

Subpart F. AMBULATORY SURGICAL FACILITIES

| Chap. | | Sec. |
|-------|--|-------|
| 551. | GENERAL INFORMATION..... | 551.1 |
| 553. | OWNERSHIP, GOVERNANCE AND MANAGEMENT | 553.1 |
| 555. | MEDICAL STAFF | 555.1 |
| 557. | QUALITY ASSURANCE AND IMPROVEMENT..... | 557.1 |
| 559. | NURSING SERVICES | 559.1 |
| 561. | PHARMACEUTICAL SERVICES..... | 561.1 |
| 563. | MEDICAL RECORDS | 563.1 |
| 565. | LABORATORY AND RADIOLOGY SERVICES | 565.1 |
| 567. | ENVIRONMENTAL SERVICES | 567.1 |
| 569. | FIRE AND SAFETY SERVICES | 569.1 |
| 571. | CONSTRUCTION STANDARDS..... | 571.1 |
| 573. | [Reserved]..... | 573.1 |

Authority

The provisions of this Subpart F issued under Chapter 8 of the Health Care Facilities Act (35 P. S. §§ 448.801a—448.820), specifically sections 448.801a and 448.803; and section 2102(a) and (g) of The Administrative Code of 1929 (71 P. S. § 532(a) and (g)), unless otherwise noted.

Source

The provisions of this Subpart F adopted January 23, 1987, effective March 25, 1987, 17 Pa.B. 376, unless otherwise noted.

CHAPTER 551. GENERAL INFORMATION**GENERAL PROVISIONS**

| Sec. | |
|----------------|------------------------|
| 551.1. | Legal base. |
| 551.2. | Affected institutions. |
| 551.3. | Definitions. |
| 551.11—551.13. | [Reserved]. |

INTERPRETATIONS

| | |
|---------|---|
| 551.21. | Criteria for ambulatory surgery. |
| 551.22. | Criteria for performance of ambulatory surgery on pediatric patients. |

APPLICATION AND AUTHORIZATION TO OPERATE AN ASF

| | |
|---------|-------------|
| 551.31. | Licensure. |
| 551.32. | [Reserved]. |

551-1

(282203) No. 324 Nov. 01

- 551.33. Survey.
- 551.34. Licensure process.

CONTINUING OPERATIONS

- 551.41. Policy.
- 551.42. [Reserved].
- 551.43. Void license.
- 551.44. Display of license.
- 551.45. Licensure information/application.

INSPECTION AND SURVEY ACTIVITIES

- 551.51. Policy.
- 551.52. ASF responsibilities.
- 551.53. Presurvey preparation.
- 551.54. Access by the Department.
- 551.55. Site survey coverage.
- 551.56. Documentation.

POST SURVEY PROCEDURES

- 551.61. Policy.
- 551.62. Compliance directive.
- 551.63. Submission of plan of correction.
- 551.64. Content of plan of correction.
- 551.65. Public inspection of compliance documents.

CONTINUING SURVEILLANCE

- 551.71. Unannounced surveys.

ISSUANCE OF LICENSE

- 551.81. Principle.
- 551.82. Regular license.
- 551.83. Provisional license.

REFUSAL OR REVOCATION

- 551.91. Grounds.
- 551.92. Modification of license.
- 551.93. Notice.

CORRECTION OF DEFICIENCY

- 551.101. Policy.

HEARINGS

- 551.111. Hearings relating to licensure.
- 551.121—551.123. [Reserved].

Authority

The provisions of this Chapter 551 issued under Chapter 8 of the Health Care Facilities Act (35 P. S. §§ 448.801a—448.820), specifically sections 448.801a and 448.803; and section 2102(a) and (g) of The Administrative Code of 1929 (71 P. S. § 532(a) and (g)), unless otherwise noted.

Source

The provisions of this Chapter 551 adopted January 23, 1987, effective March 25, 1987, 17 Pa.B. 376, unless otherwise noted.

