Code Part II (relating to [applicability of general rules] General Rules of Administrative Practice and Procedure).**

[(e)] (d) * * *

[(f) Preliminary architectural plans submitted to the Department for preliminary approval shall include the following:

(1) Site plan—1 inch equals 40 feet—indicating new and existing structures, roads, services, walls and north arrow.

(2) Floor plans using a minimum of 1/8 inch scale.

(3) One-fourth inch scale layout: Main kitchen, nurse's station, utility room, physical therapy room, occupational therapy room and the like.

(4) One-fourth inch scale layout: Typical bedroom, indicating window, door, radiator, air conditioner, electrical outlets, permanent fixtures, furniture placement or other pertinent information; typical bathroom; and a toilet room.

(5) Exterior elevation.

(6) Wall section, typical.

(7) Plans shall be on drawing sheets at least 15 by 24 inches and not exceed 32 by 42 inches in size including the borders.

(g) A copy of the local zoning approval shall be submitted to the Department before final approval is given unless final approval is needed in order to obtain zoning approval.

(h)] (e) Plans submitted to the Department for **[final]** approval shall include **[items in subsection (f)]** the following **[additional]** items:

* * * * *

(4) **[One set of specifications] Site plan—1 inch equals 40 feet—indicating new and existing structures, roads, services, walls and north arrow.**

(5) Floor plans using a minimum of 1/8 inch scale.

(6) One-fourth inch scale layout: Main kitchen, nurse's station, utility room, physical therapy room occupational therapy room and the like.

(7) One-fourth inch scale layout: Typical bedroom indicating window, door, radiator, air conditioner, electrical outlets, permanent fixtures, furniture placement or other pertinent information; typical bathroom; and a toilet room.

(8) Exterior elevation.

(9) Wall section, typical.

(10) Plans shall be on drawing sheets at least 15 by 24 inches and not exceed 32 by 42 inches in size including the borders.

§ 205.5. **[Number of building plans to be prepared] (Reserved).**

[There shall be two sets of architectural plans submitted to the Department for preliminary approval unless otherwise noted.]

§ 205.6. Function of building.

(a) No part of a building may be used for a purpose which interferes with or jeopardizes the health and safety of **[patients] residents**. Special authorization shall be given by the Department's Division of **[Long Term] Nursing** Care **Facilities** if a part of the building is to be used for a purpose other than health care.

(b) The only persons who may reside in the facility shall be **[patients] residents**, employes, the licensee, the administrator or members of the administrator's immediate family.

MINIMUM PHYSICAL PLANT STANDARDS

§ 205.7. Basement or cellar.

[(a) Basements or cellars shall be concreted, vermin-proofed and kept dry and free from dampness.

(b)] Basements or cellars may be used for storage, laundry, kitchen, heat, electric and water equipment. Approval from the Department's Division of **[Long Term] Nursing** Care **Facilities** shall be secured before areas may be used for other purposes, such as physical therapy, central supply, occupational therapy and the like.

§ 205.8. Ceiling heights.

[(a) In nursing areas, the ceiling height shall be a minimum of 8 feet, except in corridors, halls, toilet rooms and bathrooms where 7 feet 6 inches is acceptable.

(b) In rooms containing ceiling-mounted patient-lifting devices or ceiling hooks for lifting equipment, ceiling heights shall be a minimum of 9 feet.

(c) In other areas, ceiling] Ceiling heights may be 7 feet 6 inches except in boiler rooms where a minimum of 30 inches shall be provided above the main boiler heater and connecting piping. Adequate headroom for convenient maintenance and other proposed operations shall be maintained below the piping.

§ 205.9. Corridors.

(a) **[Corridors in areas used by patients shall meet the provisions of the appropriate NFPA Life Safety Code.**

(b) Handrails may project into corridors, but drinking fountains, desks, storage carts or other projections or obstructions may not reduce the required minimum corridor dimension.

(c) Patient] Resident corridors shall have a handrail on both sides with a return to the wall at each rail ending. Handrails shall be detailed and finished for safety and shall be free from snagging. Brackets may not impede the continuous progress of hands along the railing.

[(d)] (b) * * *

[(e)] (c) Areas used for corridor traffic may not be considered as area for dining, **storage,** diversional or social activities.

§ 205.10. Doors.

(a) **[In a new facility, doors into sleeping rooms used by patients may be no less than 44 inches wide and no less than 80 inches in height.**

(b)] Doors into bathrooms and toilet rooms used by **[patients may] residents shall** be **[no less than] at least** 36 inches wide, except for an existing facility where the minimum width of toilet room doors **[shall be] is [a minimum width of]** 32 inches.

[(c)] (b) A door to a **[patient] resident** room shall swing into the room.

[(d) A door into a lounge area, dining room and other multipurpose room may swing out of the room, if the door does not swing into the effective width of the corridor.

(e)] (c) * * *

[(f) Patient] (d) Resident and visitor toilet stall doors shall swing out. Curtains or equivalent shall be considered as meeting this requirement.

[(g)] (e) A door to a basement or a cellar may not be located in a **[patient] resident** room.

[(h)] (f) * * *

§ 205.11. **[Doorways] (Reserved).**

[Doorways shall be placed so that no bedroom, kitchen, bathroom or toilet room is rendered a corridor.]

§ 205.12. Elevators.

(a) Elevator service shall be provided for **[patients] residents** when a **[patient] resident** use area is located above or below the first floor or grade level

entrance in a building constructed or converted for use after January 1975 as a facility providing either skilled or intermediate care.

* * * * *

§ 205.13. Floors.

(a) Floors traveled by **[patients] residents** shall be of nonskid material.

* * * * *

§ 205.14. Locks.

Doors into rooms used by **[patients] residents** may not be locked from the outside when the **[patient] resident** is in the room.

§ 205.15. **[Outside stairs and ramps] (Reserved).**

[(a) Outside stairs and ramps used by patients shall be adequately lighted and may be no less than 44 inches wide.

(b) There shall be at least one entrance that is accessible with a ramp or a lift for handicapped persons.]

§ 205.16. Stairs.

[(a) There shall be no variations in the depth of treads and heights of risers in a flight of stairs.

(b) Stair treads shall have a nonskid surface.

(c)] Stairs used by **[patients] residents** shall have no locked gates or free swinging doors obstructing ascent or descent.

§ 205.17. Stairways.

[(a) A stairway may be no less than 44 inches wide.

(b) Handrails shall be installed on both sides for stairs 44 inches wide. If a stairway exceeds 66 inches in width, an intermediate handrail shall be installed. Wall handrails other than those on service stairs, shall be continuous through floor and intermediate landings. Handrails and balustrade shall be detailed and finished for safety in use and freedom from snagging. Brackets for handrails may not impede the continuous progress of hands along the railing.

(c) A landing at either end of a flight of stairs used by patients shall be at least as wide as a door leading to the stairs but may be not less than 44 inches in direction of travel.

(d)] There shall be indoor stairs and stairways to a basement if the stairs are to be used by personnel of the facility.

[(e) Stairways shall be adequately illuminated with electric lights controlled by switches located at the top and bottom of the stairs.]

§ 205.18. **[Walls] (Reserved).**

[(a) Walls shall be suitably finished or covered for their intended use.

(b) Walls in kitchens, bathrooms, toilet rooms, bedpan rooms, utility rooms, shower rooms and the wall area around a sink shall be smooth and have a water resistant finish to a level above the splash or spray line.]

§ 205.19. Windows and windowsills.

(a) **[A minimum total glass area on outside walls equal to 10% of the floor area shall be provided in a bedroom.**

(b) Openings providing required natural light which open onto a covered porch that exceeds 4 feet in depth shall be increased in area 10% per foot of depth over 4 feet.

(c) Openings which open to a glass enclosed porch may be included in required ventilating area if the required area is obtained in both exterior wall and porch.

(d) The heads of windows—sash opening—may not be more than 12 inches below the finished ceiling unless they are at least 6 feet 8 inches above the finished floor.

(e) Windowsills in patient bedrooms may not be more than 36 inches from the floor, and they shall be above the exterior finished grade.

(f)] * * *

[(g)] (b) Rooms with windows opening onto light or air shafts, or onto an exposure where the distance between the building or an obstruction higher than the windowsill is less than 20 feet may not be used for **[patient] resident** bedrooms.

[(h) A facility which was licensed prior to July 1, 1987, is not required to comply with the window area requirements, the head of windows, sash openings, or the minimum height of windowsills above the floor, or distance between buildings, as specified in this section.]

§ 205.20. **[Patient] Resident** bedrooms.

(a) A bed for a **[patient] resident** shall be placed only in a bedroom approved by the Department.

(b) **[No more than four beds may be in a patient room.**

(c)] The maximum number of **[patients] residents** who may be accommodated in the facility shall be indicated on the license. **[During the period of a license, the facility may increase the number of beds by not more than ten beds or by 10% of the total bed capacity, whichever is less, if other requirements are met. If the facility exercises this option, it shall notify the Department.**

(d)] (c) The number of **[patient] resident** bedrooms and the number of beds in a room may not exceed the maximum number approved by the Department.

[(e) A bedroom shall be designed to provide adequate placement of furniture and facilities essential to a patient's needs.

(f)] (d) Single bed bedrooms shall **[be provided clearance as follows:**

(1) No less than 3 feet of open space from the side of the bed to the adjacent wall, a permanent fixture or movable furniture, except bedside chair and cabinet. A bedside cabinet may be next to the bed and not counted in this space requirement.

(2) No less than 4 feet of open space from the foot of the bed to the opposing wall or furniture.

(3) Minimum] **(1) Provide minimum** room area clearance, in addition to the area of closets, vestibule, wardrobes and toilet rooms, shall be 100 square feet.

[(4) A bed may be placed against a wall if it is in the best interest of the patient, and if the minimum spacial requirements are met.

(g)] **(e)** Single **[patient] resident** bedrooms in facilities licensed prior to January 1975, shall **[comply with the following minimum requirements:**

(1) Contain] **contain** at least 80 square feet of space.

[(2) Contain no less than 2 feet of space between the side of the bed and the adjacent wall, permanent fixture or movable furniture except bedside chair and cabinet.

(3) Contain no less than 3 feet of space from the foot of the bed and the opposite wall, permanent fixture or movable furniture except bedside chair and cabinet.

(h)] **(f)** A multibed bedroom shall **[be provided clearance as follows:**

(1) No less than 2 1/2 feet of open space from the side of the bed to the adjacent wall, permanent fixtures or movable furniture, except bedside chair and cabinet. A bedside cabinet may be next to the bed and may not be counted in this space requirement.

(2) No less than 4 feet of open space between the sides of adjacent beds.

(3) No less than 4 feet of open space from the foot of each bed to the opposing wall or furniture.

(4) No less than 6 feet of open space between the foot of one bed and the foot of a bed placed against an opposing wall.

(5) No less than 3 feet of open space from the side of the bed to adjacent walls, permanent fixtures or moveable furniture, except bedside chair and cabinet if beds are placed with walls adjacent to both sides of the bed.

(6) Minimum] Provide minimum room area clearances, in addition to **the** area of closets, vestibule, wardrobes and toilet rooms **[shall be] of** 80 square feet per bed.

[(7) A bed may be placed against a wall if it is in the best interest of the patient, and if the minimum spacial requirements are met.

(i)] **(g)** In facilities licensed prior to January 1975, **[patient] resident** multi-bed bedrooms shall **[comply with the following:**

(1) There shall be] **Have** at least 65 square feet of space per **[patient] resident**.

[(2) There shall be no less than 18 inches of open space from the side of the bed to the adjacent wall, permanent fixtures or movable furniture except bedside chair and cabinet.

(3) There shall be no less than 3 feet of open space between the sides of adjacent beds.

(4) There shall be no less than 3 feet of space between the foot of a bed and opposing wall, permanent fixtures or movable furniture, except bedside chair.

(5) There shall be no less than 5 feet of open space between the foot of one bed and the foot of a bed placed against the opposing wall.

(6) There shall be no less than 2 feet of open space from the side of a bed to adjacent walls, permanent fixtures or movable furniture except bedside chair and cabinet if beds are placed with walls adjacent to both sides of the beds.

(j)] **(h)** * * *

[(k)] **(i)** * * *

[(l) A room having more than one bed shall have suitable curtain tracks, rods or equivalent durable equipment to permit enclosing a bed with curtains for privacy. The cubicle curtains shall be of sufficient length to provide privacy to the patient when the bed is at the lowest level.

(m) There shall be one clothes closet or wardrobe for each patient. The closet/wardrobe shall comply with the following standards:

(1) It shall be a minimum of 22 inches deep with 30 inches wide hanging space.

(2) It shall have a minimum of one shelf above the clear hanging space.

(3) It shall have a fixed rod or device for clothes hangers.

(4) The maximum height for the rod shall be 5 feet 6 inches above the room finished floor.

(5) The vertical clearance below the rod may not be less than 4 feet 6 inches.]

§ 205.21. Special care room.

(a) Provisions shall be made for isolating a **[patient] resident** as necessary in a single room which is ventilated to the outside. For new construction, there shall be an adjoining private bathroom which contains a toilet, lavatory and either a standard size tub or a shower.

* * * * *

§ 205.22. Placement of beds.

A bed may not be placed in proximity to radiators, heat vents, air conditioners, direct glare of natural light or drafts unless adequate provisions are made for **[patient] resident** comfort and safety.

§ 205.23. Location of bedrooms.

[(a) A bedroom shall be an outside room with direct natural light and ventilation, and shall have direct access to corridors with the floor at or above grade level. Existing facilities may have bedrooms that are an outside room with direct natural light and ventilation, and have direct access to corridors or common rooms with the floor at or above grade level.

(b) A bedroom may not be located in an area classified as a basement or cellar.

(c)] A **[patient] resident** bedroom shall have adjoining toilet facilities and shall be located conveniently near bathing facilities, except for those facilities licensed prior to January 1975.

§ 205.24. Dining room.

(a) **[There shall be at least one dining room available for patients.**

(b) No more than 50% of the floor space may be used for a dining area if it is located in, or is part of, the lounge or recreation room. If a multipurpose room is used for dining and patient activities, there shall be sufficient space to accommodate the activities and prevent interference with each other. It should be possible to serve meals without interfering with an activity program.

(c)] * * *

(b) Tables and space shall be provided to accommodate wheelchairs with trays and other devices.

§ 205.25. Kitchen.

* * * * *

(b) **[A separate kitchen may be necessary if the facility is located in a building with a residential unit which can provide joint services to both units.**

(c) Provisions shall be made in the kitchen for the preparation, refrigeration, proper storage and distribution of food to dining areas and to patients.

(d)] * * *

[(e) The kitchen and dietetic food service areas shall be properly ventilated.

(f) Safe, sufficient and sanitary equipment shall be provided for the preparation of food and food service for patients.

(g) Adequate equipment shall be provided for the washing of utensils used for eating, drinking and food preparation.

(h) If manual dishwashing is employed, equipment and utensils shall be thoroughly washed in a warm detergent solution which is kept clean, and then shall be rinsed free from the solution. Eating and drinking utensils and, where required, the food contact surfaces of other equipment and utensils, shall be sanitized by one of the following methods:

(1) Immersion for at least 30 seconds in clean, hot water at a temperature of at least 180°F.

(2) Immersion for a period of at least 1 minute in a sanitizing solution.

(i) The temperature of a refrigerator may not be higher than 45°F. A freezer temperature shall be maintained at no higher than 0°F. A thermometer shall be in place in refrigerators and freezers. Food in a refrigerator or freezer shall be covered.]

§ 205.26. Laundry.