GENERAL PROVISIONS**§ 551.1. Legal base.**

(a) This subpart is promulgated by the Department under Chapter 8 of the act (35 P. S. §§ 448.801—448.820), and section 2102(a) and (g) of The Administrative Code of 1929 (71 P. S. § 532(a) and (g)).

(b) The Department has the duty to promulgate regulations necessary to implement Chapter 8 of the act and to assure that its regulations and the act are enforced.

(c) The purpose of this subpart is to protect and promote the public health and welfare through the establishment and enforcement of regulations setting minimum standards in the construction, maintenance and operation of ASFs. The standards are intended to assure safe, adequate and efficient facilities and services, and to promote the health, safety and adequate care of the patients of the facilities. It is also the purpose of this subpart to assure quality health care through appropriate and nonduplicative review and inspection, with regard to the protection of the health and rights of privacy of the patients and without unreasonably interfering with the operation of the ambulatory surgical facility.

Source

The provisions of this § 551.1 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial pages (251633) to (251634).

§ 551.2. Affected institutions.

(a) This subpart applies to ASFs, 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.

(b) 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 ASFs.

Source

The provisions of this § 551.2 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251634).

§ 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—

(i) A facility or portion thereof not located upon the premises of a hospital which provides specialty or multispecialty outpatient surgical treatment.

(ii) This does not include individual or group practice offices of private physicians or dentists, unless the offices have a distinct part used solely for outpatient surgical treatment on a regular and organized basis. For the purposes of this provision, outpatient surgical treatment means treatment to patients who do not require hospitalization, but who require constant medical supervision following the surgical procedure performed.

Act—The Health Care Facilities Act (35 P. S. §§ 448.101—448.904).

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 route, 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.

Anesthesiologist—A physician licensed by the State Board of Medicine under the Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.45) who has completed an accredited residency training program in anesthesia.

Anesthetist—A generic term used to identify anesthesiologists, nurse anesthetists or dentist anesthetists.

Authenticate—To verify authorship for example by written signature, identifiable initials or computer key.

Authorized person to administer drugs and medications—In an ASF, the term includes the following:

(i) Persons who are currently licensed or certified by the Bureau of Professional and Occupational Affairs, Department of State, and whose scope of practice includes the administration of drugs.

(ii) Registered nurses who are currently licensed by the Bureau of Professional and Occupational Affairs, Department of State.

(iii) Practical nurses who have successfully passed the State Board of Nursing examination.

(iv) Practical nurses licensed by waiver in this Commonwealth who have successfully passed the United States Public Health Service Proficiency Examination.

(v) Practical nurses licensed by waiver in this Commonwealth who have successfully passed a medication course approved by the State Board of Nursing.

(vi) Student nurses of approved nursing programs who are functioning under the direct supervision of a member of the school faculty who is present in the facility.

(vii) Recent graduates of approved nursing programs who are functioning under the direct supervision of a professional nurse who is present in the facility and who possesses valid temporary practice permits. The permits shall expire if the holders of the permits fail the licensing examinations.

(viii) Physician assistants and registered nurse practitioners who are certified by the Bureau of Professional and Occupational Affairs.

Board certified—A physician licensed to practice medicine or osteopathic medicine in this Commonwealth who has successfully passed an examination and has maintained certification in the relevant specialty or subspecialty area, or both, recognized by one of the following groups:

(i) The American Board of Medical Specialties.

(ii) The American Osteopathic Association.

(iii) The foreign equivalent of either group listed in subparagraph (i) or (ii).

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 and during which reflexes are not obtunded.

(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 and where patients are limited to physical status (PS) PS-1, PS-2 or PS-3 patients.

Classification system—A process used to identify three levels of ASFs (A, B and C) based on the procedure, patient status and anesthesia used.

Clinical privileges—Permission to independently render medical care in the ASF which is granted by the governing body under § 553.4(c) and (d) (relating to other functions).

Compliance directive—A directive issued by the Department, citing deficiencies which have come to the attention of the Department through the survey process, or by onsite inspection and directing the ASF to take corrective action as the Department directs or to submit a plan of correction.

Deficiency—A condition which exists contrary to, in violation of, or in non-compliance with this subpart.