* * * * *

(b) **[Bed linens shall be washed and dried in a sanitary and efficient manner which will produce hygienically clean linen. The washing process shall have a mechanism for soil removal and bacteria kill.**

(c)] * * *

[(d)] (c) The facility shall have a separate room for central storage of soiled linens. The room shall be well ventilated, constructed of materials impervious to odors and moisture and easily cleaned. **Soiled linens may not be transported through areas where clean linen is stored.**

[(e)] (d) * * *

[(f)] (e) Equipment shall be made available and accessible for **[patients] residents** desiring to do their personal laundry.

[(g) Provisions shall be made in a nursing unit for a safe and sanitary method of handling and storage of soiled linens. The transportation of linens shall be designed to prevent the spread of infection.]

§ 205.27. Lounge and recreation rooms.

[(a)] There shall be a minimum of 15 square feet of floor space per bed for recreation or lounge rooms provided for the first 100 beds and 13 1/2 square feet for all beds over 100. There shall be recreation or lounge rooms for **[patients] residents** on each floor.

[(b) Floor space for recreation listed in subsection (a) may include, but is not limited to, solaria, reading rooms, enclosed heated porches, living rooms, libraries, multipurpose rooms used for recreation and similar areas.

(c) A minimum of 50% of the required lounge and recreation space shall be located at exterior walls where windows are provided with maximum 36 inch high sills, except for existing facilities.]

§ 205.28. Nurses' station.

* * * * *

(b) The nurses' station may not be more than 120 feet from the most remote **[patient] resident** room served.

* * * * *

[(d) There shall be a nursing staff toilet room including a toilet and lavatory convenient to the nurses' station.]

§ 205.29. **[Office] (Reserved).**

[(a) Private office space shall be available for the administrator, director of nursing and the business office.

(b) Space for medical records shall be available. This shall be an area which is locked.

(c) Additional office space for other department heads shall be provided as necessary.]

§ 205.31. Storage.

[(a)] General storage space shall be provided for storage of supplies, furniture, equipment, **[patients'] residents'** possessions and the like. Space provided for this purpose shall be commensurate with the needs of the nursing facility, but may not be less than 10 square feet per bed.

[(b) A floor occupied by patients shall be provided with storage space for linens, supplies, wheelchairs, stretchers, orthopedic appliances and equipment used daily for the care of patients. Space required shall relate to the number of beds on a floor. This space may not be part of the 10 square feet requirement.

(c) Storage space for patients' personal property, trunks, suitcases, seasonal clothing and the like, shall be provided in a dry and protected area. This space may be included in meeting the 10 square feet requirement.

(d) Storage space for indoor recreation equipment shall be provided in recreation areas or adjacent to them, if possible. This space may not be part of the 10 square feet requirement.]

§ 205.32. Janitor closet.

* * * * *

(b) **[The closet shall be mechanically ventilated and equipped with a service sink and storage space to accommodate janitorial supplies and equipment.**

(c)] * * *

§ 205.33. Utility room.

(a) Provisions shall be made in each nursing unit near the nurses' station for utility rooms. The area shall have separate soiled and clean workrooms. The rooms may not be more than 120 feet from the most remote room served. If one nursing station services several **[patient] resident** corridors, a soiled utility room shall be on each unit.

[(b) The clean workroom shall provide for the storage and assembly of supplies for nursing procedures, contain a counter and sink and be mechanically ventilated. This area may also contain the medicine room and the clean linen storage.

(c) The soiled workroom shall provide for the disassembly of soiled equipment, disposal of liquid and solid wastes, including disposable items. Soiled equipment may be temporarily retained in this area until it can be transported to appropriate areas.]

(b) Facilities for flushing and rinsing bedpans, such as a spray attachment for the clinical sink or a separate bedpan flusher, shall be provided in the soiled workroom of each nursing unit, unless bedpan flushing devices, together with bedpan lugs on toilets are provided in each resident's toilet for this purpose.

(c) Hand-washing facilities shall be available in the soiled and clean utility rooms.

§ 205.34. **[Treatment room or examining room] (Reserved).**

[A treatment room with a storage cabinet shall be conveniently to patients' rooms, and arranged to accommodate a treatment table, lavatory and instrument table. The treatment room may be used for consultation if the room is of sufficient size to accommodate both functions. This may be centrally located to serve more than one nursing unit.]

§ 205.35. **[Telephone] (Reserved).**

[A telephone shall be available for patient use. At least one telephone shall be installed on each nursing floor to accommodate patients on wheelchairs. When necessary, staff shall provide assistance to patients using the telephone.]

§ 205.36. Bathing facilities.

(a) The nursing facility shall provide a general bathing area in each nursing unit to serve **[patients'] residents'** bedrooms which do not have adjoining bathrooms with a bathtub or shower.

(b) **[The general bathing area shall contain at least one bathtub or one shower stall.**

(c)] * * *

[(d)] (c) * * *

[(e)] (d) Each room or compartment shall provide space for the use of bathing fixtures, wheelchairs and dressing. Sufficient space shall be provided for the attendant who may need to assist the **[patient] resident**.

[(f)] (e) * * *

[(g)] (f) * * *

[(h) Shower stalls in patient rooms may be 30 inches in least dimension when a 4 feet square shower is provided in the central bathing area.

(i)] (g) * * *

[(j) Bathtubs shall be at least 5 feet long, 30 inches in width and 16 inches in depth unless special institutional tubs are used. If special institutional tubs or bathing devices are used in lieu of the conventional tub, provisions shall be made to assure that they are fire safe, free of cross contamination and meet acceptable electrical codes, if electrical equipment is used with the bathing equipment. Bathing devices that are connected with electrical connections shall have the unit labeled as approved by Factory Mutual or Underwriters Laboratory or other testing laboratories as approved by the Department.

(k) A bathroom with three standard fixtures shall have a minimum measurement of 50 square feet. There may be no less than 4 feet from the long side of the bathtub to the opposing wall or fixture.

(l)] (h) The facility shall have at least one bathtub in each centralized bath area on each floor that is accessible from three sides with a minimum of 3 feet clearance on each side and 4 feet clearance from the foot of the tub to adjacent wall or obstruction. **[This bathing fixture shall meet one of the following criteria:**

(1) Be a standard or pedestal tub and a minimum of 5 feet long.

(2) Be an institutional style tub that is designed to provide specialized bathing features.

(3) Be an institutional full-length supine tub.

(4) Be a sit-type institutional tub.

(m) A shower in the ratio of one to 15 patients or major fraction thereof may be substituted for bathtubs if there is at least one bathtub fixture with clearance on three sides on each patient floor.]

§ 205.37. Equipment for bathrooms.

* * * * *

(b) The general bathroom or shower room used by **[patients] residents** shall be provided with one emergency signal bell located in close proximity to the tub or shower and which registers at the nursing station. This is in addition to the emergency signal bell located at each toilet unless a single bell can be reached by the **[patient] resident** from both the toilet and tub or shower.

[(c) Provisions shall be made available to get patients in and out of bathtubs in a safe way to prevent injury to patients and personnel.

(d) A dressing area shall be provided immediately adjacent to the shower stall and bathtub. In the

dressing area, there shall be provisions for keeping clothes dry while bathing.]

§ 205.38. Toilet facilities.

(a) In toilet rooms that adjoin patient bedrooms, there shall be at least one toilet for four **[patients] residents**. This shall be directly accessible from bedrooms without entering the general corridor. In no case may one toilet service more than two bedrooms. **[The minimum dimension of a patient toilet room containing only a toilet shall be 3 feet by 6 feet.**

(b) There may be no less than 3 1/2 feet of space from front of toilet to opposite wall or fixtures.

(c) There shall be at least one toilet on each floor to accommodate patients in wheelchairs. There may be no less than 2 feet of space on each side of the toilet and no less than 3 1/2 feet of space in front.

(d) At least one toilet room shall be provided for toilet training. This room shall be accessible from the nursing corridor and may serve the bathing area. Minimum dimensions for a toilet-training room containing only a toilet shall be 5 feet by 6 feet.

(e) A patient-used toilet stall may be no less than 3 feet wide and 6 feet long. The door or curtain to the toilet may be no less than 2 feet, 8 inches wide. When a door is used, it shall swing outward.

(f)] (b) Floors or units with more than eight **[patients] residents** of both sexes shall be provided with separate toilet fixtures in a ratio of 1:4 or major fraction thereof for each sex. In existing facilities, overall toilet fixtures shall be provided in a ratio of 1:8 or major fraction thereof for each bed.

[(g)] (c) * * *

[(h) The number of toilets may be reduced by the number of water urinals but the number of toilets may not be reduced to less than 2/3 of the total number required.]

§ 205.39. Toilet room equipment.

* * * * *

(b) **[Toilet paper in a suitable dispenser shall be provided within reach of the toilet.**

(c)] Toilets used by **[patients] residents** shall be provided with handrails or assist bars on each side capable of sustaining a weight of 250 pounds and an emergency call bell within reaching distance.

[(d) If a bathroom or toilet room has more than one toilet, each toilet shall be enclosed with permanent partitions.]

§ 205.40. Lavatory facilities.

(a) A floor occupied by **[patients] residents** shall have lavatories in the ratio of 1:4 **[patients] residents** or major fraction thereof. In existing facilities, lavatory fixtures shall be provided in a ratio of 1:8 or major fraction thereof for each bed.

(b) A mirror shall be over each lavatory used by **[patients] residents**.

[(c) A floor occupied by patients shall have at least one lavatory installed to accommodate patients in wheelchairs.

(d) Toilets, mirrors, switches and wall outlets shall be arranged for the convenience of patients in wheelchairs as well as in standing positions.]

MECHANICAL AND ELECTRICAL REQUIREMENTS

§ 205.61. Heating requirements for existing and new construction.

[(a) The heating system shall comply with local and State codes. If there is a conflict, the more stringent requirements shall apply.

(b) Open fires, fuel-burning space heaters and portable electric space heaters may not be used.

(c) A minimum temperature of 72°F at winter design conditions shall be provided for occupied spaces. The heat in patient-occupied areas shall be thermostatically controlled to provide an even temperature for patient comfort.

(d) Insulation, including finishes and adhesives on the exterior surfaces of pipes and equipment, shall have a maximum flame-spread rating of 25 and a maximum smoke-developed rating of 150.

(e)] Exposed heating pipes, hot water pipes or radiators in rooms and areas used by **[patients] residents** or within reach of **[patients] residents**, shall be covered or protected to prevent injury or burns to **[patients] residents**. This includes hot water or steam piping above 125°F.

§ 205.62. Special heating requirements for new construction.

(a) **[Boilers shall have the capacity based on the published Steel Boiler Institute or Institute of Boiler and Radiator Manufacturers net rating to supply the normal requirements of all systems and equipment.**

(b)] * * *

[(c)] (b) * * *

§ 205.63. Plumbing and piping systems required for existing and new construction.

* * * * *

(c) Hot water outlets accessible to **[patients] residents** shall be controlled so that the water temperature of the outlets does not exceed 110°F.

[(d) Facilities for flushing and rinsing bedpans, such as a spray attachment for the clinical sink or a separate bedpan flusher, shall be provided in the soiled workroom of each nursing unit, unless bedpan flushing devices, together with bedpan lugs on toilets are provided in each patient's toilet for this purpose.

(e) An automatic fire extinguishing system, such as sprinklers, carbon dioxide, or dry chemical shall be installed, inspected, supervised and maintained under the applicable *Life Safety Code* as required in § 203.1 (relating to application of the Life Safety Code).

(f) Hand-washing facilities shall be available in the soiled and clean utility rooms.]

§ 205.64. Special plumbing and piping systems requirements for new construction.

* * * * *

(d) Shower bases and tubs shall provide nonskid surfaces for standing **[patients] residents**.

[(e) Other piping systems, such as oxygen, shall follow the NFPA Standards applicable to the appropriate edition of the *Life Safety Code*.]

§ 205.65. **[Ventilation requirements for existing and new construction] (Reserved).**

[(a) The exhaust systems of food preparation areas shall conform to the appropriate NFPA Standard No. 96. The ventilation rates may not be less than shown in § 205.66(a) (relating to special ventilation requirements for new construction).

(b) Air handling systems shall meet the requirements of NFPA, 90-A.]

§ 205.66. Special ventilation requirements for new construction.

(a) Ventilation for new construction shall conform to the following:

Area Designation	*Pressure Relationship to Adjacent Areas*	*Min. Air Changes of Outdoor Air Per Hr.*	*Min. Total Air Changes Per Hr.*	*All Air Exhausted Directly to Outdoors*	*Recirculated within Room Units*
[Patient] Resident Room	Equal	2	2	Optional	Optional
[Patient] Resident Area Corridor	Equal	**[2] Optional**	**[4] 2**	Optional	Optional
Exam and treatment room	Equal	**[2] Optional**	6	Optional	Optional
* * * * *					
Food preparation center	Equal	2	10	Yes	**[No]Yes**
Warewashing room	Negative	Optional	10	Yes	**[No]Yes**
* * * * *					
Clean linen storage	Positive	**[2] Optional**	2	**[Optional] Yes**	**[Optional]No**
* * * * *					

(c) **[Corridors may not be used to supply air or exhaust air from a room except that air from corridors may be used to ventilate bathrooms, toilet rooms and small electrical or telephone closets opening directly on corridors.**

(d)] * * *

[(e)] (d) * * *

[(f)] (e) * * *

[(g)] (f) * * *

[(h)] (g) * * *

[(i)] (h) * * *

[(j)] (i) * * *

§ 205.67. Electric requirements for existing and new construction.

* * * * *

(c) Electric lights satisfactory for sewing or similar activities at a minimum level of 200 footcandles on the task shall be available for **[patients] residents**.

(d) Electric lights in rooms used by **[patients] residents** shall be placed or shaded to prevent direct glare to the eyes of **[patients] residents**.

(e) Night lights shall be provided in bedrooms, stairways, corridors, bathrooms and toilet rooms used by **[patients] residents**.

* * * * *

(g) **[Illumination for exit signs, corridors and stairs, including both normal and emergency circuits shall be controlled by switches accessible to authorized personnel only. Key-operated switches, switching in the nurses' station or similarly supervised or nonaccessible locations or switching in the panel boxes are acceptable means on compliance.**

(h)] In addition to night lights, **[patient] residents** bedrooms shall have general lighting. The light emitting surfaces of the night light may not be in direct view of a **[patient] resident** in a normal in-bed position.

[(i)] (h) A reading light shall be provided for each **[patient] resident**.

[(j)] (i) In each **[patient] resident** room there shall be grounding type receptacles as follows: one duplex receptacle on each side of the head of each bed except for parallel adjacent beds. Only one duplex receptacle is required between beds plus sufficient duplex receptacles to supply portable lights, television and motorized beds, if used, and one duplex receptacle on another wall.

[(k)] (j) A nurse's calling station—signal originating device—with cable with push button housing attached or other system approved by the Department shall be provided at each **[patient] resident** bed location so that it is accessible to the patient. Two cables and buttons serving adjacent beds may be served by one station. An emergency calling station within reach of the **[patient] resident** shall be provided at each bathing fixture and toilet unless a single bell can be reached by the **[pa-**

tient] resident from both the bathing fixture and the toilet. Cable and push button housing requirement will apply to those facilities constructed after July 1, 1987.

[(l)] (k) Calls shall register by a signal receiving and indicating device at the nurses' station, and shall activate a visible signal in the corridor at the **[patient's] resident's** door. In **[multi-corridor] multicorridor** nursing units, additional visible signal indicators shall be installed at corridor intersections.

§ 205.68. Special electrical requirements for new construction.

* * * * *

(c) Minimum lighting levels for long term care nursing facilities shall conform with the following:

Area	*Footcandles*

* * * * *

[Patient] Resident care unit (or room), general . .	10
[Patient] Resident care room, reading	30

* * * * *

(d) The applicable standards for lighting levels are those established by the **[United States Department of Health and Human Services publication No. 930-D-16 of January, 1969] most current edition of the *Illuminating Engineering Society of North America (IES) Lighting Handbook*. [For areas not listed, including those which house machinery and equipment, a general lighting level of 20 footcandles minimum shall be provided. The levels in footcandles except where noted "on floor" are maintained values at a horizontal plane, 30 inches above the floor]**.

FURNISHINGS, EQUIPMENT AND SUPPLIES

§ 205.71. Bed and furnishings.

[(a) A standard hospital bed no less than 78 inches long and 36 inches wide with an adjustable back rest and a firm adjustable spring or flat pan shall be provided for each patient receiving nursing care.

(b)] A bed shall be equipped with a firm supporting mattress which is **[no less than 75 inches long, 35 inches wide and 5 inches deep. It shall be covered or protected with nonporous material.**

(c) A bed shall be provided with at least one comfortable bed pillow.

(d) A bed shall be equipped with adjustable side rails if required for the protection and safety of the patient] equal to the size of the frame and provides for the comfort and safety of the resident.

§ 205.72. Furniture.

[(a) For each patient in the room the patient occupies, there shall be an aerated bedside cabinet with a drawer or an aerated bedside chest.

(b) There shall be a dresser for each patient in addition to the bedside cabinet. Built-in dressers may be used in lieu of free-standing dressers.

(c) A towel bar shall be provided for each patient in the room the patient occupies or in the adjoining bathroom.

(d) A comfortable bedside chair for each patient shall be in the room the patient occupies. A geriatric chair may replace the bedside chair.

(e) Footstools shall be available to patients who need them.

(f) Overbed tables, lap tables or an equivalent shall be provided for patients who do not eat meals in the dining area.

(g) A wall, door or dresser mirror that is accessible to patients shall be provided in each bedroom or adjoining bathroom.

(h) In the lounge and recreation areas, comfortable sitting furniture, such as easy chairs, lounge chairs, geriatric chairs or rockers and the like, shall be provided in a number equal to the number of beds in the home. The chairs shall be designed so that the patient can safely and comfortably get into and out of the chairs.

(i) Furniture shall be kept clean and safe for use.

(j)] A **[patient] resident** shall be provided with a drawer or cabinet in the **[patient's] resident's** room that can be locked. This section does not apply to existing facilities except as **[patient] resident** room furnishings are replaced.

§ 205.73. **[Sterilization] (Reserved).**

[(a) The facility shall make provisions for the sterilization of nursing care equipment and supplies by any of the methods listed below:

(1) Autoclave or automatic sterilizer sufficient in size to meet the needs of the facility. This equipment shall be in the clean utility room or in the central supply room.

(2) Arrangements made with another medical facility possessing the capability to comply with paragraph (1).

(3) A complete system of disposable equipment and supplies provided and used by patients.

(b) Prior to use by another patient, bedpans and urinals shall be processed according to any of the methods:

(1) Autoclaving may be used. This piece of equipment shall be in the clean utility room or the central supply room.

(2) Boiling at 212°F for 30 minutes in equipment designed to indicate temperature and control time.

(3) Chemical disinfectant according to manufacturer's recommended directions.

(4) Combination washer-sanitizers which wash at approximately 150°F and sanitize by rinsing with water at not less than 180°F.

(c) Bedpans used by a patient with, or suspected of having, a communicable intestinal disease, or an infection which may be transmitted by use of bedpans or urinals, shall be autoclaved prior to use by another patient.

(d) A written agreement shall be signed by responsible individuals of both institutions if sterilization of nursing care equipment and supplies is to be done at another institution possessing the capability.]

§ 205.74. **[Linen] (Reserved).**

[(a) The facility shall have available at all times a quantity of linens essential for proper care and comfort of patients. The facility shall have available at least three changes of linen per patient per day.

(b) Each bed shall have clean linen.]

§ 205.75. Supplies.

Adequate supplies shall be available at all times to meet the **[patients'] residents'** needs.

CHAPTER 207. HOUSEKEEPING AND MAINTENANCE STANDARDS FOR LONG TERM CARE NURSING FACILITIES

HOUSEKEEPING AND MAINTENANCE

§ 207.1. **[Environmental safety] (Reserved).**

[(a) Housekeeping and maintenance services shall be provided to maintain a sanitary, comfortable environment and to help prevent the development and transmission of infection.

(b) The facility shall be kept free from insects, rodents and vermin through operation of a pest control program.

(c) The grounds shall be free from accumulated rubbish and other health hazards of similar nature.]

§ 207.2. Administrator's responsibility.

* * * * *

(b) **[The administrator shall designate a full-time employe to be responsible for these functions and for the training and supervision of personnel.]** Nursing personnel may not be assigned housekeeping duties that are normally assigned to housekeeping personnel.

[(c) In a facility that has a contract with an outside resource for housekeeping services, the administrator shall ensure that the services provided under the contract meet the requirements of this chapter.]

§ 207.3. **[Housekeeping] (Reserved).**

[(a) The interior and exterior of the building shall be maintained in a clean, safe and orderly manner by accepted practices and procedures of good institutional housekeeping.

(b) Provisions shall be made for the disposal of soiled dressings and similar items in a safe and sanitary manner.

(c) Light and light fixtures shall be kept clean.

(d) Refuse containers provided for an area shall have tight-fitting covers.

(e) Ashes from furnaces or incinerators shall be placed in metal containers.]

§ 207.4. Ice containers and storage.

[(a)] * * *

[(b) Ice used for any purpose shall be made from water which comes from a safe and sanitary source, and shall be used only if it has been manufactured, stored, transported and handled in a sanitary manner.

(c) Ice shall meet the bacteriological and chemical standards for drinking water.

(d) The ice scoop shall be handled in a safe and sanitary manner.]

§ 207.5. **[Maintenance of equipment and building] (Reserved).**

[(a) The facility shall establish a written, preventive maintenance program to ensure that equipment is operative and that the interior and exterior of the building is clean, orderly and attractive.

(b) Buildings shall be maintained in good repair and free from hazards such as loose handrails, loose or broken window glass, loose or cracked floor coverings or other conditions of similar nature.

(c) Electrical and mechanical equipment used shall be maintained in good repair and safe operating condition.

(d) Patient care equipment for personal care and treatment shall be maintained in a safe and sanitary condition.

(e) Sterile equipment shall be provided where necessary.]

CHAPTER 209. FIRE PROTECTION AND SAFETY PROGRAMS FOR LONG TERM CARE NURSING FACILITIES

FIRE PROTECTION AND SAFETY

§ 209.1. Fire department service.

[(a)] * * *

[(b) A nursing facility located in a rural area shall have by each telephone the telephone number of at least two fire departments located nearest to the facility.]

§ 209.2. Hazardous areas.

Exposed heating pipes, hot water pipes or radiators in rooms and areas used by **[patients] residents** and within reach of the **[patients] residents** shall be covered or protected to prevent injury or burn to **[patients] residents**.

§ 209.3. Smoking.

(a) Policies regarding smoking shall be adopted. The policies shall include provisions for the protection of the rights of the nonsmoking **[patients] residents**. The smoking policies shall be posted in a conspicuous place where **[patients] residents**, visitors and staff can see them.

* * * * *

[(c) Smoking by patients classified as not responsible is prohibited, except under supervision.

(d) Smoking by patients in bed is prohibited unless the patient is under direct observation.

(e) Smoking is prohibited in a room, ward or compartment where flammable liquids, combustible gases or oxygen is used or stored, and in other hazardous locations. The areas shall be posted with "NO SMOKING" signs.

(f) Ash trays of noncombustible material and safe design shall be provided in areas where smoking is permitted.

(g) Metal containers with self-closing covers shall be provided in areas where smoking is permitted.]

§ 209.4. **[Fire extinguishers] (Reserved).**

[(a) Fire extinguishers shall be of an approved type and installed under State regulations and local codes.

(b) Fire extinguishers shall be inspected and tested as often as required by State and local regulations.

(c) Personnel shall be instructed in the operation of the various types of fire extinguishers used in the facility.]

§ 209.5. **[Emergency lighting system] (Reserved).**

[(a) Emergency lighting shall be in good functioning condition.

(b) Emergency lighting shall be checked weekly and a written record maintained showing date checked, by whom checked and whether or not the system was operative.]

§ 209.6. **[Fire alarm] (Reserved).**

[(a) The alarm system and its equipment shall be of the standard, approved type suitable for the purpose for which installed.

(b) The alarm system shall be under the supervision of a responsible person.

(c) The fire alarm system shall be in good functioning condition.

(d) The system shall be checked at least weekly.

(e) A written record shall be maintained showing date checked, by whom checked and whether or not the system was operative.

(f) Personnel shall be instructed in the operation of the fire alarm system.]

§ 209.7. Disaster preparedness.

(a) **[The facility shall have a comprehensive written plan, periodically rehearsed, with procedures to be followed in an internal or external disaster. The plan shall also have procedures for the care of casualties—patients and personnel—arising from potential or actual disasters such as fires, explosions, floods, nuclear incidences or other natural or man-made disasters.**

(b)] The **facility shall have a comprehensive written disaster** plan **which** shall be developed and maintained with the assistance of qualified fire, safety and other appropriate experts. It shall include procedures for prompt transfer of casualties and records, instructions regarding the location and use of alarm systems and signals and fire fighting equipment, information regarding methods of containing fire, procedures for notification of appropriate persons and specifications of evacuation routes and procedures. The written plan shall be made available to personnel, and it shall be available at each nursing station and in each department. The plan shall be reviewed periodically to determine its effectiveness.

[(c)] (b) A diagram of each floor showing corridors, line of travel, exit doors and location of the fire extinguishers and pull signals shall be posted on each floor in view of **[patients] residents** and personnel.

(c) Personnel shall be instructed in the operation of the various types of fire extinguishers used in the facility.

§ 209.8. Fire drills.

* * * * *

(b) A written report shall be maintained of each fire drill which includes date, time required for evacuation or relocation, number of **[patients] residents** evacuated or moved to another location and number of personnel participating in a fire drill.

CHAPTER 211. PROGRAM STANDARDS FOR LONG TERM CARE NURSING FACILITIES

§ 211.1. **[Infection control] Reportable diseases.**

(a) **[The facility shall establish an active Infection Control Committee composed of members of the medical and nursing staffs, administration, and dietetic, pharmacy, housekeeping, maintenance and other services charged with responsibility for overall infection control.**

(b) The Infection Control Committee shall establish written policies and procedures for investigating, controlling and preventing infections in the facility, and for identifying patients with reportable diseases.

(c) The written policies and procedures in aseptic and isolation techniques shall be followed by personnel. If the facility does not have the capability of caring for a patient with an infectious disease, the written policies shall include provisions for handling isolation cases until arrangements can be made to have the patient transferred to a facility capable of caring for the patient and the needs related to the specific organism.

(d) The Infection Control Committee shall monitor staff performance to ensure that policies and procedures are executed.

(e) Procedures shall be reviewed and revised for effectiveness and improvement at least annually or more frequently as necessary.

(f) Minutes shall be maintained for Committee meetings.

(g) A patient who develops a communicable disease after admission shall be medically isolated from other patients if ordered by the physician. If the patient cannot or should not be managed in the facility, arrangements shall be made by the attending physician for the transfer of the patient to an appropriate facility at the earliest practical time.

(h)] When a **[patient] resident** develops a reportable disease, the administrator shall report the information to the appropriate health agencies and **[Long Term Care Field Office] appropriate Division of Nursing Care Facilities field office**. Reportable diseases and conditions are:

* * * * *

Chlamydia Trachomatous Infections

[Cancer]

* * * * *

[Guillain] Guillian-Barre Syndrome

* * * * *

[(i) The following conditions shall be reported when diagnosis is confirmed by laboratory findings:

Amebiasis

Anthrax

Botulism

Brucellosis

Campylobacteriosis

Cholera

Diphtheria infections

Giardiasis

Gonococcal infections

Haemophilus influenzae type b disease

Hepatitis, viral, including types A and B

Hypothroidism in infant up to 24 months

Histoplasmosis

Lead poisoning

Legionnaires' disease

Leptospirosis

Lyme disease

Lymphogranuloma venereum

Malaria

Meningococcal isolations

Phenylketonuria

Plague

Psittacosis (ornithosis)

Rabies

Rickettsial infection including Rocky Mountain Spotted Fever

Salmonella isolations

Shigella isolations

Syphilis

Trichinosis

Tuberculosis

Tularemia

Typhoid isolations

Viral infections

Vaccine-preventable diseases

Arboviruses

Respiratory viruses

(j) If a communicable disease develops, adequate steps shall be taken to determine the source and degree of dissemination of the disease.

(k)] (b) Cases of scabies and lice shall be reported to the **[Long Term Care Field Office] appropriate Division of Nursing Care Facilities field office.**

(c) Cases of Methicillin Resistant S. Aureus (MRSA), vancomycin-resistant Staphylococcus Aureus (VRSA), vancomycin-resistant enterococci (VRE) and vancomycin-resistant S. epidermidis (VRSE) shall be reported to the appropriate Division of Nursing Care Facilities field office.

§ 211.2. **[Medical] Physician** services.

(a) **[The facility shall have or make provisions for a physician who shall be responsible for attending to the medical needs of the patients.**

(b) A patient shall be under the current care of a physician. A skilled care patient shall be seen by the attending physician at least every 30 days and an intermediate care patient at least every 60 days, or more often as necessary.

(c) A patient's total program of care, including medications, care and treatments, shall be reviewed during a visit by the attending physician at least once every 30 days for a skilled care patient and every 60 days for an intermediate care patient. Revisions shall be made as necessary. The physician shall indicate on the patient's medical record that the review has been made. Entries made by the physician on the medical record shall be dated and signed with the original signature of the physician. A physician's orders shall be renewed at least once every 30 days for skilled care patients and every 60 days for intermediate care patients.

(d) The facility shall have written procedures available at each nurses station that provide for a physician to be available to furnish necessary medical care in case of emergency. The procedures shall be reviewed periodically to determine their effectiveness.

(e)] The attending physician shall be responsible for the medical evaluation of the **[patient] resident** and shall prescribe a planned regimen of total **[patient] resident** care. **[This regimen shall incorporate all of the components of the patient's care and shall designate the patient's appropriate level of care.**

(f) The facility shall have available, prior to or at the time of admission, patient information which includes current medical findings, diagnoses and orders from a physician for immediate care of the patient. Information shall also be available at the time of admission or within 48 hours thereafter, on the patient's rehabilitation potential and a summary of the course of prior treatment.

(g) The admission requirements shall include a report of physical examination, chest X-ray, complete blood count and urinalysis. These shall be done within 1 week prior to, or within 48 hours after admission. A chest X-ray taken within 60 days prior to admission will fulfill the admission requirement for a chest X-ray. When the patient is admitted to the facility directly from a hospital, the hospital report of these examinations and tests accompanying the patient shall be considered to meet this requirement, if the attending physician in the facility documents, in the patient record, that these reports are acceptable. When a patient is admitted to another level of care within a facility, or to another licensed nursing facility, the medical reports transferred with the patient shall be considered to meet this requirement, if the attending

physician in the facility documents, in the patient's record, that these reports are acceptable.

(h) Annually thereafter, there shall be a physical examination, complete blood count and urinalysis completed for each patient. The results of the tests shall be available on the patient chart.

(i) A progress note shall be written or typed and signed and dated by the physician on the day the patient is seen.

(j) A physician's orders shall be dated and signed with the original signature of the physician.

(k) A facility shall have a medical director who is licensed as a physician in this Commonwealth and who is responsible for the overall coordination of the medical care in the facility to ensure the adequacy and appropriateness of the medical services provided to the patients. The medical director may serve on a full- or part-time basis depending on the needs of the patients and the facility and may be designated for single or multiple facilities. There shall be a written agreement between the physician and the facility.