Dentist—A person licensed by the State Board of Dentistry under The Dental Law (63 P. S. §§ 120—130b).

Dentist anesthetist—A person licensed by the State Board of Dentistry who has met the requirements for providing anesthesia care services in accordance with the regulations of that Board.

Department—The Department of Health of the Commonwealth.

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.

Drug administration—An act in which a single dose of an identified drug is given to a patient.

Drug dispensing—The issuance of one or more doses of a prescribed medication under §§ 25.41—25.101.

Facilities—Buildings, equipment and supplies necessary for implementation of ASF services.

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.

Graduate nurse—A graduate of an approved program of professional nursing practicing the profession under The Professional Nursing Law (63 P. S. §§ 221—225).

Licensed practical nurse—A person licensed to practice practical nursing under The Practical Nurse Law (63 P. S. §§ 651—667).

Medical—Pertaining to the practice of medicine, osteopathy, podiatry or dentistry.

Medical staff—The organized group of practitioners who has been appointed by the governing body of the ASF to function under §§ 555.1—555.3 (relating to principle; medical staff membership; and requirements for membership and privileges).

NFPA—The National Fire Protection Association.

New construction—New buildings, additions to existing buildings, conversion of existing buildings or portions thereof or portions of buildings undergoing alterations other than repair.

Nurse anesthetist—A registered nurse licensed by the State Board of Nursing providing anesthesia care in accordance with the requirements of the regulations of that Board.

Nurse practitioner—A person who has been certified by the State Board of Nursing and the State Board of Medicine to perform acts of medical diagnosis or prescription of medical, therapeutic or corrective measure in collaboration with and under the direction of a physician licensed to practice medicine in this Commonwealth, under the Medical Practice Act of 1985 and The Professional Nursing Law.

Nursing services—Patient care aspects of nursing that are performed by registered nurses or by licensed practical nurses and ancillary nursing personnel under the direct supervision of a registered nurse.

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.

Outpatient surgical treatment—Surgical procedures performed upon patients who do not require hospitalization but who require constant medical supervision following the surgical procedure performed.

Person in charge—The individual appointed by the governing body to act in its behalf in the overall management of the ASF.

Pharmacist—A person licensed to engage in the practice of pharmacy in this Commonwealth under The Pharmacy Act (63 P. S. §§ 390.1—390.13).

Pharmacy—A place where the practice of pharmacy is conducted under The Pharmacy Act.

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.

Physician—A doctor of medicine or osteopathy who holds a current and valid license to practice in this Commonwealth.

Physician assistant—A person who has been certified by the State Board of Medicine or the State Board of Osteopathic Medical Examiners to assist a physician or group of physicians under The Medical Practice Act of 1985 or The Osteopathic Medical Practice Act (63 P. S. §§ 271.1—271.18).

Podiatrist—A person licensed by the State Board of Podiatry Examiners to practice podiatry under The Podiatry Act of 1956 (63 P. S. §§ 42.1—42.21a).

Practitioner—A licensed physician, dentist or podiatrist.

Preboard certification status—A physician licensed to practice medicine or osteopathic medicine in this Commonwealth who has completed the requirements necessary to take a certification examination offered by a specialty board recognized by the American Board of Medical Specialties, the American Osteopathic Association or the foreign equivalent of either group, and who has been eligible to take the examination for no longer than 3 years.

Premises of a hospital—Buildings, equipment and supplies licensed as a hospital to provide inpatient and outpatient services.

Professional nurse/registered nurse—A person licensed to practice professional nursing under The Professional Nursing Law.

Provider—An individual; a trust or estate; a partnership; a corporation including associations, joint stock companies, health maintenance organizations, professional health service plan corporations and insurance companies; the Commonwealth or a political subdivision or instrumentality thereof, including a municipal corporation or authority that operates an ambulatory surgical facility; and any other legal entity that operates an ambulatory surgical facility.

Secretary—The Secretary of the Department.

Surgery—The branch of medicine that diagnoses and treats diseases, disorders, malformations and injuries wholly or partially by operative procedures.