(l)] (b) The medical director's responsibilities shall include at least the following:

(1) **[Coordination of care of patients provided by attending physicians and ensurance of compliance with the facility's written bylaws and rules which delineate responsibilities.**

(2)] Review of incidents and accidents that occur on the premises and addressing the health and safety hazards of the facility. The administrator shall be given appropriate information from the medical director to help insure a safe and sanitary environment for **[patients] residents** and personnel.

[(3) Execution of patient care policies as they relate to the patient's total plan of care.

(4)] (2) * * *

[(m) The requirement for a medical director may be waived by the Department for an appropriate period of time depending on the following:

(1) The facility is located in an area where the supply of physicians is not sufficient to permit compliance with this requirement without seriously reducing the availability of physician services within the area.

(2) The facility has made continuous efforts in good faith to recruit a medical director but has not been able to hire a physician due to the unavailability of physicians.]

§ 211.3. Oral and telephone orders.

(a) A physician's oral and telephone orders shall be given to a licensed nurse, physician or other individual authorized by appropriate statutes and the State Boards in the Bureau of Professional and Occupational Affairs and shall immediately be recorded on the **[patient's] resident's** medical record by the person receiving the order. The entry shall be signed and dated by the person receiving the order.

(b) A physician's oral and telephone orders for care and treatments, exclusive of medication orders—see § 211.9(h) (relating to pharmaceutical services)—shall be dated and countersigned with the original signature of the physician within 7 days of receipt of the order. If the physician is not the attending physician, he shall be authorized and the facility so informed by the attending physician and shall be knowledgeable about the **[patient's] resident's** condition.

§ 211.4. Procedure in event of death.

(a) **[The patient's physician or the physician's designee shall be notified immediately of the apparent death of a patient. Documentation shall be on the patient's medical record of this notification or attempt to notify the physician.**

(b) Written and dated documentation by the physician shall be on the patient's medical record that death has occurred.

(c) Death certificates shall be completed and signed by the physician under Article V of the Vital Statistics Law of 1953 (35 P. S. §§ 450.501—450.506).

(d)] Written postmortem procedures shall be available at each nursing station.

[(e)] (b) Documentation shall be on the **[patient's] resident's** medical record that the next of kin, guardian or responsible party has been notified of the **[patient's] resident's** death. The name of the notified party shall be written on the **[patient's] resident's** medical record.

§ 211.5. **[Medical] Clinical** records.

(a) **[The facility shall maintain, in accordance with accepted professional standards and practices, an organized patient record system. These records shall be available to professional and other staff directly involved with the patient and to authorized representatives of the State and Federal government. Records] Clinical records** shall be available to, but not be limited to, representatives of **the** Department of Aging Ombudsman Program.

(b) **[The medical record service shall have sufficient staff, facilities and equipment to provide medical records that are documented completely and accurately, readily accessible and systematically organized to facilitate retrieving and compiling information.**

(c)] Information contained in the **[patient's] resident's** record shall be privileged and confidential. Written consent of the **[patient] resident**, or of a designated responsible agent acting on the **[patient's] resident's** behalf, is required for release of information. Written consent is not necessary for authorized representatives of the State and Federal government during the conduct of their official duties.

[(d) The facility shall provide the patient or the patient's designee, upon request, access to information contained in the patient's medical records unless medically contraindicated. If the patient or patient designee wants a copy of the medical record, the facility shall provide the copy and may charge a reasonable fee for reproducing copies.

(e) If requested, after the death of a patient, the facility shall make the patient's medical record available to the deceased patient's executor or administrator of the decedent's estate or to the person who is responsible for the disposition of the body. If a copy of the medical record is requested,

the facility shall provide one copy and may charge a reasonable fee for reproducing copies.

(f) Records shall be adequately safeguarded against destruction, fire, loss or unauthorized use.

(g) The facility shall maintain adequate facilities and equipment, which are conveniently located, in order to provide efficient processing of medical records.

(h)] **(c)** Records shall be retained for a minimum of 7 years following a **[patient's] resident's** discharge or death.

[(i) Medical records] (d) Records of discharged **[patients] residents** shall be completed within 30 days of discharge. Clinical information pertaining to a **[patient's] resident's** stay shall be centralized in the **[patient's medical] resident's** record.

[(j)] (e) When a facility closes, **[patient] resident** medical records may be transferred with the **[patient] resident** if the **[patient] resident** is transferred to another health care facility. Otherwise, the owners of the facility shall make provisions for the safekeeping and confidentiality of medical records and shall notify the Department of how the records may be obtained.

[(k)] (f) At a minimum, the **[patient] resident** record shall include physicians' orders, observation and progress notes, nurses' notes, medical and nursing history and physical examination reports; identification information, admission data, documented evidence of assessment of **[patient's] resident's** needs, establishment of an appropriate treatment plan and plans of care and services provided; hospital diagnoses authentication—discharge summary, report from attending physician, or transfer form—diagnostic and therapeutic orders, reports of treatments, clinical findings, medication records and discharge summary including final diagnosis and prognosis or cause of death. The information contained in the record shall be sufficient to justify the diagnosis and treatment, identify the **[patient] resident** and show accurately documented information.

[(l)] (g) * * *

[(m)] (h) Each professional discipline shall enter the appropriate historical and progress notes in a timely fashion in accordance with the individual needs of a **[patient] resident**.

[(n)] (i) Overall supervisory responsibility for the medical record service shall be **[assigned to a full-time employe of the facility. If the person is not a qualified medical records administrator, this person functions with consultation from a person so qualified] performed by qualified personnel competent to carry out the functions of the medical record service**. The facility shall also employ sufficient supportive personnel competent to carry out the functions of the medical record service.

[(o) The following information shall be incorporated by members of the nursing staff into the nurses' notes section of the medical record:

(1) Drugs or treatment administered to patients shall be recorded daily on the proper record.

(2) Observations made concerning the condition of critically or acutely ill patients shall be recorded daily on the proper record on each tour of duty.

(3) Observations made concerning the condition of patients who are not critically or acutely ill shall be recorded in summary at least once each month for each tour of duty.

(4) Nurses' notes shall be written in chronological order and shall be signed and dated by the person making the entry. Nurses' notes include, but are not limited to, observations made concerning the general condition of the patient, change in the physical or mental condition, an incident or accident and significant items of care.]

§ 211.6. Dietary services.

(a) **[The facility shall provide a hygienic dietetic service that meets the daily nutritional needs of patients, ensures that special dietary needs are met and provides palatable and attractive meals. A facility that has a contract with an outside food management company may be found to be in compliance with this section if the facility or company, or both, meets the standards listed in this section.**

(b) Menus shall be planned and followed to meet nutritional needs of patients under physician's orders and, to the extent medically possible, under the recommended dietary allowances of the Food and Nutrition Board, National Research Council—National Academy of Sciences.

(c)] * * *

[(d)] (b) Sufficient food to meet the nutritional needs of **[patients] residents** shall be prepared as planned for each meal. There shall be at least 3 days' supply of food available in storage in the facility at all times.

[(e) At least three meals or their equivalent shall be served daily at regular times with not more than a 14-hour span between a substantial evening meal and breakfast. If not medically contraindicated, bedtime nourishments shall be offered routinely to patients.

(f) Foods shall be prepared by methods that conserve nutritive value, flavor and appearance, and are attractively served at proper temperatures and in a form to meet individual needs.

(g) If a patient refuses food served, appropriate substitutions of similar nutritive value shall be offered.

(h) When necessary, individuals shall be provided special equipment, implements or utensils to assist them with eating.

(i) Food shall be procured from sources approved or considered satisfactory by Federal, State or local authorities. Food shall be stored, prepared, distributed and served under sanitary conditions. Waste shall be disposed of properly.

(j) Written reports of inspections by State and local health authorities shall be on file at the facility with notation made of action taken by the facility to comply with recommendations.

(k)] (c) * * *

[(l) If the dietary services supervisor is not a qualified dietitian, the supervisor shall function with frequent regularly scheduled consultation from a person who is qualified.

(m)] (d) If consultant dietary services are used, the consultant's visits shall be at appropriate times and of sufficient duration and frequency to provide continuing liaison with medical and nursing staff, advice to the administrator, **[patient] resident** counseling, guidance to the supervisor and staff of the dietary services, approval of menus, and participation in development or revision of dietary policies and procedures and in planning and conducting inservice education and programs.

[(n) The facility shall employ sufficient supportive persons who are competent to carry out the functions of the dietary services.

(o) Food service personnel shall be on duty over a period of 12 or more hours.

(p) Therapeutic diets shall be prescribed by the attending physician.

(q) Therapeutic menus shall be planned in writing. They shall be prepared and served as ordered under supervision or consultation from the dietetic supervisor and advice from the physician whenever necessary.

(r)] (e) * * *

[(s) Procedures shall be established and regularly followed which assure that the serving of meals to patients for whom special or restricted diets have been medically prescribed is supervised. Observation of the patient's eating habits shall be made and charted on the patient's medical record.

(t)] (f) * * *

§ 211.7. Physician assistants/nurse practitioners.

(a) Physician assistants/nurse practitioners may be utilized in long term care facilities, in accordance with their training and experience and the requirements **[set forth] in statutes and regulations governing their respective practice. [They may not be used in lieu of licensed physicians, with respect to the requirements of § 211.2(b) and (c) (relating to medical services).]**

(b) If the facility utilizes the services of physician assistants/nurse practitioners, the following apply:

* * * * *

(4) A notice plainly visible to **[patients] residents** shall be posted in prominent places in the institution explaining the meaning of the terms "physician assistant" and "nurse practitioner."

(c) Physician assistants'/nurse practitioners' documentation on the **[patient's] resident's** record shall be countersigned by the supervising physician within 7 days with an original signature and date by the licensed physician. This includes progress notes, physical examination reports, treatments and any other notation made by the physician assistant/nurse practitioner.

* * * * *

§ 211.8. Use of restraints.

(a) **[Restraints shall be used to prevent injury to the patient or other patients only as necessary.]** Restraints may not be used in lieu of staff effort. Locked restraints may not be used.

(b) **[Restraints] Physical restraints** may not be used or applied in a manner which causes injury to the **[patient] resident**.

(c) **[Restraints] Physical restraints** shall be removed at least 10 minutes out of every 2 hours during the normal waking hours to allow the **[patient] resident** an opportunity to move and exercise. Except during the usual sleeping hours, the **[patient's] resident's** position shall be changed at least every 2 hours. During sleeping hours, the position shall be changed as indicated by the **[patient's] resident's** needs.

(d) A signed, dated, written physician order shall be required for a physical **or chemical** restraint. This includes the use of **[posey,]** chest, waist, wrist, ankle or other form of restraint. The order shall include the type of restraint to be used.

(e) The physician shall document the reason for the **initial** restraint order and shall review the **continued** need for the **use of the restraint** order by evaluating the **[patient] resident. Need for the continued use of a restraint shall be evaluated at least every 30 days by an interdisciplinary team. [If the order is to be continued, the order shall be renewed for at least every 30 days for skilled patients and every 60 days for intermediate care patients by the physician in accordance with the patient's total program of care.**

(f) **[A written order is not required for the use of a geriatric chair. If the patient is placed in a geriatric chair, the patient shall be removed from the chair and exercised at least every 2 hours.] Every 30 days, the interdisciplinary team shall review and reevaluate the use of all restraints ordered by physicians.**

§ 211.9. **[Pharmaceutical] Pharmacy** services.

(a) **[The facility shall have written policies and procedures which are used to ensure that all aspects of medication control and pharmaceutical services are acceptable practices and comply with applicable State, Federal and local statutes and regulations. The] Facility** policies **[and procedures]** shall ensure that **[the following are complied with:**

(1) The identity of the patient shall be unquestionably established before medication is administered.

(2) The employe who administers medications to patients shall record and sign on the individual medication record of each patient the medication, dosage and time it was given. This shall be done as soon as possible after the medications have been given.

(3) Appropriate facility staff shall be knowledgeable of the policies and procedures.

(4) Only] only licensed pharmacists shall dispense medications for **[patients] residents.** Licensed physicians may dispense medications to the **[patients] residents** who are in their care.

[(5) The records of receipt and disposition of controlled substances shall be maintained in sufficient detail to enable an accurate reconciliation.

(6) Drug records shall be in order and an account of controlled substances shall be maintained and reconciled.

(7) A drug formulary shall be available readily to medical and nursing staff to use as a cross reference if generic drugs are used.

(8) Self-administration of medications shall be allowed only with written permission of the attending physician.]

* * * * *

(e) Each **[patient] resident** shall have a written physician's order for each medication received. This includes both proprietary and nonproprietary medications. **[These physician's orders shall be on each patient's individual chart and shall be reviewed, renewed, signed and dated by the physician every 30 days for skilled patients and 60 days for intermediate care patients.**

(f) Written medication orders which are not specifically limited to time or number of doses shall be controlled by automatic stop orders or other methods under written policies. The attending physician shall be notified of an automatic stop order prior to the last dose so that he may decide if the medication order is to be renewed.

(g) If a prescribed medication is not given, the reason shall be recorded on the patient's medical record, and the prescribing practitioner shall be notified of the information under acceptable medical and nursing practices.

(h)] (f) A physician's telephone and oral orders for medications shall be given only to a licensed nurse, pharmacist, physician or other individual as authorized by the appropriate statutes and the State Board in the Bureau of Professional and Occupational Affairs. Telephone and oral orders shall be recorded immediately on the **[patient's] resident's** medical record and dated and signed by the person receiving the order. Telephone and oral orders shall be countersigned by the prescribing practitioner/attending physician within 48 hours. **Orders may be by facsimile transmission**. Oral orders for Schedule II drugs are permitted only in a bona fide emergency.

[(i) A prescription container shall be labeled individually by the pharmacist for each patient. The label shall include the name of the prescribing practitioner, name of patient, Federal Drug Enforcement Administration number—if appropriate—name and address of the pharmacy, directions for use, required warnings, name and strength of the drug, prescription serial number, date originally dispensed, quantity of drug dispensed and initial or name of dispensing persons. The name of the manufacturer shall be on the label if generic drugs are used.

(j) Patients] (g) Residents shall be permitted to purchase prescribed medications from the pharmacy of their choice. If the **[patient] resident** does not use the pharmacy that usually services the facility, the **[patient] resident** is responsible for securing the medications and for assuring that applicable pharmacy regulations and facility policies are met.

[(k) If over-the-counter drugs are maintained in the facility, they shall bear the original label and shall have the name of the patient on the label of the container. The charge nurse may record the patient's name on the nonprescription label. The use of nonprescription drugs shall be limited by quantity and category according to the needs of the patient. Facility policies shall indicate the procedure for handling and billing of nonprescription drugs.

(l)] (h) If a unit of use or multiuse systems are used, applicable statutes shall be met. Unit of use dispensing containers or multiuse cards shall be properly labeled **[under subsection (i)]**. Individually wrapped doses shall be stored in the original container from which they were dispensed.

[(m)] (i) At least quarterly, outdated, deteriorated or recalled medications shall be identified and **[referred to the Pharmaceutical Services Committee or consultant pharmacist] returned to the dispensing pharmacy** for disposal **[under State and Federal statutes and regulations] in accordance with acceptable professional practices**. Written documentation shall be made regarding the **[disposal] disposition** of these medications.

[(n)] (j) Disposition of discontinued and unused medications and medications of discharged or deceased **[patients] residents** shall be handled by facility policy which shall be developed in cooperation with the consultant pharmacist **[or Pharmaceutical Services Committee]**. The method of disposition and quantity of the drugs shall be documented on the respective **[patient's] resident's** chart. The disposition procedures shall be done at least quarterly under Commonwealth and Federal statutes.

[(o) The facility shall maintain written policies and procedures relating to medications and biologicals which provide the following:

(1) If the facility maintains a licensed pharmacy, a licensed pharmacist shall be in charge and present during the pharmacy's normal hours of operation.

(2) If the facility does not maintain a licensed pharmacy, it shall have arrangements with at least one licensed pharmacy to provide required services and consultation.

(3) Arrangments shall be made to assure that pharmaceutical services will be available on an emergency basis.

(4) The pharmacist, if not a full-time employe of the facility, shall devote a sufficient number of hours during a regularly scheduled visit to carry out the specified contractual responsibilities. Consultation shall be provided at least monthly on methods, procedures, storage, administration, disposal and recordkeeping of medications and biologicals and patient records. The consulting pharmacist shall submit a written monthly report on the status of the facility's pharmaceutical services and staff performance to the Pharmaceutical Services Committee.

(5) The Pharmaceutical Services Committee shall review medication errors and irregularities and shall document the review and corrective action plans in the minutes.

(p) No drug intended solely for study or experimental use may be administered unless authorized by 21 CFR (relating to food and drugs) and then, only with the written consent of the patient or the legal guardian.

(q) Written policies and procedures shall be established in conjunction with the consulting pharmacist or Pharmaceutical Services Committee regarding the proper storage and maintenance of drugs and biologicals. The storage policies shall ensure that:

(1) Drugs and biologicals, including those that require refrigeration, shall be stored in locked compartments and properly maintained. Only authorized personnel shall have access to the keys.

(2) Separately locked, permanently affixed compartments shall be provided for storage of controlled substances listed in Schedule II in section 4(2) of The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-104(2)) and § 25.72(c) (relating to schedules of controlled substances), and other drugs subject to abuse.

(3) If mobile medication carts are used, they shall:

(i) Have a double locked box within the cart for storage of controlled Schedule II substances.

(ii) Be secured in an acceptable fashion if not in use to insure security control.

(iii) Be stored away from corridors when not in use.

(4) Internal and external medications shall be stored separately in locked compartments.

(r) A Pharmaceutical Services Committee shall perform the following:] (k) The oversight of pharmaceutical services shall be the responsibility of the quality assurance committee. Arrangements shall be made for the pharmacist responsible for the adequacy and accuracy of the services to have committee input.

[(1) Develop] The quality assurance committee shall develop written policies and procedures for drug therapy, distribution, administration, control and use.

[(2) Develop procedures for control and accountability for drugs and biologicals in the facility.

(3) Be comprised of at least a registered pharmacist, director of nursing, administrator and one licensed physician.

(4) Oversee the pharmaceutical services in the facility, make recommendations for improvement, monitor the service to ensure accuracy and adequacy and make provisions for annual inservice training programs for facility staff.

(5) Meet at least quarterly and document in writing its activities, findings and recommendations.

(6) Assure that the drug regimen of each patient is reviewed at least monthly by a registered pharmacist and that the pharmacist documents the findings of the review on each patient's medical record.

(7) Review and approve the contents, storage and use of emergency medication kits.

(s)] (l) A facility shall have at least one emergency medication kit. The kit used in the facility shall be governed by the following:

(1) The facility shall have written policies and procedures pertaining to the use, content**, storage** and refill of the kits.

* * * * *

(3) The emergency medication kits shall be under the control of a practitioner **[licensed by statute] authorized** to dispense or prescribe medications **under the Pharmacy Act (63 P. S. §§ 390.1—390.13).**

* * * * *

§ 211.10. **[Patient] Resident** care policies.

(a) **[A facility shall have written policies to govern the continuing nursing care and related medical and other services provided. The policies shall reflect the philosophy of the facility.**

(b) The facility shall have policies which are developed by the administrator and director of nurses with the advice of the medical director or the organized medical staff and of other professional personnel. The policies shall govern the nursing care and medical care or other related services it provides.

(c) The] Resident care policies **[which]** shall be available to admitting physicians, sponsoring agencies, **[patients] residents** and the public, shall reflect an awareness of, and provision for, meeting the total medical and psychosocial needs of **[patients] residents**. The needs include admission, transfer and discharge planning. **[The range of services available to patients also includes the frequency of physician visits by each category of patients admitted.**

(d) The policies shall include provisions to protect patients' personal and property rights.

(e) The medical records and minutes of staff and committee meetings shall reflect the rendering of patient care under the written patient care policies.

(f) The facility shall appoint in writing a physician or a registered nurse to be responsible for the execution of the policies. If the responsibility for day-to-day execution of patient care policies has been delegated to a registered nurse, the facility shall make available an advisory physician from whom medical guidance is received.

(g)] (b) * * *

[(h)] (c) The policies shall be designed and implemented to ensure that each **[patient] resident** receives treatments, medications, diets and rehabilitative nursing care as prescribed.

[(i)] (d) The policies shall be designed and implemented to ensure that the **[patient] resident** receives proper care to prevent **[decubitus ulcers] pressure sores** and deformities; that the **[patient] resident** is kept comfortable, clean and well-groomed; that the **[patient] resident** is protected from accident, injury and infection; and that the **[patient] resident** is encouraged, assisted and trained in self-care and group activities.

§ 211.11. **[Patient] Resident** care plan.

[(a) A registered nurse on the staff of the facility shall be designated by the director of nursing services to be responsible for the coordination of a written patient care plan. This responsibility shall be in the nurse's job description.

(b) The patient care plan shall be developed upon admission and implemented as soon as possible thereafter.

(c) The patient care plan shall be reviewed, evaluated and updated, as necessary, by professionals involved in the care of the patient.

(d) The patient care plan shall be an interdisciplinary care plan that shall include input as appropriate but not limited to physicians services, nursing services, social services, rehabilitative services, dietary, pharmacy and activities service.

(e) The patient plan of care shall establish goals and define the approach to be utilized by each discipline toward achievement of the goals. Goals of care shall be set through the evaluation of the patient's present state of physical and emotional health, potential for improvement or potential to maintain the present level of functioning. Goals of the plans of care shall be set through the evaluation of the patient's present state of physical and emotional health, potential for improvement or potential to maintain the present level of functioning.

(f)] The **[patient] resident** care plan shall be available for use by personnel caring for the **[patient] resident**.

[(g) The patient, when able, shall participate in the development and review of the plan.]

§ 211.12. Nursing services.

(a) The facility shall provide **[nursing to meet the needs of patients] services by sufficient numbers of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans.**

* * * * *

(d) **[If the director of nursing services has institutional responsibilities other than nursing responsibilities, a qualified registered nurse shall serve as an assistant and act in the absence so there is the equivalent of a full-time director of nursing services.**

(e)] The director of nursing services shall be responsible for:

(1) **[The development and maintenance of nursing service objectives.**

(2)] Standards of **[good] accepted** nursing practice.

[(3)] (2) * * *

[(4) Written job descriptions for each level of nursing personnel.

(5)] (3) Methods for coordination of nursing services with other **[patient] resident** services.

[(6)] (4) * * *

[(7) Schedules of daily rounds to see patients. Rounds shall be made daily by the director of nursing services or a delegate.

(8) Nursing staff development.

(9)] (5) General supervision, guidance and assistance for a **[patient] resident** in implementing the **[patient's] resident's** personal health program to assure that preventive measures, treatments, medications, diet and other health services prescribed are properly carried out and recorded.

[(f) Until July 1, 1988, there shall be a qualified licensed nurse as the charge nurse who is responsible for supervising total nursing activities in the facility for each tour of duty in accordance with the following:

(1) There shall be a licensed registered nurse on the day tour of duty each day of the week and a registered nurse or licensed practical nurse on the evening and night tour of duty in a facility that has skilled patients.

(2) There shall be a registered nurse or licensed practical nurse on each tour of duty each day of the week in a facility that has only intermediate care patients.

(g) After July 1, 1988, there shall be] (e) The facility shall designate a registered nurse as the charge nurse who is responsible for supervising total nursing activities **within the facility** on each tour of duty each day of the week.

[(h)] (f) In addition to the director of nursing services, the following daily professional staff shall be available **[except as provided in subsection (j).]:**

(1) The following **[is effective July 1, 1988] apply:**

* * * * *

(2) **[If] When the facility designates** an LPN **[is in] as a** charge **nurse,** a registered nurse shall be on call and located within a 30-minute drive of the facility.

[(i) The following requirement is effective until July 1, 1988, in a facility that has skilled care patients except as provided in subsection (j).

Census	*Day*	*Evening*	*Night*
59 and under	**—**	**1 RN or LPN**	**1 RN or LPN**
60/150	**1 RN**	**1 RN**	**1 RN**
151/250	**1 RN and 1 LPN**	**1 RN and 1 LPN**	**1 RN and 1 LPN**
251/Upward	**2 RNs**	**2 RNs**	**2 RNs**

(j) The director of nursing services may also serve as the day professional staff nurse in a facility with an average daily census of 59 patients or less.

(k) The charge nurse shall delegate responsibility to nursing personnel for the direct nursing care of specific patients during each tour of duty on the basis of staff education qualifications, size and

physical layout of the facility, characteristics of the patient load and the emotional, social and nursing care of patients.]

(l)] (g) There shall be at least one nursing staff employe per 20 **[patients] residents** on duty.

[(m)] (h) * * *

[(n)] (i) A minimum number of general nursing care hours shall be provided for each 24-hour period. The total number of hours of general nursing care provided in each 24-hour period shall, when totalled for the entire facility, be a minimum of **[2.7] 2.3** hours of direct **resident** care for each **[skilled care patient and a minimum of 2.3 hours of direct patient care for each intermediate care patient] resident**. The total number of daily required hours shall be computed by multiplying the number of **[intermediate care patients] residents** by 2.3 hours **[and by multiplying the number of skilled care patients by 2.7 hours. The two figures shall be added; the sum shall be the minimum total number of hours of general nursing provided in each 24-hour period for the entire facility.**

(o)] (j) Nursing personnel shall be provided on each **[patient] resident** floor.

[(p)] (k) Weekly time schedules shall be maintained and shall indicate the number and classification of nursing personnel, including relief personnel, who worked on each tour of duty **on each nursing unit.**

[(q)] (l) The Department may require an increase in the number of nursing personnel from the minimum requirements if specific situations in the facility—including, but not limited to, the physical or mental condition of **[patients] residents, the** quality of nursing care administered**, the** location of **[patients] residents, the** location of the nursing station and location of the facility—indicate the departures as necessary for the welfare, health and safety of the **[patients] residents**.

[(r) Nursing personnel shall be aware of the nutritional needs and food and fluid intake of patients and assist promptly where necessary in the feeding of patients. A procedure shall be established to inform the dietetic service of physicians' diet orders and of patients' dietetic problems. Food and fluid intake of patients shall be observed, and deviations from normal shall be recorded and reported to the charge nurse and the physician.

(s) The facility shall have an active program of restorative care for patients who need the service. The service shall be an integral part of nursing service and shall be directed toward assisting a patient to achieve and maintain an optimal level of self-care and independence. Records shall be maintained when the services are performed.]

§ 211.13. **[Rehabilitative services] (Reserved).**

[(a) The facility shall maintain a specialized rehabilitative program for those patients who need the service. Either directly or through arrangements with qualified outside resources, the service is designed to preserve and improve abilities for independent function, to prevent progressive disability and to restore maximum function.

(b) Rehabilitative services are provided upon a physician's written order and with a written plan of care developed in conjunction with the attending physician and appropriate therapist and nursing service personnel.

(c) Information regarding rehabilitative services shall be recorded on the patient's record and shall be signed and dated. This includes the physician's written order and the progress note of the person providing the service.

(d) Safe and adequate space and equipment shall be available commensurate with the service offered.

(e) If the facility does not offer the services directly, it may not admit nor retain patients in need of rehabilitative care unless provision is made for the services under arrangement with qualified outside resources under which the facility assumes professional responsibility for the service rendered.

(f) The patient's progress shall be reviewed regularly by the physician and the therapist. They shall reevaluate the plan of rehabilitative services as necessary, but at least every 30 days for skilled patients and every 60 days for intermediate care patients.

(g) Specialized rehabilitative services shall be provided under accepted professional practices by qualified therapists, or by qualified assistants or other supportive personnel under the supervision of qualified therapists.

(h) Written administrative and patient care policies and procedures shall be developed for restorative services by appropriate therapists and representatives of the medical, administrative and nursing staffs.]

§ 211.14. **[Diagnostic services] (Reserved).**

[(a) The facility shall have provision for promptly obtaining required laboratory, X-ray and other diagnostic services.

(b) If the facility provides its own X-ray services, it shall be in compliance with 25 Pa. Code Part I, Subpart D, Article V (relating to radiological health). If the facility provides its own clinical laboratory services, it shall be in compliance with Chapter 5 (relating to clinical laboratories).

(c) If the facility does not provide diagnostic services, arrangements shall be made for obtaining the services from a physician's office, a hospital or facility, a portable X-ray supplier or independent laboratory which is approved by the necessary agencies to provide the services.

(d) Services shall be provided only on the orders of the attending physician who shall be notified promptly of the findings.

(e) Signed and dated reports of a clinical laboratory, X-ray and other diagnostic services shall be reviewed by the physician and shall be filed with the patient's medical record.

(f) The facility shall assist the patient, if necessary, in arranging for transportation to and from the source of service.]

§ 211.15. Dental services.

(a) The facility shall **[make satisfactory arrangements to assist patients in obtaining emergency and routine dental care on a regularly scheduled basis] assist residents in obtaining routine and 24-hour emergency dental care.**

[(b) An advisory dentist or dental hygienist under the supervision of a dentist shall participate in the staff development program for nursing and other appropriate personnel, and shall recommend oral hygiene policies and practices for the care of patients.

(c) The facility shall have a cooperative agreement with a dental service, and shall maintain a list of dentists in the community for patients who do not have a private dentist.

(d) The facility shall assist the patient if necessary in arranging transportation to and from the dentist's office.

(e)] (b) The facility shall make provisions to assure that **[patient] resident** dentures are retained by the **[patient] resident**. **[When possible, dentures] Dentures** shall be marked **[with the patient's name] for each resident.**

§ 211.16. **[Social services] (Reserved).**

[(a) The facility shall provide social services designed to promote preservation of the patient's physical and mental health and to prevent the occurrence or progression of personal and social problems.

(b) In the absence of a qualified social worker on the staff who is a graduate of a school of social work accredited by the Council on Social Work Education, a designated staff member suited by training or experience shall be responsible for arranging for social services through health and welfare resources in the community, and for the integration of the social services with other elements of the patient's plan of care.

(c) Social work consultation by a qualified social worker consultant shall be provided and documented on a regular basis.

(d) The social work employe shall maintain a written record of the frequency and nature of the qualified social work consultation and services provided or obtained.

(e) There shall be an evaluation of each patient's social needs. The plan for providing care shall be formulated and recorded in the patient's record and periodically reevaluated in conjunction with the patient's total plan of care.

(f) Pertinent social data shall be collected upon admission for a patient or immediately prior to admission and the data shall be placed in the patient's medical record. The data shall include information about the personal and family problems related to the patient's illness and care, and of actions taken to meet the patient's needs. Pertinent social data shall be made available to the attending physician and other appropriate staff members. After the data is collected, an evaluation shall be made to determine if the patient needs continued social service.

(g) For patients receiving social services, there shall be a clearly defined plan prepared by qualified persons to assist a patient to adjust to the social and emotional aspects of the illness, treatment and stay in the facility. This plan shall be formulated in conjunction with the patient's total plan of care and shall be reevaluated periodically.

(h) Policies and procedures shall be established for ensuring the confidentiality of the patient's social information.]

§ 211.17. **[Patient activities] Pet therapy.**

[(a) The facility shall provide for an activities program appropriate to the needs and interests of a patient which shall encourage self-care, resumption of normal activities and maintenance of optimal self-functioning and contact with the environment.