Survey—The process of evaluation or reevaluation of the compliance of an ASF with this subpart.

Source

The provisions of this § 551.3 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial pages (251634) to (251637).

Cross References

This section cited in 28 Pa. Code § 555.32 (relating to administration of anesthesia).

§§ 551.11—551.13. [Reserved].

Source

The provisions of these §§ 551.11—551.13 reserved October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251637).

INTERPRETATIONS

§ 551.21. Criteria for ambulatory surgery.

- (a) Ambulatory surgical procedures are limited to those that do not exceed:
 - (1) A total of 4 hours of operating time.
 - (2) A total of 4 hours directly supervised recovery.
- (b) The time limits in subsection (a) may be exceeded only if the patient's condition demands care or recovery beyond the 4-hour limit and the need for the additional time could not have been anticipated prior to surgery.
- (c) 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.
- (d) Surgical procedures may not be of a type that:
 - (1) Are 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 emergency or life threatening in nature, unless no hospital is available for the procedure and the need for the surgery could not have been anticipated.

(e) In obtaining informed consent, the practitioner performing the surgery is responsible for disclosure of:

(1) The risks, benefits and alternatives associated with the anesthesia which will be administered.

(2) The risks, benefits and alternatives associated with the procedure which will be performed.

(3) The comparative risks, benefits and alternatives associated with performing the procedure in the ASF instead of in a hospital.

(f) The Department may issue interpretations of this subpart, which apply to the question of whether the performance of certain surgical procedures will require licensure as an ASF.

(g) Interpretations issued under this section do not constitute an exercise of delegated legislative power by the Department and will expressly be subject to modification by the Department in an adjudicative proceeding based upon the particular facts and circumstances relevant to a proceeding. Interpretations are not intended to be legally enforceable against a person by the Department. In issuing an adjudication, the Department may consider, but is not bound by, interpretations.

(h) Interpretations adopted by the Department under this section will be reviewed for form and legality under the Commonwealth Attorneys Act (71 P. S. §§ 732.101—732-506) and, upon approval, will be submitted to the Legislative Reference Bureau for recommended publication in the *Pennsylvania Bulletin* and *Pennsylvania Code* as a statement of policy of the Department as a part of this subpart.

(Editor's Note: Under section 2 of the act of July 11, 2022 (P.L. 1575, No. 87), the provisions of § 551.21 are abrogated insofar as they are inconsistent with section 822 of the Health Care Facilities Act (35 P.S. § 448.822)).

Source

The provisions of this § 551.21 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251638).

Cross References

This section cited in 28 Pa. Code § 551.22 (relating to criteria for performance of ambulatory surgery on pediatric patients).

§ 551.22. Criteria for performance of ambulatory surgery on pediatric patients.

In addition to the criteria in § 551.21 (relating to criteria for ambulatory surgery), the following criteria apply to the performance of ambulatory surgery on children under 18 years of age:

(1) A child under 6 months of age may not be treated in an ASF.

(2) The medical record shall include documentation that the child's primary care provider was notified by the surgeon in advance of the performance

of a procedure in an ASF and that an opinion was sought from the primary care provider regarding the appropriateness of the use of the facility for the proposed procedure. When an opinion from the child's primary care provider is not obtainable, the medical record shall include documentation which explains why an opinion could not be obtained.

(3) Surgical procedures on persons older than 6 months and younger than 18 years of age shall be performed only under the following conditions:

(i) Anesthesia services shall be provided by an anesthesiologist who is a graduate of an anesthesiology residency program accredited by the accreditation council for graduate medical education or its equivalent, or by a certified registered nurse anesthetist trained in pediatric anesthesia, either of whom shall have documented demonstrated historical and continuous competence in the care of these patients.

(ii) The practitioner performing the surgery shall be either board certified by or have obtained preboard certification status with the American Board of Medical Specialties, the American Osteopathic Board of Surgery, the American Board of Podiatric Surgery or the American Board of Oral and Maxillofacial Surgery.