(b) A full-time member of the facility's staff shall be designated as responsible for the patient activities program. If he is not a patient activities coordinator, he shall function with frequent regularly scheduled consultation from a person so qualified.

(c) Provision shall be made for an ongoing program of meaningful activities appropriate to the needs and interests of patients, designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice. The activities shall be designed to promote the physical, social, religious and mental well being of the patients.

(d) A patient's activities plan shall be approved by the patient's attending physician to insure that it is not in conflict with the treatment plan. The activity plan shall be incorporated into the overall plan of care, and it shall be reviewed at least quarterly by the patient and appropriate staff. The plan shall be changed as needed.

(e) The facility shall make available adequate space and a variety of supplies and equipment to satisfy the individual interests of patients. If the space used is a multipurpose room, the activities program space may not interfere with other activities.

(f)] If pet therapy is utilized, the following standards apply:

(1) Animals are not permitted in the kitchen or other food service areas, dining rooms, utility rooms and rooms of **[patients] residents** who do not want animals in their rooms.

(2) Careful selection of types of animals shall be made so they are not harmful or annoying to **[patients] residents.**

(3) The number and types of pets shall be restricted according to the layout of the building, type of **[patients] residents**, staff and animals.

(4) Pets shall be carefully selected to meet the needs of the **[patients] residents** involved in the pet therapy program.

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Subpart [E] **F.** AMBULATORY SURGICAL FACILITIES

CHAPTER 551. GENERAL INFORMATION

GENERAL PROVISIONS

§ 551.1. Legal base.

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(b) The Department has the duty to promulgate**[, after consultation with the Health Care Policy Board,]** the regulations necessary to implement Chapter 8 of the act and to assure that its regulations and the act are enforced.

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§ 551.2. Affected institutions.

This subpart applies to ambulatory surgical facilities, profit or nonprofit, operated within this Commonwealth. **Only those facilities which are licensed under this subpart shall provide ambulatory surgery in this Commonwealth, except as provided in Class A facilities. This subpart does not apply to outpatient surgery performed at licensed hospitals, or to dentists' or oral surgeons' offices except to the extent the offices seek licensure as ambulatory surgical facilities.**

§ 551.3. Definitions.

The following words and terms, when used in this subpart, have the following meanings, unless the context clearly indicates otherwise:

ASF—*Ambulatory surgical facility* **[(*ASF*)—A facility which provides outpatient surgical treatment and is not located upon the premises of a hospital. The term does not include the office of an individual or group practice physician or dentist, unless the office has a distinct part used solely for outpatient surgical treatment on a regular and organized basis.] A facility or portion thereof not located upon the premises of a hospital which provides specialty or multispecialty outpatient surgical treatment. The term does not include individual or group practice offices of private practitioners unless the offices have a distinct part used solely for outpatient surgical treatment on a regular and organized basis.**

* * * * *

***Ambulatory surgery*—Surgery which is performed:**

(i) On an outpatient basis in a facility which is not located in a hospital.

(ii) On patients who do not require hospitalization but who do require constant medical supervision following the surgical procedure performed and whose total length of stay does not exceed the standards in this subpart.

***Anesthesia*—The use of pharmaceutical agents to induce the loss of sensation. For the purpose of this chapter, the term applies when any patient, in any setting receives, for any purpose, by any routine one of the following:**

(i) General, spinal or other regional anesthesia.

(ii) Sedation (with or without analgesia), for which there is a reasonable expectation that, in the manner used, will result in the loss of protective reflexes for a significant percentage of a group of patients.

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Authorized person to administer drugs and medications—In an ASF, the term includes the following:

(i) **[Physicians and dentists] Practitioners** who are currently licensed by the Bureau of Professional and Occupational Affairs, Department of State.

* * * * *

***Classification levels*—ASFs shall be classified as follows:**

(i) *Class A*—A private or group practice office of practitioners where procedures performed are limited to those requiring administration of either local or topical anesthesia, or no anesthesia at all. Class A enterprises shall receive ASF accreditation from a Nationally recognized accrediting body such as the Accreditation Association for Ambulatory Health Care (AAAHC), or the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) to be identified as providing ambulatory surgery.

(ii) *Class B*—A single-specialty or multiple-specialty facility with a distinct part used solely for ambulatory surgical treatments involving administration of sedation analgesia or dissociative drugs wherein reflexes may be obtunded; and where patients are limited to Physical Status (PS) PS-I or PS-II patients, unless the patient's PS status would not be adversely affected or sought to be remedied by the surgery. A Class B ASF may be a distinct part of a private or group practice medical or dental office so long as the requirements of this subpart are met.

(iii) *Class C*—A single-specialty or multiple-specialty facility used exclusively for the purpose of providing ambulatory surgical treatments which involve the use of a spectrum of anesthetic agents, up to and including general anesthesia. PS-I, PS-II and PS-III patients may be treated at a Class C facility, within limitations imposed by regulations regarding anesthesia and recovery time, if the facility is freestanding.

***Classification system*—A process used to identify three levels of ambulatory surgical facilities (A, B and C) based on the procedure, patient status and anesthesia used. Only ASF's classified as a B or C facility are eligible for licensure.**

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***Distinct part*—An area which is part of a practitioner's office which is physically identifiable and where surgery is performed on a regular and organized basis.**

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***Governing body*—The individuals, group or entity that has ultimate authority and responsibility for establishing policy, maintaining quality patient care and providing for organizational management and planning.**

* * * * *

Organized—Administratively and functionally structured **to include the following:**

(i) Governing body.

(ii) Medical staff.

(iii) Quality assurance.

(iv) Nursing services.

(v) Pharmacy services.

(vi) Medical record services.

(vii) Laboratory and radiology services.

(viii) Environmental services.

(ix) Fire and safety services.

* * * * *

Physical status classifications—The evaluation of the patient's overall health as it would influence the conduct and outcome of anesthesia or surgery, or both. Physical status shall be defined within one of five assigned classes which are:

(i) Class 1 patients have no organic, physiologic, biochemical, metabolic or psychiatric disturbance. The operation to be performed is for a local pathologic process and has no systemic effect.

(ii) Class 2 patients have a systemic disturbance which may be of a mild to moderate degree but which is either controlled or has not changed in its severity for some time.

(iii) Class 3 patients suffer from significant systemic disturbance, although the degree to which it limits the patient's functioning or causes disability may not be quantifiable.

(iv) Class 4 patients suffer from severe systemic diseases that are already life-threatening and may or may not be correctable by surgery.

(v) Class 5 patients are moribund and not expected to survive without surgery.

* * * * *

Surgery—The branch of medicine that diagnoses and treats diseases, disorders, malformations and injuries wholly or partially by operative procedures.

* * * * *

[EXCEPTIONS]

§ 551.11. [Principle] (Reserved).

[The Department may, within its discretion and for good reason, grant exceptions to this subpart when the policy and objectives of this subpart are otherwise met, or when compliance would create an unreasonable hardship, and when an exception would not impair the health, safety or welfare of a patient.]

§ 551.12. [Requests for exceptions] (Reserved).

[Requests for exceptions to this subpart shall be made in writing to the Department by the ASF. Requests, whether approved or not approved, will be documented and retained on file by the Department. Approved requests shall be retained on file by the ASF during the period the exception remains in effect.]

§ 551.13. [Revocation of exceptions] (Reserved).

[(a) An exception granted under this chapter may be revoked by the Department for a good reason. Notice of revocation will be in writing and will include the reason for the action of the Department and a specific date upon which the exception will be terminated.

(b) In revoking an exception, the Department will provide for a reasonable time between the date of written notice of revocation and the date of termination of an exception for the ASF to come into compliance with this subpart. Failure by the ASF to comply after the specified date may result in enforcement proceedings under this chapter.

(c) If an ASF wishes to request a reconsideration of a denial or revocation of an exception, it shall do so in writing to the Director of the Bureau of Quality Assurance of the Department within 30 days of receipt of the adverse notification.]

INTERPRETATIONS

§ 551.21. [Definition of] Criteria for ambulatory surgery.

(a) Ambulatory surgical procedures are limited to those that do not generally exceed:

(1) A total of 4 hours of operating time.

(2) A total of 4 hours directly supervised recovery.

(b) If the surgical procedures require anesthesia, the anesthesia shall be one of the following:

(1) Local or regional anesthesia.

(2) General anesthesia of 4 hours or less duration.

(c) Surgical procedures may not be of a type that:

(1) Generally associated with the risk of extensive blood loss.

(2) Require major or prolonged invasion of body cavities.

(3) Directly involve major blood vessels.

(4) Are generally emergency or life threatening in nature.

(5) Are performed on patients younger than 6 months of age or on low birth weight babies up to 1 year of age.

[(a)] (d) ***

[(b)] (e) ***

[(c)] (f) ***

APPLICATION AND AUTHORIZATION TO OPERATE AN AMBULATORY SURGICAL FACILITY

§ 551.31. [Certificate of Need] Licensure.

[A Certificate of Need shall be obtained under the act.]

(a) A license shall be obtained to operate a freestanding Class B or Class C ambulatory surgical facility.

(b) An ASF license shall designate the licensed facility as either Class B or Class C.

(c) An applicant for a license to operate an ASF request licensure by the Department by means of written communication which sets forth:

(1) A list of operative procedures proposed to be performed at the facility and the ages of the patients to be served.

(2) The highest level of anesthetic proposed to be used for each proposed operative procedure.

(3) The highest PS patient level proposed to receive ambulatory surgery at the facility.

(4) A statement from the applicant which may be accompanied by a written opinion from a Nationally recognized accrediting body stating the most appropriate facility Class (A, B or C) or licensure ready.

(d) If a facility desires to change its classification level from a Class B enterprise to a Class C enterprise, the facility shall request and obtain a license prior to providing services to ASA Class III or PS-III patients.

§ 551.32. **[Building occupancy] (Reserved).**

[New construction, alterations or renovations that provide space for patient rooms may not be used or occupied until authorization for the occupancy has been received by the ASF from the Department.

(1) The Department will require at least one inspection during the construction phase of an ASF. The inspection shall take place at approximately 75% of the estimated time of completion of the facility.

(2) The Department shall be notified in writing when an ASF is at least 75% complete in construction, so arrangements may be made for inspection.

(3) It is the responsibility of the ASF to request a preoccupancy survey at least 2 weeks prior to the anticipated occupancy of an ASF or an addition or remodeled part thereof. The Department will conduct an on-site survey of the new or remodeled portion of the ASF prior to granting approval for occupancy. The Department, acting through the Director of the Division of Hospitals, may give the authorization orally, either in person or by telephone. The Department will provide the ASF with written confirmation of the oral authorization within 30 days.]

§ 551.33. Survey.

The Department will conduct a survey to insure that the applicant is in compliance with this subpart. The survey will include an **[on-site] onsite** inspection and review of written approvals submitted to the Department by regulatory agencies responsible for building, electric, fire and environmental safety. **The Department may designate Nationally recognized accrediting agencies whose standards are at least as stringent as the Department's to perform some or all aspects of licensure surveys.**

§ 551.34. Licensure process.

(a) An application for **[a] the appropriate** license to operate an ASF shall be made in accordance with section 807 of the act (35 P. S. § 448.807).

* * * * *

(c) Applications for renewal of a license shall be made **[annually] biannually** on forms obtained from the Department of Health.

(d) Applications or renewal forms shall be accompanied by a fee of **$ [50] 250.**

CONTINUING OPERATIONS

§ 551.41. Policy.

The Department will issue a license valid for **[1 year] 2 years** to an ASF which is in compliance with this subpart.

§ 551.42. **[Nontransfer of license] (Reserved).**

[An ASF shall advise the Department no later than 90 days prior to an intended change of ownership or control of the ASF. A license is not transferable to new owners or controlling parties except upon a finding by the Department that they are responsible persons, and that other provisions of the act and this subpart have been met.

§ 551.43. Void license.

(a) The license of an ASF becomes automatically void when one of the following occurs:

(1) The license term of **[1 year] 2 years** expires.

* * * * *

(b) If the ASF locates or relocates services at a site other than the current site or a site contiguous thereto, **[it] the ASF** shall notify the Department 30 days prior to the change **[in order] so** that the Department may determine if a new license **[and certificate of need review are] is** necessary.

INSPECTION AND SURVEY ACTIVITIES

§ 551.53. Presurvey preparation.

(a) Prior to **[an annual] a biennial** survey site visit of an ASF by the Department, the Department may request from the ASF documents or records of the ASF, or other information necessary for the Department to prepare for the site visit. The ASF shall provide the information requested, **including a declarative statement that sets forth the information requested in § 551.31 (relating to licensure) as follows:**

(1) A list of operative procedures proposed to be performed at the facility.

(2) The highest level of anesthetic proposed to be used for each proposed operative procedure.

(3) The highest PS patient level proposed to receive outpatient surgical treatments at the facility.

ISSUANCE OF LICENSE

§ 551.81. Principle.

The Department will issue **an** ASF **[licenses] license to a facility which complies with this subpart. The license will reflect the regular [or],** provisional **or limited** status **[of] and the classification assigned to** the ASF. The license applies only to **[those facilities designated] the designated facility.**

§ 551.82. Regular license.

(a) The Department will issue a regular **[1] 2** year license to an ASF when that ASF is in compliance with section 808 of the act (35 P. S. § 448.808) and is in full or substantial compliance with this subpart.

(b) As used in subsection (a) "substantial compliance" means:

(1) Deficiencies are, individually and in combined effect, of a minor nature so that neither the deficiencies **[nor] or** efforts toward their correction will **not** do one of the following:

* * * * *

(iii) Exceed the assigned classification of the ASF.

* * * * *

§ 551.83. Provisional license.

* * * * *

[(d) A provisional license will not be issued to services or facilities, or parts of facilities, which are subject to Certificate of Need review, if the review has not been completed.]

REFUSAL OR REVOCATION

§ 551.91. Grounds.

(a) The Department may refuse to issue a license for **[any] one or more** of the following reasons:

* * * * *

[(5) A Certificate of Need, if necessary, has not been issued.]

(b) The Department may refuse to renew a license, or may suspend or revoke or limit a license for all or a portion of an ASF, or for a particular service offered by an ASF, or may suspend admissions for any of the following reasons:

* * * * *

(10) Providing services exceeding the scope of the classification assigned in the license.

[(c) Failure to obtain a Certificate of Need will necessitate a licensure modification to exclude the areas lacking certificate of need approval.]

§ 551.93. Notice.

(a) If the Department proposes to revoke, modify**, limit** or refuse to issue or renew a license or to issue a provisional license, or to suspend admissions or to levy a civil penalty against the ASF, it will give written notice to the ASF by certified mail.

(b) Written notice will specify the reasons for the proposed action of the Department and will notify the ASF of its right to a hearing. The order will specify the time within which a request of the ASF for a hearing shall be filed with the **[State Health Facility Hearing Board] Health Policy Board.**

HEARINGS

§ 551.111. Hearings relating to licensure.

Hearings relating to licensure, including the issuance of a provisional license, or the suspension of admissions, will be conducted by the **[State Health Facility Hearing] Health Policy** Board, 37 Pa. Code Chapter 197 (relating to practice and procedure).

[CIVIL RIGHTS]

§ 551.121. **[Principle] (Reserved).**

[An ASF shall comply with the Pennsylvania Human Relations Act (43 P. S. §§ 951—963) and 16 Pa. Code Part II, Subpart A (relating to Human Relations Commission).]

§ 551.122. **[Civil rights compliance] (Reserved).**

[Civil rights compliance shall be a condition required for the issuance of a license. The Department may make on-site visits to verify the civil rights compliance status of the ASF.]

§ 551.123. **[Civil rights compliance records] (Reserved).**

[The following records shall be maintained to indicate that no person is excluded from participation in, is denied the benefits of, or is otherwise subjected to discrimination in the provision of care or services on the ground of age, race, creed, color, sex, national origin, religion, handicap or disability.