(4) A medical professional who has successfully completed a course in advanced pediatric life support offered by the American Academy of Pediatrics and either the American College of Emergency Physicians or the American Heart Association shall be present in the facility.

Source

The provisions of this § 551.22 adopted October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583.

Cross References

This section cited in 28 Pa. Code § 553.3 (relating to governing body responsibilities).

APPLICATION AND AUTHORIZATION TO OPERATE AN ASF

§ 551.31. Licensure.

(a) A Class A ASF shall meet the following criteria:

(1) A license is not required for the operation of a Class A ASF. The facility shall be accredited by the Accreditation Association for Ambulatory Health Care, the Joint Commission on the Accreditation of Health Care Organizations, the American Association for the Accreditation of Ambulatory Surgical Facilities or another Nationally recognized accrediting agency acknowledged by the Medicare Program in order to be identified as providing ambulatory surgery.

(2) A Class A ASF shall register with the Department and shall forward a copy of its accreditation survey to the Department.

- (3) The Class A registration form shall request the following information, which shall also be provided to the Department by the Class A ASF on an annual basis.
- (i) A list of operative procedures proposed to be performed at the facility and the ages of the patients to be served.
 - (ii) The type of anesthetic proposed to be used for each operative procedure.
 - (iii) The facility's current accreditation survey and the designation of accreditation status by the Nationally recognized accrediting agency.
 - (iv) Other information the Department deems pertinent to registration requirements.
- (b) A license shall be obtained to operate a freestanding Class B or Class C ASF.
- (c) An ASF license shall designate the licensed facility as either a Class B or Class C.
- (d) An applicant for a license to operate an ASF shall 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 (B or C).
- (e) 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 ASF Class III or PS-III patients.
- (f) The Department may enter and inspect an ASF (Class A, B or C), at any time, announced or unannounced, to investigate any complaints. The Department may mandate closure of an ASF that the Department determines is providing substandard care or for any other lawful reason.

Source

The provisions of this § 551.31 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251638).

Cross References

This section cited in 28 Pa. Code § 551.53 (relating to presurvey preparation).

§ 551.32. [Reserved].**Source**

The provisions of this § 551.32 reserved October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial pages (251638) to (251639).

§ 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 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.

Source

The provisions of this § 551.33 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251639).

§ 551.34. Licensure process.

(a) An application for the appropriate license to operate an ASF shall be made in accordance with section 807 of the act (35 P. S. § 448.807).

(b) The application form for a license to operate an ASF shall be obtained from the Department of Health, Division of Acute and Ambulatory Care Facilities, Post Office Box 90, Harrisburg, Pennsylvania 17108.

(c) Applications for renewal of a license shall be made annually on forms obtained from the Department.

(d) Applications or renewal forms shall be accompanied by a fee of \$250.

Source

The provisions of this § 551.34 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251639).

CONTINUING OPERATIONS**§ 551.41. Policy.**

The Department will issue a license valid for 1 year to an ASF which is in compliance with this subpart.

Source

The provisions of this § 551.41 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251639).

§ 551.42. [Reserved].**Source**

The provisions of this § 551.42 reserved October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251639).

§ 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 expires.

(2) The ASF substantially changes its name or location, in which case a new license will be automatically issued upon application by an ASF if the ASF is otherwise in compliance with this subpart.

(b) If the ASF locates or relocates services at a site other than the current site or a site contiguous thereto, the ASF shall notify the Department 30 days prior to the change so that the Department may determine if a new license is necessary.

Source

The provisions of this § 551.43 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial pages (251639) to (251640).

§ 551.44. Display of license.

The current license shall be displayed in a public and conspicuous place in the ASF.

§ 551.45. Licensure information/application.

Information regarding licensure shall be completed annually on forms supplied by the Department. Both the Annual ASF Questionnaire and the Application for Licensure and other data requested by the Department shall be completed each year.

INSPECTION AND SURVEY ACTIVITIES**§ 551.51. Policy.**

Representatives of the Department will annually conduct a survey of every ASF required to be licensed.

§ 551.52. ASF responsibilities.

An ASF shall comply with applicable standards which are required by Federal, State and local authorities. This includes, but is not limited to, standards at 49 Pa. Code Chapters 17, 21 and 27 (relating to State Board of Medicine—medical doctors; State Board of Nursing; and State Board of Pharmacy) in addition to standards related to radiologic health, sanitation, food service, electric wiring and

life safety code compliance. When the ASF has been inspected by another regulatory agency, it shall have available during the survey by the Department written confirmation of compliance as required by the other regulatory agency.

§ 551.53. Presurvey preparation.

Prior to an annual 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.

Source

The provisions of this § 551.53 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251640).

Cross References

This section cited in 28 Pa. Code § 553.4 (relating to other functions).

§ 551.54. Access by the Department.

Upon presenting the official Department identification card to the ASF's person in charge, authorized agents of the Department will have access to the ASF to determine compliance with this subpart. The access shall include:

- (1) Entry to the entire ASF premises.
- (2) Inspection and examination of the facilities, records, documents and phases of operations, including those relating to compliance with Chapter 553 (relating to ownership, governance and management).
- (3) Interviews of staff, employees, members of the governing body and patients.
- (4) Examination of a patient, with the patient's consent.

§ 551.55. Site survey coverage.

The Department will survey on-site those aspects of the ASF as it deems necessary to fully and fairly assess the compliance of the ASF with this subpart.

§ 551.56. Documentation.

The Department will document the extent of an ASF's compliance with this subpart in at least one of the following ways:

- (1) The statement of a person in charge or staff member.

- (2) Documentary evidence provided by the facility.
- (3) Answers by the ASF to detailed questions provided by the Department concerning the implementation of this subpart or examples of the implementation which will enable a judgment about compliance to be made.
- (4) On-site observation by surveyors.
- (5) Interviews with patients, employees or other persons or sources capable of providing reliable information to the Department.

POST SURVEY PROCEDURES

§ 551.61. Policy.

After completion of the site visit, the Department will evaluate relevant information gathered during the survey, formulate its compliance findings and determinations, and order the ASF to correct, within a specified period of time, deficiencies found.

§ 551.62. Compliance directive.

(a) If there is noncompliance with this subpart, the Department will notify the ASF in writing of deficiencies and will direct the officers governing or managing the ASF to take corrective action as the Department directs or to submit a plan of correction, or to do both, within the time specified by the Department. In its compliance directive and request for plan of correction, the Department will state its findings and the reasons for its determination.

(b) The ASF shall be presumed to be in compliance with provisions of this subpart for which the compliance directive does not cite a deficiency.

§ 551.63. Submission of plan of correction.

A plan of correction shall be submitted to the Department within 30 days of receipt of written notification by the Department. The plan shall be attested to by the signature of the chairman of the governing body or the person in charge. The plan of correction shall be submitted to the governing body as a whole for its review at its regular meeting.

§ 551.64. Content of plan of correction.

A plan of correction shall address deficiencies cited in the compliance directive of the Department. The plan shall state specifically what corrective action is to be taken, by whom and when.

§ 551.65. Public inspection of compliance documents.

Copies of compliance directives and plans of correction will be kept readily available by the Department in appropriate regional offices for the purpose of

public inspection, examination and duplication at a reasonable cost. An ASF shall make available a current copy of these documents for inspection and examination.

CONTINUING SURVEILLANCE

§ 551.71. Unannounced surveys.

Whenever the Department has received a complaint or has other reasonable grounds to believe that a deficiency exists, the Department may without notice to the ASF investigate, inspect or survey the facility, or portion of the ASF to which the alleged deficiency relates.

ISSUANCE OF LICENSE

§ 551.81. Principle.

The Department will issue an ASF license to a facility which complies with this subpart. The license will reflect the regular, provisional or limited status and the classification assigned to the ASF. The license applies only to the designated facility.

Source

The provisions of this § 551.81 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251642).

§ 551.82. Regular license.

(a) The Department will issue a regular 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 efforts toward their correction will do one of the following:

- (i) Interfere with or adversely affect normal ASF operations.
- (ii) Adversely affect a patient's health or safety.
- (iii) Exceed the assigned classification of the ASF.