(1) A signed and dated copy of the policies of the ASF pertaining to the admission of patients and visitors. The date the policies were adopted shall also be indicated. The policies shall set forth in clear terms nondiscriminatory practices with regard to age, race, creed, color, religion, national origin, sex, handicap or disability.

(2) Other records or reports as may be required by the Department, to determine compliance with the Pennsylvania Human Relations Act (43 P. S. §§ 951—963).]

CHAPTER 553. OWNERSHIP, GOVERNANCE AND MANAGEMENT

GOVERNING BODY

§ 553.2. Ownership.

(a) The owner of the ASF may be an individual, partnership, association, a corporation or a combination thereof. **[The following rules apply to ASFs according to the mode of ownership:]**

[(1) *Individual ownership.*] (b) A complete list of the names and addresses of owners **[and of the persons in charge] , directors, officers and managers** shall be submitted with the application. **[When a sole owner of an ASF dies, the executor or administrator of the estate may apply for, and the Department may, after review, approve the transfer of the license for the ASF.**

(2) *Partnerships.* A complete list of names and addresses of the persons in charge and partners shall be submitted with the application. If a license is issued to a partnership and one or more of the partners dies, the executor or administrator of the deceased's estate, together with the surviving partners may apply for a license. After review, the Department may transfer the license.

(3) *Association or corporation.* A complete list of names and addresses of the officers and directors, of the corporate owner and of the parent corporation, if applicable, and of the persons in charge, who are responsible for the management of the ASF, shall be submitted with the application.

(4) *Stockholders with 5% ownership interest.* A facility shall list persons who have a direct or indirect ownership interest of 5% or more in the ASF, including, for example, stockholders.

(b) The Department shall be notified in writing within 30 days after a change has taken place in

the officers, directors, stockholders with 5.0% or more ownership interest or persons in charge of an ASF.]

(c) **[The Department shall be notified in writing at least 90 days before a change in ownership or the form of ownership or name of the facility takes place. The license is transferable upon approval by the Department]** Owners shall be considered any person who has a direct or indirect equity interest in the facility of 5% or more, including, shareholders and partners.

* * * * *

§ 553.3. Governing body responsibilities.

Governing body responsibilities include**[, but are not limited to]**:

* * * * *

(8) Establishing personnel policies and practices which adequately support sound patient care to include**[, but not be limited to,]** the following:

(i) Require the employment of personnel with qualifications commensurate with a job's responsibilities and authority, including appropriate licensure and certification.

[(i)] (ii) ***

[(ii)] (iii) * * *

[(iii) An employe shall be determined to be physically able to perform duties. Reasonable precautions shall be taken to assure the absence of detectable active communicable disease.]

(iv) Compliance with Occupational Safety and Health Administration (OSHA) Universal Precautions for prevention of transmission of diseases.

[(iv)] (v) ***

(vi) Compliance with Federal and State regulations including, The Americans with Disabilities Act of 1990 (42 U.S.C.A. §§ 12101—12213), civil rights and OSHA regulations.

* * * * *

(13) Approving major contracts or arrangements affecting the medical care provided under its auspices, including, **[but not limited to,] those concerning:**

(i) The employment **[of practitioners] for contractual arrangements with practitioners and others providing direct patient care.**

(ii) The provision of **all treatment related services including,** radiology, medical laboratory, pathology**, anesthesia** and pharmaceutical services.

(iii) The provision of care by other health care organizations**[, such as hospitals under § 555.24(d)—(f) (relating to post-operative care)].**

* * * * *

(16) Assuring that at least one **medical** professional **[working staff person]** in the **[surgical suite] facility** is **[certified] currently and** on an ongoing basis **certified** in advanced cardiac life support**, or its successor.**

(17) Assuring that all ASF personnel wear identification tags which include the person's name and professional designation.

§ 553.4. Other functions.

* * * * *

(c) If **[a majority of its members are practitioners,] the governing body is comprised of two or more members, and if the majority of those members are practitioners,** the governing body, either directly or by delegation, shall make—based on evidence of the education, training and current competence **[of the practitioners]**—initial appointments, reappointments and assignment or curtailment of clinical privileges **of the practitioners.**

(d) If **the governing body is comprised of only one member, or if** a majority of the members of the governing body are not practitioners, the ASF bylaws or similar rules and regulations shall specify a procedure for establishing medical review by practitioners for the purpose of recommending to the governing body for its approval—based on evidence of the education, training and current competence **[of the practitioner]**—initial appointments, reappointments and assignment or curtailment of clinical privileges **of the practitioners.**

* * * * *

(g) The governing body shall ensure that **[the following disclosure requirements are met:] the licensee provides to the Department, the documents under § 551.53 (relating to presurvey preparation).**

[(1) The licensee provides to the appropriate health systems agency information that the health systems agency is required to collect under section 1512(b) of the National Health Planning and Resources Development Act (42 U.S.C.A. § 3001-1(b)).

(2) The licensee makes available to the public and the Department upon request the licensee's current reimbursement under Blue Shield, Blue Cross, Medical Assistance, Medicare and other third-party payment arrangements for a service, as well as the average usual and customary charge for a service to noninsured private pay patients.]

(h) The governing body shall appoint a medical director who shall be board certified by an American Board of Medical Specialties recognized board or the dental, podiatric or osteopathic equivalent.

ADMISSION, TRANSFER AND DISCHARGE

§ 553.21. Principle.

* * * * *

(d) A patient shall be discharged only with appropriate discharge instructions under § 555.24 (relating to postoperative care).

§ 553.22. Admission criteria.

The governing body, with the advice of and in conjunction with the medical staff, shall establish medical criteria for admissions under § 555.22(a) (relating to preoperative care). **Medical criteria shall be congruent with the assigned ASF class level stated on the facility license.**

§ 553.25. Discharge criteria.

A patient may only be discharged from an ASF if the following physical status criteria are met:

(1) *Vital signs.* Blood pressure, heart rate, temperature and respiratory rate are within the normal range for the patient's age or at preoperative levels for that patient.

(2) *Activity.* The patient has regained preoperative mobility without assistance or syncope, or function at his usual level considering limitations imposed by the surgical procedure.

(3) *Mental status.* The patient is awake, alert or functions at his preoperative mental status.

(4) *Pain.* The patient's pain can be effectively controlled with medication.

(5) *Bleeding.* Bleeding is controlled and consistent with that expected from the surgical procedure.

(6) *Nausea/vomiting.* Minimal nausea or vomiting is controlled and consistent with that expected from the surgical procedure.

MANAGEMENT AND ADMINISTRATION OF OPERATIONS

§ 553.31. Administrative responsibilities.

* * * * *

(b) Administrative policies, procedures and controls shall be established**, documented** and implemented to assure the orderly and efficient management of the ASF.

CHAPTER 555. MEDICAL STAFF

MEDICAL STAFF

§ 555.3. Requirements for membership and privileges.

* * * * *

(b) Privileges granted shall reflect the results of peer review or utilization review programs, or both, specific to ambulatory surgery.

[(b)] (c) ***

[(c)] (d) ***

(1) A written record of the application, which **[include] includes** the scope of privileges sought and granted. **The delineation "clinical privileges" shall address the administration of anesthesia.**

* * * * *

[(d)] (e) ***

(f) The governing body shall request and consider reports from the National Practitioner Data Bank on each practitioner who requests privileges.

§ 555.4. Clinical activities and duties of physician assistants and nurse practitioners.

* * * * *

(b) Physician assistants shall perform within the limits established by the medical staff and consistent with the Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.45). Nurse practitioners shall perform within the limits established by the medical staff and consistent with the Professional Nursing Law (63 P. S. §§ 211—225.5) **and the joint regulations of the Boards of Medicine and Nursing.**

* * * * *

MEDICAL ORDERS

§ 555.12. Oral orders.

[Orders given orally for drugs and biologicals shall be followed by a written order, signed by the prescribing practitioner, within 24 hours of the order] Oral orders for medication or treatment shall be accepted only under urgent circumstances when it is impractical for the orders to be given in written manner by the responsible practitioner. Oral orders shall be administered in accordance with § 555.13 (relating to administration of drugs) only by personnel qualified according to medical staff bylaws or rules, who shall document the orders in the proper place in the medical record of the patient. The order shall include the date, time and full signature of the person taking the order and shall be countersigned by a practitioner within 24 hours of the order. If the practitioner is not the attending physician, the practitioner must be authorized by the attending physician and shall be knowledgeable about the patient's condition.

§ 555.13. Administration of drugs.

Drugs shall be administered only upon the proper order of a practitioner acting within the scope of his license and authorized according to medical staff bylaws, rules and regulations. Drugs shall be administered directly by a practitioner qualified according to medical staff bylaws, rules and regulations or by a professional nurse or by a licensed practical nurse with pharmacy training. Further policies on the administration of drugs shall be established by the medical staff in conjunction with pharmaceutical services or personnel.

SURGICAL SERVICES

§ 555.21. Surgical procedures.

Procedures performed in the ASF are limited to procedures that are approved by the governing body, on an annual basis, upon the recommendation of the medical staff **and congruent with ASF classification as stated on their ASF license.**

§ 555.22. Preoperative care.

(a) Pertinent medical histories and physical examinations, and supplemental information regarding drug sensitivities shall be documented the day of surgery or one of the following:

(1) If medical evaluation, examination and referral are made from a private **[physician's] practitioner's** office, hospital or clinic, pertinent records thereof shall be available and made part of the patient's clinical record at the time the patient is registered and admitted to the ASF. This information is considered valid only if the evaluation was performed no more than **[7] 30** days prior to date of surgery.

[(2) If it is a referred evaluation, a physician] A practitioner shall examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. **The information shall be clearly documented in the medical record.**

(b) A written statement indicating informed consent, obtained by the **[surgeon] practitioner**, and signed by the patient, or responsible person, for the performance of the specific **[surgical procedure] procedures** shall be procured and made part of the patient's clinical record. **It shall contain a statement which evidences the appropriateness of the proposed surgery, as well as any alternative treatments discussed with the pa-**

tient. It shall also identify any practitioner who shall participate in the surgery.

(c) Written instructions for **[pre-operative] preoperative** procedures, which have been approved by the medical staff, shall be given to the patient or responsible person, and shall include **[, but not be limited to]**:

* * * * *

(5) **[The requirement that, upon] Upon** discharge of a patient who has received sedation or general anesthesia, a responsible person shall be available to escort the patient home. **[A medical decision shall be made as to whether another patient needs a responsible person to escort him home.]**

(d) **[Pre-operative] Preoperative** diagnostic studies, if performed, shall be evaluated, **annotated, signed** and entered into the patient's medical record before surgery.

(e) **[After the patient has been placed on the operating table] Prior to the administration of anesthesia,** it is the responsibility of the primary operating surgeon and the person administering anesthesia to properly identify the patient and to document this identification in the patient's medical record. This procedure shall be in written policies designating the mechanism to be used to identify each surgical patient.

§ 555.23. Operative care.

(a) Approved surgical procedures shall be performed only by a qualified physician, dentist or podiatrist within the limits of his defined specific practice privileges. Physician assistants **and nurse practitioners** may be permitted to assist in the performance of surgical procedures in accordance with their legally authorized scope of practice and the policies and procedures of the ASF.

* * * * *

(e) The ASF shall have a written transfer agreement with a hospital which has emergency and surgical services available, **[or] and** physicians performing surgery in the ASF shall have admitting privileges at a hospital in close proximity to the ASF.

* * * * *

§ 555.24. **[Post-operative] Postoperative** care.

(a) The findings and techniques of an operation shall be accurately and completely written or dictated immediately after the procedure by the practitioner **medical staff member** who performed the operation. If a physician assistant **or nurse practitioner** performed part of the operation, **[he shall accurately record]** the findings and techniques of the procedure **shall be accurately recorded.** This description shall become a part of the patient's medical record.

(b) **[Patients who have had general anesthesia, or local anesthesia with sedation,] A patient who has received anesthesia** shall be observed in the facility by a registered nurse or a practitioner for a period of time which is sufficient to ensure that no immediate **[post-operative] postoperative** complications are present.

* * * * *

(d) **[An anesthesiologist or another physician qualified in resuscitative techniques] A medical professional certified in advanced cardiac life support** shall be present until patients operated on that day have been discharged **from the facility. If a patient receives general anesthesia or IV sedation, the anesthetist who provides the anesthesia or sedation shall remain present until that patient has been discharged from the facility.**

[(e) Patients who have received sedation or general anesthesia shall be examined by a physician prior to discharge, after recovery from anesthesia.]

[(f)] (e) ***

[(g)] (f) Protocols approved by the medical staff shall be established for instructing patients in self-care after surgery **[. Written] including written** instructions **which,** at a minimum, shall include the following:

* * * * *

(2) An explanation of prescribed drug regime **[. Directions] including directions** for use **[on the medical label are adequate to fulfill this requirement] of any medications.**

(3) The limitations and restrictions on activities of the patient**, if necessary.**

* * * * *

[(h)] (g) Patients shall be discharged only on the written signed order of a **[physician] practitioner.**

ANESTHESIA SERVICES

§ 555.31. Principle.

(a) Anesthesia services provided in the facility are limited to those techniques that are approved by the governing body upon the recommendation of qualified medical staff. They shall be limited to those techniques appropriate to the assigned classification per ASF license.

(b) The governing body **[or its designee shall determine the extent of anesthesia services and]** shall define the degree of supervision required and the scope of responsibilities delegated to anesthesiologists and nurse and dentist anesthetists, as well as the corresponding responsibilities of supervising physicians.

§ 555.32. Administration of anesthesia.

(a) Anesthetics shall be administered by anesthesiologists and **certified registered** nurse **anesthetists** and dentist anesthetists, **or qualified practitioners,** as defined in § 551.3 (relating to definitions).

(b) If a nonphysician administers the anesthesia, the anesthetist shall be under the medical direction of an anesthesiologist or a **qualified** physician **or dentist** who is present in the ASF.

(c) The Director of Anesthesia Services shall be responsible for designating the physician **or dentist** who will be responsible for the medical direction of the anesthetist.

§ 555.33. Anesthesia policies and procedures.

* * * * *

(b) In ASFs where there is no anesthesiologist, the governing body shall designate a qualified physician **or dentist** to function as the Director of Anesthesia Services, who shall be responsible for directing the anesthe-

sia services and establishing the general policies and procedures for the administration of anesthesia in the ASF which shall be approved by the governing body.

(c) Policies and procedures shall be developed for anesthesia services and shall include the following:

(1) Education, training and supervision of personnel.

(2) Responsibilities of nonphysician anesthetists.

(3) Responsibilities of supervising physicians or dentists.

[(b)] (d) Anesthesia procedures shall provide at least the following:

(1) A patient requiring anesthesia shall have a preanesthesia evaluation by a **[physician] qualified practitioner**, with appropriate documentation of pertinent information regarding the choice of anesthesia.

(2) A review **and documentation** shall be made of the condition of the patient immediately prior to induction of anesthesia, including pertinent laboratory findings, time of administration and dosage of pre-anesthesia medications.

* * * * *

(4) Following the procedure for which anesthesia was administered, the anesthetist **[or a designee]** shall remain with the patient as long as necessary to insure **[that the patient has recovered. Personnel] safe transport to the recovery area and shall advise personnel** responsible for **[post-anesthetic] postanesthetic** care **[shall be advised as to specific problems presented by] of** the condition of the patient.

* * * * *

(6) Intraoperative physiologic monitoring shall include the following at a minimum:

(i) The use of pulse oximeter.

(ii) The use of End Tidal CO2 monitoring during Endotracheal anesthesia.

(iii) The use of EKG monitoring.

(iv) The use of blood pressure monitoring.