(2) The ASF has adopted a plan of correction approved by the Department.

Source

The provisions of this § 551.82 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial pages (251642) to (251643).

Cross References

This section cited in 28 Pa. Code § 551.91 (relating to grounds); 28 Pa. Code § 551.92 (relating to modification of license); and 28 Pa. Code § 551.101 (relating to policy).

§ 551.83. Provisional license.

- (a) The Department may issue a provisional license if:
- (1) There are numerous deficiencies or a serious specific deficiency in compliance with applicable statutes, ordinances or regulations.
 - (2) The ASF is taking appropriate steps to correct the deficiencies in accordance with a plan of correction submitted by the ASF and agreed upon by the Department.
 - (3) There is no cyclical pattern of deficiencies over a period of 2 or more years. A cyclical pattern is one where an ASF is alternately in and out of substantial or full compliance, which is corrected only when actively supervised by the Department.
- (b) A provisional license is valid for a specific time period of no more than 6 months.
- (c) A provisional license may be renewed no more than three times.

Source

The provisions of this § 551.83 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251643).

Cross References

This section cited in 28 Pa. Code § 551.91 (relating to grounds); and 28 Pa. Code § 551.92 (relating to modification of license).

REFUSAL OR REVOCATION**§ 551.91. Grounds.**

- (a) The Department may refuse to issue a license for one or more of the following reasons:
- (1) The health care provider is not a responsible person.
 - (2) The place to be used as an ASF is not adequately constructed, equipped, maintained and operated to safely and efficiently render the services offered.
 - (3) The ASF does not provide safe and efficient services which are adequate for the care, treatment and comfort of the patients or residents of the facility.
 - (4) There is not substantial compliance with this subpart.
- (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:
- (1) Serious violation of or noncompliance with the act or with this subpart except when the ASF is in compliance or substantial compliance as defined in § 551.82 (relating to regular license) or otherwise meets the conditions in

§ 551.83 (relating to provisional license). A serious violation is one which poses a significant threat to the health of a patient.

(2) Failure to submit a plan of correction when required to do so, or failure, by the holder of a provisional license, to correct a deficiency under a plan of correction, unless the Department approves an extension or modification of the plan of correction.

(3) Incompetence, negligence or misconduct in operating the ASF, or in providing services to patients.

(4) Fraud or deceit in obtaining or attempting to obtain a license.

(5) Lending, borrowing or using the license of another ASF.

(6) Knowingly aiding or abetting the improper granting of a license.

(7) Mistreating or abusing individuals cared for by the ASF.

(8) The existence of a cyclical pattern of deficiencies over a period of 2 or more years. A cyclical pattern means an ASF is alternately in and out of full or substantial compliance, which is corrected only when actively supervised by the Department.

(9) Serious violation of the laws relating to Medical Assistance or Medicare reimbursement.

(10) Providing services exceeding the scope of the classification assigned in the license.

Source

The provisions of this § 551.91 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial pages (251643) to (251644).

§ 551.92. Modification of license.

The Department may modify a license by substituting a provisional license for a regular license if the Department determines that the ASF is not in compliance or substantial compliance as defined in § 551.82 (relating to regular license) but the ASF otherwise meets the requirements of § 551.83 (relating to provisional license).

§ 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 Health Policy Board.

Source

The provisions of this § 551.93 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251644).

CORRECTION OF DEFICIENCY**§ 551.101. Policy.**

If an ASF notifies the Department that it has completed a plan of correction and corrected its deficiencies, the Department will conduct a survey to ascertain completion of the plan of correction. Upon finding full or substantial compliance, as defined in § 551.82(b) (relating to a regular license), the Department will issue a regular license.

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 Health Policy Board, under 37 Pa. Code Chapter 197 (relating to practice and procedure).

Source

The provisions of this § 551.111 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251645).

§§ 551.121—551.123. [Reserved].**Source**

The provisions of these §§ 551.121—551.123 reserved October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (251645).

[Next page is 553-1.]