(7) A patient may not receive general anesthesia unless one or more additional health care professionals besides the one performing the surgery, are present, one of whom is trained in the administration of anesthesia.

[(6)] (8) Before discharge from the ASF, a patient shall be evaluated for proper anesthesia recovery **by the person who administered the anesthesia, operating room surgeon, anesthesiologist or dentist.** Depending on the type of anesthesia and length of surgery, the **[post-operative] postoperative** check shall include at least the following:

* * * * *

(v) **[Patient color] Pulse oximeter.**

§ 555.35. Safety regulations.

(a) Appropriate precautions shall be taken to ensure the safe administration of anesthetic and other medical gas agents, in accordance with the latest edition of NFPA Code 56G, and other applicable NFPA Codes as required.

(b) The machines used for anesthesia shall have at least one annual function testing by technicians with appropriate training and a log of this testing and outcomes shall be maintained.

CHAPTER 557. QUALITY ASSURANCE **AND IMPROVEMENT**

§ 557.1. Policy.

The ASF, with active participation of the medical and nursing staff, shall conduct an ongoing quality assurance **and improvement** program designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems.

§ 557.2. The plan.

(a) The ASF shall have a written plan for the quality assurance **and improvement** program that describes the program's objectives, organization, scope and mechanisms for overseeing the effectiveness of monitoring, evaluation and problem solving activities.

(b) The written plan shall be endorsed by the governing body **[which is] and the medical director who are** responsible for establishment and direction of the program and which indicates the staff person responsible for implementation of the program.

(c) The plan shall emphasize the ongoing nature of the quality assurance program and the comprehensiveness of the scope of the program which shall include monitoring and evaluation of the following:

(1) Medical staff functions including:

(i) [Clinical] Peer-based review of clinical performance of individuals with clinical privileges.

* * * * *

(d) The plan shall **[define] include** participation of **[physicians] practitioners** and other health care personnel.

§ 557.3. The **quality assurance and improvement** program.

(a) The quality assurance program shall include monitoring and evaluation of data collected, based on defined criteria that reflect current knowledge and clinical experience and relate to the care provided by the service. **Sources of data include the medical records, incident reports, infection control records and patient complaints. The medical record shall contain sufficient data to support the diagnosis and determine that the procedures are appropriate to the diagnosis.**

(c) **[Sources of data shall include, but not be limited to, the medical records, incident reports, infection control records and patient complaints. The medical record shall contain sufficient data to support the diagnosis and determine that the procedures are appropriate to the diagnosis.] The frequency, severity and source of suspected problems or concerns are evaluated by practitioners and nurses.**

(d) **[Corrective actions and the results] Measures shall be implemented to resolve important problems or concerns identified. The results of these corrective measures** shall be monitored to assure

that the problem has been satisfactorily resolved. **[Actions] Measures** which may be taken include**[, but are not limited to]**:

* * * * *

§ 557.4. Quality **[Assurance Committee] assurance and improvement committee.**

(a) The committee shall consist of the following:

(1) A **[physician] practitioner** who is not an owner.

* * * * *

(c) Committee records of the activities shall include:

(1) Reports made to the governing **[authority] body.**

* * * * *

CHAPTER 559. NURSING SERVICES

§ 559.2. Director of nursing.

The director of nursing shall be **[an employe]** currently licensed as a registered nurse in this Commonwealth and be responsible and accountable to the person in charge of the ASF for:

* * * * *

§ 559.3. Nursing personnel.

(a) An adequate number of licensed and **[ancillary nursing] unlicensed** personnel shall be on duty to assure that staffing levels meet the total nursing needs of patients based on the number of patients in the facility and their individual nursing care needs.

(b) At least one registered nurse shall be in **[the facility] attendance** during the hours **[it is in operation, and available for emergency treatment] patients are present.** Nursing personnel shall be assigned to duties consistent with their training and experience.

(c) **[Persons employed and classified as registered] Registered** professional nurses or licensed practical nurses **practicing at an ASF** shall be licensed to practice in this Commonwealth. There shall be a procedure to verify the licensure status of the nurses.

CHAPTER 561. PHARMACEUTICAL SERVICES

GENERAL PROVISIONS

§ 561.1. Drugs and biologicals.

The ASF shall provide drugs and biologicals in a safe and effective manner to meet the needs of the patients **and to adequately support the organization's clinical capabilities commensurate with their licensed classification,** in accordance with accepted ethical and professional practice and applicable State and Federal law, including **[but not limited to]** the Pharmacy Act (63 P. S. §§ 390.1—390.13), 49 Pa. Code Chapter 27 (relating to State Board of Pharmacy), The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144) and Chapter 25 (relating to controlled substances, drugs, devices and cosmetics).

§ 561.2. Pharmaceutical service.

[A pharmacy operated by the ASF shall be supervised by a licensed pharmacist. If the ASF does not operate a licensed pharmacy, a practitioner shall be appointed in charge of the pharmaceutical service and shall be responsible for maintaining an adequate supply of drugs. Practitioners may dispense drugs only to the patients who are in their care].

(a) Pharmaceutical services shall be supervised by a physician or dentist who is qualified to assume professional, organization and administrative responsibility for the quality of services rendered. Practitioners may dispense drugs only to the patients who are in their care.

(b) A pharmacy owned and operated by the ASF shall be supervised by a licensed pharmacist.

(c) Contracted pharmaceutical services shall be provided in accordance with the same ethical and professional practices and legal requirements that would be required if these services are provided directly by the organization.

PHARMACEUTICAL FACILITIES

§ 561.13. Storage.

The area in the ASF where drugs are stored shall be periodically checked by the responsible pharmacist or practitioner **and proper logs maintained.**

POLICIES AND PROCEDURES

§ 561.21. Principle.

The scope of the pharmaceutical service shall be consistent with the medication needs of the patients **and congruent with the licensed classification of the ASF.** The pharmaceutical policies shall include a program for the control and accountability of drug products throughout the ASF. **If drugs are used for an experimental purpose, the use thereof shall be approved by an Institutional Review Board (IRB) or an IRB shall waive review and proper consent for shall be obtained.**

§ 561.23. Use of **[dangerous drugs] controlled substances and other drugs.**

There shall be policies and procedures developed and approved by the medical staff which establish controls governing the use of **[dangerous drugs] controlled substances and other drugs, including sedatives, anticoagulants, antibiotics, oxytoxics and corticosteroids. Policies shall be established regarding written orders for appropriate dosage of all drugs.**

[(1) Dangerous drugs include controlled substances, sedatives, anticoagulants, antibiotics, oxytoxics and corticosteroids.

(2) Policies shall be established regarding written orders for appropriate dosage of dangerous drugs.]

CHAPTER 563. MEDICAL RECORDS

§ 563.8. Automation **or computerization** of medical records.

Nothing in this subpart **[may be construed to prohibit] prohibits** the use of automation **or computerization** in the medical records service, if the provisions in this chapter are met and the information is readily available for use in patient care. Innovations in medical record formats, compilation and data retrieval are specifically encouraged.

§ 563.12. Form and content of record.

The ASF shall maintain a **separate** medical record for each patient. Every record shall be accurate, legible and promptly completed. **Patient medical records shall be**

constructed to stand alone and be easily identified as ASF records. Medical records shall include at least the following:

* * * * *

(2) **[Significant] Pertinent** medical history and results of physical examination.

(3) **[Pre-operative] Preoperative** diagnostic studies—entered before surgery—if performed.

(4) **[Allergies or abnormal] The presence or absence of allergies and untoward** drug reactions **recorded in a prominent and uniform location in all patient charts on a current basis.**

* * * * *

(9) **[Disposition] Written and verbal disposition** recommendations and instructions given to the patient.

* * * * *

§ 563.13. Entries.

* * * * *

(e) Necessary documentation on the patient's medical record as specified in § 563.12 (relating to form and content of record) shall be completed **[on the day of surgery] within 24 hours.**

CHAPTER 565. LABORATORY AND RADIOLOGY SERVICES

RADIOLOGY SERVICES

§ 565.12. Radiology service policy.

* * * * *

(b) Applicable provisions of the Department of Environmental **[Resources] Protection regulations at** 25 Pa. Code Chapters 221—233 and 25 Pa. Code §§ 235.1 and 235.11—235.15, and the United States Nuclear Regulatory Commission **regulations at**, 10 CFR Chapter I (relating to Nuclear Regulatory Commission) shall be met by the ASF**, or its contracted radiology service.**

§ 565.13. Organization and staffing.

* * * * *

(b) Sufficient adequately trained**, certified** and experienced personnel shall be available to supervise and conduct the work of the radiology services.

§ 565.15. Records.

Authenticated, dated reports of services performed shall be made a part of the patient's medical record**[, in a timely manner] within 24 hours.**

CHAPTER 567. ENVIRONMENTAL SERVICES

INFECTION CONTROL

§ 567.1. Principle.

The ASF shall have a sanitary environment, properly constructed, equipped and maintained **to protect surgical patients and ASF personnel from cross-infection and** to protect the health and safety of patients.

§ 567.3. Policies and procedures.

(a) Only authorized persons, who are properly attired, shall be allowed in the surgical area.

(b) Current written policies and procedures to assure definite and valid infection control shall include, **[but not be limited to,] the following:**

* * * * *

(3) Sterilization and disinfection**, including suitable equipment for routine and rapid sterilization.**

(4) Sterilized materials are packaged, labeled and dated in a consistent manner.

[(4)] (5) ***

(6) Cleaning of surgical suites prior to each operation.

[(5)] (7) Clean and soiled **linen and** utility rooms.

[(6)] (8) ***

[(7)] (9) ***

[(8)] (10) Isolation **[standards] protocols.**

[(9) Strict and protective isolation of appropriate patients.]

[(10)] (11) ***

[(11)] (12) ***

[(12)] (13) ***

[(13)] (14) ***

[(14)] (15) ***

[(15)] (16) ***

[(16)] (17) ***

SUPPLIES

§ 567.11. Operating suite equipment.

The operating suite shall be adequately equipped **with age appropriate equipment** for the types of procedures to be performed and the recovery area shall be adequately equipped for the proper care of **[post anesthesia] postanesthesia** recovery of surgical patients. The following equipment shall be available in the operating suite and recovery area.

* * * * *

(7) Tracheostomy **[set]** and **necessary pulmonary reexpansion supplies.**

[(8) Thoracotomy set.]

HOUSEKEEPING SERVICES

§ 567.32. Policies and procedures.

Procedures shall be developed for cleaning and care of equipment, for establishment of cleaning schedules, for cleaning methods and for proper use of cleaning supplies and disposal of waste. **Suitable equipment shall be provided to facilitate cleaning.**

CHAPTER 569. FIRE AND SAFETY SERVICES

INTERNAL DISASTER PLAN

§ 569.11. Firefighting service.

The person in charge of the ASF shall establish a workable plan with the nearest fire department for firefighting service. The ASF shall provide the fire department with a current floor plan of the building showing the location of **[fire fighting] firefighting** equipment, exits, patient rooms, storage places of flammable and

explosive **[gases] substances** and other information that the fire department requires or as may be necessary.

EVACUATION DRILLS

§ 569.21. Fire drills.

* * * * *

(b) **[If multiple shifts are employed, these drills shall be alternated to:] The CEO shall:**

(1) Ensure that **all** personnel are trained to perform assigned duties.

(2) Ensure that **all** personnel are familiar with the use and operation of the **[fire-fighting] firefighting** equipment in the ASF.

* * * * *

[(c) At least one ASF fire drill each year should be supervised by the local fire department.

(d)] (c) ***

[(e)] (d) ***

SAFETY PRECAUTIONS

§ 569.33. Smoking.

[(a) The governing body shall adopt written rules governing smoking within the ASF, which shall be made known to ASF personnel, patients and the public.

(b) These rules shall include at least the following:

(1) Smoking shall be prohibited in an area where flammable liquid, combustible gas or oxygen is being used or stored, and in any other hazardous area of the ASF. The areas shall be posted with no smoking signs.

(2) Patients classified as not mentally or physically responsible for their actions shall be prohibited from smoking unless constant supervision is provided.]

Smoking is not permitted in an ASF.

§ 569.35. General safety precautions.

The following safety precautions shall be met:

* * * * *

(7) Only nonflammable agents may be present in a surgical suite.

CHAPTER 571. CONSTRUCTION STANDARDS

GENERAL PROVISIONS

§ 571.2. Modifications to HHS requirements.

[The following provisions modify and supplement the HHS Requirements cited in § 571.1 (relating to minimum standards):

(1) An item in the HHS Requirements which refers to the]

(a) Life Safety Code **[shall meet] means** the standard as defined in § 569.2 (relating to fire safety standards).

[(2) A design of an ASF which constitutes a single enclosed cubicle or room for patients shall be a minimum of 100 square feet per cubicle or room, exclusive of equipment, toilet room, vestibule and furnishings.

(3)] (b) ***

[(4)] (c) ***

[(5) Modify Section 9.5 to read as follows:

(N) Elevators.

(1)] (d) In **[multi-story] multistory** buildings, where the ASF may be provided on floors other than at grade level, at least one hospital type elevator shall be provided.

[(2)] (e) Elevators shall conform to **[Section 7.28 of the]** "HHS Requirements"**[.] and**

[(3) In Section 7.28 of the HHS Requirements, the reference made to ANSI A-17.1 is] the latest edition of the "American National Standard Safety Code for Elevators, Dumbwaiters, Escalators and Moving Stairs."

(f) The Americans with Disabilities Act of 1990 (ADA) (42 U.S.C.A. §§ 12101—12213).

SUBMISSION OF PLANS

§ 571.13. **[Approval of plans] (Reserved).**

[For practical reasons, construction drawing should not be submitted for final approval to the Division of Safety Inspection until a Certificate of Need (CON) has been obtained where necessary. Final approval of construction drawings will not be construed as a CON approval. See § 551.31 (relating to Certificate of Need).]

CHAPTER 573. **[STATEMENT OF POLICY] (Reserved)**

§ 573.1. **[Criteria for ambulatory surgical facility] (Reserved).**

[(a) A facility is considered an ASF if the surgical procedures performed are all of the following:

(1) Commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASF.

(2) Not of the type that are commonly performed, or that may be safely performed in physicians' offices without a separate operating room or suite that is dedicated to the performance of surgery for a set period of time each week.

(3) Limited to those requiring a dedicated operating room—or suite as described in paragraph (2)—and generally requiring a post-operative recovery room or a short term (not overnight) convalescent room.

(b) A facility performing surgical procedures which appear on the list, published by the United States Department of Health and Human Services, of procedures which are reimbursed under Medicare at 47 Fed. Reg. 34099 (August 5, 1982) (relating to Medicare Program, List of Covered Surgical Procedures for Certain Ambulatory Surgical Services) or procedures which appear on the list, to be published by the Department of Public Welfare, of procedures which are reimbursed under Medical Assistance, may be considered an ASF, if the facility meets other criteria in this section.

(c) A physician's office may be considered an ASF if the following exist:

(1) The office has an area dedicated to performing surgery for a set period of time each week.

(2) The procedures performed are those described in this section.]

§ 573.2. **[Criteria for ambulatory surgical procedures] (Reserved).**

[(a) Surgical procedures are limited to those that do not generally exceed:

(1) A total of 90 minutes operating time.

(2) A total of 4 hours recovery or convalescent time.

(b) If the surgical procedures require anesthesia, the anesthesia shall be either of the following:

(1) Local or regional anesthesia.

(2) General anesthesia of 90 minutes or less duration.

(c) Surgical procedures may not be of a type that:

(1) Generally result in extensive blood loss.

(2) Require major or prolonged invasion of body cavities.

(3) Directly involve major blood vessels.

(4) Are generally emergency or life threatening in nature.]

[Pa.B. Doc. No. 97-1177. Filed for public inspection July 18, 1997, 9:00 a.m.]